

# **“PROLIFERATION OF PTAS AND EU TRADE POLICY”**

**“Variations in the design of regulatory cooperation  
mechanisms in CETA”**

**Thèse en cotutelle  
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Sous la direction de :

Louis Bélanger, directeur de recherche (Université Laval)

Arlo Poletti, directeur de cotutelle (Università di Trento)

Raffaele Marchetti, codirecteur de recherche (LUISS Guido Carli)

## Résumé

La coopération réglementaire joue un rôle croissant dans la stratégie d'externalisation européenne. Cette recherche vise à améliorer la compréhension de ce phénomène en fournissant une typologie des différents formats réglementaires utilisés dans les accords commerciaux. Bien que les recherches antérieures se soient concentrées sur la variation entre les accords commerciaux de ces formats juridiques cette thèse concentre ses efforts sur la variation des formats juridiques à l'intérieur des accords, en particulier entre les secteurs réglementaires dans un seul accord. Récent ajout au réseau commercial européen, l'UE et le Canada ont présenté l'Accord Commercial Global et Économique (AECG) comme « l'étalon-or » pour la nouvelle génération d'accords commerciaux. Cette thèse examine donc ce traité référentiel et tente de répondre à la question suivante: quels sont les différents types de format réglementaire au sein de l'AECG, et comment expliquer la variation des types entre les secteurs réglementaires?

En me référant à la littérature sur la légalisation internationale et à certaines de ses évolutions récentes, je propose deux dimensions pour construire une typologie de quatre types de «format réglementaire», à savoir: la nature de l'obligation (Hard / Soft ) et le mode de décision (Ex-ante / ex-post). Quatre types de conception sont établis pour classer les différents schémas réglementaires possibles: Type 1 (Ex-Ante / Hard); Type 2 (Ex-Post / Hard); Type 3 (Ex-Ante / Soft); Type 4 (Ex-post / Soft). En examinant l'AECG, j'ai identifié 7 secteurs de réglementation institutionnalisés selon les quatre types mentionnés: biotechnologie, produits forestiers, indications géographiques, véhicules à moteur, produits pharmaceutiques, qualifications professionnelles et matières premières.

Pour expliquer les processus de négociation aboutissant au choix des types de format juridique, j'ai mobilisé un cadre théorique institutionnaliste rationnel en suivant les prémisses du programme de recherche « rational design ». Ce modèle suit une compréhension structurelle du processus de négociation, composée de deux risques d'interdépendance affectant ses résultats de la négociation et donc le format juridique choisie : risque élevé / faible de «hold-up» et risque élevé / faible de shirking. Le risque de «hold-up» fait référence à une éventuelle renégociation des termes de l'accord et de ses potentielles conséquences pour les signataires. Elle pose que l'intégration économique résultant de la coopération peut rendre certains états plus dépendants et donc dans une position plus difficile pour résister à de nouvelles demandes de concessions. Le risque de « shirking » se rapporte à la littérature sur les mécanismes de sanction et de non-conformité. Il examine la possible défection par l'une des parties de ses obligations légales et son utilisation opportuniste des divergences réglementaires préexistantes ou existantes pour créer des barrières commerciales supplémentaires.

Cette thèse postule que lorsqu'un risque de blocage est élevé, les négociateurs utiliseront une conception Ex-ante, ce qui limite la coopération dans le temps et réduit les futures situations d'otages. Si ce risque est faible, les parties à la négociation s'engagent pour une fonctionnalité de conception Ex-post. Un niveau élevé de risque de contournement se traduit plutôt par le recours à une obligation « hard » dans le but de réduire le risque possible de « shirking » des engagements juridiques. À l'opposé, lorsqu'un tel risque est faible, les parties préfèrent utiliser l'obligation « Soft » pour concevoir leur coopération.

Pour expliquer la variation des types de conception, quatre hypothèses sont formulées: le type 1 est causé par des risques élevés de «hold-up» et élevé de « shirking », le type 2 par des risques faibles d' «hold-up» mais élevé de « shirking », le type 3 par des risques élevés d'«Hold-up» mais faible de « shirking », et Type 4 par des risques faibles d'« Hold-up »et de « shirking ». Les résultats soutiennent les quatre hypothèses pour six secteurs sur sept, la biotechnologie étant un cas déviant. Le type 3 est indirectement vérifié car il a été trouvé absent de l'AECG et aucun secteur avec ses résultats connexes n'a pu être trouvé. Pour les tests empiriques, une approche qualitative multiméthodes a été adoptée. Deux méthodes de comparaison ont été combinées: entre les cas et à l'intérieur des cas. L'analyse empirique est ainsi divisée en deux parties, la première

compare les sept secteurs, tandis que la seconde utilise le traçage des processus pour chaque secteur. En termes de données, différentes sources sont exploitées: statistiques commerciales d'Eurostat, documents réglementaires et prises de position. J'ai également interviewé 24 organisations européennes et canadiennes représentant l'industrie ou les pouvoirs publics.

Politique commerciale - Coopération en matière de réglementation - Légalisation - AECG - Conception rationnelle - Chaînes de valeur mondiales

# Summary

Regulatory cooperation plays an increasing part in the European externalization strategy. This research aims for increasing the understanding of this phenomenon by providing a typology of different regulatory schemes used within trade agreements. While past research focused on legal design variation across trade agreements, this thesis concentrates its efforts on legal design variation intra-agreement, specifically variation between regulatory sectors. In a recent addition to the European trade network, the EU and Canada presented the Comprehensive and Economic Trade Agreement (CETA) as the “gold standard” for the new generation of trade agreements. This thesis thus looks at this referential treaty and attempts to answer the following question: **What are the different types of regulatory design within CETA, and how can the variation in types across regulatory sectors be explained?**

Based on the literature on international legalization I propose two dimensions of “regulatory design”: nature of obligation (Hard/Soft) and mode of decision (Ex-ante/Ex-post). This typology establishes four design types that describe the different possible regulatory schemes: Type 1 (Ex-Ante/Hard); Type 2 (Ex-Post/Hard); Type 3 (Ex-Ante/Soft); Type 4 (Ex-post/Soft). Through reviewing CETA, I identify 7 regulatory sectors institutionalized within CETA according the four mentioned types: Biotechnology, Forest products, Geographical Indications, Motor Vehicles, Pharmaceutical Products, Professional Qualifications, Raw Materials.

To explain the negotiation processes resulting in the choice of design types, I mobilize a Rational Institutionalist framework following the premises of the Rational Design research agenda. I develop an explanatory framework based on a structural understanding of the negotiating process. This structure is composed by two interdependence risks affecting the results of the negotiation and thus the design type : High/Low risk of “hold-up” and High/Low risk of shirking. The risk of “hold-up” refers to the possible future re-negotiation of the terms of the agreement and its consequences. It poses that the mutual economic integration resulting from cooperation could make such re-negotiation particularly damage for vulnerable parties. Shirking relates to the literature on enforcement and non-compliance issues. It looks at the possible defection by one party from its legal obligations and to the possibility that a party might opportunistically use pre-existing or existing regulatory divergences to create additional barriers to trade.

This thesis posits that when a risk of hold-up is High, negotiators will use an Ex-ante design, which limits in time cooperation and reduces future “hostage” situations. If this risk is Low, negotiating parties will commit to an Ex-post design. A high level of shirking risk results instead in the use of Hard obligation with the aim of reducing the possible risk of avoidance of legal commitments. At the opposite, when such a risk is low, parties will rather use Soft obligation to design their cooperation.

To explain the variation of design types, three hypotheses are formulated: Type 1 is caused by High “hold-up” and High shirking risks, Type 2 by Low “hold-up” but High shirking, Type 3 by High “Hold-up” but Low shirking, and Type 4 by Low “Hold-up” and Low shirking. The results support the four hypotheses for six sectors out of seven, Biotech being a deviant case. Type 3 is indirectly verified as it is absent from CETA and no sectors with its related results could be found. For empirical testing, a qualitative multi-method approach was adopted. Two methods of comparison were combined: across-case and within-case. The empirical analysis is thus divided in two parts, the first one compares all seven sectors, while the second uses process-tracing for each sector. In terms of data, different sources are harnessed: trade statistics from Eurostat, regulatory documents and position papers. I also interviewed 24 European and Canadian organizations either representing industry or public authorities.

Trade policy – Regulatory cooperation – legalization – CETA – Rational Design – Global Value Chains

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## List of abbreviations

<b>ACE</b>	Architects' Council of Europe
<b>ASEAN</b>	Association of Southeast Asian Nations
<b>Biotech</b>	Biotechnology
<b>CA</b>	Canada
<b>CALA</b>	Canadian Architectural Licensing Authorities
<b>CBAN</b>	Canadian Biotechnology Action Network
<b>CETA</b>	Comprehensive Economic and Trade Agreement
<b>CFIA</b>	Canadian Food Inspection Agency
<b>CITES</b>	Convention on International Trade in Endangered Species of Wild Fauna and Flora
<b>CMA</b>	Canadian Mining Association
<b>CSA</b>	Canadian Standards Association
<b>DDA</b>	The Doha Development Agenda
<b>DG Agri</b>	Directorate-General for Agriculture and Rural Development
<b>DG Trade</b>	Directorate-General for Trade
<b>EC</b>	European Commission
<b>EFSA</b>	European Food Safety Agency
<b>EFPIA</b>	European Federation of Pharmaceutical Industries and Association
<b>EU</b>	European Union
<b>EUTR</b>	EU Timber Regulation
<b>FAO</b>	Food and Agriculture Organization of the United Nations
<b>FLEGT</b>	Forest Law Enforcement, Governance and Trade
<b>FPAC</b>	The Forest products Association of Canada
<b>Forest</b>	Forest Products
<b>FSC</b>	Forest Stewardship Council
<b>GM</b>	Genetically Modified
<b>GRP</b>	Good Regulatory Practice
<b>GVCs</b>	Global Value Chains
<b>GIs</b>	Geographical Indications
<b>GMP</b>	Good Manufacturing Practices
<b>GRPs</b>	Good Regulatory Practices

<b>GVCs</b>	Global Value Chains
<b>ISO</b>	International Standardization Organization
<b>JCPA</b>	Joint Comprehensive Plan of Action
<b>MNEs</b>	Multinationals Enterprises
<b>MRA</b>	Mutual Recognition Agreement
<b>MS</b>	European Union Member States
<b>MVs</b>	Motor Vehicles
<b>NTBs</b>	Non-Tariff Barriers
<b>NTMs</b>	Non-Tariff Measures
<b>OECD</b>	Organization for Economic Co-operation and Development
<b>PEFC</b>	Program for the Endorsement of Forest Certification
<b>Pharma</b>	Pharmaceutical Product
<b>PIC/S</b>	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
<b>PQ</b>	Professional Qualification
<b>PTAs</b>	Preferential Trade Agreements
<b>Raw</b>	Raw Materials
<b>RCC</b>	Regulatory Cooperation Council
<b>RCF</b>	Regulatory Cooperation Forum
<b>RD</b>	Rational Design
<b>RMI</b>	Raw Materials Initiative
<b>SME</b>	Small Medium Enterprise
<b>SDG</b>	Sustainable Development Goal
<b>SFI</b>	Sustainable Forestry Initiative
<b>SPS</b>	Sanitary and Phytosanitary measures
<b>TBT</b>	Technical Barriers to Trade
<b>TiVA</b>	OECD Trade in value Added database
<b>TSM</b>	Towards Sustainable Mining
<b>TTIP</b>	Transatlantic Trade and Investment Partnership
<b>UK</b>	United Kingdom
<b>USA</b>	United States of America
<b>VPA</b>	Voluntary Partnership Agreement
<b>WMI</b>	Whitehorse Mining Initiative
<b>WTO</b>	World Trade Organizations

**WTO DSB**

WTO Dispute Settlement Body

**UNCTAD**

United Nations Conference on Trade and Development

**UNECE**

United Nations Economic Commission for Europe

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# Introduction

Recent years have seen a “regulatory turn” in trade policy, whether in the initial rallying cries of the Obama administration to set “the rules of the 21st century” or the ongoing efforts of the European Union (EU) to conclude “new generation trade agreements”. This turn, however, has also stirred up domestic debates on the social impact of including regulatory cooperation in agreements. As a result, the context around the negotiations of two agreements considered “new generation”, the Transatlantic Trade and Investment Partnership (TTIP) and the Comprehensive Economic and Trade Agreement (CETA), was not free from controversy. The fear of a “Race to the Bottom” seems to be one of the main concerns raised by opponents, who argue that this type of cooperation would downgrade protection for consumers and the environment<sup>1</sup>.

Following this policy background and since the TTIP negotiation (2016), the EU has included “Good Regulatory Practices” (GRPs) in its trade policy and agreements<sup>2</sup>. It was not the first nor the only actor to integrate GRPs into its externalization policies. Back in 2011, the U.S. and Canada created the U.S. – Canada Regulatory Cooperation Council (RCC) with the overall goal “to remove or reduce unnecessary differences and unnecessary or duplicative requirements across a range of areas”<sup>3</sup>. The congruence of this joint interest in regulatory cooperation by the EU, U.S. and Canada found its origin in the search for additional economic benefits through regulatory cost reduction for trade (Hoekman 2015b). Among the arguments often voiced is that regulatory cooperation is beneficial for both Multinationals and SMEs.

According to this line of thinking, Multinationals and SMEs can benefit naturally from the elimination of regulatory duplications that are costly for their global integration. Non-tariff Measures (NTMs) can especially prevent smaller firms from taking part in the international economic environment, which harms their productivity<sup>4</sup>. According a study published by the OECD in 2006, SMEs identify regulatory barriers as one of the major impediments to their

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<sup>1</sup> Euractiv, *TTIP negotiators get an earful from American critics*, 24<sup>th</sup> April 2015, <https://www.euractiv.com/section/trade-society/news/ttip-negotiators-get-an-earful-from-american-critics/>, accessed the 30<sup>th</sup> October 2019.

<sup>2</sup> European Commission, Good Regulatory Practices (GRPs) in TTIIP: An introduction to the EU’s revised proposal, 21 March 2016,

<sup>3</sup> Whitehouse, “United States – Canada Regulatory cooperation Council, Joint Forward Plan”, August 2014, [https://www.trade.gov/rcc/documents/RCC\\_Joint\\_Forward\\_Plan.pdf](https://www.trade.gov/rcc/documents/RCC_Joint_Forward_Plan.pdf), accessed the 30<sup>th</sup> October 2019.

<sup>4</sup> BusinessEurope & U.S. Chamber of Commerce, *Transatlantic Trade and Investment Partnership (TTIP)*, 2014, <https://www.businesseurope.eu/sites/buseur/files/media/imported/2014-00496-E.pdf>, accessed the 30<sup>th</sup> October 2019.

exports (Fliess and Busquets 2006, 5). “NTBs matter equally if not more than import tariffs”, which can include behind-the-borders regulations and technical measures (e.g. standards & certifications) (Fliess and Busquets 2006, 7). Among the policy recommendations, the authors suggest governments to initiate bilateral regulatory cooperation negotiations, including when discussing trade policy (Fliess and Busquets 2006, 11). Since this study, the OECD compiled several recommendations, presenting regulatory cooperation as the way forward to trade liberalization<sup>5</sup>.

Besides the above-mentioned gains that SMEs could obtain from regulatory cooperation, the other effects of regulatory cooperation remain overall unclear. Nor is there much clarity about whose interests are best served by regulatory cooperation. This uncertainty on distribution effects can be explained by the variety of regulatory approaches that can be found in this type of cooperation. From the establishment of equivalences, facilitation of conformity assessment procedures to standards harmonization, the tools available are multiple and not always easy to assess (Drezner 2005; De Ville and Siles-Brügge 2017, 2016; Young 2015a).

## **WTO “Legalization” and its regulatory turn**

In retrospect, the development of GRPs and their integration within trade agenda supported a “regulatory turn” in multilateral governance. This turn orientated multilateral negotiations towards the economic benefits obtained through the reduction of regulatory costs. At the WTO, it was translated into a “legalization” of the multilateral trade agenda (Young and Peterson 2006, 797; De Bièvre 2006; Shaffer 2006). More specifically, it resulted in an expansion of the subjects covered by the organization, notably topics that were previously considered belonging strictly to the domestic sphere of states. Consequently, scientific discussion on trade policy started to investigate the cause and consequences of this integration of regulatory issues into WTO agenda.

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<sup>5</sup> OECD, OECD Legal Instruments, “Recommendation of the Council on Improving the Quality of Government Regulation”, OECD/LEGAL/0278”: <https://legalinstruments.oecd.org/public/doc/128/128.en.pdf>, accessed the 28<sup>th</sup> May 2019; OECD, “OECD Guiding Principles for Regulatory Quality and Performance”: <http://www.oecd.org/fr/reformereg/34976533.pdf>, accessed the 28<sup>th</sup> May 2019; OECD, “Recommendation of The council on Regulatory Policy and Governance”: <http://www.oecd.org/gov/regulatory-policy/49990817.pdf>, accessed the 28<sup>th</sup> may 2019.

As early as 2000, Goldstein and Martin expressed their fears that the new trend of “legalization” in the international trade regime could negatively impact liberalization (Goldstein and Martin 2000). They argued that more precise and binding legal commitments could stir up protectionist opposition “by providing more and better information about the distributional implications of commercial agreements”, which could encourage mobilization from affected groups (Goldstein and Martin 2000, 604). Several other studies followed and adopted a similar research interest. Among the mechanisms studied, the legal design of dispute settlement received significant attention from scholars (Smith 2000; Maggi 2008). This is not surprising as the creation of the Dispute Settlement Body, following the Uruguay round in 1994, was a major component in the legalization turn in trade policy (Holmes 2006, 817).

Despite earlier concerns on legalization, Rosendorff found that the WTO Dispute Settlement Body (DSB) appeared to have had a positive impact on the global trade regime (Rosendorff 2005). By being flexible enough in case of exceptional circumstances, the DSB succeeded in gathering support from WTO membership. Fulfilling the role of insurance, this flexibility enabled states to plan and implement deeper commitments in the long run (Kucik and Reinhardt 2008). One of the main cause identified was that safeguards scheduled in agreements, anti-dumping clauses for instance, were a reassuring factor for states (Rosendorff and Milner 2001). Besides the WTO, this branch of research also looked at flexibility in PTAs’ legal design. It investigated the trade-off between transparency and flexibility (Baccini 2010), depth and rigidity (Johns 2014), and depth versus flexibility (Baccini, Dür, and Elsig 2015). More recent studies focus on the role of domestic factors to explain legal design variation on Non-Trade Issues (NTIs) (environment, labor, civil and political rights) (Lechner 2016; Raess, Dür, and Sari 2018; Eckhardt and Lee 2018).

Despite its benefits, the regulatory turn in WTO negotiations was not without practical consequences for the last multilateral round of negotiation: the Doha Development Agenda (DDA). While the WTO’s early legalization turn appeared to have been well received; within the DDA the legalization emphasis resulted in the emergence of new cleavages. By pursuing a deep approach to trade policy, the WTO has foregrounded new types of conflicts more “fundamental” and harder to solve than traditional ones, such as free trade versus protectionism (De Bièvre and Poletti 2016, 6). To explain this breakdown, several researchers pointed at the progressive emphasis on “regulatory” issues as its major cause (Jones 2006; Young and Peterson 2006; De Bièvre and Poletti 2016). While shared values, institutions and policy preferences facilitated the integration of regulatory topics into the consolidation of the European market, this level of consensus is absent at the global level (Jones 2006).

The WTO's failure appears thus less surprising, especially recalling that even though the process of "legalization" was significant and extended to a wider range of subjects outside trade (Goldstein et al. 2000), the original authors of "legalization" themselves recalled that it does not imply that politics and power relations disappear, quite the opposite:

We view law as deeply embedded in politics: affected by political interests, power, and institutions. As generations of international lawyers and political scientists have observed, international law cannot be understood in isolation from politics. Conversely, law and legalization affect political processes and political outcomes. The relationship between law and politics is reciprocal, mediated by institutions (Goldstein et al. 2000, 387).

The "legalization" process of international cooperation extends the bargaining conflicts to the design of the legal texts themselves, responsible for the creation of international institutions. Studying international institutions requires thus looking at the strategic calculations that resulted in specific choices of design, as recalled by the authors of the *Rational Design* (RD) research agenda (Koremenos, Lipson, and Snidal 2001a, 2001b). To explain the variation of design observed internationally, it becomes necessary to explore at the link between countries' costs/benefits assessments and their design choices when cooperating and creating international institutions.

### **EU and regulatory cooperation, a co-constituting relationship**

From a European perspective, the political importance of regulatory tools has been stressed since the creation of the EU. It is one consequence of European regulators' contribution to the creation of the Single Market. As described by Majone (1994), the emergence of an EU regulatory state found its origin in two parallel trends. It is partly a result of the privatization movement of the 80s, notably the shift towards regulations instead of industrial policy as main states interventionist tool within the economy (Majone 1994, 193–94). But it is also a product of the consolidation of the European Market, especially after the adoption of the Single European Act (SEA). The SEA notably played a major role in opening a window of opportunity for the European Commission to expand its competences through regulations (Majone 1994, 200). Multinational firms supported this movement as preexisting regulatory divergences were often harming their economic activities (Majone 1994, 201–3).

A particular feature of EU regulations, the so-called “Brussels’ effect” describes the European ability to externalize regulations at a global scale (Bradford 2012). Besides the influence of the centrality and size of the EU market (Drezner 2007; Bradford 2012; Damro 2012) in explaining this diffusion, the role played by European domestic institutions was also instrumental (Bach and Newman 2007). European independent regulatory agencies, for instance, contributed largely to the evolution of policymaking towards regulatory economic governance, indirectly supporting EU regulatory externalization (Thatcher 2002, 2011). The European Court of Justice also contributed to this movement, notably in its role of promoting labor mobility (J. a. Caporaso and Tarrow 2009). The intervention of public institutions has led to the creation and addition of new regulatory instruments and legalized arrangements for the European economic governance. This trend was observed by several studies that scrutinized the questions of competence delegation and distributions within the EU sphere while looking their impacts on EU regulatory capacities inside and outside European borders (Eberlein and Grande 2005; Levi-Faur 2011; Gilardi 2008; Caporaso et al. 2015). More recently, Lavenex proposed to describe the EU as a loose “conglomerate of sectoral regimes” pursuing their own separate regulatory diffusion processes (Lavenex 2014, 884).

The negotiation and legalization of regulatory cooperation in Preferential Trade Agreements (PTAs) is however a relatively new trend for the EU. For a while, the union adopted a moratorium on all new PTAs and pushed for integrating these regulatory issues into the WTO agenda. This eagerness to push these topics were a result of the global context of the later 90s and early 2000s. Following the end of the Cold War and faced with the consequences of the acceleration of globalization, domestic opposition towards economic liberalization rose in Western countries. Reacting to this wave of discontent, the EU adjusted its trade doctrine by adopting a “managing globalization” discourse, starting 1999 (Abdelal and Meunier 2010). Promoted by the EU trade commissioner at the time, Pascal Lamy, this new doctrine aimed at supporting the EU’s efforts in introducing a new set of issues at the WTO between 1995 and 2005, notably the so-called “Singapore issues”<sup>6</sup> (Howse and Nicolaïdis 2003). To support this EU regulatory offensive, Commissioner Lamy succeeded in implementing a moratorium on all new Preferential Trade Agreements (Woolcock 2007). Partly a consequence of this shift in priority, the global trade agenda evolved from a driven tariff-cuts approach, towards the “legalized” negotiations in trade policy mentioned previously (Baldwin 2006, 2011; Young and Peterson 2006; Shaffer 2006; De

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<sup>6</sup> Singapore issues: competition, trade facilitation, government procurement, investment

Bièvre 2006). In sum, it is partly under the pressure of the EU that the scope of the subjects covered by WTO negotiations expanded, including fisheries subsidies, anti-dumping measures...

Nevertheless, the failure of the multilateral approach to achieve its regulatory ambition in its pursuit of a “deep trade agenda” (Young and Peterson 2006) meant that the EU had to revise its strategy again. This shift was enacted in 2010 with the adoption of the “Trade for All” strategy. Pursuing the aim of “Reinforcing international regulatory cooperation, this new trade agenda sees regulatory provisions in PTAs as a crucial part of any real “deep and comprehensive” trade packages<sup>7</sup>. This “new generation” of trade agreements embodies in a bilateral/plurilateral approach the preceding failed efforts of the EU to promote regulatory issues at the multilateral level. Within the overall purpose of trade liberalization, PTAs become a new instrument for the European Commission to promote its vision of economic governance. Among this corpus of newly signed PTAs, the Comprehensive Economic and Trade Agreement (CETA), between the EU and Canada, plays the role of “Gold Standard” for this new generation of trade agreements<sup>8</sup>.

Presented as early as June 2007 at the EU-Canada Summit in Berlin, the negotiation of CETA started in May 2009 in Prague<sup>9</sup>. The talks lasted until September 2014, when the complete text of the agreement was released at the Canada-EU summit in Ottawa. Approved by the European Council in 2016, the European Parliament<sup>10</sup> and the House of Commons of Canada<sup>11</sup> adopted the text on the 14 and 15 February 2017. CETA entered provisionally into force in September 2017. As it marked a turning point in EU trade policy, CETA stirred up controversies. In October 2016, the regional Parliament of Wallonia in Belgium refused to approve the agreement<sup>12</sup>. European civil society opposition notably highlighted the regulatory risks carried by the agreement chapters on regulatory cooperation and investment. Worried that these new types of adjudication and

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<sup>7</sup> European Commission, 2010, Trade for All: Towards a more responsible trade and investment policy, [http://trade.ec.europa.eu/doclib/docs/2015/october/tradoc\\_153846.pdf](http://trade.ec.europa.eu/doclib/docs/2015/october/tradoc_153846.pdf), accessed the 4<sup>th</sup> May 2019.

<sup>8</sup> European Commission, *Joint statement Canada-EU Comprehensive Economic and Trade Agreement (CETA)*, Monday, 29 February 2016, [http://trade.ec.europa.eu/doclib/docs/2016/february/tradoc\\_154330.pdf](http://trade.ec.europa.eu/doclib/docs/2016/february/tradoc_154330.pdf), accessed the 2nd May 2019.

<sup>9</sup> Government of Canada, Global Affairs Canada, Chronology of events and key milestones, <https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agracc/ceta-aecg/chronologie-chronologie.aspx?lang=eng>, accessed the 2nd May 2019.

<sup>10</sup> European Commission, Trade policy: Canada, <http://ec.europa.eu/trade/policy/countries-and-regions/countries/canada/>, accessed the 2nd May 2019.

<sup>11</sup> Parliament of Canada, House of Commons, BILL C-30, <https://www.parl.ca/DocumentViewer/en/42-1/bill/C-30/third-reading>, accessed the 2nd May 2019.

<sup>12</sup> Cécile Ducourtieux & Jean-Pierre Stroobants, Le Monde, 20 Octobre 2016, [https://www.lemonde.fr/europe/article/2016/10/20/la-wallonie-maintient-son-opposition-au-traité-commercial-ceta-avec-le-canada\\_5017686\\_3214.html](https://www.lemonde.fr/europe/article/2016/10/20/la-wallonie-maintient-son-opposition-au-traité-commercial-ceta-avec-le-canada_5017686_3214.html), accessed the 2nd May 2019.

regulatory mechanisms could empower multinationals at the expense of states, they feared a “race to the bottom” between national regulatory frameworks<sup>13</sup>. These concerns were a repetition of the one raised during the previous debate over the Transatlantic Trade and Investment Partnership (TTIP).

The controversies that occurred during the negotiations of these agreements often reflect the multiple interpretations around the conclusion of PTAs and their integration of regulatory cooperation. According to several researchers, TTIP, CETA and PTAs in general are geopolitical instruments following a strategic reasoning on a global scale (Bull et al. 2015; García 2013; Dee 2015). Competition against potential competitors, such as China, mostly drives this preferential movement. For these authors, the failure of TTIP and civil society contestation result thus from concerns over EU weaker strategic bargaining capacities (Johan Eliasson and García-Duran 2016).

In contrast, other scholars have emphasized the economic interests driving the conclusion, design and shape of these agreements (Alemanno 2015; Young 2016; Hoekman 2015a; De Bièvre and Poletti 2016; Lester and Barbee 2013; Ravenhill 2017). This type of research attempts to uncover which economic interests and actors are benefitting and driving trade negotiation, at the expense of other industries. According this interpretation, civil society has limited influence as the diffused interests they defend will not be able to compete with concentrated economic interests (Olson 1975). Finally, a third current has emphasized the liberalization logic underpinning trade negotiations. Oppositions from non-firm actors are in this context an attempt to contest the extension of market logic to non-traditional trade subjects, especially public regulations (De Ville and Siles-Brügge 2015, 2017; Dominguez 2017; Bollen, De Ville, and Orbis 2016).

## **Research Contribution**

What these previous and ongoing debates inform us are the recurrent difficulties that both public opinion and scholars have in categorizing, identifying and explaining effectively what regulatory cooperation is. This is especially difficult as the recent years have seen the rising political salience of individual PTA that led to intense debate, as illustrated by the TTIP case. A certain gap in the

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<sup>13</sup> Arnaud Zacharie, CNCD 11.11.11, *Les Déséquilibres du CETA*, <https://www.cncd.be/Les-desequilibres-du-CETA>, accessed the 2nd May 2019.

literature exists in this aspect as previous works on legalization in the 2000s, cited earlier, looked mostly at the multilateral level, or focused on overall design variation between several treaties instead of focusing on one. Since TTIP, the TPP and CETA, additional efforts have been deployed to study individual treaties in depth (Young 2016; Alemanno 2015; Ravenhill 2017; Hübner, Deman, and Balik 2017). Nevertheless, these contributions did not establish a generalized framework, tended to stress treaties idiosyncrasies, and lacked a certain level of empirical depth in the data mobilized. They moreover rather described the regulatory mechanisms used and marginally attempted to explain how and why they differed between each other. There are thus still significant needs to explore in-depth regulatory cooperation in trade. It is especially important that the findings can be linked to an overall theoretical framework to be used or replicated to study other international regulatory instruments. This would allow to situate regulatory cooperation within a broader International Relations perspectives, conducive to a better understanding of the recent evolution in international politics.

This research focuses thus on the literature's shortcomings just identified. It attributes itself two main tasks. First, it creates a typology of internal regulatory design, which fulfills the function of dependent variable. Then, it explains the variation between these different types by developing a replicable theoretical framework, referring to previous works on international cooperation. Among its main research contribution, it uses as units of analysis *regulatory sectors* (e.g. Motor Vehicles). Indeed, previous works has led to the perception that most of the design variation was present across international agreements and not within. This thesis disputes this notion and attempt to reveal how the regulatory schemes contained in CETA-like agreements vary as much if not even more internally according to the issues or sectors regulated.

Within this theoretical framework, types of regulatory design are conceptualized as the solutions found by States to solve "strategic Interdependence problems" resulting from their interaction. This research identifies four types of design, each corresponding to a different configuration of these problems. Type 1 includes regulatory cooperation schemes that contain significantly detailed technical requirements but are limited in time. They use an Ex-ante design format to include this information. This design type is also highly binding, containing Hard obligations for the treaties' signatories to respect. Type 2 does not have such a level of detail but rather institutionalizes in the long run cooperation with a wider mandate. It is an Ex-post type of mechanism. It also uses Hard obligation to bind jointly parties to the cooperation mechanism. Design Type 3 is technically detailed and also limited in time, through Ex-ante design features,

but only contains Soft obligations for parties to comply. Type 4 uses also Soft obligations but adopt a longer term and wider cooperation scope, through Ex-post mechanism.

As said, each of these types corresponds to different problem configurations. This research identifies two types as particularly significant to explain design variation across the four types: risk of “hold-up” and risk of shirking. “Hold-up” risk is a concept originating from the literature of contract “in-completeness” (Cooley and Spruyt 2009; Koremenos 2012; Horn, Maggi, and Staiger 2010; Bernheim and Whinston 1998; Carnegie 2014). It poses that when engaging in interstate cooperation, there are potential risks that in the future one state might hold “hostage” the cooperative relation and extracts further concessions due to an evolution of the cooperative situation that results in a relative benefit for the state in question. In other terms, due to the evolution of states’ capabilities over time, there are risks that one actor ends up in a better bargaining situation than when it originally negotiates. It can thus require to re-negotiate the terms of the agreement to obtain even better condition.

Shirking risk pertains to the potential opportunistically use by one of the parties of existing and pre-existing regulatory divergences to renege its legal commitments and impose new regulatory costs to its counterpart. This concept originates jointly from the literature on states “orchestration” (Abbott and Snidal 2009, 2010) and non-compliance problems in international cooperation (Koremenos 2013; Smith 2000; Guzman 2005; Posner and Sykes 2011; Shaffer and Pollack 2010). It emphasizes the impacts that preexisting regulatory convergence or divergences have on states calculated decision to abide by their legal obligation or decide to shirk them.

Following this short overview, this research attempts to answer the following research question:  
**What are the different types of regulatory design within CETA and how can type variation across regulatory sectors be explained?**

In sum, this thesis establishes a typology of different forms of legal design, which are manifestations of Regulatory Cooperation within trade agreements. It proposes to uncover the causal mechanism behind the variation of these different design types within a single agreement. In other words, it aims at identifying the causes behind a state’s decision to use a certain design type for a specific “regulatory sector” (e.g. Motor Vehicles). It takes a sector focused approach to conceptualize, categorize, and explain regulatory design variation.

This research selects CETA as a paradigmatic case of the new generation of trade agreements. Looking at CETA offers a potentially representative picture of the type of technical discussion

that characterizes regulatory negotiations. It can also provide an overview of the different cooperation format used in PTAs generally. This research does not aim at merely describing, but also at explaining the causes underlying the choice of different regulatory design types. By identifying the explanatory factor and the causal mechanism, it becomes also possible to define the strategic reasoning responsible for the variation of states design choices across sectors within a single agreement.

## **Research structure**

This thesis is divided into three main parts. Part I. looks at the theoretical foundation of this research. Chapter 1 defines and specifies the scope of the dependent variable “types of regulatory design”. It situates “technical regulatory activities” among the broad spectrum of norm diffusion and establishes it as qualitatively separate category, different from “general norms of behaviors” (Finnemore and Sikkink 1998; Wiener 2007). The same chapter describes the two main dimensions composing the dependent variable: the nature of obligations and the mode of decision. This conceptualization uses as references previous contributions from the “legalization” and “rational choice” literature, including some of its recent discussion (Abbott et al. 2000; Koremenos, Lipson, and Snidal 2001b).

These two dimensions are also situated within the larger literature studying legal design of international institutions. From the intersection of these two dimensions, four types of regulatory design are established and illustrated, creating a 2x2 matrix: Type 1 (Ex-ante/Hard), Type 2 (Ex-post/Hard), Type 3 (Ex-ante/Soft) and Type 4 (Ex-post/Soft). As already introduced, these four “Types of Regulatory Design” represent four possible forms of regulatory settings that states might use in their cooperation: immediate rules-setting and binding (Type 1), delayed rules-setting and binding (Type 2), immediate but voluntary (Type 3), delayed and voluntary (Type 4).

Chapter 2 reviews previous contributions to explain legal design variation within international institutions, notably the Constructivist and Rational Institutionalist theoretical schools (Shaffer and Pollack 2012). As will be reviewed, constructivism inspired explanation looks at norms diffusion and long-term socialization to explain design variation (Jackson 2011, 197; 202; Wendt 1992; Lynn Doty 1993; Finnemore and Sikkink 1998; Dobbin, Simmons, and Garrett 2007; Goodman and Jinks 2004). It argues that the legal design of international treaties is largely replicated across several agreements (Baccini, Dür, and Haftel 2015; Allee and Elsig 2016).

On the contrary, Rational Institutionalism, especially the RD research agenda, rather focuses on design variation, attributing it to different cooperation problems that states are confronted to and attempt to solve (Koremenos, Lipson, and Snidal 2001a, 1051). It includes various empirical studies that investigated different legal mechanism and provisions while looking at their strategic implication for inter-state relations (Kucik 2012; Rosendorff and Milner 2001; Milner, Rosendorff, and Mansfield 2004; Kim 2017; Baccini, Dür, and Elsig 2015; Raess, Dür, and Sari 2018; Stone 2008; Shaffer and Pollack 2010; Abbott 2000).

According this research framework and following past literature, the cooperation problems that emerge result from states “strategic interactions” at the international level (Lake 1999, 4). These interactions result in the creation of a holistic structure, that impacts the process of negotiation independently from states original preferences (Lake 1999, 46–47). This conceptualization originate heavily from the concept of Complex Interdependence of Keohane and Nye, stressing the impact of transnational factors on states strategic reasoning and negotiating results (Keohane and Nye 2012, 28–29).

This same chapter introduces and review the literature on the two main risks constituting this structure: “Hold-up” and shirking. Mobilizing the literature already mentioned earlier, this section of the chapter argues that States uses Ex-ante design feature when the risk of “Hold-up” is high, and Ex-post when it is low. Indeed, when cooperation is plagued by “hold-up” risks, states are incentivized to mitigate them by limiting in time the cooperation. On the contrary, when such risks are absent Ex-post becomes a viable mean to institutionalize cooperation in an area. Risks of shirking are considered responsible for the design variation between Hard and Soft. This thesis poses that risks of a country shirking its obligation is higher when an existing or preexisting situation of divergences between countries regulatory frameworks exist in an area.

This divergence enables one of the parties to opportunistically use this pre-existing gap between countries’ regulations to erect new regulatory barriers to trade. Consequently, parties will design their cooperation through a highly binding language. The purpose is to obtain a strong legal commitment from both sides, to eventually allow the use of sanction mechanisms in case of obligations’ violations. On the contrary, when regulatory frameworks are converging, the benefits obtained from regulatory coordination will reduce this potential of shirking. Therefore, countries will rather use Soft obligation language to design their cooperation. The subsequent 2X2 matrix is created, where high risks of “hold-up” and shirking result in design Type 1 (Ex-ante/Hard; a high ); a high risk of “hold-up” but a low one of shirking causes Type 3 (Ex-ante/Soft); a low risk

of “hold-up” but a high risk of shirking lead to Type 2 (Ex-post/Hard); and low risks in both “hold-up” and shirking produces the use of Type 4 (Ex-post/Soft).

Following the presentation of the theoretical framework, Part II establishes the methodological approach of this project, including the operationalization of the two just mentioned explanatory factors, “*hold-up*” and *shirking risks*. In chapter 3, It introduces the multimethod comparative analysis, combining cross-case and within-case analyses, following Goertz (2017). As basis for comparison, this research uses as units of analysis: “Regulatory sectors”, as defined in Chapter 4. In CETA, 7 sectors are identified: Biotechnology (Biotech), Forest Products (Forest), Geographical Indications (GIs), Motor Vehicles (MV), Pharmaceutical Products (Pharma), Professional Qualifications (PQ) and Raw Materials. Chapter 4 specifies the operationalization process of the two risks. For “*hold-up*”, it refers mostly to the contribution of Cooley and Spruyt *Contracting States* (2009), providing a comprehensive framework for the study of contract incompleteness. It also includes works on the political-economy implication of firms positioning, upstream or downstream, along Global Value Chains (Gereffi 1994, 1999; Antràs and Chor 2013; Ponte and Sturgeon 2014). Shirking operationalization is based on the works of Abbott & Snidal (2009, 2010) on the role of States “orchestration” for Transnational New Governance and additional works looking at the impacts of private standards in contributing to the governance of value chains (Ponte and Gibbon 2005; Beghin, Maertens, and Swinnen 2015; Nadvi 2008).

In terms of empirical indicators used. “Hold-up” risk is measured through an overview of trade statistics from Eurostat and other sources of economic information, looking at the types of commodity exchanges and structure of the industry. These additional sources of data were found in more fine-grained trade databases, governmental and trade association websites. Shirking is assessed by looking at regulatory documents, position papers and regulatory meeting minutes. In addition, 22 representatives from public and private actors were interviewed, in Ottawa and Brussels (10 Canadians, 12 Europeans, list Appendix IV). Interviews followed a semi-structured approach and served as confirmatory source focusing on the negotiating process.

The empirical analysis starts with Part III. It is divided into two types of comparisons. Chapter 5 analyzes the legal design of the 7 sectors mentioned and classifies them into their related design types, as follows: GIs & MV (Type 1), PQ & Pharma (Type 2), Biotech/Raw/Forest (Type 4). It is followed by a general assessment of the sectors overall, through a cross-sectoral comparison. It compares first sectors belonging to Type 1 (GIs, MVs) with Type 2 (PQ, Pharma) to explain the role of high/low hold-up risk in the use of Ex-ante/Ex-post design. It then contrasts sectors

shirking risks results between sectors of Type 2 (PQ, Pharma) with Type 4 (Biotech, Forest, Raw). Among the 7 sectors analyzed , the explanatory frameworks supported the hypotheses for 6 cases, the only deviant case being Biotechnology. The chapter discusses potential causes of this outlier in this section 5.4, along with a counter-factual analysis, investigating constructivism-based explanations such as treaties replication impacts and Civil Society mobilization to control the main explanations. The following chapters (6,7 & 8) proceed through a separate process-tracing of the 7 sectors, organized along their belonging to the same design type. Chapter 6 looks at GIs and MV, Chapter 7 PQ/Pharma and Chapter 8 analyzes Biotech/Forest/Raw. Each chapter are concluded by a summary of the empirical findings. The conclusion discusses the empirical findings and their implication both for the research fields and societal implications of the different design of regulatory cooperation mechanisms.

## **Part I. Theory**

The first part of this thesis details the theoretical foundations of this research. At first, it defines the dependent variable, Regulatory Design type, and situates it within a larger theoretical corpus inspired by past contributions on Legalization and Rational Design (K. W. Abbott et al. 2000; Koremenos, Lipson, and Snidal 2001b). Two relevant dimensions are identified to conceptualize and classify four types of regulatory design: Hard/Soft Obligations and Ex-ante/Ex-post Mode of decision. Chapter 2 introduces the mechanism used to explain the design variation between these four different types (Type 1 Hard/Ex-ante; Type 2 Hard/Ex-post; Type 3 Soft/Ex-ante; Type 4 Soft/Ex-post). It discusses first Constructivism and Rational Institutionalism take on institutional design variation, arguing that the latter is more adequate for this research's purpose. Inspired by past literature, this thesis argues that two main sources of references are particularly pertinent to establish an explanatory framework: contributions centered on "contract (in)completeness problems" and "non-compliance problems". It creates a 2x2 matrix that will serve as main canvass to understand the decisions made by the parties when choosing design types, described in Part III. Empirics of this research

# Chapter 1. The concept of regulatory design

This chapter introduces and defines the dependent variable of this research: type of regulatory design. As contained in its name, Regulatory Design is a type of legalization used to institutionalize a certain type of cooperation activities at the international level. In other words, it represents different legal options that are available for states when they decide to engage in so-called “Regulatory Cooperation” activities.

## 1.1. *Definition and scope*

The notion of Regulatory Cooperation is difficult to conceptualize. It can include a wide set of policies and legal commitments, from sanitary measures to professional qualifications. The purpose and benefits of cooperation can be multiple, from solving a lake pollution conflict between two neighboring states, to addressing double taxation issues (Abbott and Snidal 2001). For public authorities, collaborating with their foreign counterparts on regulatory issues is already part of day-to-day activities. Nevertheless, in this maelstrom of transnational activities, it is useful to further specify what “Regulatory Cooperation” actually implies at the international level.

Despite several IOs attempting to categorize them, available classifications remain unsatisfactory. The OECD identifies 11 regulatory cooperation mechanisms, which include International Organizations, private codes of conduct and supranational organizations<sup>14</sup>. At the WTO, Regulatory Cooperation is divided between Technical Barriers to Trade (TBT), Sanitary and Phytosanitary Measures (SPS) and the General Agreement on Trade in Services (GATS)<sup>15</sup>. Cooperation is naturally not restricted to these organizations and myriad forms of collaboration exist between states, covering all different sectors. Telecommunication, environment and labor are all fields where states decided to integrate their ongoing cooperation into the trade agreements they sign with their counterparts. Nevertheless, in all these efforts for cooperation, it remains unclear to determine whether they are all similar to each other, or if some fundamental distinction

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<sup>14</sup> OECD, International Regulatory Co-operation – Better rules of globalization, <https://www.oecd.org/gov/regulatory-policy/irc.htm>, accessed the 24th April 2019

<sup>15</sup> Mavroidis, Petros C. 2016. *Regulatory Cooperation: Lessons from the WTO and the World Trade Regime*. E15 Task Force on Regulatory Systems Coherence – Policy Options Paper. E15Initiative. Geneva: International Centre for Trade and Sustainable Development (ICTSD) and World Economic Forum: [https://www.ictsd.org/sites/default/files/research/WEF\\_Regulatory\\_Cooperation\\_Lessons\\_WTO\\_WTR\\_report\\_2015\\_1401.pdf](https://www.ictsd.org/sites/default/files/research/WEF_Regulatory_Cooperation_Lessons_WTO_WTR_report_2015_1401.pdf), accessed the 24<sup>th</sup> April 2019.

can be made. Such a distinction would help determine whether this “new generation” of trade agreements do indeed distinguish themselves from their predecessors. More fundamentally, making a distinction in cooperation types between what could be considered standards/technical forms versus general behavior norms is instrumental to clarify the exact economic and social effects of different types of cooperation. This is even more important for this research as it determines the exact scope of the regulatory activities to be scrutinized. A good means to achieve this objective is to first define the object of cooperation, specifically what is a regulation.

In the literature, regulations and norms are often viewed alike and defined as: “a standard of appropriate behavior for actors with a given identity” (Finnemore and Sikkink 1998, 891). A public regulation is thus a “public norm” promoted by the states in a legal document. It prescribes or forbids certain types of general behavior. Several conceptual issues remain with this definition though, as acknowledged by Finnemore and Sikking themselves. These difficulties originate from the difficult to establish relationship between what is commonly seen as a “norm”, an abstract concept, and what is a “standard”, an apparently more material and concrete one. To solve this conundrum, Finnemore and Sikking include standards on the same continuum of norms, based on the degree of contestation/appropriateness (Finnemore and Sikkink 1998, 897–98). An emerging norm tends to be ideally/normatively based, and thus more contested in the public sphere. On the contrary, a norm that survives this contestation is internalized by actors and reflects in its contents the technical characteristics agreed upon (often) by consensus (e.g. the diameter of a machinery part). This approach is a major contribution as it initiates a distinction between different types of norms, that are often intuitively understood as different. Nevertheless, technical standards remain in this context simply another type of norms and do not exist as a separate category. Anya Wiener pursues this approach and makes a distinction between three types of norms: fundamental norms, organizing principles, and standardized procedures (Wiener 2007, 7). In her own words, a relation is established between the degree of contestation and level of specification of the details contained in the norm:

They evolve through the process of politics and policymaking and include such norms as accountability, transparency, gender-mainstreaming, peacekeeping or peace enforcement (Bovens, 2007, 104, Jackson, 2005). Finally, standardized procedures entail detailed and clearly articulated advice for specific activities such as, for example, a manual accompanying a flat-packed set of shelves (see Kratochwil, 1989). It follows logically that the most contested norms are the least

specific, that is, the fundamental norms, while the least contested are the most specific, that is, the standardized procedures (Wiener 2007, 9).

Even if these authors put norms and technical standards on one dimension (degree of contestation), in their respective conceptualizations they acknowledge that the degree of contestation does qualitatively impact the content of the norms. This distinction is even conceptualized as different categories, or types, in both Wiener and Finnemore & Sikking. This distinction is not without implications as it opens the doors to several possible assertions: first technical standards and general rules of behavior can be qualitatively differentiated based on the features of their content. Second, their process of production and function are also differentiated. While Norms, or what are called here general rules of behavior, emerged from normative discussions by ‘norms entrepreneurs’ taking place in the public sphere (Finnemore and Sikkink 1998, 897), technical standards emerged from authority-led problem-solving processes (Börzel and Risse 2003, 61). While norms question the “normative” legitimacy of general rules of behaviors, standards focus instead on the technical implementation steps of already agreed upon “norms”.

Besides empirical observation, this distinction between norms and standards is also reflected in different strands of research. Norms scholars are investigating mostly how shared ideas, meanings and identities can explain states’ behaviors (Finnemore and Sikkink 1998; Legro and Moravcsik 1999; Wendt 1992; Haas 1992; Risse-Kappen 1996; Checkel 1999). On the contrary, the standards-setting and micro-economics research agenda focuses rather on the role of standards as tools for economic actors to succeed in integrating their production processes, despite diverging interests (Genschel 1997; Ponte and Gibbon 2005; Beghin, Maertens, and Swinnen 2015). Standards act in this context as means of information, informing actors on the technical characteristics of a product or a production process (Nadvi 2008; Mattli and Büthe 2003).

As stated by Wiener and Finnemore, despite being potentially placed on different extremes of a same continuous dimension (degree of contestation), norms and standards do in fact distinguish each other qualitatively by many features, as presented. Several previous studies in trade policy have often conflated both notions and studied them jointly under the label “regulatory cooperation” (Alemanno 2015; Young 2015a). While this choice can be justified under many circumstances, I believe that a distinction between both is empirically useful and theoretically well grounded. Therefore, in the frame of this work, this study’s scope only includes “technical standards” cooperation and excludes “general norms of behaviors” forms of cooperation. This

choice is justified by the qualitative difference as presented, between “norms” and “standards”, specifically in the origin of their emergence, their content and the respective functions they fulfill domestically and internationally. This implies that certain forms of cooperation considered in previous studies as “Regulatory Cooperation” are excluded, such as Labor or Sustainable Development.

To help build this conceptualization of Regulatory Cooperation as “technical standards cooperation”, I mobilize ISO Guide 2 providing useful definitions of regulations:

Regulations that provide technical requirements, either directly or by referring to or incorporating the content of a standard, technical specification or code of practice<sup>16</sup>.

Regulatory Cooperation aims in this context at harmonizing, cooperating in the development of or facilitating mutual recognition of technical characteristics of products. As an instance, the International Accounting Standards Board elaborates standards for international accounting<sup>17</sup>. Actors can refer to these standards as a set of rules agreed upon worldwide. By respecting them, they have the guarantee that participants in this organization will recognize their accounts. Beyond mutual recognition, there are other regulatory instruments possible. Technical regulations are an overarching concept in ISO; therefore, it includes many diverse standardization and regulatory activities related to goods or services. In line with ISO, this research focuses only on ‘standards setting’ practices included in Preferential Trade Agreements. It adopts the following definition: “all types of cooperation between parties, which targets regulations providing technical requirements for goods or services”. The mention of “goods and services” is important, as the term “technical” can be applied to both material and immaterial products traded across the border.

This work thus looks at legal provisions related to standard setting throughout trade agreements. It does not discriminate certain chapters but adopts a transversal approach. It is possible to find standards on pollution in environment chapters and in motor vehicles annexes. Therefore, only by looking article by article was it possible to determine whether the provision related to standard setting or not. The method chapter details this process further, as well as Appendix I, II and III.

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<sup>16</sup> The International Organization for Standardization (ISO). 2004. “ISO/IEC Guide 2 Standardization and Related Activities - General Vocabulary”, p. 17: <https://www.iso.org/standard/39976.html>, accessed the 28<sup>th</sup> May 2020.

<sup>17</sup> International Financial Reporting Standards Foundation, <https://www.ifrs.org/>, accessed the 14th January 2018.

In the meantime, it suffices to say that the corpus includes all regulatory cooperation activities in CETA if they provide or aim to provide technical characteristics. Chapter divisions such as Labor, Environment, TBT, etc. are irrelevant if the legal provisions contained correspond to the definition provided. This view of regulatory cooperation departs from how states portray Regulatory Cooperation. For instance, CETA only calls chapter 21: “Regulatory Cooperation”<sup>18</sup>. This chapter 21 includes a horizontal approach to cooperation. Focusing on this chapter would result in the exclusion of other types of regulations notably sectoral ones. By using a common definition, this study can thus avoid this trap and target regulatory provisions irrespective of their form of legal design. It is then possible to classify all forms of regulatory cooperation into the different types.

As reviewed in this section, Regulatory Cooperation within this project only includes regulatory activities related to technical standards and excludes “norms” based forms of cooperation. This distinction and reasons for exclusion originated from the qualitative differences between the two, as acknowledged by the literature (Wiener 2007; Finnemore and Sikkink 1998). Therefore, the study of Regulatory Cooperation requires to look at how states legally designed their technical standards cooperation. These legal features are key to determine the characteristics of the cooperation and its potential consequences for non-states actors. In this context, this research argues that two main legal features, dimensions, are instrumental to classify different potential design types: degree of “Obligation” and mode of “Decision”. The choice of these dimensions is grounded in recent theoretical discussion on legal design at the international level and is justified in following section.

## *1.2. Two dimensions: nature of “Obligation” and mode of “Decision”*

When signing a trade agreement parties do not simply commit legally to cooperate. They also decide how to cooperate and on which legal basis. “Legalization” in an international agreement is a “particular form of institutionalization” (Abbott et al. 2000, 386) of a certain form of relation between more than two states. Not all legalizations are similar though, they differentiate from one another based on characteristics contained in their legal provisions. For regulatory cooperation, this research argues that two characteristics are instrumental in classifying these different types

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<sup>18</sup> European Commission, CETA chapter by chapter, <http://ec.europa.eu/trade/policy/in-focus/ceta/ceta-chapter-by-chapter/>, accessed the 10th May 2019.

of cooperation: nature of obligation and mode of “decision”. These two features matter for states and determine how they decide to legally organize their cooperation regarding a particular issue.

This choice refers to the descriptive agenda of Rational Design, which looks at the design of international institutions (Koremenos, Lipson, and Snidal 2001b). While relating to “legalization” (Abbott et al. 2000), this conceptualization departs from the original account, however, as it only retains one dimension (obligation) of the original three (obligation, delegation, precision). It also introduces the mode of “Decision” dimension. “Obligation” continues to measure the binding nature of the legal provisions (Hard/Soft), while “Decision” looks at the timing of the regulatory cooperation (Ex-ante/Ex-post). “Decision” could be seen as being part of the original “Delegation” dimension. Nevertheless, the scope of the dimension focuses rather on the timing of “rule-making” instead of the formal delegation of authority. The next two-subsections justify this choice through exposing the shortcoming of the disregarded dimensions (precision, delegation) and the strengths of the one selected.

### **“Nature of Obligation”**

In concrete terms, “nature of obligation” looks at the binding essence of legal treaties. In other words, how much a state agrees to legally commit to a treaty. For instance, the Copenhagen Summit on Climate Change in 2009 did not result in states’ legal commitments to act on climate change<sup>19</sup>. On the contrary, the Paris summit of 2015 does legally bind its signatories to make nationally determined contributions to reduce CO2 emissions<sup>20</sup>. This difference in level of commitment refers to the variation between Hard and Soft law in international law. Legalization’ authors introduce three dimensions to assess and determine the variation between the two: obligation, precision and delegation (Abbott et al. 2000). In their view, the dimensions complement and reinforce each other:

The term hard law as used in this special issue refers to legally binding obligations that are precise (or can be made precise through adjudication or the issuance of

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<sup>19</sup>John Vidal, Allegra Stratton / Suzanne Goldenberg, “Low targets, goals dropped: Copenhagen ends in failure”, *The Guardian*, 19<sup>th</sup> December 2009, <https://www.theguardian.com/environment/2009/dec/18/copenhagen-deal>, accessed the 1<sup>st</sup> June 2019.

<sup>20</sup> United Nations Framework Convention on Climate Change, “The Paris Agreement”, <https://unfccc.int/fr/process-and-meetings/the-paris-agreement/l-accord-de-paris>, accessed the 1<sup>st</sup> June 2019.

detailed regulations) and that delegate authority for interpreting and implementing the law (Abbott and Snidal 2000, 421).

The realm of “soft law” begins once legal arrangements are weakened along one or more of the dimensions of obligation, precision, and delegation. This softening can occur in varying degrees along each dimension and in different combinations across dimensions (Abbott and Snidal 2000, 422).

The high or low level of the three dimensions taken together determines whether a legal provision belongs to hard or soft law. However, it appears after scrutiny that not all the three dimensions are of similar importance (Bélanger and Fontaine-Skronski 2012). A high or low level of “Obligation” often seems sufficient to produce hard or soft law. When assessing the three dimensions, the 2000 special issue of International Organization used a logic of “unequal partial compensation” (Bélanger and Fontaine-Skronski 2012, 245). This helped the authors to “artificially” downplay the real influence of “Obligation”. Obligation appears hence in reality to play a disproportionate role compared with precision and delegation, being close to becoming a sufficient condition (Bélanger and Fontaine-Skronski 2012, 242). Further, when looking at the variation in the three dimensions, only obligation seems to vary independently (Bélanger and Fontaine-Skronski 2012, 243). The variation in precision and delegation appears instead to depend on the level of Obligation.

Other studies corroborated these findings, notably for Precision. Goodman and Jinks (2004, 656) found that a high level of Precision can deinstitutionalize hard law, undermining its compliance. In her case study of mercenary legalization, Percy (Percy 2007, 390) also showed how precise conditions can create loopholes, undermining a norm. Looking at the precision of a legal provision can thus be self-defeating. A high level of precision can act *a contrario*, weakening the institutionalization of the cooperation. Intuitively this is less surprising than it appears. To avoid having to implement its commitments, a state can devise very strict conditions to reduce the scope of application. By limiting the latter to only marginal or unlikely cases, they can exonerate themselves from their legal obligations. Delegation also encounters several limits. The next section discusses these shortcomings, which are related to the time of “Decision”.

If not Precision and Delegation, the question remains: why is Obligation important? Reus-Smit originated this particularity by the “interstitial” conception of politics underlying legal “obligation” (Reus-Smit 2003). Legal agreements require parties to respect their commitments

even when they run against their short-term interests. A commitment is more than a simple given agreement. It mobilizes deep underlying social and historical references, at the foundation of political legitimacy itself (Reus-Smit 2003, 621). Thus, violating a legal commitment has political consequences. It can undermine the legitimacy of its author and hence its right to rule. To avoid that, using the nuance of legal design is a privileged tool for states. Obligation is hence not only what states agree to do legally but also politically. Not respecting its obligation risks jeopardizing its reputation and compromising future cooperation. Therefore, states are careful when designing legally their respective obligations.

Overall, these findings are important to guide the researcher in the analysis of legal language. As precision and delegation become dimensions depending *in fine* to the variation of “Obligation”, “Obligation” takes priority when looking at international institutions. The analysis of legal language focuses hence on the discursive term related to the “bindingness”, such as “The Parties shall implement [...]”, “The Parties should [...]” or “are encouraged to [... ]”. Following previous works on legalization, the dimension “Obligation” varies dichotomously, between Hard and Soft. Hard Obligation includes legal provisions that are legally binding for signatories of the agreement, while Soft Obligations are voluntary rules. Appendix I and Chapter 4 detail the procedure used to make this distinction. To note that the analysis of legal language only focuses on the legal features of the rules, not their substance (Abbott et al. 2000, 402). Only the legal form of the regulation matters for the research, not the consequences of their implementation.

### **“Mode of Decision”**

As political commentators can observe, states do not always take decisions immediately. In certain cases, even after concluding an agreement, they might prefer to defer decisions. For instance, even after concluding the Uruguay Round, some agriculture issues remained pending and are currently discussed at the WTO Committee on Agriculture<sup>21</sup>. This committee is an instance of an “Ex-post” mode of decision. On the contrary, the “Anti-Dumping Agreement” at WTO is an example of an Ex-ante mode of design, as a series of rules are decided upfront by the parties. Another analogy is the one of contracts. Contracting parties can write down the precise terms in the contract itself or they can simply commit in the contract to agree on precise terms

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<sup>21</sup> WTO, “WTO organization chart”, [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org2\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/org2_e.htm), accessed the 1<sup>st</sup> June 109.

later following certain decision-making rules. Besides Obligation, rules have also a temporal feature. Are they immediately listed in the agreement or do they postpone regulatory cooperation? The second-dimension time of “Decision” considers this possibility. Present in the literature, this dichotomy distinguishes Ex-ante rules, designed in the text before the entry into force, from the rules developed after treaty implementation or Ex-post (Ress 1994; Kim 2012; Postnikov and Bastiaens 2014).

Legalization and Rational Design theories also indirectly touch upon this concept, notably through “delegation”. Both Delegation and Decision attempt to understand the creation of new bodies in charge of the production of new regulations. As Bradley and Kelley (2008, 3) define it, international delegation is a “grant of authority by two or more states to an international body to make decisions or take actions”. Both dimensions envision the possibility of creating new regulatory bodies *ex nihilo*. Creating regulatory bodies can also provide flexibility by allowing negotiators to delay rule-making (Koremenos 2008). It offers a temporal flexibility to parties until they feel ready to regulate. Nevertheless, it is not the only way. As illustrated by Koremenos (2005, 2008), escape and withdraw clauses play the same role. All these legal instruments (withdraw clauses, regulatory bodies, etc.) fulfill the function of “international insurance” for states. In case domestic opposition prevents collaboration, states can delay or carve out specific points of contention without compromising the whole agreement (Rosendorff and Milner 2001, 842). Delegation nevertheless encounters certain issues. After scrutiny, it appears to include two forms of delegation, one “internal” and one “external”:

[...]internal delegation is defined as delegation to a collective formed by the members of the agreement themselves, as distinguished from external delegation, defined as delegation to a third party outside of the agreement (Koremenos 2008, 152).

In internal delegation, states keep their regulatory cooperation authority while in external they delegate it to an external body (Bélanger 2010, 25). The concept of delegation intuitively seems to correspond to “external” delegation instead of “internal”. This is how the authors of legalization see “Delegation” as cited earlier, defining it as a “grant of authority” (Abbott et al. 2000, 401). However, and according to a survey of 97 existing international agreements, no instances of external delegation could be found (Koremenos 2008, 162). On the contrary, this study identified ten cases of internal delegation. Put into perspective with the definition of Bradley and Kelley, this suggests that regulatory cooperation delegation of authority does not seem to exist (Bélanger

2010, 24–25). Other studies also confirm this result either by observing that delegation is irrelevant in international environmental regime (Böhmelt and Pilster 2010) or simply absent for international institutions (Guzman and Landsidle 2008). The concept of delegation appears hence inadequate to study rule-making. To note that the notion of delegation here excluded cases of adjudication. Adjudication can indeed be considered as an instance of “delegated” enforcement authority. It is, however, different from rule-making, which is the focus of this research. In fact, the delegation of authority in regulatory affairs is very limited as stressed by the research of Koremenos (2008), which induced the idea of rejecting delegation. Nevertheless, in another research context looking at adjudication, delegation would become instrumental.

As an alternative, this research proposes to focus on cases of “internal delegation” and other regulatory mechanisms that include temporal flexibility. The relevant point is not the delegation of regulatory competences (it is absent) but the temporal decision to regulate, either now or later (Bélanger 2010, 24–25). By looking at the time of decision in legal provisions, it is possible to study dilemmas faced by states in designing their cooperation. To explicate the differences between Ex-post and Ex-ante, the former postpones the decision to create rules, while the latter directly integrates regulations into the legal corpus of the agreement. In Ex-ante, joint rules enter into force at the same moment than the agreement with immediate legal effects. For instance, parties could list the regulations in an annex, joined to the agreement. On the contrary, an Ex-post provision establishes a committee responsible for developing new rules or amending existing one.

As reviewed in this section, both the degree of “Obligation” and time of “Decision” dimensions appear to be the most appropriate to analyze the design of legal provisions in Regulatory Cooperation. Among the three dimensions mentioned in the legalization corpus (obligation, precision and delegation), level of "Obligation" remains the only dimension to vary independently. Both precision and delegation suffer from several shortcomings notably their variation dependence towards obligation. Complementary to obligation, the dimension time of "decision" measures the temporal variation between immediate (Ex-ante) and postponed (Ex-post) regulatory cooperation. From the interaction of these dimensions (Obligation and Decision), a matrix of four categories emerged. The next section describes these four types of design, coupled with empirical instances from contemporary international cooperation. To note that the variation of “Types of Regulatory Design”, covered in the next section, is the dependent variable of this research.

### *1.3. Four types of Regulatory design*

From the previous review of the dimensions: “Obligation” and “Decision”, this research states that parties to an international agreement design their cooperation according to four alternatives (Table 1): Hard Obligation / Ex-Ante Decision (Type 1); Hard Obligation / Ex-Post Decision (Type 2); Soft Obligation / Ex-Ante Decision (Type 3); Soft obligation / Ex-Post Decision (Type 4). According the circumstances, interstate cooperation can take the form of either of these four types. Legal language varies among four prominent features: immediate, binding, delayed or voluntary. These characteristics have important implications for states’ cooperation as will be presented later.

It is important to stress that this typology does not imply that alternatives are not useful, for instance the three types of regulatory cooperation proposed by Drezner (2007) (co-ordination, convergence and harmonization). This research argues that the linkages of exclusive specific “mechanism” (equivalence, mutual recognition...) to each type might be dubious. States appear to be more pragmatic in their use of “regulatory instruments” and focus rather on their legal effects to design their regulatory cooperation. While it is possible to use Drezner’s types in other contexts, in CETA it appears to be problematic as no instances of “harmonization” seems to be present. While that does not signify that there are no forms of regulatory alignment between parties, as illustrated by the GIs and Motor Vehicles cases in Part III., but rather that the mechanism chosen might be different or the term inadequate. It is also possible that within a single trade agreement this variation is less visible than with a database comparing all different forms of regulatory cooperation at the international level. Irrespective of the reasons behind, this research looks only at the regulatory effects categorize in the design types.

The four design types conceptualized here have their own particularities. To assess the impact of Regulatory cooperation activities, it is key to understand the nature of each type and their respective differences. In a second step and covered in the following, the mechanism, and factors responsible for the variation of these regulatory design types are identified. In the meantime, this section describes them one by one. To note that each type includes a different form of rule-making present in international agreements but also in other contexts of transnational cooperation. Therefore, even if the empirical evaluation of this study focuses on CETA, fields other than international trade can use these design types. The descriptions that follow include several illustrations of non-trade instances to illustrate this last point.

Degree of Obligation		
	Hard	Soft
Ex-ante	Type 1	Type 3
Mode of Decision		
Ex-post	Type 2	Type 4

*Table 1 Types of Regulatory Design*

#### **Type 1: Hard Obligation / Ex-ante Decision**

When faced with the possibility to set a joint regulatory framework, inter-state cooperation has the option to integrate rules directly into the main text of the agreement. This takes different legal forms, but a common instance is the addition of an annex at the end of an international treaty. Although, they follow the main corpus of the agreement, legal provisions contained in legal design of Type 1 have the same legal value as the rest of the treaty. The Vienna Convention on the law of treaties specifies these conditions of interpretation in Article 31<sup>22</sup>. Beyond adding an annex, Type 1 legal provisions can also list detailed regulations in the agreement's chapter or be the sole object of an entirely different treaty. All options are possible and do not predetermine the instrument but only the legal status of the rules produced. As Hard/Ex-Ante rules contain Hard obligations, they often go in deep technical details to assure the good implementation of the cooperation between the parties. They specify precise requirements, which can be technical characteristics of products/services, conditions for production, conformity assessment procedures, etc.

Although, this research looks at regulatory cooperation in trade agreements, regulatory design is not only present in trade fields. Similarly types of design are also used for cooperation on security, environmental issues, etc. As an illustration of a well known case of security regulatory cooperation through an international treaty, the “Annex 1 - Nuclear Related Commitments” of the Joint

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<sup>22</sup> United Nations. 1969. “Vienna Convention of the law of treaties”: [https://treaties.un.org/doc/publication/unts/volume\\_1155/volume-1155-i-18232-english.pdf](https://treaties.un.org/doc/publication/unts/volume_1155/volume-1155-i-18232-english.pdf), accessed the 12th December 2018.

Comprehensive Plan of Action (JCPOA)<sup>23</sup> is a good instance of design Type 1. Like traditional trade agreements, which add tariff schedules after the main text, the JCPOA followed a similar structure:

The Joint Comprehensive Plan of Action comprises of a main text, and five technical annexes - on nuclear, sanctions, civil nuclear energy cooperation, a joint commission, and implementation. These documents are detailed and specific: that is important because all sides wanted clarity so as to ensure the full and effective implementation of the agreement<sup>24</sup>.

The JCPOA Annex 1 lists specific mandatory technical conditions:

Iran will redesign and rebuild the reactor, based on the agreed conceptual design (as attached to this Annex) to support its peaceful nuclear research and production needs and purposes, including testing of fuel pins and assembly prototypes and structural materials<sup>25</sup>.

Both in terms of structure and content, this annex is an ideal example of a Type 1 regulatory cooperation design. The language of commitment is clear and establishes a high level of “bindingness”. It also specifies technical conditions, notably reactor plant designs that will have immediate legal effects. Even if the rules allow Iran some time for implementation, the legal obligations have constraining effects. According to the agreement, after the conclusion of the treaty Iran will have to demonstrate that it is taking immediate steps to effectively implement the rules specified. This illustration exemplifies well the features of a Type 1 design, which contains constraining legal obligations simultaneous with the entry into force of the agreement.

A lesser-known instance of Type 1 cooperation is the conclusion of the Veterinary agreement between the EU and Canada, signed in February 2005. This agreement lists the exact technical

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<sup>23</sup> Council of the European Union. 2015. “JCOPA - Annex I – Nuclear-related measures.”: [https://eeas.europa.eu/sites/eeas/files/annex\\_1\\_nuclear\\_related\\_commitments\\_en.pdf](https://eeas.europa.eu/sites/eeas/files/annex_1_nuclear_related_commitments_en.pdf), accessed the 14th June 2020.

<sup>24</sup> Delegation of the European Union to Papua New Guinea, “Joint statement by EU High Representative Federica Mogherini and Iranian Foreign Minister Javad Zarif”, 14<sup>th</sup> July 2015: [https://eeas.europa.eu/delegations/papua-new-guinea/3244/joint-statement-by-eu-high-representative-federica-mogherini-and-iranian-foreign-minister-javad-zarif-vienna-14-july-2015\\_en](https://eeas.europa.eu/delegations/papua-new-guinea/3244/joint-statement-by-eu-high-representative-federica-mogherini-and-iranian-foreign-minister-javad-zarif-vienna-14-july-2015_en), accessed the 14<sup>th</sup> June 2020.

<sup>25</sup> Council of the European Union. 2015. “JCOPA - Annex I – Nuclear-related measures.”, p. 2: [https://eeas.europa.eu/sites/eeas/files/annex\\_1\\_nuclear\\_related\\_commitments\\_en.pdf](https://eeas.europa.eu/sites/eeas/files/annex_1_nuclear_related_commitments_en.pdf), accessed the 14th June 2020.

standards considered as equivalent in EU and Canada for a precise list of animal products<sup>26</sup>. For instance, the EU and Canada established an equivalence between EU and Canadian standards on “live aquaculture animals and products destined for human consumption or aquaculture”<sup>27</sup>. This type of agreement satisfies the criteria for Ex-ante/hard as it specified upfront the exact products/regulations to be recognized with binding obligations. It shares similar features with the JCAP as they both contained already decided lists of regulations/products on which parties agree jointly to recognize.

In sum, Type 1 contains strongly binding commitments to abide by rules that have already been decided; there are no provisions for adding rules in the future to the set of previously decided ones. At the conclusion of the agreement, the design defines all the components of regulatory activities and strongly commits the parties. It shows which technical rules need to be respected following the successful conclusion of the negotiation. As previously mentioned, fields other than nuclear or trade policy use similar cooperation frameworks. As long as the regulations agreed upon in the legal text are defined and listed at the entry into force of the agreement with constraining provisions, they belong to Type 1. Contrary to Type 1, Type 2 design uses similar binding language but postpones rule-making.

### Type 2: Hard Obligation / Ex-post Decision

Certain types of legal mechanism, despite their competence to produce binding rules, adopt general principles and postpone the adoption of common binding standards. When the agreement enters into force, only the regulatory mechanism is in place while the rules themselves are missing. Type 2 establishes the basis of a joint cooperative framework without listing all the enforceable regulations or technical requirements. Proposals of new regulations or amendments are the subject of later discussion, as scheduled in the agreement. This type of design typically

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<sup>26</sup> European Commission DG AGRI, “Sanitary and Phytosanitary Agreements”, [https://ec.europa.eu/food/safety/international\\_affairs/trade/agreements\\_en](https://ec.europa.eu/food/safety/international_affairs/trade/agreements_en), accessed the 12<sup>th</sup> December 2018.

<sup>27</sup> EUR-Lex, « 2013/397/EC : Commission Decision of 26 May 2009 approving on behalf of the European Community certain amendments to Annex V to the Agreement between the European Community and the Government of Canada on sanitary measures to protect public and animal health in respect of trade in live animals and animal products”, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013D0397>, accessed the 12<sup>th</sup> December 2018.

creates a committee composed of representatives from both parties. As the parties of the agreement do not delegate formal regulatory cooperation competences, the committee depends on the will of the states to regulate. Usually, while the committee produces the rules, the latter are then made binding by a process involving a superior body (commission, conference, etc). States nevertheless legally commit to respect the rules adopted *in fine*. It offers a framework in which negotiators can discuss and adopt joint binding regulations. Naturally, mechanisms others than committees are possible. Parties can set binding equivalence guidelines that national accreditation bodies will have to follow. For instance, the EU can list a series of conditions that need to be followed for foreign regulations, e.g. Canadian ones, to be considered as equivalent. This is different from Ex-ante as the design is left open regarding which regulations it will apply. Indeed, it sets conditions that can then be applied with flexibility to assess the safety, for instance, of regulations and products.

The mechanism creates a binding obligation to recognize a product/regulation if the conditions specified are met. For instance, a Canadian firm following a Canadian regulation on health, which is considered as equivalent to its European equivalent, will not have to demonstrate twice that it complies with requested health requirements. The equivalence mechanism allows regulatory authorities from both sides to detect whether a firm is already compliant without having to duplicate the conformity assessment procedure. In this configuration, the entry into force of the agreement will not immediately establish equivalences between regulations, but will be put in place progressively, upon parties' mutual agreement. Not all equivalences can enter in Type 2 however. This type only includes binding regulations, which accreditation organs have the legal obligation to recognize.

The European Union system of equivalence and recognition for organic production rules and control systems is a good illustration of Type 2. Both, the Council Regulation (EC) No 834/2007 on organic production and labelling of organic products and Commission Regulation (EC) No 889/2008 of 5 September 2008 contain the rules for equivalence and recognition<sup>28</sup>. These regulations set the criteria used by control authorities to establish equivalences in the EU. Regulation (EC) 1235/2008 also specifies requirements to recognize third countries' production rules and control systems, listed in annex III of the same regulation. Bilateral equivalence agreements with third countries also complement these rules. Taken together, these regulations

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<sup>28</sup> DG Agriculture and Rural Development, "Importing organic produce", [https://ec.europa.eu/agriculture/organic/eu-policy/eu-rules-on-trade/non-eu-trading-partners\\_en](https://ec.europa.eu/agriculture/organic/eu-policy/eu-rules-on-trade/non-eu-trading-partners_en), accessed the 16th January 2019.

and agreements establish a regulatory Hard/Ex-post design type. The regulations do not list the foreign regulations considered equivalent but put into place a mechanism that will recognize them following the conditions set in the text. Enshrined in EU legal texts, the results of this Ex-Post mechanism are binding. Article 8 the EC regulation 1235/2008 illustrates how the EU equivalence procedure works:

#### Article 8

##### Procedure for requesting inclusion in the list of third countries

1. The Commission shall consider whether to include a third country in the list provided for in Article 7 upon receipt of a request for inclusion, from the representative of the third country concerned.
2. The Commission shall only be required to consider a request for inclusion which meets the following preconditions.

The request for inclusion shall be completed by a technical dossier, which shall comprise all the information needed for the Commission to ensure that the conditions set out in Article 33(1) of Regulation (EC) No 834/2007 are met for products intended for export to the Community, namely:

- (a) general information on the development of organic production in the third country, the products produced, the area in cultivation, the production regions, the number of producers, the food processing taking place;
- (b) an indication of the expected nature and quantities of organic agricultural products and foodstuffs intended for export to the Community; [...]<sup>29</sup>

This article does not mention precise conditions for production but oversees the establishment of technical equivalence. It sets a list of technical conditions to be fulfilled without prescribing the means to do so. For instance, one way could be to directly implement a European standard in the production. Another option would be to keep national standards but certify the products by a

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<sup>29</sup> EUR-Lex Commission Regulation (EC) No 1235/2008, 8 December 2008, “laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries”, <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1235>, accessed the 14th June 2020.

European accreditation organ or establish a recognition agreement between equivalence organs. In fact, this article does not have immediate legal effects for third countries but instead determines the equivalence conditions within the EU. Upon obtaining equivalences for their products, these foreign countries will have access to the European market.

PTAs also have their own solutions for designing Type 2 regulatory cooperation. For example, they can have an empty annex or contain the formulation: “to be agreed in a later stage”<sup>30</sup>. Even though the main text directly refers to the annex as legally binding, the absence of technical information leaves the definition of future rules open. As an alternative, negotiators define guidelines for future cooperation. While they do not take immediate decisions on which rules or regulations to amend or implement, they agree on a binding road map. Another possibility is the creation of an implementation committee. Working groups are a classical instrument at the disposal of negotiators to institutionalize their ongoing administrative cooperation. Bilateral consultations and their related obligations (to notify the other party of a new regulation and provide answers to his comments) are also part of the tools available. Overall, Type 2 legal design designates a type of framework with the same level of legal obligation as Type 1 but with a delayed regulatory mechanism. Type 3 instead puts forward voluntary but immediate rules, a sensitively diverse approach towards regulatory cooperation.

### Type 3 : Soft Obligation / Ex-ante Decision

Before describing this type of design, it is important to inform the reader that CETA contains no instances of Type 3 (detailed in Chapter 4 and 6). The fact that trade agreements are legally binding might be responsible for this omission. Negotiators might prefer to save time and resources by not discussing voluntary technical requirements in great details. Instead, as the rules will be voluntary, they might feel that it is more productive to postpone the subjects to later discussions. This way, they might as well avoid legally inflating the agreements with weak provisions.

This does not imply that instances of Type 3 do not exist in international instruments other than formal agreements. Type 3 can complement certain legal documents by offering optional best

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<sup>30</sup> For instance, Annex 5-D of CETA (SPS): Guidelines to determine, recognize and maintain equivalence; Determination and Recognition of Equivalence: To be agreed at a later stage

practices for the purpose of facilitating implementation. As an illustration, it is possible to mention as illustration the “Agreement on Sustainable Garment and Textile”<sup>31</sup> signed by the Dutch government and a wide coalition of stakeholders<sup>32</sup>. Signed July 4<sup>th</sup> 2016, this agreement aims a regulating the Dutch textile sector through a “Corporate Social Responsibility” (CSR) canvass. To do so, the text contains direct references to voluntary guidelines and non-bindings rules of conduct. While the signatories commit themselves to the text, the provisions nevertheless remain as “best endeavor” type without strict legal requirements to be fulfilled:

At most two and a half years after signature of the Agreement, an independent evaluation (mid-term review) will be conducted to assess both the progress and the operation of the Agreement and ascertain whether it is possible or necessary to establish a supervisory board to oversee the Agreement. This will be followed, after five years, by a (final) review. If it is found on these occasions that the number of participating enterprises and/or the results do not meet expectations, additional measures can be taken. These can also be of a more binding nature, where it will be ascertained whether legislation and regulations would be an option<sup>33</sup>.

This agreement includes several regulations, notably the UN Guiding Principles on Business and Human Rights (UNGPS) and the OECD Guidelines for Multinational Enterprises. These international rules of conduct support regulations on international trade through voluntary requirements. They do not contain strong legal injunctions and offer wide flexibility in the definition of obligations. The legal effects of the rules are hence weaker relative to Type 1 or 2. Their main aim appears to guide actors without forcing them to abide by strict technical requirements. These regulations remain interesting as they detail directly all the technical requirements without making them compulsory. This does not mean that they will have no effects whatsoever. Parties might feel obliged to implement their commitments based on self-constraint. Beyond this agreement, other similar legal instruments possibly exist for topics other than value chains.

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<sup>31</sup> The Social and Economic Council of the Netherlands, “75 signatures endorse Sustainable Garment and Textile Sector agreement”, 2016, <https://www.ser.nl/en/publications/news/20160704-sustainable-garment-textile-sector.aspx>, accessed the 25 March 2018

<sup>32</sup> There are currently no other states signatory of the agreement, but other international actors are members of the treaty, such as international Organizations (UNICEF) and NGOs (Stop Child Labour Coalition)

<sup>33</sup> The Social and Economic Council of the Netherlands, “75 signatures endorse Sustainable Garment and Textile Sector agreement”, 2016, p. 6: <https://www.ser.nl/en/publications/news/20160704-sustainable-garment-textile-sector.aspx>, accessed the 25 March 201

Type 3 design includes documents that despite listing comprehensive rules do not legally bind their signatories. Even if parties implement none of the provisions contained, this will not result in a violation of their commitments as the document did not specify obligations regarding results, such as effective implementation. Demonstrating that efforts were deployed to apply the rules is sufficient. On the legal language format, Type 3 design can take the form of best endeavor clauses such as “parties are encouraged to ...” followed by a list of requirements. If the provision contains stronger terms, it will be categorized in Type 1, as non-compliance would cause a violation of commitments. On the contrary, in Type 3 even unsuccessful efforts can fulfil legal obligation. Present in trade agreements, Type 4 keeps this Soft obligation characteristic of Type 3 but postpones the decision on the choice of common rules. To do so, it relies on working groups and future cooperation as described below.

#### **Type 4: Soft Obligation / Ex-post Decision**

In certain cases, immediately setting the terms and conditions of regulatory cooperation might be inadequate. General parameters or principles agreed between parties are enough and details can be discussed in later stages. Legal design of Type 4 corresponds to this configuration. It makes available different solutions that allow countries to show their good will for collaboration, without deciding immediately on technical aspects.

Among the examples of Type 4 design, the Asian Regional Forum (ARF) is a good illustration of a mechanism for promoting peace, security and economic exchanges without strong legal commitments. In fact, the ARF’s legal design has limited ability to intervene in topics within national sovereignty (Emmers and Tan 2011). The organization plays an important role in developing and promoting regional security principles in Asia (Katsumata 2006). Instead of using formal legal agreements, the ARF privileges the diffusion of codes of conduct and best practices to contribute to regional governance. It offers its members the tools and a framework to develop regulations on security. For instance, in August 2018, China and the ASEAN countries agreed on a draft document for a code of conduct in the South China Sea at the ASEAN Regional Forum<sup>34</sup>.

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<sup>34</sup> NIKKEI Asian review, “ASEAN and China create ‘single draft’ for South China Sea code of conduct”, <https://asia.nikkei.com/Politics/International-Relations/ASEAN-and-China-create-single-draft-for-South-China-Sea-code-of-conduct>, accessed the 16th January 2019.

The ARF offers a useful mechanism for states to produce voluntary rules when they feel the need. These voluntary rules were not agreed originally with the creation of the forum but were developed progressively through an “informal framework to carry out a security dialogue” (Katsumata 2006, 182). The first action plan of the Association of Southeast Asian Nations (ASEAN), the “Hanoi Plan of Action”, only specifies the regulatory cooperation competences of the ARF without giving actual regulations<sup>35</sup>. By design, the ARF acts as a forum to regulate and produce weakly binding rules without impeding on the sovereignty of its members. Its soft legal obligation and Ex-post decision-making process are key features of its regulatory style. It relies on voluntary instruments such as technical cooperation, information exchange, and promotion of international standards.

Many fields other than peace and security contain similar legal instruments, notably international trade. The United States – Canada Regulatory Cooperation Council (RCC)<sup>36</sup> is another instance of a non-binding and delayed channel of cooperation. According the Joint Forward Plan of August 2014, the RCC is to establish bilateral dialogue between the two countries, without binding commitments of regulatory recognition<sup>37</sup>. Under its umbrella, different discussion by states can take place while preserving the policy space of both parties. Indeed, while requirements for dialogue might be included, there are no obligations of results in the form of a list of harmonized standards, for instance. The purpose of these Type 4 frameworks, such as RCC or ARF, aims at providing general guidance on technical cooperation between national administrations. While they do not specify at the outset the exact regulations, they offer flexible options to prepare regulations and convergence. For instance, bilateral dialogue can serve as a channel of communication for states and bureaucrats.

This subsection concludes Chapter 1 on the concept of Regulatory Cooperation and its types of design. As seen throughout the text thus far, when negotiators cooperate but do not want to establish a highly binding regulatory framework or an optional list of regulations, they use Type 4 voluntary design. When there is goodwill among parties, they might include in the legal document a list of rules directly implementable but without strict binding obligations, under a

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<sup>35</sup> Asean Regional Forum. 2009. “Hanoi Plan of Action”: [http://aseanregionalforum.asean.org/files/library/Plan%20of%20Action%20and%20Work%20Plans/Hanoi%20Plan%20of%20Action%20to%20Implement%20ARF%20Vision%20Statement%20\(2010\).pdf](http://aseanregionalforum.asean.org/files/library/Plan%20of%20Action%20and%20Work%20Plans/Hanoi%20Plan%20of%20Action%20to%20Implement%20ARF%20Vision%20Statement%20(2010).pdf), accessed the 16th January 2019.

<sup>36</sup> U.S. International Trade Administration, “U.S.-Canada Regulatory Cooperation Council”, <https://www.trade.gov/nacp/rcc.asp>, accessed the 16th January 2019.

<sup>37</sup> The White House, “United States – Canada Regulatory Cooperation Council: Joint Forward Plan”, [https://www.trade.gov/rcc/documents/RCC\\_Joint\\_Forward\\_Plan.pdf](https://www.trade.gov/rcc/documents/RCC_Joint_Forward_Plan.pdf), accessed the 16<sup>th</sup> January 2019.

Type 3 design. On the contrary, when strong rules are necessary components of an agreement, states have the choice between putting into place a mechanism for future rules production, according to Type 2, or write all the regulations directly in the agreement following a Type 1 design. The four types as described earlier are the different options that states' representatives might choose when designing regulatory cooperation.

## Chapter 2. Explaining design variation through “Strategic Interdependence problems”

As introduced in Chapter 1, this research aims at explaining the variation between four different types of regulatory design that can be found in international regulatory arrangements. This second chapter introduces the explanatory mechanism used for this purpose. Reviewing past literature on institutional design, this research proposes to design a Rational Institutionalist framework mobilizing past contributions centered around the problems of “contract (in)completeness” and “non-compliance”. Constructivism’s take on institutional design is also discussed and integrated within the framework as a control explanatory pathway.

### *2.1. Explaining design variation in IR*

As reviewed in preceding sections, a wide range of legal instruments are available for international negotiators to design inter-state cooperation. Classified in four types by this research, they vary both in terms of legal obligation (Hard/Soft) and mode of decision (Ex-ante/Ex-post). Although the classification of these dimensions into four types is an innovation of this research, past literature has already attempted to discuss and explain similar variations. In their own review on “Hard” and “Soft” Law, Shaffer & Pollack (2012) presents two main theoretical approaches: “Rational institutionalism” and “Constructivism”. According the theoretical premises underlying these two “schools”, the explanation of design choices will rely on fundamentally different transmission mechanism.

#### **Constructivism’s take on legal design**

There are some merits in looking first at constructivist explanations for legal variation. As “formalized” norms within a socially constructed system of references, legal provisions are embedding the values of actors at their origins. Their social meaning remains closely related to a general system of belief and values that characterized society following rules of law principles. These premises were behind the critical reaction of Finnemore and Toope (2001) towards the authors of the IO issue on “legalization” (Abbott et al. 2000). Irrespectively of the debate that

ensued (Goldstein et al. 2001), the critical stand of Finnemore and Toope illustrate a different perspective that the authors of “legalization” might not have expected, namely a focus on the social construction of concepts such as obligation and compliance. Reus-Smit (2003) and Howse & Teitel (2010) are representative of this current, followed by several other studies focusing on the role of legitimacy in international law design (Karlsson-Vinkhuyzen and Vihma 2009; Wiener 2004).

In retrospect, several constructivist contributions indirectly investigated a large number of subjects that are particularly relevant for this research, such as regulatory cooperation, trade agreements, Ex-ante/Ex-post effects and degree of legal obligations. Although these studies did not follow an overall research framework aiming at explaining the use of specific design features, they accomplished similar purposes:

for constructivists, the creation of soft law might not reflect a “choice” at all, but the accumulation and gradual transformative effect of shared understandings and state practices over time (Shaffer and Pollack 2012, 3).

Due to the emphasis on shared intersubjective knowledge and identity, the explanatory efforts focused on norm diffusion and long-term socialization instead of functional mechanisms to explain institutional variation (Jackson 2011, 197,202; Wendt 1992; Lynn Doty 1993; Finnemore and Sikkink 1998).

In this vein, several social constructivist explanations attempted to explain the origin of international treaty design. Dobbin, Simmons and Garrett (2007) categorized several socialization process leading to the diffusion of “best practices” at the international level, for instance. Previously, Goodman and Jinks (2004) looked at the impact of international socialization to explain design variation in the Human Rights regime. Simmons studied this phenomenon in the context of IMF promotion of so-called “structural adjustments” packages of measures and call to domestic reforms globally (Simmons and Elkins 2004). The research of Simmons and Elkins notably focuses on the role of commitments and Ex-ante/Ex-post features to explain a different issue, namely the decision of states to comply to IMF requirements, uncovering at the same time the role of peer pressures and mutual socialization processes (Simmons 2000; Simmons and Hopkins 2005).

From a different angle, other researchers have emphasized the role of networks to explain the diffusion of norms and replication of specific legal provisions in international agreements.

Hafner-Burton notably contributed in establishing a methodological and theoretical sound framework of network analysis that enabled the “operationalization of processes such as socialization and diffusion” (Hafner-Burton, Kahler, and Montgomery 2009, 560). She notably empirically investigated the integration of Human rights provision in PTAs and their constraining - or not – legal effects. By doing so, she provided insightful findings on the impacts and also limits of socialization processes relative to material conditionality mechanisms (Hafner-Burton 2005, 2009). While not belonging strictly to Constructivism theoretical school, further empirical studies also tested the hypothesis of treaties replication for the purpose of determining if international treaties were in fact simply copy paste from pre-existing agreements or at least heavily influenced by their predecessors (Baccini, Dür, and Haftel 2015; Allee and Elsig 2016). Empirical results appear to often support that a certain level of copy-pasting is taking place for significant important provisions (Allee and Elsig 2016, 4), and the existence of a clustering effect among commonly used template of Trade agreements promoted by major trade powers (EU versus US model) (Baccini, Dür, and Haftel 2015, 3).

Overall, this previous research brought interesting insights on social processes that characterize the diffusion of certain norms and practices globally. They showcase especially the certain degree of similarity between global practices, across governments and international institutions. This is not without theoretical implications, as in their efforts to uncover shared values and norms, they focus their explanatory efforts on what brough international treaties together instead of what differentiated them with each other. By downplaying the variation of treaties, they indirectly missed the point of the “legalization” research agenda original contribution, which is to explain the variation in the uses of different designs. This latter puzzle is in fact one of the most important elements as it relates to identifying the “determining” factor of states’ action. While other information can be contextually interesting, their relevance must be judged in their ability to explain a choice made in the presence of its alternative.

## **Design variation through Rational Institutionalism**

The limitation of Constructivist explanation encourages thus to look at another theoretical framework that could fulfill the role of explaining the variation of Design Types in international treaties. Rational Institutionalism follows the necessary premise that states have “a large menu of

choices when it comes to designing agreements [...]” (Shaffer and Pollack 2010, 5). It attempts to:

explain why and under what conditions states might opt to conclude agreements of a hard or soft nature, and what advantages and disadvantages hard and soft law present to states from an *ex ante* negotiating perspective (Shaffer and Pollack 2010, 5).

It fulfills thus the explanatory requirements of this research. To further describe the instrumental logic underlying Rational Institutionalism, it is useful to look at one of its most influential research agenda: the Rational Design program (RD). Rational Design presents institutional design variation as the functional solution found by states to solve specific cooperation problems (Koremenos, Lipson, and Snidal 2001a, 1051). The solutions adopted for each cooperation problem become the different dimensions in which the legal design of international institutions vary. When introduced, the choice of a specific legal design results from cooperation issues that states aim to solve (Koremenos 2012). In solving these cooperation problems through institutions, states use them “to further their own goals” (Koremenos, Lipson, and Snidal 2001b, 763). While not a direct independent variable, “power” and its relations are indirectly integrated in the cooperation problems that states face (Koremenos, Lipson, and Snidal 2001a, 1067). Rational Institutionalism takes preferences before negotiation as stable and exogenous, delegating to other theories the task of looking at the mechanisms and factors responsible for preferences variation (Koremenos, Lipson, and Snidal 2001a, 1074). From the confrontations of originally diverging preferences, institutions are designed accordingly to solve cooperation problems.

The Rational Institutionalist literature is large and includes multiple studies of institutional/legal design such as escape clause (Kucik 2012; Rosendorff and Milner 2001; Milner, Rosendorff, and Mansfield 2004), anti-dumping provisions (Kim 2017), flexibility and depth of legal commitments (Baccini, Dür, and Elsig 2015; Raess, Dür, and Sari 2018; Johns 2014), formality and informality of rules (Stone 2008, 2011) . On the specific dimension of Hard/Soft, besides Abbott and Snidal mentioned earlier, Shaffer and Pollack themselves made significant contributions in explaining the use of Hard or Soft law by States in their international commitments (Shaffer and Pollack 2010). They notice that when loopholes exist between two regulatory frameworks, states can take advantage of this fragmentation to advance their interests (Shaffer and Pollack 2010, 745). Design variations, notably hard versus soft law can become instruments in their hands to alter distribution consequences between states (Shaffer and Pollack

2010, 710). Acting as antagonists, hard and soft law are used by both weak and strong states to shape international institutions in their favor. In sum, by looking at the functions fulfilled by “Hard” or “Soft” law or their distributive consequences in the context of the cooperation, they draw a causal links between their consequentialist characteristics and the choice made in the international treaty (Shaffer and Pollack 2012, 5). They demonstrate the complementary but also conflictual relations entertained by Hard and Soft law.

Several other contributions supported similarly the influence of distributional conflicts in explaining the variation of Hard and Soft obligations. The contribution of Marcoux & Uperlainen (2013), and Abbott and Snidal themselves (2004) tended to confirm similarly the role of costs/benefits expectation in this variation. Nevertheless, it remains difficult to establish with certainty the direction of the variation. Indeed, authors disagree on the causal relation between the use of either hard or soft law and the rational calculation of states, which seems to vary according to multiple exogenous factors altering the strategic expectation and motivation behind their use.

For instance, while the original contribution of Abbott and Snidal (2000) sees the use of Hard law as means to compensate for a high risks of non-compliance, Down, Rocke & Barsoom (1996, 380) rather argues that hard law is mobilized when the risks of non-compliance is relatively low and that punishment will not be costly if they chose to violate their commitments. Indeed, the contribution of the latter introduces the notion that the design is not a pure product of solving a present risk, but also anticipate scenarios where the parties at stake might wish not to comply. This notion was recently updated by Marcoux & Uperlainen (2013, 165), which argue that states expecting “enforcement provision not to be used” will tend to accept the use of hard law. These authors also stressed that when the risks that enforcement will be effective and could result in real costs for the violators, states will oppose strict legal language. This create a type of hard law described by the authors as “moribund”, adopted specifically because it has no real effectiveness (Marcoux and Uperlainen 2013, 163).

From the above review, it appears that previous contribution saw Hard law functions as either a mean to solve a risk of non-compliance during the negotiation, or because of anticipated costs in case of non-compliance. While the former argues that Hard is used to mitigate the risks of violation through enforceable punition, the latter states that it is this exact risk of future punition that prevents parties from using hard law. What this apparent contradiction seems to indicate is that the use of hard law can fulfill multiple functions and depends largely on the structural context

in which states are embedded when they are interacting. As described previously by Shaffer and Pollacks sensible efforts have already been deployed to map these different uses of hard/soft law but areas of uncertainties in states motivations for choosing either hard or soft remain present. This apparent inconsistency in the literature deserves thus to be clarified as to establish clearly the causal linkages between Hard/Soft and identify which are the key variables in creating this variation of circumstances that justify different use of hard/soft law.

Less studied than Hard and Soft, Ex-ante and Ex-post features are nevertheless part of several major contributions in the fields and framed notably within the “shadow of the future” type of issues. As non-exhaustive illustrations, early on Georg Ress (1994) analyzed the use of *Ex-ante* provisions in treaties as means to prevent the *Ex-post* opportunism of states, incentivized to breach commitments when they become too costly. It was nevertheless the publication of the *Legalization* article in IO (Abbott et al. 2000) that would facilitate research around these features. In the same issue, F. Abbott (2000) notably compared the NAFTA and EU legalization approaches, noticing that while both agreements contained a high level of obligation, NAFTA was characterized by a higher level of precision but a minor one in delegation, and the EU framework by a higher level of delegating at the expense of precision (Abbott 2000, 547). While the terms “ex-ante” and “ex-post” are not explicitly used in this contribution, it is retrospectively pertinent to re-formulate F. Abbott’s findings, as NAFTA being characterized by an Ex-ante form of legalization, while the EU privileges Ex-post legalization forms.

In this line but with a more thorough approach, David Lake studied Ex-ante/Ex-post legal features within the context of international mechanisms of authority delegation (Hawkins, Lake, and Nielson Daniel 2006; Lake 2007). Looking at the delegation of authority by states to International Organizations (IOs), his works mobilized a principal-agent framework to describe the relation between states and IOs. This relation takes the form of a “contract”, which describes the condition of the cooperation between the delegating actor, the state or principal, and the recipient of authority, its agent (e.g. IO) (Hawkins, Lake, and Nielson Daniel 2006, 8). Legal design features result from the varying conditions and functions that contracts are supposed to fulfill. Ex ante and Ex post are thus instances of legal features that compose and support the design of contracts by agents and their principals, such as for “control mechanism”:

Broadly, principals attempt to structure the incentives of agents ex ante so that it is in the interests of those agents to carry out their principals’ desires faithfully ex post (Hawkins, Lake, and Nielson Daniel 2006, 26).

In the field of EU studies”, the principal-agent relation was also frequently mobilized to explain the relation between the different European Institutions, notably the European Council and the European Commission (EC) (Bjurulf and Elgström 2005; Servent 2014; Jančić 2017). To specify that this type of contractual arrangement targets relations between a principal and agent where a relationship of formal subordination between them is present, for instance, the Council relative the EC. In this thesis, contract arrangements target rather inter-state relations, where from a formal point of view actors are equal. No state can “command” another one in virtue of a formalized hierarchical structure, as in the domestic sphere or between International Organizations and their member states.

Indeed, Ex-post and Ex-ante were the most consistently studied within researches focusing on the notion of contracts notably around the features of “complete-ness” or “incomplete-ness” (Koremenos 2013; Cooley and Spruyt 2009). They however diverge from previous works by looking this time at contracts between negotiating parties instead of principal-agents. Cooley and Spruyt notably kept the notion of contract conditioning the delegation of “sovereignty” but rather adopted a more horizontal understanding as mutual exchanges instead of a principal-agent hierarchical vision (Cooley and Spruyt 2009, 23).

Their approach look at the variation between what they describe as “complete contracts”, which fully describes the responsibilities and obligations of the contracting parties (Cooley and Spruyt 2009, 8), and “(in)complete” one that sets the initial basis of the agreements but left open to ongoing cooperation the further elaboration of the full extent of the cooperation’ conditions (Cooley and Spruyt 2009, 8–9). They explain this choice by two types of states’ motivations: first, “procedural” motivations due to “uncertainty,” “negotiating costs,” and “enforcement costs”, and second, “strategic” motivations, where one of the state is in a position of superiority and decide to maintain the cooperation open in order to exploit in the long term his advantage (Cooley and Spruyt 2009, 9). As a consequence, a “complete” contract will have detailed ex-ante conditions while an “incomplete” one will contain less complete preliminary provisions (Cooley and Spruyt 2009, 12). This dichotomy is reinforced by a later contribution of Koremenos, which poses that:

Incomplete contracts arise because ex ante it is difficult to get a particular group to agree on specific provisions and because ex post parties may prefer discretion in how they react to particular events (Koremenos 2013, 143).

For regulatory cooperation, the notion of contract (in)completeness provides an avenue to look at the depth of technical cooperation, especially at the time of conclusion. It is particularly pertinent for trade, as it shows the extent of immediate regulatory requirements compared to long-term adjustments trends. In the case of labor provisions in PTAs for instance, Moonhawk Kim (2012) compares diverging US and EU design approaches. While the US emphasizes Ex-ante due diligence, the EU prefers Ex-post monitoring mechanisms. A contribution of Louis Bélanger (2007) is similar in this extent, demonstrating how NAFTA attempted to solve “(in)completeness” issues by adopting well-defined provisions with precise technical requirements. This was done however at the expense of long-term revision mechanisms, which characterized the potentially less clear but also more adaptable EU institutional construction process. Further research also studied Ex-post and Ex-ante phenomena in similar veins, such as Raustiala and Victor with the regime for the Plant Genetic Resources (2004), Postnikov and Bastiaens also for labor provision in PTAs (2014) and Cafaggi for its overall analysis of Transnational Private Regulation (2011).

### **Pursuing and clarifying the Rational Institutionalist agenda**

As just reviewed, the study of design can take the form of one of two complementary but opposed research agendas. The constructivist strand tends to look at shared practices and design to reveal process of global convergence in legalization. On the contrary, Rational Institutionalism focuses instead on divergences of design, demonstrating the consequentialist logic that motivates states when determining their design. These two approaches integrate in their subject of studies Hard/Soft law and Ex-Ante/Ex-post design variation. The Rational Institutionalist theoretical framework appears nevertheless more suited to study the choices of these features in regulatory cooperation treaties. In fact, as demonstrated in Chapter 1 several different types of Regulatory design coexist internationally. Therefore, an approach that aims in priority at explaining divergences is well fitted.

Furthermore, past theoretical attempts run into difficulties in putting into place a clear explanatory framework that could establish a functional link between the motivation of states to engage in negotiation – “strategic interdependence problems” to solve – and the outcome of their negotiations – institutional design. This is one contribution of this research. It aims at explaining the variation of different forms of international institutionalization through joint international

factors that defines specific problems to be solved. Constructivism provides nevertheless, an interesting “control” approach, encouraging the researcher to check for existing practices outside his object of study. It requires to verify that the variation observed is not the product of already existing practices but the results of costs/benefits calculations by the specific actors involved in the agreement. Next section will further specific the dimension of potential independent variables capable of explaining the variation between the four design types introduced in Chapter 1.

## 2.2. *Design types variation as “Strategic Interdependence Problems”*

Following preceding review, this thesis argues that states used design features to solve interdependence issues in their interactions.

To do so, parties involved in the negotiation adopt the design type corresponding to the structure of the cooperation problem at stake. This notion is inspired by the previous proposition of Lake to center the analysis around states’ “strategic interactions”, which becomes the units of analysis (Lake 1999, 4). While this thesis does not follow the full extent of his premise and use “sectors” as units of analysis to compare design types, it similarly considers that “an actor’s ability to further its ends depends on the actions others take” (Lake 1999, 8). This results in the creation of a holistic negotiation structure, which distinguishes the aggregation of the original preferences of the actors that might originate from domestic factors from the structure of the interaction itself (Lake 1999, 46–47). The latter becomes an independent entity that will impact both actors-states participating to the negotiating process.

This view is consistent with the original notion of Keohane and Nye of *Complex Interdependence* that emphasized the role of transnational linkages in altering decision-makers strategic calculation and the dynamics logic of negotiation bargaining (Keohane and Nye 2012, 28–29). Slaughter (2004) similarly acknowledged the rising importance of transnationality for international issues relevant to this thesis, such as trade and regulatory issues. As states are embedded in cross-borders transnational ties, the design types they choose represent the solution found to the cooperation problem emerging from this transnational dimension. As the interaction of the negotiation obeys to a different logic than the simple juxtaposition of different domestic preferences. It is the answer provided to the common cooperation problem faced, produced by the interdependent structure and decided during the negotiating process. This does not prevent it from being mutually beneficial for both parties. It is rather a “holistic” result instead of a simple aggregation.

Each of the four design types presented in Chapter 1 correspond to one of 4 “strategic interdependence problems”. The diversity and types of specific “interdependence” problems during states negotiation depends on the cooperation context confronted by states during their negotiation. In other terms, the choice of a design types results from the existence of a specific “strategic interdependence issue” that plagues inter-states collaboration. States do understand the different strategic problems they face in their cooperation and, thus, the legal design they chose are “explicit arrangements, negotiated among international actors, that prescribe, proscribe, and/or authorize behavior” (Koremenos, Lipson, and Snidal 2001b, 762).

These problems are defined by two main factors, namely two different types of strategic problems: **the problem of completeness and the problem of compliance**. The Type of Structure of Interdependence, as its name indicates, classifies thus strategic interdependence problems into two main issues-types: completeness issue and compliance one. A completeness issues addresses the risk of hold-up when states need to determine the extent and timing of their cooperation. Due to their interdependence resulting from their transnational ties, they have to think carefully the future consequences of their cooperation, especially if the latter requires extensive regulatory adjustment and thus long-term investments. Indeed, investments in new cooperation might result in creating new relations of dependences that could be exploited afterwards by one of the partners attempting to extract further concessions. A compliance issue is traditionally modeled through a Prisoner dilemma (PD) game theory, where actors have constant incentives to cheat and maximize their gain rendering all forms of long-term cooperation inherently unstable. As the danger of future non-compliance grows, increases at the same time the need to anticipate this possibility during the negotiation and to take pre-emptively measures that could mitigate this risk.

As theoretical innovation towards the field, this thesis argues that completeness risks determine the use of Ex-ante or Ex-post design, while compliance one defines the writing of cooperation through Hard obligations language or soft one. The role that Uncertainties and their related risks play in the choice of design *per se* is not new however. Previously mentioned, the Rational Design research agenda includes among its independent variables three forms of uncertainties: about behavior, about the state of the World and about Preferences (Koremenos, Lipson, and Snidal 2001b, 773). Although these division of uncertainties appear relevant to a wide range of subjects, Koremenos herself in her empirical works departed from this division in three to focus on Uncertainty about distributional consequences (Koremenos 2005, 550, 2002, 260). This is in line with other studies that looked at uncertainty impact in relation with bargaining issues and States expectations of costs/benefits consequences (Urpelainen 2012, 136; Thompson 2010, 272).

The importance of uncertainties on bargaining issues is not surprising though, as before looking at how actors decide to mitigate the different risks the question of “why” they should care about them need to be answered first. This can be attributed to their sensitivity towards the possible unequal distribution of gains and their fears in change of their relative capabilities (Grieco 1997, 176). Distribution of costs and benefits can impact their relative power and thus their capacity to exercise more regulatory control on one another economic activities. In this context, state takes in consideration their state of knowledge on current and potential future risks that could impact costs/benefits distribution and design their cooperation according to the different types of uncertainties they identify during the negotiation.

The literature well covers the issues of complete or incomplete “contracts” in international cooperation design (Koremenos 2012; Bernheim and Winston 1998; Koremenos 2005; Horn, Maggi, and Staiger 2010; Cooley and Spruyt 2009; Gruber 2000). The next sub-section will elaborate on the contribution of this strand of research and the use of Ex-ante or Ex-post design in regulatory cooperation legal design. Previous studies have repeatedly identified the role that Hard and Soft obligations plays in managing the bargaining consequences of inter-state cooperation. This research builds on these previous contributions, notably works that emphasized the role of Hard/Soft design features in managing compliance risks within cooperation schemes.

### **The issue of completeness in regulatory cooperation**

The first element to stress in any forms of cooperative agreements, and this is particularly the case for regulatory cooperation, it is their inherent “(in)completeness”:

In a world of rapid political, economic, and technological change, it is simply not possible to determine ahead of time which types of conflicts and questions will arise over the lifetime of a long-term contractual (Gruber 2000, 72).

Consequently, the design of the agreements targets rather second-best or good-enough solutions rather than looking for ideal formats. Certain parts of the contracts are left incomplete or imprecise, letting future cooperation to define further the full extent of the terms and conditions of the cooperation. This is the case for WTO treaties, which combines “rigidity” and flexibility” in order to ensure the effective respects of states’ commitments and the availability of sufficient policy space for states to adapt their commitments according to evolving circumstances (Horn,

Maggi, and Staiger 2010). In regulatory cooperation, the variation of regulatory design reflects this dual necessity.

The literature on contract “in-completeness” contextualizes upfront the choice between Ex-ante and Ex-post mode of design (Cooley and Spruyt 2009, 9). Confronted by the impossibilities to anticipate initially all potential events that could affect their cooperative relations, states are forced to make a balance. They can either define extensively the technical characteristics at the start of their relations or rather decide to postpone their elaboration within a long-term mechanism. Interestingly, while the “shadow of the future” is present in all cases, its existence in itself is not as relevant as states interpretation over it. Indeed, overall uncertainty over the future is a constant feature of any human activities, but as mentioned previously it is states’ concerns over its impacts on relative capabilities that is determinant.

More specifically, the risks of “hold-up” is a major risk for countries when they are engaging in lasting cooperation (Cooley and Spruyt 2009, 9–10). When countries decide to put into place cooperative mechanisms, voluntary or compulsory, the probability is high that it will result in an intensification of interdependence and specialization. Baier & Bergstrand (2007) analysis on PTAs effects notably found out that the conclusion of a trade agreements tends to double existing trade flows overall. This findings is corroborated by an extensive literature, which supports the reinforcing trade effects of PTAs and their deep provisions, intensifying cross-borders economic activities with potential trade distortion effects (Manger 2012; Cole and Guillen 2015; Kohl 2014; Egger et al. 2014; Foster, Poeschl, and Stehrer 2011).

As an intensification of exchanges follows the conclusion of a PTAs, states relative position might evolve also similarly. International trade literature, especially research on “heterogenous firms”, reveals that trade liberalization tends to reinforce the most productive firms in a given sectors, resulting in the emergence of “super-star exporters” that are able to dominate the production and distribution of goods/services globally (Osgood et al. 2016; Melitz 2003; Melitz and Ottaviano 2008). As trade exchanges intensified, countries that are more specialized in these dominant sectors could benefit more from the cooperation at the expense of their partners. The German car industry or the U.S. Pharmaceutical sectors are illustrations of highly productive firms that are able to obtain an important share of intra-industrial global trade.

Other consequences, cooperation pushes countries to invest in the production of specialized products that corresponds to the demands of the other markets (e.g. premium cars) (Osgood 2016).

This is however not without consequences as it makes them more vulnerable to the other party regulatory decision. This can take the form of regulatory changes that could restrict market access or denial access to vital raw materials (Cooley and Spruyt 2009, 11). Cooperation entails thus necessary an element of risk, especially in the form of one of the parties deciding to change its regulations or even re-negotiate the terms of the agreements in its favor (Koremenos 2005).

This type of power relations within transnational economic relations is far from being a novelty and is very well explored by the literature of Global Value Chains (GVCs). Initiator of the GVC concept, the geographer Gary Gereffi describes in its early works the global conflicts taking place between buyers and manufacturers in the management of the garment distribution chain (Gereffi 1994). These works often reflected the unequal power distribution between the producers mostly located in Southern developing countries with main retailers' chains possessed by Northern capital-rich actors. Subsequent works will build on this earlier dichotomy to expand it towards other industry by introducing the notions of "upstream" and "downstream" segment of the value chains (Gereffi, Humphrey, and Sturgeon 2005; Ponte and Sturgeon 2014).

Certain of these contributions notably highlighted the instrumental role of states in managing these value chains and their development of industrial policy aiming at controlling and mitigating the risks coming with GVC integrations (Yeung 2014; Neilson, Pritchard, and Yeung 2014; Mayer and Phillips 2017). To help their management, public and private actors jointly supported the development of instruments such as standards and "quality conventions" (Ponte and Gibbon 2005). These instruments contain detailed technical information that helps producers, distributors and public authorities coordinate with each other in order to ensure the integrity and good functioning of the value chain. The adoption of detailed technical requirements in Ex-ante design becomes legal vehicle for states to coordinate the chains and manage the risks of "hold-up". As limited in time, Ex-ante provides indeed a template that can allow some limited regulatory alignment without committing fully in the long term to a full-scale regulatory adjustment. On the contrary, Ex-post long term nature provides a useful cooperation channel for states to continuously manage jointly the upstream and downstream part of the chains.

In brief, this thesis poses that states negotiate for setting the terms of their regulatory cooperation within this context of "hold-up" risk, which can lead to a "weaponization of their interdependence" (Farrell and Newman 2019) and subsequent renegotiation of their terms of cooperation. The decision on the level of "completeness" of their agreement will thus vary according to the propensity of this risks. Cooley notably argues that more detailed or "complete"

contracts tend to “increase the possibility of hold-up” (Cooley and Spruyt 2009, 12). When the risk is high there is an incentive to make the contract more “incomplete” by limiting the scope of the cooperation, especially in time. Indeed, the main danger of “hold-up” is that a country decides to re-negotiate terms of the agreement after its partner has already made significant investment in its value chains to benefits from the previous market access concessions obtained. Logically, when states are thus uncertain of the completeness’ consequences, they will tend to limit it in time through an Ex-ante design feature. On the contrary, where these risks are moderated or weak, hence relative certainty, they will agree to commit in the long term through an Ex-post design feature.

### **Compliance issues in regulatory cooperation**

A second element to consider when designing cooperation terms is the risk of the shirking of legal commitments. Cooperation is constantly plagued by the existence of an enforcement problem: when the incentives to defect are significant, states want to insure themselves against potential violation by having at their disposal sufficient punishment instruments (Koremenos, Lipson, and Snidal 2001b, 786). Enforcement problems correspond to the celebrated Prisoners’ Dilemma, a situation where two players are confronted by two choices. They can either decide to collaborate and mutually gain from the cooperation or defect obtaining a higher pay-off if the other player keeps cooperating, thus losing all its gains (Osborne 2003, 13–14).

The main issue with this type of game is that the most rational strategy to adopt in terms of gains/costs expectation is the defection strategy, which is considered as a “pareto-suboptimal equilibrium” but corresponds to a Nash equilibrium (Binmore 2007, 18–20). Therefore, for all players there is a constant incentive to cheat and maximize their gains, which renders all forms of cooperation inherently unstable. One way to address such problems is to impose severe and credible sanctions on defectors. By lowering the noncooperation payoff of the original game, defections become less attractive for each party, thus decreasing the chance of mutual defections. Expecting the maintenance of cooperation, states are thus willing to sign into agreements that would be unfeasible in the absence of punishment provisions. Hence, a first conjecture is that “other things equal, the presence of uncertainty about behavior results in the inclusion of punishment provisions” (Koremenos 2013, 143).

Hard obligations are in this context a particularly useful way to design cooperation. Hard obligations require binding commitments from states and thus their respect for the provisions contained in the cooperation. While violations can still occur, they will be considered as legal breaches of their commitments and would allow the other party to take sanctions or retorsion measures. These are the main premises of the functioning of dispute settlement mechanisms as integrated into PTAs. When a plaintiff accuses another state of violating its commitments, a panel of experts is composed and will assess veracity of this claim and the extent of the possible damage. If it is confirmed, it can authorize the victim to suspend its concessions for a certain amount of value equivalent to the damage until the other party decides to comply. In the WTO, the appellate body is the ultimate judge of the legal breach of commitments. The purpose of this type of mechanism is to ensure the respect of binding obligations by adding it a sanction mechanism.

While shirking is a general issue present in all sorts of international arrangements, in this research it specifically targets the risks of apparition of new regulatory barriers to trade that could impede trade. For instance, the COOL case at the WTO (DS384), on US mandatory country of origin labelling for meat products, was an illustration of a regulatory practice that had discriminatory consequences for Canadian and Mexican firms involved in the US meat value chains. The appellate body determined that the US measures were in violation of WTO GATT, TBT and Rules of origin commitments, and following the unwillingness of the United States to remove its trade distorting measures, allowed Canada to suspend certain tariff concession to the U.S.<sup>38</sup>. This case illustrates well the enabling role of legally binding commitments that allows a mechanism of sanctions in the context of regulatory cooperation. To note, the same type of dispute settlement system is present in PTAs. Therefore, the pertinence of Hard obligations for non-compliance is not exclusive to multilateralism but also to plurilateral arrangements.

This, however, is not a new phenomenon. A wide strand of the literature already largely covers the relation between compliance, Hard obligations and dispute settlement. The early contribution of Smith (2000) emphasized how the increased legalization of dispute settlement witnessed in PTAs did aim at improving treaty compliance. Later, Guzman (2005) supported this finding but contextualized higher legalization among a wider range of possible choices. When designing their obligation, the desire for treaty compliance is integrated into states' calculation, especially the costs that these types of hard-legalized dispute settlement mechanisms could result in. Hard

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<sup>38</sup> WTO website, DS384: United States – Certain Country of Origin Labelling (COOL) Requirements: [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds384\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds384_e.htm), accessed the 20<sup>th</sup> June 2019.

provisions are thus not always used, but rather mobilized when there are strong – economic– incentives in making sure that both parties will comply with their obligations.

The implication of such research is that the choice between soft and Hard obligation is part of a larger strategic game, which includes estimation of the costs/benefits for dispute proceedings. The choice of Hard obligation is thus an assumed decision made by the parties to ensure that certain (but not all) issues regulated are strictly protected from treaty violations. Indeed, due to trade instability and domestic opposition, there are good chances that states will be pressured to defect on their previous commitments. Hard obligations make sure that when strong risks are present that one of the parties will breach its obligations, it will be liable and could incur penalties for its behaviors in case of violation (Goldstein and Martin 2000; Rosendorff 2005; Milner, Rosendorff, and Mansfield 2004). These obligations act thus as incentives to respect legal obligations and mitigate the risks of shirking.

Interestingly, more recent research by Posner and Sykes (2011) has shown that in certain cases states intentionally weaken compliance obligations when they do not intend to severely punish the violators. This concept of “Legalized Noncompliance” introduced by the two authors embodies the notion that the choice of Hard or Soft obligation is a more calculated decision rather than tools of a unilinear process towards higher legalization of international regulatory and trade regimes. As mentioned earlier, Pollack & Shaffer (2010) describe several circumstances when “soft law” is rationally used by states to undermine “hard” legalized regimes for strategic reasons.

Hard and Soft obligation potentially act as antagonists when designing international legal provisions for regulatory cooperation, as they could disrupt and weaken already existing regimes. As seen for Hard obligation, they can also reinforce it. Soft obligations can be used for instance as tools for “orchestrating” states when the latter participates in the development of international regimes (Abbott and Snidal 2009, 2010). The literature on “New Governance” initiated by Abbott and Snidal notably shows how soft laws are used to regulate an ever-increasing range of subjects through more flexible approach than Hard obligations. This is even more necessary when private actors have a predominant role as regulators and standards-setters (Cafaggi 2011; Henson and Humphrey 2010; Shiroyama 2013).

In brief, following past findings this thesis poses that when uncertainty is present about the risks of shirking by one of the parties, states will tend to use Hard obligations. This design feature acts as an incentive for the respect of commitments. On the contrary, when there is less uncertainty

about shirking, states will rather use soft law to design their cooperation and contribute jointly to the orchestration of the regime.

## Hypotheses

As developed in the two preceding sections, this thesis supports the theoretical propositions that the literature on “contract (in)completeness” & “compliance” can explain the design variation of the two dimensions Ex-ante/Ex-post & Hard/Soft. Specifically, it formulates four hypotheses:

*When for a specific sector risks of hold-up and shirking are both high, the institutional design of choice combines Ex-ante rule determination coupled with Hard obligation, namely a design of Type 1*

*When the risk of hold-up is low, but shirking is high, they will use Ex-post mode of design with Hard obligations, specifically design Type 2*

*When the risk of hold-up is high, but shirking is low, they will tend to privilege Ex-ante with Soft obligation corresponding to Type 3*

*When the risk of hold-up is low, but shirking is high, they will choose a design Type 4 with Ex-post and Soft design features.*

These four propositions are represented in a 2X2 under:

		<i>Risks of "Hold-up"</i>	
		High	Low
<i>Risks of shirking</i>	High	<b>Type 1 (Hard/Ex-Ante)</b>	<b>Type 2 (Hard/Ex-Post)</b>
	Low	<b>Type 3 (Soft/Ex-Ante)</b>	<b>Type 4 (Soft/Ex-Post)</b>

*Table 2 Strategic Interdependence structure, modeled through two types of strategic risks*

As discussed in section 2.1, an alternative theoretical current inspired by constructivism premises proposes another approach to look at design variation. Instead of products of rational calculation, they rather emphasize norms diffusion practices based on emulation of “best practices” among epistemic communities, such as trade states. Among its implications, international treaties replicate existing design templates, especially within trade diplomatic circles of the EU or USA, the two major international actors active in the proliferation of PTAs.

Due to the reasons exposed previously in the same section, this thesis does not privilege this theoretical approach to explain design variation. It supports Rational Institutionalism’s main points, especially the contribution of RD in arguing that different design features are adopted to the “Strategic Interdependence problems”, characterizing the negotiating at stake and following states’ rational calculation. Nevertheless, even if this thesis departs from constructivism’s premises, the latter are useful to serve as control explanations to check the explanatory power of the framework just described. While the next chapter on the methodology employed describes the operationalization of this “control” framework in detail, it is useful to summarize the main contradicting hypothesis here:

*If a design type found in CETA is replicated as such in other EU trade agreements, while the strategic calculation modeled by the two uncertainty variables differ from CETA, the main hypothesis of this thesis will be considered invalidated.*

In the following Part II of this work, the method of this research is detailed further, notably its qualitative comparative approach of “regulatory sectors” in CETA, following a multi-method logic.

## **Part II. Method**

This part presents the method used by this research to provide empirical scrutiny of the hypotheses formulated in the previous section. Chapter 3.1. presents the multi-method approach followed by this study and the two pillars of its investigation: cross-case and within-case. As Chapter 3.2. details, in this research the basis of comparison or units of analysis are “regulatory sectors” within CETA. Each sector is a case. The study follows a framework aiming at explaining the variation of institutional design among cases into the different design types identified in CETA, notably Type 1 (Ex-ante/Hard), Type 2 (Ex-ante/Hard), Type 3 (Ex-ante/Soft) and Type 4 (Ex-post/Soft). This chapter also contains details on the strategy used to collect data and measure the presence or absence of the two main risks responsible for design variation: “hold-up” and shirking. As introduced in Chapter 2.2, “hold-up” risks refer to the discussion around contract “(in)completeness”, which relates to the challenges of international economic integration and its distributional benefits or costs. Instead, shirking risks looks at the tendency of states to opportunistically take advantage of pre-existing international and domestic regulatory frameworks. This commonly takes the form of new regulatory barriers that favor domestic firms at the disadvantage of foreign ones. To measure the first type of risks, this thesis uses trade data from different sources, such as Eurostats, to look at economic interdependencies that are conducive of hold-up risks. The second uses international and domestic regulatory documents to evaluate the risks that one state uses pre-existing and existing regulatory divergence to create new barriers to trade and thus not comply with the agreement. It specifically employs data collected from official documents, such as legislations, industry position papers and reports. Interviews are also used for these two risks, to triangulate information found in other sources.

## Chapter 3. A multimethod comparison

This section poses the methodological foundation of this research and presents its logic of empirical inquiry. At first, it reviews the methodological literature around qualitative comparative research and presents the methodological foundations of this work. It also argues that a multi-method approach is particularly valuable for this research question, notably by combining two strategies for making causal inferences: cross-case comparison and within-case process tracing. It concludes on the operationalization procedure and indicators used, including the two risks identified as components of the interdependent strategic structure underlying the negotiated outcomes: “hold-up” and shirking.

### A multi-method design for qualitative research

Investigating causal relations remains a delicate task, especially when the cases available are limited. Looking at a limited population of cases within a single agreement legitimately raises some questions on the study’s aim of generalization. This issue is present in multiple previous qualitative studies and is not particular to this research. Among the potential ways to solve this limitation, qualitative research methods have developed the use of the multi-method approach. To compensate the limited number of cases, this approach “combines different causal inferences that can provide independent support for a causal mechanism” (Goertz 2017, 66).

Multi-method studies enable researchers to look with more details at the causal mechanisms contained in few cases (Goertz 2017, 41). Instead of focusing on testing variable correlations through many observations, this type of methodology concentrates its research efforts on the causal mechanism itself. This choice starts from the premise that “case-level causation is ontologically prior” to law generating from large populations (Mahoney 2008, 414). This bottom-up approach is essential to avoid the trap of applying inferences found at a statistical level to individual cases, a shortcoming also called “ecological fallacy”. Starting the investigation from a few cases to potentially enlarge to a larger population remains a surer approach to avoid this trap (Mahoney 2008).

In this endeavor, the purpose of researcher is the identification of necessary or sufficient conditions that can explain the typology of regulatory design introduced in the theory part. As described by George & Bennett, typological theories “specifies independent variables, delineates

them into the categories for which the researcher will measure the cases and their outcomes [...]” (George and Bennett 2005, 275). To observe the conditions required for the category to happen, translates into looking for “necessary conditions” for the typology variation. This implies following a counterfactual logic of condition, testing whether the absence of the condition would provide a different result, meaning that it would result in another type of the typology (Goertz 2017, 100). For each hypothesis, the question becomes what are the conditions for a certain type to “necessarily” happen? Related to this research, the investigation attempts thus to test, for instance, whether risks of “hold-up” and of shirking are joint necessary conditions for the use of design Type 1 (hard/Ex-ante) by states. The absence of negative cases does not allow for the evaluation of their “sufficiency”. The next section details this operationalization process.

To test the “necessary” feature of the factor and following Goertz recommendation, the multi-method approach requires the combination of different observational strategies into a mutually reinforcing research triad (Goertz 2017, 230). This methodology combines causal mechanisms, cross-case inference and within-case inference into a triangle. Cross-case analysis includes a first batch of case studies that help to test whether the mechanisms hold through a certain number of instances, enabling generalization. This can be also compared to the role of “statistical analysis” into a larger multi-method framework (Goertz 2017, 230). They are “not-too-deep case studies” that aim at testing general claims of causality without too much pretension. As a second step, within-case studies fulfill two other purposes: reconstructing the causal mechanism fully and testing the robustness of the explanatory factors (Goertz 2017, 233). It looks at the internal mechanism within the case is situated and tests the causal mechanism faced with idiosyncratic information and potential counterfactual explanations.

Cross-case and within-case target different types of causal inquiries. Cross-case applies Boolean logic to look at the presence/absence of variations on variables. Within-case looks at evidence that the causal mechanism at play is the one predicted by the theory. It focuses on the presence/absence of factors across cases to explain the variation of design type. Within-case inferences look at the causal mechanism itself, linking the factors present and the choice of design type. The following section describes in detail these differences of causal approaches between cross-case and within-case. It explains as well as how these two procedures are implemented in this research in order to empirically test the four hypotheses formulated in the theoretical part.

### *3.1. Cross-Sectoral Comparison*

Qualitative comparative method is a methodological approach (Przeworski and Teune 1970; Collier 1993; Ragin 1987), which aims at testing the causal role played by certain variables along several cases. As argued by David Lake, the formulation and testing of these middle-range theories (Lake 2011) is an equally valid scientific endeavor. As reviewed earlier, the research agenda on legal design in PTAs has adopted a similar turn, focusing on the variation of specific legal provisions (e.g. environments, labor) and using exogenous factors to explain it.

Comparative analysis can be described as a “method of discovering empirical relationships among variables” (Lijphart 1971, 683). It “supplements with logical reasoning the lack of a sufficient number of cases (... )” (D. Della Porta 2008, 201). Qualitative comparative approaches investigate and test substantive claims prior to a statistical test (Collier 1993; Lijphart 1971, 685). To note that comparative analysis is a general method and not a “specialized technique” (Lijphart 1971, 683). It does not pre-determine the tools to investigate the variables and their relations.

This thesis focuses on identifying necessary conditions for an outcome (a specific type of design type) to be present: “Generally speaking, a condition X is necessary if, whenever the outcome Y is present, the condition is also present” (Schneider and Wagemann 2012, 69). In other words, if the same outcome (Y) is observed systematically when the same explanatory variables (X) are also present, the latter are considered necessary for the outcome to appear. In terms of hypothesis verification, it signifies that the necessary relationship between the DV (Y) and the explanatory factors (X) formulated through a hypothesis is accurate. The mechanism underlying the relation between Y and X, formulated in the theoretical part, is probed through the verification of the hypothesis. For additional information on the epistemological and methodological premises underlying the study of necessary conditions, the contribution of Carsten and Wagemann (2012) on *Set-Theoretic Methods for the Social Sciences* is particularly informative, especially section 3.2 “Necessary Conditions”.

Although present in the same trade agreement, this research’s units of analysis or cases, “regulatory sectors” are sectors of activities *a priori* perceptively different from each other. For instance, in terms of products and economic activities, geographical indications and motor vehicles appear to share very little in common. Nevertheless, this study argues that when exposed to the same variation of explanatory factors, namely the High/Low of the same risks (“hold-up” and shirking), these sectors will be regulated by a similar legal design.

To demonstrate this correlation between the design types and the factors, the empirical analysis starts with an overall comparison of the entire population of cases ( $N = 7$ ). The purpose is to test the validity of the four hypotheses formulated earlier, corresponding to the four design types found in CETA (Type 1,2, 3 and 4). To do so, it proceeds in three steps. First, it analyzes from a legal standpoint the regulatory provisions concerning each regulatory sector. In other words, it determines whether the provision targeting a specific sector contains hard or soft degree of obligations, and Ex-ante or Ex-post mode of decision-making mechanism. According the results of this assessment, the provision and the regulatory sector concerned is classified in each of the four types of regulatory design. The results of this coding process are available in the Annex.

Then, an analysis of all the sector follows, comparing the results of the two explanatory factors (Types of risk/uncertainty). This comparison proceeds by an overall description of sectors' results for each explanatory factor, displayed in a comparison table like the following one.

	<b>Risks of Hold-up'</b>	<b>Risks of Shirking</b>	<b>Design Types Expected</b>	<b>Design Types Observed</b>	<b>Hypothesis</b>
<i>Sector A</i>	Low	High	Type 2	Type 4	Unsupported
<i>Sector B</i>	Low	High	Type 2	Type 2	Supported
<i>Sector C</i>	High	High	Type 1	Type 1	Supported

*Table 3 Illustration table of sector comparison*

This table provides a hypothetical general picture of each sectors' trade and regulatory features and helps to determine whether the theorized linkage between hold-up/shirking risks and different types of regulatory design is empirically observable. This table also helps to determine which hypotheses appear to be verified preliminarily, on a sector-by-sector basis. It gives an overall view of the hypotheses' results and its generalization capacities and limits. Nevertheless, this table only initiates the analysis. The aim of the research is then to test the causal mechanism underlying the tables and demonstrates that it is indeed responsible for the variation of design types. The following cross-case analysis focuses then on the causal mechanism responsible for the variation of design. In other words, it compares cases belonging to different types by looking at their factors' results, theorized to be responsible for the variation. This includes the role of

“hold-up” risk in determining the choice of Ex-ante or Ex-post; and the influence of the shirking risk in the use of Soft or Hard design. As said earlier, the systematic presence of the same explanatory factors results for the same outcome provide information on the necessary relationships between them.

The purpose of these dedicated sections is to make observations coherent with the presence/absence of the causal mechanism behind hypotheses. For instance, the analysis compares motor vehicles and pharmaceuticals to demonstrate how the presence of “hold-up” risks can cause the use of Ex-ante design and the absence of Ex-post. The focus is thus on the causal power of the explanatory factors in terms of different types of design. By proceeding to this assessment, it becomes possible to show with empirical evidence that the relationship between the factors and the design types is not incidental but fits with observations coherent with a specific causal mechanism. Again, the purpose of cross-case analysis is to use variations between cases to investigate causal theories.

As introduced earlier, this research follows Goertz’s multi-method prescriptions and combines thus cross-sector analysis with within-case process tracing for each sector. Details on the empirical procedure are exposed below.

### *3.2. In-depth case studies*

As stated previously, looking at causality requires the combination of different approaches, especially case studies. In fact, case studies have as strengths the ability to explore and disentangle the imbrication of complex causal mechanisms (Goertz 2017, 45). In this context, in-depth case studies (Bennett and Elman 2007a) can serve as plausibility probes to check the validity of the two explanatory factors and control the intervention of possible third variables (Harvey and Brecher 2005, 137). They follow the logic of process tracing by attempting “to identify the intervening causal process—the causal chain and causal mechanism—between an independent variable (or variables) and the outcome of the dependent variable” (George and Bennett 2004, 141). The purpose of using process tracing in these limited cases is to control for the risks of equifinality in explaining the variation of the dependent variable, here types of regulatory design. Following cross-case analysis, the process tracing aimed at adding a logic of within-case inference to test for the causal mechanism between “hold-up” and shirking risks with states’ choice of a specific legal design (Goertz 2017, 8).

To note that Goertz (2017) and Beach & Pedersen (2016) provide different advices on case selection for these in-depth analyses. However, this research does not select a particular case but analyzes the entire population of cases. The following operationalization chapter describes the units of analysis of this research: regulatory sectors. Seven sectors in CETA were identified as being subjected to a regulatory design type of cooperation. The cross-case analysis compares these seven cases and focuses on the variation of explanatory factors. Within-case analysis looks instead at the sectors through the design types they belong to.

As it will be described in Chapter 5 of Part III. *Empirics*, the legal analysis of CETA identifies seven sectors distributed between three types of regulatory design: Type 1 (Ex-ante/Hard), Type 2 (Ex-post/Hard) and Type 4 (Ex-post/Soft). Type 3 empirical instances are absent from the agreement. Logically, the absence of expected conditions for Type 3 is a confirmatory result for the related hypothesis. Following the same logic exposed before, the correlation between the absence of an outcome and the simultaneous and systematic absence of its theorized explanatory factors' results would indicate the confirmation of the necessary relationship between them. Indeed, if the explanatory factors' results theorized for Type 3 is absent for all the 7 cases identified, it is less likely that the absence of Type 3 is simply a coincidence and not the products of the former. This needs naturally to be empirically verified by looking at the explanatory factors for all the cases.

This procedure follows two research objectives. The first is to look at whether the explanatory factors' values are consistent between sectors. In other words, it compares sectors with each other to check that they do share the same strategic feature within the same types. For instance, is a "hold-up" risk present in both motor vehicles and geographical indications (both belonging to Type 1)?

The second aim is to explore how the explanatory values resulted in the same types for each sector. More precisely, how did the explanatory factors in different sectors lead to the same design types? The focus is thus more on the internal causal chain between the factors and the design. By comparing several sectors within each type, the purpose is to demonstrate the presence of the same causal mechanism in different cases and the similarity of their results. Overall, these in-depth case studies fulfill the role of plausibility probe to provide details on the causal mechanism and potentially identify some scope conditions for the explanatory models (Bennett and Elman 2007b, 116).

As explained, these in-depth case studies pursued a process-tracing logic, with the aim of checking the presence of the causal mechanism (Beach and Brun Pedersen 2013, 11). Chapter 2.1 lays out the main theoretical premise of the causal mechanism following Rational Institutionalism principles:

- The choice of design type results from the strategic calculation of states when looking at the interdependence structure that characterizes the sector to be regulated. The design types fulfill a role of “problem solver” or in other words provide a legalized institutional solution to a cooperation problem. These cooperation problems relate to interdependence risks that are pertaining to the decision of both states to regulatory cooperate with each other. Thus, through identifying the risks of cooperation and assessing their potential costs/benefits consequences, it is possible to draw the causal mechanism that determine the choice of design type in a specific sector by negotiating states.

This causal pathway will be tested during the case study for each of the 7 sectors identified, organized around the three design types they belong to (Type 1, Type 2 & Type 4). These case studies will contain technical and economic details, as well as information on the negotiating process obtained through policy documents and interviews. Details on the data collection, including interviews, are thoroughly presented in the following chapter dedicated to the operationalization process of this research’s units of analysis, regulatory sectors, and its two explanatory factors, risks of “hold-up” and of shirking.

## Chapter 4. Operationalization

This chapter describes the operationalization for several key concepts in this research namely: regulatory sectors, risks of “hold-up” and shirking. It provides information on the identification strategy used to identify and classify regulatory cooperation provisions in CETA within the types of regulatory design theorized earlier. It also gives similar information for the units of comparison of this research: regulatory sectors. This includes also a discussion on the value of using “sectors” as a basis for comparison relative to other studies. Finally, dedicated sections describe the measurement process for the explanatory factors, as well as the data source used.

### *4.1. Regulatory sectors*

In this part, the different regulatory issues targeted by negotiating parties are regrouped through the concept of “regulatory sectors”. The subsequent section defines this term and justifies using a sector approach instead of traditionally comparing chapters of agreements or agreements themselves. Then, it discusses the sectors’ nomenclatures available in existing databases. Due to several shortcomings of existing nomenclatures, this research proceeds with its own ad-hoc identification strategy of sectors. To note that regulatory sectors are the units of comparison of this research. The purpose of the latter is to explain the variation of design types between the sectors in question. The last part of this section assesses thus how the sectors are classified within the design types introduced in the theoretical part.

#### **Why look at sectors in trade negotiation?**

Different approaches for the study of trade policy are at the disposal of researchers. Among them, looking at the domestic fields often brings valuable results to explain the proliferation of trade agreements and international behavior (Milner and Rosendorff 1996). By disentangling the interactions between the domestic and international spheres, it becomes possible to identify the factors responsible for the conclusion of treaties. This is not new; trade policy studies often analyze the effects of tariff reduction on a sector-by-sector basis. This approach is equally relevant for looking at the legal design of international agreements.

New regulations can also create distribution effects between economic sectors and firms (Ravenhill 2010; Baldwin and Low 2008). Overall, in trade policy, aggregate benefits no longer explain new international developments. The role played by specific sectors brings more insights on the negotiation and thus more explanatory value. Previous political-economy studies have adopted the same approach by either looking at distribution effects at the firm-level (Baccini, Pinto, and Weymouth 2017), analyzing the impact of a single policy on different industries (De Bièvre and Eckhardt 2011) or comparing trade policy areas between different PTAs (Horn, Mavroidis, and Sapir 2010). In all these instances, the explanations for states' behavior in trade policy were found through analyzing specific actors or economic areas. Sectors are at the heart of the trade negotiation conundrum and to look at their features is instrumental to understand states' trade positions.

This thesis advances that to understand the real use and value of PTAs' regulatory design, it becomes necessary to open its black box and look specifically at how each sector is regulated. This enables the explanation of the internal variation of legal design, present within treaties. Hence, in the context of this research, studying an entire agreement as a whole does not provide a sufficiently fine-grained scope. Disentangling the different sectors of activities, can serve as a useful basis of comparison, especially when looking at design variation inside trade agreements.

### **Regulatory sectors definition and identification**

In trade policy and regulatory cooperation, economic sectors are important for explaining negotiation results. This thesis follows the same perspective. Although at a first glance, the term "sectors" may seem relatively vague, it is widely used in international economic statistics and studies. The OECD defines it as "a group of establishments engaged in similar kinds of economic activity"<sup>39</sup>. From the OECD definition, this research replaces the term "economic" by "regulatory". As the sectors are not producing rules but are rather subjected to them, it will also change "engage" with "are subjected". Therefore, the regulatory sectors are defined as a "group of establishments subjected to similar kinds of regulatory activity". To answer potential criticisms on the term "Regulatory Sectors", I justify my use of the term "regulatory" instead of "economic" because of the narrow scope of "economic sectors" commonly used in official statistics. Although

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<sup>39</sup>OECD, Glossary of Statistics Terms: <https://stats.oecd.org/glossary/detail.asp?ID=5691>, accessed the 17th January 2019

“economic sectors” might be a useful label to analyze regulations, grouping regulatory areas along traditional economic lines of understanding can be problematic.

Besides the issues related to defining sectors, the strategy of the sectors’ identification in CETA remains to be discussed. Regulatory Cooperation encompasses a wide variety of actors and issues. It is thus difficult to choose the right scope to conduct the analysis and use the right tools, e.g. existing databases, to conduct the comparison. An attempt must be made to find a Euclidian point to identify and list all possible sectors through a deductive approach.

As of today, different international nomenclatures coexist. Developed by several international organizations, four are accessible and widely used in research: The Harmonized System (HS), the Standard International Trade Classification (SITC), the Broad Economic Categories (BEC) and the International Standard Industrial Classification of All Economic Activities (ISIC).

The World Customs Organization harmonized system<sup>40</sup>, or the Harmonized Commodity Description and Coding System, covers 98% of the goods exchanged around the world. It classifies over 5000 commodity groups “each identified by a six-digit code, arranged in a legal and logical structure and is supported by well-defined rules to achieve a uniform classification”. The level of detail is determined by the digit, HS6 level being the most common use of digit for trade negotiation. Its greatest limit remains its focus on trade in goods only. It excludes services, and a wide range of regulations that do not follow this goods-focused approach: professional qualifications, etc.

The Standard International Trade Classification (SITC) system<sup>41</sup> is currently maintained by the United Nations, who recommended its “use in all countries for their external trade data and thus promotes international comparability of trade statistics”. Despite small variations, SITC shares the same focus on goods as the HS system. Therefore, despite being widely used across countries, including for the European trade database Eurostat, and in many international trade’s studies, these same limitations prevent its direct use in studying regulatory cooperation, without modifications.

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<sup>40</sup> The World Customs Organization, “What is the Harmonized System (HS)?”: <http://www.wcoomd.org/en/topics/nomenclature/overview/what-is-the-harmonized-system.aspx>, accessed the 20<sup>th</sup> May 2019.

<sup>41</sup> United Nations Statistics Division, “SITC Rev 4”: <https://unstats.un.org/unsd/trade/sitcrev4.htm>, accessed the 20<sup>th</sup> May 2019.

The United Nations also developed the Broad Economic Categories (BEC) nomenclature<sup>42</sup>. Originally established as a product focused nomenclature, it offers information on each product's end-use, for example intermediary parts for manufacturing or household consumption goods. Despite services being added in its 5th revision, this new update has not yet been fully implemented in available statistical databases, notably in UN Comtrade. The classification is also either too broad, the category "Industrial Supplies" for instance, or imprecise. The availability of data is uneven, such as for the categories "Food and beverages" and "Fuel and Lubricants". Although, the classification might be useful to look at manufacturing processes, it remains inappropriate for regulatory cooperation. In addition, the data does not include all categories. Using this system would thus exclude certain regulatory sectors.

The International Standard Industrial Classification of All Economic Activities (ISIC) approach<sup>43</sup> remains one of the most adequate to look at regulatory cooperation, compared to the others. Not only does it include services extensively, but the OCDE disposes also of a large amount of bilateral data between its members. While the 4th classification includes activities particularly important such as "Professional, scientific and technical activities", the 3rd version remains the one in use by the OCDE and crucial parts of data are missing. While in some areas the classification is well developed, in others it is too broad such as for the category "manufacturing for instance.

As reviewed, the already existing systematic compilation of sectors does not fulfill the needs of this research. To proceed nevertheless, this project adopts an inductive approach to recognize and identify "Regulatory Sectors" within CETA itself. By conducting an article-by-article scrutiny, it identifies the relevant sectors of activities. The coding process used in this approach is available in Appendices I, II and III. This choice of method allows a correspondence between a specific legal provision and a sector of activity to be established, facilitating further steps in identifying variations of regulatory types between sectors.

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<sup>42</sup> United Nations Statistics Division, "Classification by Broad Economic Categories (rev.4)": <https://unstats.un.org/unsd/tradekb/Knowledgebase/50089/Classification-by-Broad-Economic-Categories-Rev4>, accessed the 20th May 2019.

<sup>43</sup> OECD, "Glossary of Statistics Terms": <https://stats.oecd.org/glossary/detail.asp?ID=1467>, accessed the 20<sup>th</sup> May 2019.

## **Regulatory cooperation: Sectoral or Horizontal approaches**

By looking throughout CETA, this research identified seven economic sectors that were targeted by dedicated regulatory cooperation provisions. Appendix I of this research describes the coding process used to identify the relevant provisions inside the agreement, while Appendices II and III present the process for identifying sectors and classifying them among the different design types.

The reason for this project to choose CETA to investigate sector variation, finds its origin in its presentation by both Canada and the EU as the “gold standard” of the new generation of trade agreements<sup>44</sup>. Its reference role in trade policy is an attractive reason to focus research efforts on this particular treaty. For the future of trade negotiations, it is to be expected that both Canada and the EU potentially attempt to emulate some of their regulatory approaches. Studying CETA can thus become an interesting starting point to observe how regulatory cooperation between sectors can vary or remain similar across multiple trade agreements.

CETA includes entire chapters and provisions that target general regulatory issues such as “Sanitary and Phytosanitary measures” and “Technical Barriers to Trade”. These horizontal types of cooperation are applicable to all sectors and are non-discriminatory. As one of the contributions of this research is to highlight and explain the variation in design between sectors, it was not possible to include horizontal provisions into the population of cases.

This leads to a certain divergence with earlier studies as illustrated in Table 4. Compared with the sector selection of A. Young (2015a) in his article on EU regulatory externalization in PTAs, the case population of this research differs. This reference is mentioned because of Young’s comparison of regulatory cooperation across several EU PTAs. Some divergences emerged between this research and Young’s selection, as he was comparing different agreements rather than looking at sectors. This divergence originates from the choices made to focus on sectors as units of analysis, excluding thus horizontal issues from this research scope. Future research deepening the variation of horizontal design between trade agreements could bring valuable insight into this crucial regulatory turn in trade policy.

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<sup>44</sup> European Commission, “Joint statement Canada-EU Comprehensive Economic and Trade Agreement (CETA)”, Monday, 29 February 2016, [http://trade.ec.europa.eu/doclib/docs/2016/february/tradoc\\_154330.pdf](http://trade.ec.europa.eu/doclib/docs/2016/february/tradoc_154330.pdf), accessed the 2nd May 2019.

### Sector Identification & Selection

<b>Current Research project</b>	<b>Young 2015, Table p. 1267</b>
Biotechnology	Goods
Forest Products	TBT
Geographical Indications	Vehicles
Motor vehicles	Food
Pharmaceuticals	
Professional Services	Financial Services
Raw Materials	Competition Policy
	Data protection
	Environment
	Labour

*Table 4 Comparison's table of sector identification with Young 2015a, p. 1267*

### **Evaluating design for sector's regulatory cooperation mechanism**

To measure the variation in design between the seven sectors identified, this research looks at the legal features of the provisions regulating the sector in question. More specifically, the questions to be answered are: is the determination of joint rules of the cooperation immediate or delayed? Do the legal provisions list Ex-ante regulations or products targeted by the cooperation? Do they include pre-established standards, such as technical requirements of the products? Do the provisions create a special committee with extensive regulatory power? Do countries commit to cooperation, or do they rather profess their “good-will”?

The purpose of these questions is to assess to which design types do regulatory sectors belong. The analysis looks at the provisions and attempts to determine to which category the sectors belong across the two axes: Ex-ante/Ex-post & Hard/Soft.

For Ex-ante and Ex-post, this research observes whether the provisions list specific products or regulations inside the agreement. This detailed technical information needs to be either found within the text of the agreement, or in an annex. The nature of the information can be of different nature, as long as it is “technical”, such as metrology indicators, specific measurements, or references to existing documents providing similar technical prescriptions. If these specific technical measurements are absent, it is an indication that the mechanism might not be Ex-Ante. Nevertheless, this does not classify necessarily in Ex-post. The text of the treaty detailing the type

of cooperation needs to describe the condition of representation, membership, and general rules of proceedings of the Ex-post mechanism. For instance, this can be the identity of the chairpersons of a bilateral dialogue, the timing of the meeting (two times per year) and the mandated regulatory cooperation of this group (e.g. drafting equivalences rules). The information does not need to be systematically similar across Ex-post mechanisms, rather it should indicate clearly the “institutionalization” of the cooperation or, in other words, the repeated and long term nature of the interactions between states on regulatory matters.

For Hard/soft, the legal language is scrutinized. The technique used is the decomposition of the sentences into several parts with the purpose of identifying “common” and well-established legal forms that indicate the voluntary or compulsory nature of a provision, from a legal perspective. Instances of these formulations can be “Parties shall”, for clear legal obligations. “Parties should...” or “Parties endeavor...” indicate instead voluntary obligations. In these instances, it is the use of the term “shall”, that indicates a precise obligation, while “should” or “endeavor to” rather shows good intentions without the presence of a legal obligation.

This type of differentiation of legal languages for informing on the “voluntary” or “compulsory” nature of obligations is a well-known feature of international law. Chapter 2 of Downes on *The Impact of WTO SPS Law on EU Food Regulations* (2014, 2:34–54) provides an informative review of these aspects within international law. It specifically provides guidance on the different approaches to interpret international law, especially the WTO’s approach, regarding regulatory issues. It also provides specific theoretical background on how to interpret legal features, notably the use of “shall” to express legal obligations (Downes 2014, 2:35). In terms of coding, Appendix III classifies which provisions belong to which types with the precise number of the articles. Indeed, this research looks article by article to determine the type of design.

As a side note, it is useful to take into consideration that even if “regulatory instruments” are present in CETA, e.g. equivalences or recognition, this research found that they are often used irrespectively of their legal effects. As the empirical Chapter 5.1 describes in more detail, “equivalences” can be found both in Ex-ante and Ex-post, as well as bilateral dialogue. This research proceeds thus to classify the sectors across the different types uniquely based on their legal effects and not on the label of the “instruments” used. The same section provides a thorough textual analysis of all the mechanisms for all the cases identified in CETA, relying on the coding results displayed in Appendix III. Following this description of the operationalization of “regulatory sectors” in CETA, the next sections proceed similarly with “Hold-up” and shirking.

#### *4.2. The risks' structure*

The analysis of a strategic structure is not an easy task. States look at their situation from a certain bargaining position and make decisions according to their relative strengths and/or weaknesses compared to other states and their potential partners. This implies that data must come from different sources and be used in a combined manner to represent in the most accurate way possible the complexity of the situation confronted by states when designing their cooperation.

As explained in section 2.2, this thesis argues that two main risks are instrumental for composing the strategic structure underlying the design results. These two risks are of different nature and therefore their observation requires the use of different sorts of data sources. “Hold-up” risk relates to the potential exploitation by one of the parties of existing and/or future economic linkages to extract economic concessions in the future. This possibility becomes particularly real according to the type of Global Value Chains integration in which the firms from either country active in a specific sector are embedded. To measure and assess these different forms of value chains integration that could lead to potential “hold-up” situations, this thesis harnesses economic data from trade statistics, available in official countries or trade association websites and IOs online databank. The next subsection describes further its operationalization process and the type of data collected to identify the presence or absence of “hold-up” risks.

For measuring the risk of shirking, this thesis argues that a pertinent way is to look at the co-participation of the two negotiating countries to joint international regimes, standards and regulatory systems. It states that the risks that a country decides after treaty conclusion to shirk its commitments will depend on its existing and preexisting regulatory convergence with its negotiating partner. When sectors are characterized by different regulatory frameworks, the opportunities for states to renege on their sectoral commitments is more present. Indeed, the divergence of their system and the potential conflictual technical requirements will reduce the costs of defection and increase its potential benefits. It will also provide more avenues to “reactivate” regulations as barriers to trade, notably as they will target mostly foreign firms. On the contrary, joint integration of both states within a common framework renders it more costly for one of them to create an alternative regulatory framework anew. Furthermore, joint integration provides benefits that are self-enforcing due to the alignment of regulations. To measure this joint

belonging – or not – to similar regulatory systems, qualitative data is collected from official documentations, position papers, reports and international treaties.

Finally, interviews act as a secondary source of data in both factors, aiming at enriching information, completing, verifying if actor's view of the strategic independence is similar to the one deducted from data throughout the documents and statistics. Meeting with relevant stakeholders, such as officials, also helped establish the functionalist externalization process, connecting factors' results and the regulatory design in CETA. They provide valuable information into what trade or regulatory aspects states prioritized during the negotiation. In terms of numbers, I conducted semi-structured interviews with 26 representatives of 22 organizations (10 Canadians, 12 Europeans), ranging from public administration, public regulatory authorities to industry associations (Appendix IV). Each individual interview is anonymized through a code, listed in the same Appendix. The questions asked and general procedure of outreaching followed a "neo-positivist" conception of interview, according to the typology of Roulston (2010). The selection of the interviewees was made according to the population of the cases and strived to obtain several perspectives (CA-EU officials & industry) for each case. When actors would not answer positively an interview request, regulatory and policy documents were used to reconstruct their position. The questions asked interviewee's perspectives on the regulatory and trade challenges they were facing in their activities. Their opinion on the negotiation process and results were also included. During the analysis, the answers collected were put into perspective with other sources of data and served as confirmatory sources.

The interviews took place in Brussels, Ottawa or on the phone according to the time and availability of the interviewed. All participants provided their explicit written consents under conditions of anonymity. Anonymity was indeed privileged so as to facilitate open exchanges, more prone to provide useful insights on negotiations conditions. This was a necessary condition as the interviewees were in certain cases public officials, which provided personal analysis on their experiences as negotiators or regulators. The highly politically contentious nature of certain negotiated issues also supported this choice. Appendix VI contains the consent forms used. These documents and the overall study received ethical clearance by the Ethics Committee of Université Laval, approbation number : 2018-375 / 11-03-2019. To implement required anonymity, I used two types of designation, "industry" and "officials", to distinguish trade association positions from governmental ones. Location of the interviews was also specified for the purpose of transparency. However, this thesis contains no names, personal contacts or the exact units or official title of the individuals interviewed. The name of the overall organization interviewed is

contained in Appendix IV, such as DG Trade or European Dairy Association but not mentioned within the text. Furthermore, the fact that several associations were interviewed for one sector also limits the possibility to identify precisely to which association the interviewee belong. These choices were made in order to strike a balance between transparency and research needs for information, and the risks of identifying individuals by cross-cutting information. Transcripts of interviews were also anonymized through a code, encrypted and stored in the GEM-STONES database, accessible only upon request. The list with the names, codes and the consent forms signed are locked separately.

In terms of cited references, they are divided in two: primary sources, websites containing official documents/legislation and data, cited in footnotes; and secondary sources such as reports, and scientific articles cited in bracket following Chicago style of references. The motivation behind this division being the large amount of websites being cited and the inadequacy of the Chicago style of reference in certain cases to cite non-authored primary data. For instances, websites are more easily cited in footnotes than through the bracket reference system, and footnotes allow the possibility to immediately provide the URL of the document without having to refer to the bibliography, situated after the conclusion. It then becomes easier to directly check the data sources and provide additional transparency.

The following sections expand on the operationalization process for the explanatory factors: “hold-up” and shirking risks.

## **Hold-up**

In their original contribution of contract “(in)completeness”, authors Cooley and Spruyt argue that “when transaction-specific assets are at stake, the possibility of hold-up arises” (Cooley and Spruyt 2009, 10). The ownership of a specific asset becomes a leverage to obtain concessions during the renegotiation phase even with larger and more powerful states (Cooley and Spruyt 2009, 38). These concessions can take the form of regulatory adjustments required by one of the parties, which would provide “surplus rent or revenue stream”. An example can be found in the harmonization of American beer producers with the German requirements laid out in the 1516 “Beer purity law”<sup>45</sup>. Through restricting the conditions of production, such requirements would

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<sup>45</sup>BBCnews, “German beer: 500 years of ‘Reinheitsgebot’ rules”, 22<sup>nd</sup> April 2016, <https://www.bbc.com/news/world-europe-36110288>, accessed the 18<sup>th</sup> may 2020.

advantage German beer producers at the expense of their competitors, allowing them to capture consumers surplus in the market. Such an effect would be magnified if furthermore the type of “hops” culture allowed, is only or more easily found in German soil rather than American one. This is one illustration of how regulatory adjustments can potentially lead to additional direct economic benefits for the firms able to force their competitors to align on the regulatory requirements to which they are already subjected.

This advantage is amplified within the concept of the hold-up when one state is furthermore able to exercise a control-right on a specific asset (Cooley and Spruyt 2009, 10–11). In a context of regular trade exchanges, potentially conducive to a situation of mutual dependency, control over a specific asset become a tool for influence. It can provide its controlling state with a leverage to open a renegotiation phase and obtain better trade terms from the depending state (Cooley and Spruyt 2009, 27). Oil and natural gas are traditional instances of these type of assets, but this can include a wide variety of products, finished or only parts. Nevertheless, in regulatory cooperation “hold-up” does not refer only to the direct control or dependence towards one specific asset. It includes also the role of investment for its production’s conditions.

To produce this type of “specialized” or “specific” asset, firms need to make significant investments domestically or abroad with the objective of integrating a value chain. Regulatory cooperation can be conceptualized as one of these types of investments (see EEC example in Cooley and Spruyt 2009, 147). By accepting to cooperate—regulatorily harmonize—with a specific sector, a state makes a decision equivalent to one of investment. It amends its regulations and technical requirements to facilitate the integration of its firms in a value chain that would hopefully provide additional surplus and income. This type of decision is particularly strategic as it relies on an anticipation of what would be the future conditions of the bilateral trade exchanges and the value chain (Cooley and Spruyt 2009, 22–23).

Different scenarios are possible, and the authors of “(in)completeness” identify two main: “actor who might be vulnerable to hold-up by the possessor of the transaction-specific assets will seek vertical integration”; “if both contracting actors have shared assets with equal vulnerability (i.e., mutual vulnerability), then the likelihood of hold-up may well decrease” (Cooley and Spruyt 2009, 22). According them, the risk of “hold-up” is particularly high when a situation of asymmetry in controlling specific assets exists. In this case, investment in this sector, by a negotiating party with less assets, is particularly risky as this investment can further accentuate

dependency towards the “richer-assets” country, which then exploits this relation during a renegotiation phase.

Regulatory adjustments—or investments—within a sector, for which the technical requirements have already been set by the previous “rich-asset” country, is costly for domestic firms and put them in a situation of dependency towards the controlling state. The regulatory cost is made to integrate the value chain incentives to accept further concessions instead of losing the investment already made. On the contrary, when both parties trade specific assets, this relative symmetry tends to remove the risks of hold-up as both have the means to take each other hostage (Cooley and Spruyt 2009, 23). As both trade specific assets and share the same investment/regulatory costs necessary to integrate the value chains, the risks that one of them unilaterally takes hostage the value chain is reduced. Indeed, in such a configuration costs and benefits of re-negotiation and regulatory adjustments would be equally carried by the two parties.

These two conjectures are however mitigated by other factors, which might interfere and reduce or increase “hold-up” risks. The global substitutability of assets and the types of industry integration within GVCs play similarly significant roles in the determination of “hold-up” risks during regulatory negotiation. As stressed by Cooley and Spruyt (2009, 27), “without alternative partners for exchange and/or given high levels of initial investment, either party might be reluctant to continue investing in the relationship”. As argued just before, this reluctance of investment has significant repercussions for regulatory cooperation as it can limit the willingness of parties to regulatory cooperate in the long term, for fear of being take “hostage”. Limited substitutability of assets can thus play an enhancing effect on “hold-up” risk, while complete substitutability instead reduces drastically this risk. If products can easily find another buyer, the decision by one party to stop purchasing this product is less meaningful than if it was the sole buyer for this specific asset.

Last, it can be informative to look at how the main exporting firms for each party are geographically organized and structured. If one country’s firms are located upstream along the value chain, its dependency on the complex imbrication of production reduces the risks that this country will take hostage the downstream segment to impose its regulation (Antràs and Chor 2013, 2191). On the contrary, if a country’s manufacturing firms are concentrated on the final stage of production, this state is in a better position to decide the regulatory conditions to be applied. The risks of hold-up increase consequently. The works of the GVCs field of research have often revealed how positioning in the finalized stage of production tends to reinforce the

firms occupying it (retailers such as Walmart or Tesco), providing them leverage to decide the regulatory requirements governing the value chains at the expense of the suppliers (Gereffi 1994, 1999; Ouma 2010). As just previously mentioned, this possibility depends on the substitutability of products and the organization of the suppliers. Oil extracting companies organized in a consortium might have more leverage compared to decentralized Kenyan beans producers. Naturally the “substitutability” nature of an asset remains only one important factor among others, as illustrated by the continuous collapse of oil price since the peak of 2008<sup>46</sup>.

To measure the risk of “hold-up”, this research looks at several elements for its assessment, notably the distribution of “specific assets” between negotiating parties, the possibility of “assets substitutability”, the type of GVCs or anticipated costs of regulatory adjustments. A wide range of economic indicators are used. Statistical data on how much each country exchanges with each other is naturally included, the measurement being made in traded values, specifically in Euros. One index calculated and used in this thesis is export surplus, converted in percentage, comparing the ratio between bilateral imports and exports of countries. This index should not be reified but must be seen as one useful indicator among others. Eurostats used a similar measurement<sup>47</sup> (Table 23, Appendix V.) and is useful to quickly identify which of the trading parties might be subject to a hold-up risk in case of regulatory adjustments.

Indeed, trade liberalization through regulatory cooperation impacts the firms involved in the bilateral trade exchanges. It stimulates trade and intensifies the overall flows of goods and services between parties (Baier and Bergstrand 2003). This is especially taken in consideration by negotiators, notably as the most productive firms are generally the ones able to enter foreign markets and exporting (Melitz 2003; Melitz and Ottaviano 2008). These highly productive firms, or “superstar exporters”, can end-up being even reinforced by the trade policy pursued and dominate entire industry (Osgood et al. 2016). This can create additional competition to foreign import-competing firms and challenge their production model. Trade flows are thus useful to identify this possible scenario and allows to compare sectors that have different trade figures and volumes. Converting in percentage points allowed thus a better comparability between them

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<sup>46</sup> Jillian Ambrose, The guardian, 20<sup>th</sup> April 2020, “Oil prices dip below zero as producers forced to pay to dispose of excess”, <https://www.theguardian.com/world/2020/apr/20/oil-prices-sink-to-20-year-low-as-un-sounds-alarm-on-to-covid-19-relief-fund>, accessed the 18<sup>th</sup> may 2020

<sup>47</sup> Eurostats, “Canada-EU International trade in goods statistics”, [https://ec.europa.eu/eurostat/statistics-explained/index.php/Canada-EU\\_-\\_international\\_trade\\_in\\_goods\\_statistics#EU\\_and\\_Canada\\_in\\_world\\_trade\\_in\\_goods](https://ec.europa.eu/eurostat/statistics-explained/index.php/Canada-EU_-_international_trade_in_goods_statistics#EU_and_Canada_in_world_trade_in_goods), accessed the 15<sup>th</sup> September 2019.

instead of absolute numbers. Table 7 in chapter 5.2 contains the statistical results for all sectors, as well as individual number details.

More information on the products or assets exchanged bilaterally are also gathered in official governments' websites or trade associations, such that of the Canadian Mining Association<sup>48</sup>. Certain international organizations also contain additional precision on EU-Canada bilateral trade, such as for forest products with the Food and Agriculture Organization (FAO) of the United Nations<sup>49</sup>. In addition, this research identifies the main exporting firms, how they are organized (national or international trade association) and the physical presence of their production and commercial facilities. It also looks at their zone of integration if their production is integrated locally or global.

Analyses, reports and statistics indicative of this type of data can be found in newspapers articles, trade association websites, official government websites, think tank reports and statistical databases. For instance, the website of the Government of Canada Heath ministry provides a list of the leading pharmaceutical firms in Canada<sup>50</sup>. To identify leading firms, public and private statistics are available for public access on relevant websites. In certain cases, it is possible to identify the firms by looking at the membership of prominent trade associations. Not all information is public though and in certain cases, it is necessary to combine different sources to obtain an accurate picture of the sector. In certain cases, geographical locations of main exports clusters can provide important information, especially for certain sectors such as geographical indications.

As a complementary source of data, interviews with negotiators and representatives of the industry were used to confirm when states acknowledged the existence of a large export surplus and when they did not. Indeed, these actors themselves identify when a risk of “hold-up” affected the negotiating process. These insights and actors’ perceptions are particularly useful to reconstruct the strategic calculation that led to the adoption of a specific design type.

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<sup>48</sup> The Mining Association of Canada, “Facts and figures 2017 of the Canadian mining industry: Annex 9 & 10”, <https://mining.ca/documents/facts-and-figures-2017/>, accessed the 20<sup>th</sup> September 2019.

<sup>49</sup> Food and Agriculture Organization of the United Nations, “Forestry Production and Trade”, <http://www.fao.org/faostat/en/#data/FO>, accessed the 20<sup>th</sup> September 2019.

<sup>50</sup> Government of Canada, “Pharmaceutical Industry profile”, [https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h\\_hn01703.html](https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html), accessed the 20<sup>th</sup> September 2019.

## **Shirking**

To measure the risk of shirking, there are merits in determining the indicators often used to identify the compliance of states to shared rules and international commitments. In this aspect, the empirical contribution of the regulatory “orchestration” literature is particularly valuable (Abbott and Snidal 2010, 2009). Through analyzing various international regimes, they were able to identify a series of regulatory instruments and vehicles that tend to support the joint adhesion of states to the same technical requirements. Furthermore, this same literature, reviewed in section 2.2, also indicated how the pre-existence of a vast number of regulations and non-formal rules tends to reinforce international states’ compliance.

Following these premises, this research poses that in a given sector, the more a state’s regulatory framework is similar or compatible, the less there will be opportunities to shirk cooperation commitments at low cost by adopting new regulations acting as regulatory barriers to trade. This argument stands on the suggestion that the opportunity for shirking will be higher when cooperating states tend to have diverging regulatory requirements. Regulatory divergences provide the room for potentially opportunistic domestic actors, such as firms, to pressure their states in adopting new regulations that will protect them from import competition (Kucik 2012; Osgood et al. 2016). On the contrary, when the same rules are followed across-borders, the adoption of new rules by states will be opposed by firms from both sides as they are all already compliant with the preexisting regulatory system. Regulatory alignments in fact provide benefits to firms already aligned and any departure might be seen as costly disruptions of the sector. Hence, future shirking risks through the opportunistic use of new regulations is less viable when all actors are similarly aligned and follow the same technical requirement. To measure this joint adhesion, it is useful to look at several data sources, notably international regime, domestic regulations and conformity assessment systems.

International regimes are particularly pertinent to assess regulatory divergences as the belonging of two states to different treaties and/or IOs can have drastic regulatory repercussions for firms. The United National Economic Commission for Europe’s agreement on motor vehicle standards is an instance of this type of international agreement. Belonging to this treaty or not strongly determines the regulatory alignment of global producers on the same technical requirements and thus the establishment of equivalence among their products. Indeed, a wide range of international treaties often combined technical prescriptions and obligations for equivalence or mutual recognition. Membership in such treaty/IO implies thus that the firms of the country need to

follow internationally recognized standards but also that states need to recognize and accept on their territory products respecting the same technical requirements.

Overall, it is possible to classify international rules into two categories: rules coming from international treaties and rules originating from standards, certification or codes of conducts developed by private actors with the potential support of states. The use of common global standards is particularly informative, especially as firms extensively use these private rules to facilitate coordination among them, particularly in the context of a global value chains. Even if these rules are mostly private, states must take them in consideration when specifying the modalities of their regulatory activities. This is due to potential costs in diverging from internationally recognized standards. Indeed, when firms follow different standards crossing borders, they need to obtain equivalences from administrative authorities, which can incur some additional time and extra fees. Furthermore, in certain cases equivalences are not possible and different production chains have to be set up according to the technical requirements of each country. If firms followed diverging standards before the negotiation, the apparition of new technical barriers to trade is naturally unwelcome but will not change the fact that the firms are already evolving in a fragmented environment. Their activity will be thus less affected by these new barriers. On the contrary, if firms already followed the same international standards and regulations, new barriers would be particularly costly as it upsets the existing framework, which facilitates cross-border trade and brings mutual benefits. New barriers would then remove benefits for both states' firms.

Approbation mechanisms, notably conformity assessment methods play a vital role in this regard as it establishes the conditions for the potential recognition of products following similar but also diverging technical requirements. They indeed fulfill two functions: do the products produced domestically respect the technical requirements specified in the standard/public regulations? And, do the imported products correspond to the essential requirements specified in the domestic regulations (e.g. safety)? This aspect is an important component of regulatory cooperation and depends on the methods used within each country. Certain approbation systems have additional tests and unique requirements. This can result in significant regulatory divergences between countries. To illustrate, a country might decide that facilities' inspection should only be performed by accredited authorities of its own. It can also require testing procedures to be repeated in its own territories, even if the products were already tested abroad.

Checking the presence or absence of these test duplication requirements and other additional probation procedures can help determine whether firms are easily recognized on both sides of the border or if they are blocked because the testing requirements are more stringent on one side, for instance. This provides interesting information in the state of convergence or divergence of regulatory systems of the two parties and the incentives to either further align or defect. To give an instance of conformity assessment divergence, while Canada follows a “self-certification” system for motor vehicles accreditation, the EU requires a “type-approval” process for commercialization of motor vehicles in the common market. This divergence prevents the exports and imports of vehicles across the two states without costly regulatory adjustments.

In sum, the analysis of regulatory divergence/convergence requires mainly the analysis of regulatory documents, private standards, and other regulatory process for products’ approval. As an instance of international standards, one can cite the *OECD guidelines for Multinational Enterprises and for supply chains minerals from conflict-affected and High-Risk areas*<sup>51</sup>. Controlling that both Canada and the EU require their firms to comply with this standard is a useful indicator to verify their regulatory convergence. International treaties and organizations’ memberships is also a useful source of information. It can quickly inform whether the two countries belong to the same international regime or instead are part of diverging ones. A classic illustration is to verify that both Canada and the EU signed the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This treaty is indeed particularly relevant for trademarks, a key regulatory question for the sector of Geographical Indications.

The consultation of position papers and regulatory documents published by trade association is likewise useful. These documents are often easily available online, as both the EU and Canada organized consultations period during which industry could submit a position paper expressing formally their regulatory wishes for CETA. They provide details on the requirements of technical specifications in the domestic regulations of the two negotiating countries, and the presence/absence of pre-existing or existing regulatory conflicts between them. Indeed, trade associations regularly publish position papers to alert authorities on regulatory barriers their members encounter in their activities. These documents often contain useful technical details on the issues at stake and the political economy behind them.

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<sup>51</sup> OECD, “OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas”, <https://www.oecd.org/corporate/mne/mining.htm>, accessed the 14<sup>th</sup> June 2020.

Following the presentation of the methodology and operationalization process used in this research, Part III proceeds with the empirical analysis of the seven regulatory sectors identified in CETA: Geographical Indications (GIs), Motor Vehicles (MVs), Professional Qualifications (PQ), Pharmaceutical Products (Pharma), Biotechnology (Biotech), Forest Products (Forest) and Raw Materials (Raw).

## **Part III. Empirics**

The empirical analysis is divided in two parts. The first Chapter 5. *Cross-Sectoral Comparison* compares the seven sectors together and proceeds to describe each of them. It starts by assessing the regulatory instruments in CETA. Then it describes the legal provisions for each sector and presents the legal reasoning that led to classify the sectors in three types (1,2 & 4). Instances of sectors regulated under Type 3 could not be found in CETA. In addition, none of the 7 cases had the following factors' results: presence "hold-up" risks & absence of "shirking" one. The latter being identified in the theoretical section 2.2 as the necessary conditions for Type 3, the congruence of these absences appears to support the related hypothesis for this design type formulated earlier. The following sections will look further at the sectors from the perspective of the two interdependent risks responsible for design variation.

Providing an overview of the results, Chapter 5 also reveals the underlying causal mechanism between presence/absence of hold-up, notably by comparing Geographical Indications (GIs), Motor Vehicles (MV) (both Ex-ante) with Pharmaceuticals (Pharma) and Professional Qualification (PQ), two instances of Ex-post design. It proceeds similarly with Hard/soft and shirking presence/absence by contrasting GIs & MV (Hard) with Raw Materials (Raw), Forest Products (Forest) and Biotechnology (Biotech) (all Soft). Note that the explanatory framework is verified for all sectors at the exception of Biotechnology, which appears to be a deviant case. To complement this analysis, the three following chapters (6, 7 and 8) look at each sector, regrouped by design types, and demonstrate the causal links between strategic risks, and the regulatory design adopted.

## Chapter 5. Cross-Sectoral Comparison

What is sectoral regulatory cooperation in CETA? What are the legal provisions that cover this type of cooperation and how are they designed? How are specific economic activities targeted in the text? This first empirical chapter attempts to answer these questions and provides an overview of sectoral regulatory cooperation in CETA. At first, the next section discusses the different regulatory mechanisms that are present in CETA. This research argues that it is the legal effects of these mechanisms that matter and less the form they take (equivalence, mutual recognition...). Hence, the focus of this research is on explaining the legal variation that is present in the agreement. To do so, an article-by-article legal assessment of the seven regulatory sectors identified follows, showcasing how these sectors are distributed according to the three types of regulatory design present in the agreement (Type 1, 2 & 4). It also performs a preliminary cross-sectoral analysis, presenting and describing the variation of the explanatory factors for each of the seven sectors identified in the text: Geographical Indications (GIs), Motor Vehicles (MVs), Pharmaceutical Products (Pharma), Professional Qualification (PQ), Raw Materials (Raw), Forest Products (Forest) and Biotechnology (Biotech).

### *5.1. Textual Analysis of CETA regulatory mechanism*

To initiate this analysis, it is useful to pinpoint that sectoral regulatory cooperation in CETA is not organized within a single specific chapter. Instead, sectors are regulated through different chapters across the agreement, often belonging to different sections of the treaties. While the sector of Geographical Indications (GIs) is part to chapter 20 Intellectual property complemented by an annex (Annex 20-A), Motor Vehicles (MVs) are regulated in a single stand-alone annex (Annex 4-A). Pharmaceutical Products (Pharma) are mentioned within the TBT chapter 4, under a legal provision dedicated to conformity assessment (Article 4.5). This provision refers to a protocol on mutual recognition for pharmaceutical products present among the annexes. Professional qualification (PQ) enjoys its own dedicated chapter (Chapter 11) also supplemented by Annex 11-A “Guidelines for MRA”. Cooperation on Biotechnology (Biotech), Raw Materials (Raw) and Forest Products (Forest) are scheduled in the Chapter 25 “Bilateral Dialogue and Cooperation”, which contains dedicated provisions for each sector.

The structure of CETA and its scheduled regulatory mechanism follow a sectoral logic, where the cooperation proposed correspond to the type of activities it regulates, and the government entities involved in the negotiation. This might vary between countries according to their understanding of the issues. For instance, while the EU sees GIs as a component of its agriculture policy, Canada sees it through its trademark regulations lens. Therefore, while the EU had agriculture experts strongly involved in the negotiations, Canada instead mobilized its Intellectual Property specialists within its trade policy division (officials B2-B4-D7, Ottawa & Brussels). This differentiation is also visible for raw materials, which involved DG Growth and Natural Resources Canada. The influence of different bureaucratic legacies and economic visions explains this variation.

During the interviews made for this research, all actors stressed the importance of the sectoral logic to understand these differences of regulatory approaches throughout the agreement (industries & Officials, Interviews in Brussels and Ottawa). The logic of the sector, especially its economic and regulatory state of play, was determinant in explaining why a certain choice of legal design was made, notably Hard / Soft obligation & Ex-ante / Ex-post. The next empirical chapters provide additional details and information on similar trade-offs that appeared during the CETA negotiation.

To note that “legal instruments”, such as “equivalences” or “mutual recognition” were not significantly discussed during CETA negotiation and often resulted from the internal logic of sectors. For instance, the actors involved in the motor vehicles or pharmaceuticals sector did not consider any alternatives to the use of “mutual recognition” for regulatory cooperation (Industry C6-C1, interview in Brussels). For them, the use of these instruments was natural and followed a legalistic logic. Furthermore, these instruments were also found across different types of legal design without really impacting the Hard/Soft & Ex-ante/Ex-post dimensions. As it will be described later, despite both using “mutual recognition”, the textual analysis found that these sectors belong to different types of regulatory design (Type 1 for motor vehicles and Type 2 for pharmaceuticals). This is the case for several other instruments, such as annexes and bilateral dialogue, as will be presented further. Textual analysis noticed that similarly labelled instruments had different effects according to the sectors and the overall regulatory backgrounds. While two cooperation schemes can be labelled similarly as “bilateral dialogues”, one might be able to produce binding rules, while the other is unable. This might be misleading for researchers, as it disguises the real regulatory effects of the regulatory design used.

As mentioned in the previous section the seven sectors regulated are distributed across CETA. This distribution throughout the agreement thus requires a fine-grained approach to identify what are the different legal provisions pertaining to regulatory cooperation in each sector. This section proceeds with this description with two purposes in mind. One is to show how these provisions relate with each other and design a regulatory cooperation mechanism between the two parties in a specific sector. The second uses comparison to present the variation of design between sectors. The legal effects of these regulatory provisions are thus assessed according to the two dimensions developed in the earlier theoretical parts: nature of obligation (Hard/Soft) and mode of decision (Ex-ante/Ex-post).

In parallel, a brief recollection of previous cooperation and countries' negotiating positions accompanies the description for each sector contextualizing the negotiation and its results. Summarizing briefly the results (Table 5), GIs and MVs are two sectors with a regulatory design of Type 1 (Hard/Ex-ante), containing technically detailed regulations and products. Pharma and PQ are instead two cases, where both parties committed for the long term through an Ex-post regulatory format (Type 2), without taking immediate decisions. For the three remaining sectors: Biotech, Forest and Raw, CETA scheduled a bilateral cooperative dialogue for each of them without providing for future binding rules (Type 4).

		Mode of Decision	
		Ex-ante	Ex-Post
		Type 1	Type 2
Nature of Obligation	Hard	Automobile and motor Vehicles Geographical Indications	Pharmaceuticals Professional Services
	Soft	Type 3	Type 4
			Biotechnology Forest Products Raw Materials

*Table 5 Table of sectors' distribution in CETA by design types*

Before starting the description, it is necessary to see CETA in continuity with previous regulatory efforts between the EU and Canada. Officials from both sides recalled that in certain cases, CETA integrates earlier treaties or cooperation schemes already in place before the negotiation (official

B2-B4-D1, interviews in Brussels and Ottawa). As this research focuses on CETA only the new forms of cooperation are included in the analysis. The research's aim is to understand the negotiation process between the two parties during the negotiations and its results. Therefore, what happen before or outside of CETA falls out of the scope. Previous regulatory efforts are mentioned, as to contextualize the negotiations and each parties' positions, but they are not the direct object of this research.

## Geographical Indications

Concerning GIs, Article 30.8 recalls the past bilateral agreements between the EU and Canada on trade in wines and spirits, concluded in 2003-2004<sup>52</sup>. This agreement allows the GIs registration of Wines and Spirits in Canada, accompanied with additional recognition and trade facilitation measures. CETA furthermore lists the alcoholic drinks protected<sup>53</sup>. This past collaboration includes GIs on Wine and Spirits, also present in Canada's previous Trademark Act<sup>54</sup>. The Act nevertheless precluded food GIs from registration and recognition in Canada. Integrating the subsection C within chapter 20 on intellectual property, is thus a major change in the Canadian regulatory system. Following the provision, Canada amended its Trademark acts to allow for the recognition of food GIs. The list of products recognized is at the Annex 20-A, part A for the EU and B for Canada. Following this recognition, Canada<sup>55</sup> is required to prevent the use of listed indications in its territories by non-allowed parties (Article 20.19). This includes an obligation to use administrative action to enforce the prohibition (Article 20.19.4) and establish a complaint mechanism (Article 20.19.5.) An *ex officio* prohibition for products falling in the product class is also scheduled (Article 20.19.6). This signifies that even before the filling of a complaint, administrative authorities need to remove non-compliant products from retailers' shelves.

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<sup>52</sup>Global Affairs Canada, "Agreement Between Canada and the European Community on Trade in Wines and Spirit Drinks", <https://www.treaty-accord.gc.ca/text-texte.aspx?id=104976>, accessed the 5<sup>th</sup> July 2019.

<sup>53</sup>Official Journal of the European union, "Agreement between the European Community and Canada on trad ein wines and spirit drinks", [http://www.europarl.europa.eu/cmsdata/121890/Agreement\\_trade\\_wines\\_spirits\\_EU-Canada\\_2003.pdf](http://www.europarl.europa.eu/cmsdata/121890/Agreement_trade_wines_spirits_EU-Canada_2003.pdf), accessed the 5<sup>th</sup> July 2019.

<sup>54</sup>Minister of Justice Canada, "Trademarks Act R.S.C., 1985, c. t-13", <https://laws-lois.justice.gc.ca/PDF/T-13.pdf>, accessed the 15<sup>th</sup> august 2019.

<sup>55</sup> Both parties are submitted to the obligation, but as the EU has already in place regulations protecting GIs (as detailed in dedicated chapter), this does not change or affect its system. In this instance only Canada is required to adjust its domestic regulatory framework.

As described, these legal provisions create strong legal obligations for Canadian authorities to protect the indications it accepted to recognize, as listed in the Annex. Among others, Canada is also required to prevent products produced in Canada or imported from all over the world from using (“usurping”) recognized indications. This protection is however valid only for the products in the annexed lists. This implies that the newly adopted Canadian GIs system excludes other non-recognized GIs from its protection. Certain additional conditions of exceptions for certain products are also scheduled (Article 20.21). For meat and dairy producers, which started production prior to the 18th October 2013 (Articles 20.21.3 & 20.21.4), they are still allowed to use the denomination if accompanied by expressions such as “kind”, “type”, “style” and “imitation” (Article 20.21.1). These exemptions, labeled as “grandfather rights”, take into consideration the European descent of producers that are using the original denomination of their products. Under CETA, they can benefit from these exemptions if they can prove they were already producing before the start of the negotiation. This is the case for a selected number of products, all cheese related: feta, Asiago, Gorgonzola, Fontina, Munster. Also, annex 20-B contains a list of generic names such as “parmesan”, which are exempted from the general obligations (Articles 20.21.11 & 20.21.12). To summarize the legal obligations specified in the text, Canada is required to change its trademark act and recognizes a precise 143 GIs from its request of recognition. While the CETA joint committee is theoretically competent to amend the European lists (Article 20.22), its competence to add new indications is restricted if the indication is already registered in the EU or Canada (Article 20.22.2-3). This clause thus limits possibilities to further enlarge the list. GIs regulatory design is thus characterized by the following features: it contains strong binding obligations, a limited list of indications and a weak Ex-post mechanism. It corresponds thus to a regulatory design of Type 1.

## **Motor Vehicles**

Sharing similar features with GIs, CETA lists MVs regulations at the Annex 4-A *Cooperation in the Field of Motor Vehicle Regulations*. Article 1 of the annex specifies the exact scope of the regulations. Parties frame their collaboration in line with previous efforts conducted under the 1998 Global Agreement administrated by the World Forum for the Harmonization of Vehicle Regulations (WP.29) of the United Nations Economic Commission for Europe (UNECE). They also referred their efforts to the Chapter 21 of CETA, dedicated to Regulatory Cooperation.

The annex announces that parties commit to cooperate through sharing information on the development of technical regulations and standards, the dissemination of information to consumers and new advancements in vehicle safety and emission reductions. Article 3 schedules the possibility of this cooperation, in which parties “endeavor” to maintain an open dialogue for future collaboration around technical regulations and the UNECE 1998 Global Agreement. This provision is noteworthy, as it appears to belong to a regulatory design of Type 4 (Soft/Ex-post), in which parties set a mechanism for future collaboration without binding obligations. However, as demonstrated below, this dialogue is not at the heart of the cooperation and should be seen in the broader context of the annex.

Indeed, Article 4 below acknowledges that Canada:

has incorporated, with the adaptations that it considered necessary, technical regulations contained in United Nations Regulations into its Motor Vehicle Safety Regulations, C.R.C., c. 1038, as listed in Annex 4-A-1<sup>56</sup>

Recalling the case of GIs, this article specifies that Canada again made significant changes to its regulatory frameworks in integrating UNECE regulations, as listed in Annex 4-A-1. While some adaptations were made so that the regulations would fit with the Canadian system, as in GIs, it remains that Canada has accepted to recognize new regulations outside its previous regulatory system. Annex 4-A-1 lists the 17 U.N. regulations that Canada agreed to recognize equivalent to its own. Article 4.2 states that Canada retains its rights to end its recognition of equivalence with UN regulations, if these equivalences “provide for a lower level of safety” or “would compromise North American integration” (Article 4.2). In other words, Canada always has the legal rights to end its recognition of equivalence. Thus, while the recognition of these 17 regulations is enacted, Canada can still, with notice, end their recognition. Ex-post legal obligations of Canada are strictly limited and only voluntary. On the contrary, the main and most dominant feature of the regulatory mechanism is the recognition of the 17 regulations agreed upon at the time of the negotiation, with weakly and voluntary obligations for future cooperation. Even if further provisions leave open the possibility to add further U.N. regulations listed in Annex 4-A-2, there are no legal commitments from Canada to do so as it is solely on a voluntary basis.

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<sup>56</sup> Council of the European Union website, “Comprehensive Economic and Trade Agreement between Canada”, “Annex 4-a cooperation in the field of motor vehicle regulations: Article 4”, <http://data.consilium.europa.eu/doc/document/ST-10973-2016-ADD-3/en/pdf#page=10>, accessed the 29th May 2020.

Even if present in the annex, these provisions are secondary to cooperation on motor vehicle regulations, which is instead centered on this limited set of recognized UNECE regulations.

Like GIs, MVs regulatory design lists the exact regulations or requirements that parties enforce in their own jurisdictions. Additional provisions support the regulations, by specifying the scope and potential exceptions for certain products. The text also schedules future cooperation centered and constrained by the annex itself. Both sectors' designs frame voluntary and limited exchanges of information or future discussion within the purpose of potentially enlarging, amending or facilitating the annex's implementation. The Ex-ante/Hard annex remains the main legal instrument for these two sectors and creates the conditions of their cooperation. Additional provisions also limit cooperation, reducing the possibility to add further recognized regulations to the cooperation. Articles 2 and 3 schedules future cooperation but without commitments to expand the list of regulations jointly recognized. Cooperation only includes voluntary exchanges of information and principles of support for international cooperation without concrete harmonization aims. As mentioned already, Article 4 strongly limits the extend of this cooperation and provides strong safeguard for Canada to end regulatory recognition at any times. These two sectors contain a limited set of already agreed upon regulations with binding legal languages, they represent in both cases an instance of Type 1 of regulatory design. They are thus two cases of regulatory design where hard nature of obligation and Ex-ante mode of decision design feature dominate largely the mechanism (Type 1).

## **Pharmaceutical Products**

Before CETA, the European Union and Canada had already in force a Mutual Recognition Agreement on good manufacturing practices for pharmaceuticals products, since 2003<sup>57</sup>. This agreement faced several limitations nevertheless, as it only included minimal GMP standards<sup>58</sup> (Industry A6, interview in Ottawa). The cooperation did not schedule efforts to reduce regulatory duplication. In contrast, the newly adopted CETA protocol contains the obligation to review

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<sup>57</sup> Government of Canada, “Mutual recognition Agreement between Canada and the European Community (EC)”, <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/international/mutual-recognition-agreements/updates/mutual-recognition-agreement-canada-european-community.html>, accessed the 15<sup>th</sup> August 2019.

<sup>58</sup> European Medicines Agency, “Good Manufacturing practice”, <https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice>, accessed the 15<sup>th</sup> August 2019.

existing requirements for regulatory alignments. CETA cooperation in Pharma adds stronger requirements for regulatory alignments, deepening existing cooperation. CETA also strengthens the use of common standards and reduces regulatory duplication.

In the agreement, the Pharma sector's technical regulations focus on the angle of conformity assessment. Article 4.5 requires that “parties shall observe [...] the Protocol on mutual recognition of the compliance and enforcement program regarding good manufacturing practices (GMP) for pharmaceutical products”. Joined at the end of the agreement, this protocol establishes a specific mechanism of equivalence for conformity assessment between the parties. Article 2 specifies that cooperation through mutual recognition is taking place between the authorities in charge of issuing certificates of GMP compliance. Article 5 poses the conditions for the recognition of certificates, and Article 7 for the acceptance of batch certificates. Article 8 and 9 cover the possibility for on-site evaluation by one party to a manufacturing center certified by the other party. Article 12 establishes the process for regulatory authority to be recognized as equivalent by the other party.

These provisions establish strong legal obligations for both parties to recognize the certificates issued by the other authorities. If these batch and GMP certificates contain minimal information specified in the protocol, which include compliance with international standards, parties are required to accept them. The next articles look at the recognition of manufacturing facilities inspection. This can take the form of the EU recognizing an authorization issued under Canadian authority, after an inspection of an EU or Canada-based manufacturing facility. Overall, these obligations focus on the mutual recognition of controls and inspection on manufacturers performed by regulatory authorities. The cooperation scheme aimed at establishing strong obligations for both parties to cooperate and recognize each other's controls. The legal language and repeated use of the phrase “Parties shall accept [...]” are indicative of the Hard obligations used in the text, which commit the parties to collaborate. Complementing this system of equivalence and recognition, Article 26.2.1(a) creates the Joint Sectoral Group on Pharmaceutical products in charge of managing the protocol (Article 15 of the protocol). Article 13 specifies that:

the Joint Sectoral Group shall develop an equivalence maintenance program under the GMP Administrative Arrangement referred to in Article 15.3 to maintain the equivalence of the regulatory authorities<sup>59</sup>.

The Joint Sectoral Group is thus in charge of putting into place the equivalence mechanism for conformity assessment of GMP certificates between authorities of both parties. This Joint Sectoral Group acts thus as an Ex-post mechanism in charge of managing future regulatory cooperation, through the mutual recognitions of certifications, batches and facilities inspection. The list of products it covers is large and non-specific (Annex 1 of the protocol *Annex 1 medicinal products or drugs*). The mechanism covers a large spectrum of medicines, drugs and other pharmaceuticals, without listing precisely which Pharma are included and which are out. The recognition of equivalences and product certificates is hence postponed to future cooperation, on a case-by-case basis. This mechanism corresponds to a Type 2 (Ex-post/Hard), in which parties establish the foundation of their cooperative framework without deciding ex-ante the exact content of their regulatory adjustments.

## **Professional Qualifications**

The sector of PQ follows a similar logic. Chapter 11 of CETA establishes an Ex-post “MRA committee” composed of domestic authorities and professional bodies in charge of developing MRAs for each professional qualification (Article 11.2). The MRA committee oversees propositions made by professional organizations (Article 11.3.3) and sets the next steps for the negotiations conducted by the initiators of the proposition (Article 11.3.4). The committee is then competent to adopt the draft negotiated and makes it binding (Article 11.3.6). After an MRA is accepted, the principles of National Treatment and non-discrimination for services suppliers enter into force (Article 11.4). It is then required from states that they not provide less favorable treatment to foreign citizens for the recognition of their professional qualification. Article 11.6 specifies that parties of the agreement have set-up non-binding guidelines, contained in Annex

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<sup>59</sup> Council of the European Union website, “Comprehensive Economic and Trade Agreement between Canada”, “Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products: Article 13”, <http://data.consilium.europa.eu/doc/document/ST-10973-2016-ADD-8/en/pdf>, accessed the 29th May 2020.

11-A, to help domestic authorities and bodies in their MRA negotiation process. While the guidelines are voluntary, the result of the negotiation (the MRA) is binding for both parties.

In these two cases (Pharmaceutical & PQ) parties of the agreement developed a mechanism for future technical requirements and regulations. As there are no precise regulations listed, the mechanism acts as a bridge between both regulatory systems without determining which country will have to adjust its regulations to the other. Within the agreement, the EU and Canada only specify the conditions, competences and process for rulemaking without listing the exact technical requirements. They ensure that both parties respect the results of future collaboration. Indeed, the legal language shows a clear commitment for the signatories, with strict requirements of non-discrimination. The delayed but compulsory nature of the mechanisms in these two cases correspond thus to a regulatory design of Type 2 (Hard obligation and Ex-post decision).

### **Biotechnology, Forest Products & Raw Materials**

It is at the Article 25.1 that CETA schedules three bilateral dialogues for sector's regulatory cooperation: Biotechnology (Biotech), Forest Products (Forest) and Raw Materials (Raw). It might be useful to start with Biotech (Article 25.2) as it concerns a previous WTO dispute between the EU and Canada: "European Communities–Measures Affecting the Approval and Marketing of Biotech Products WT/DS292"<sup>60</sup>. Following the EU's decision in 1998 to suspend the approbation of Biotech products, Canada contested this restriction of its market access and initiated a formal complaint to the WTO Dispute Settlement Body. The DSB found the EU's decision inconsistent with WTO commitments. As part of a mutually agreed upon solution found with Canada, a bilateral dialogue on Biotech market issue was established in 2009.

This dialogue scheduled in CETA refers directly to the previous WTO dispute. It rests on two pillars: the evolution of the biotech legislation pertaining to the WTO case (Article 25.2.1) and future cooperation in Biotechnology (Article 25.2.2). In fact, the second pillar of the dialogue planned information exchanges on policy, regulatory and technical issues, notably in terms of risks assessments. One of the objectives is "to engage in regulatory cooperation to minimize adverse trade impacts of regulatory practices related to biotechnology products". The dialogue

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<sup>60</sup> WTO DSB, "DS292: European communities – Measures Affecting the Approval and Marketing of Biotech Products", [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds292\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds292_e.htm), accessed the 16<sup>th</sup> August 2019.

reflects two elements. One is the legal obligation of the EU to hold this dialogue with Canada, following the WTO decision. The other is future cooperation on biotechnology products, potentially requested by Canada. In fact, this second pillar concerns information on risks assessment and testing methods of genetically modified organisms. It requires the EU to provide information on specific decisions to deny market access and its overall product approval system. Overall, this dialogue institutionalized regular meetings between Canadian and European representants to exchange information and notify regulatory changes between the two parties. This dialogue includes no strict obligations though and only includes future cooperation. No regulatory decisions are taken, nor are products listed. It remains a voluntary process of information exchange on products' technical characteristics and approbation processes.

Following Biotech, Article 25.3 establishes a bilateral dialogue on Forest. The dialogue covers the following areas: regulations, law, policies and standards, including certification and accreditation of forest products; sustainable management of forest; legal and sustainable origin of forest products; multilateral cooperation on relevant topics, for instance illegal logging. The dialogue covers a large spectrum of regulatory aspects for the trade and production of forest products. Like Biotech, there are no strict obligations for cooperation and the cooperation relies rather on voluntary legal provision. The dialogue establishes the framework for future cooperation taking no immediate regulatory decision. It institutionalizes regular meetings between representants from both actors.

The Bilateral Dialogue on Raw Materials (Article 25.4) is similar to Forest Products as it also includes: market access issues for raw material goods, including non-tariff barriers; the exchanges of best practices and regulatory policies; multilateral cooperation to support international standards, such as "OECD guidelines for Multinational Enterprises" and "for supply chains minerals from conflict-affected and High-Rise areas". As in Forest Products and Biotech, there are no legal obligations for cooperation and only future efforts for collaboration are covered without immediate regulatory consequences. Similarly to these two others dialogues, it institutionalizes regular meetings between representants from both the EU and Canada.

For these three sectors, Biotechnology-Forest Products-Raw Materials, CETA creates specific channels of communication between the EU and Canada. These provisions institutionalize bilateral dialogues, which can become places to discuss specific regulatory challenges. Among them, technical requirements and standards have an important place. The treaty encourages collaboration on these aspects through information exchanges and regular meetings between

states. Obligations are limited and there is no obligation for results. The mechanisms do not have the competences to produce binding regulations or to create new obligations for states to respect. They do not contain provisions that schedule the possibility of producing new rules. They remain thus consultative organs for future ongoing cooperation on certain sectors. Overall, the dialogues' features correspond to a regulatory design of Type 4. Regulatory convergence is delayed (Ex-post) and the future rule produced only contains soft legal obligations for states to cooperate.

Following this presentation of the three types of regulatory design found in CETA, the next part compares the sectors to assess whether their strategic structure, namely the presence/absence of "hold-up" and "non-compliance risks, corresponds with the theory explicated earlier. The purpose is to demonstrate how in different sectors risks configurations can help to explain the decision made by states to choose different types of regulatory design. The following section compares the seven sectors found in CETA together and links the variation of the two explanatory factors with the three types of regulatory design (Type 1,2 & 4). The instance of Type 3 absence is discussed as well. As explained previously, the purpose is to compare these sectors to determine whether expected variation in explanatory factors in fact corresponds with the legal design found in CETA.

## *5.2. Cross-sectoral analysis*

This thesis tests the capacity of the two factors in explaining sectors' variation between the three design types: risks of "hold-up", and risks of "non-compliance". As explained in Chapter 2, section 2.2, when a sector is characterized by a high-level risk of both "hold-up" and of "shirking", parties to the negotiation are hypothesized to opt for a design of Type 1 to cooperate. When risk of "hold-up" is low, while risk of "shirking" is high, a design of Type 2 would be privileged. Finally, when hold-up and shirking are both low, CETA negotiating parties should consider using a Type 4 to design their cooperation. To recall the rational institutional framework detailed in Chapter 2, this thesis sees regulatory design as institutionalized solutions chosen by states in order to solve strategic interdependence problems they face when regulating a sector. The purpose is to adopt a design type that will successfully mitigate the risks pertaining to the bargaining structure of a given sector. It is first and foremost a rational evaluation of bargaining distribution of risks between the two states.

In this context, the explanatory factor "hold-up" relates to the potential risk related with the economic integration into interdependence networks that could be subsequently exploited by an

actor to obtain further concessions post agreements. It is measured by indicators pertinent for describing these interdependent economic linkages, namely trade flows between parties, the assessment of costs/benefits of regulatory cooperation and the type of value chain integration. It is expected that when indicators of interdependence are present in a given sector, negotiating sectors will tend to use Ex-ante design to limit the opportunities given to one party to take advantage of hold-up situations in ex post negotiations.

“Shirking” implies that there is an inherent risk in cooperation for one actor to renege on its past commitments and decide to defect from agreed terms of the agreements, for instance by adding new regulatory barriers to trade. This risk is considered more likely when a situation of regulatory divergence exists between the regulatory systems of the two negotiating states. This is due to the reduced costs of defection within an already fragmented regulatory environment. Indeed, two independent regulatory areas, with their own incompatible requirements, would often be tempted to privilege their national/domestic rules and regulations. Especially, taking in consideration that domestic firms are already compliant with their own local regulations. Thus, States can have the incentive to end the recognition of foreign rules, reimpose their own with the purpose of protecting their domestic firms from foreign competition. On the contrary, the mutual benefits provided by existing or pre-existing regulatory convergence reinforce cooperation incentives and discourage “rogue” behavior. Adopting new regulations in regulatory environments that are already compatible with each other would be costly for firms from both sides, not only foreign ones.

Within a context of regulatory divergence, states attempt thus to mitigate this risk by using Hard obligations to ensure that a future potential violation could be dealt with by adjudication or by a legalized dispute settlement mechanism. At the same time, these Hard obligations would also force the two parties to legally commit to their cooperation, bridging the existing regulatory divergences. On the contrary, when regulatory systems are relatively similar, states will privilege an “orchestration” type of bilateral governance by designing their cooperation through Soft obligations. To assess regulatory similarities or divergences, the analysis looks at various sources of international and domestic regulatory documents, such as international treaty memberships, jointly used international standards, domestic legislation, and conformity assessment methods.

Through a comparison of the seven sectors mentioned using trade statistics and regulatory documents, this chapter found support for the three hypotheses, formulated in section 2.2, in six cases out of seven. As portrayed by Table 6 only Biotechnology does not correspond to the

expected results. Results in “hold-up” and “shirking” in the six other sectors correspond to their legal design identified in CETA. Some variation is present for certain sectors in certain dimensions, but their overall results fit with the expected hypotheses.

	Geographical Indications	Motor vehicles	Pharmaceutical products	Professional qualifications	Raw materials	Forest products	Biotechnology
<i>Risk of "Hold-up"</i>	High	High	Low	Low	Low	Low	Low
<i>Risk of shirking</i>	High	High	High	High	Low	Low	High
<i>Observed Regulatory Design</i>	Type 1 Hard/Ex-ante	Type 1 Hard/Ex-ante	Type 2 Hard/Ex-post	Type 2 Hard/Ex-post	Type 4 Soft/Ex-post	Type 4 Soft/Ex-post	Type 4 Soft/Ex-post
Expected Regulatory Design	Type 1	Type 1	Type 2	Type 2	Type 4	Type 4	Type 2
Hypothesis	Supported	Supported	Supported	Supported	Supported	Supported	Unsupported

*Table 6 Cross-sector comparison, tables of results*

From the results shown in Table 6, two main causal mechanism need to be addressed, namely the choices between predetermined, written down lists of regulations (Ex-ante) instead of a delayed mechanism (Ex-post), and binding, hard law obligation provisions instead of soft ones. These two inquiries guide the empirical comparison of this chapter, focusing first on the variation between Type 1 and Type 2, then on the variation between Type 2 and Type 4. Comparison is organized so that one of the factors is held constant at each time. Only the varied factor is analyzed across cases for each comparison. The following section compares GIs and MVs with Pharma and PQ with the aim of explaining the causal relation between High/Low “hold-up” and Ex-ante/Ex-post design. Indeed, empirical investigation has found that the four sectors are all characterized by a high level of shirking risk. Shirking being constant, the next section focuses on hold-up risk variation.

In a second step, the same mechanism is reproduced this time between Pharma/PQ and Forest/Raw. These four sectors have all low “hold-up” risk and thus the latter is held constant. On the contrary, they diverge in shirking risk level. The cross-case analysis focusses thus on the relations between level of shirking risk and Hard/Soft design. Although regulated through a Type 4, Biotech is characterized by a high level of “hold-up” and shirking risks. It is therefore a deviant case according to this research theoretical framework. This specific case is discussed in the second

section with preliminary elements of answers to explain this unexpected result. Before proceeding to the analysis of the cross-case variation, it is useful to introduce a preliminary overview of the trade flow features of the 7 cases.

### **Cross-case Analysis, trade data overview**

Table 7 under compares exports surplus in all the seven sectors. From the results, it appears that the EU has a significantly large export surplus in three sectors: GIs, MVs and Pharma. The following numbers of EU export surplus for the year 2017 are: 614% for Motor Vehicles, 58% for Geographical Indications and 266% for Pharmaceuticals. It has a smaller surplus in Professional Qualification slightly reaching 25%. As comparison, the overall export surplus balance between the EU and Canada, from 2015 to 2018, reaches in average 25% (Table 24, Appendix V). These numbers indicate a higher involvement of European firms within the Canadian market than the opposite, for at least three sectors (GIs, MV & Pharma). On the contrary, Canadian firms are more involved in cross-border activities in Raw and Forest sectors, with respective export surplus of 1065% and 141% for 2017. Biotech data were not available in comparatively similar sources as trade statistics do not distinguished genetically modified agri-food from non-genetically modified one (see chapter 8.1 for details)

Exports, Value in € EUR rounded to the Million			Trade Balance (EU)			Export differences in %, rounded without decimals
			EU	Canada		
Eurostats - EU trade since 1988 by HS2-HS4	Biotechnology	2015	NA	NA	NA	NA
		2016	NA	NA	NA	NA
		2017	NA	NA	NA	NA
Eustats, Comext, EU trade by SITC	Forest Products *	2015	419	1213	-794	189
		2016	460	1242	-782	170
		2017	493	1190	-697	141
Eustats, Comext, EU trade by SITC	Geographical Indications "Agri-food products"**	2015	3419	2249	1170	52
		2016	3451	2238	1213	54
		2017	3560	2251	1309	58
Eustats, Comext, EU trade by SITC	Motor vehicles 78 ROAD VEHICLES (INCLUDING AIR-CUSHION VEHICLES)(1988-2500)	2015	3879	329	3550	1079
		2016	4546	506	4040	798
		2017	4809	673	4136	615
Eustats, Comext, EU trade by SITC	Pharmaceuticals 54 MEDICINAL AND PHARMACEUTICAL PRODUCTS(1988-2015)	2015	3967	1312	2655	202
		2016	4192	1115	3077	276
		2017	4645	1266	3379	267
International trade in services (since 2010) (BPM6)	Professional Services Trade in "Services"***	2015	1518	1373	145	11
		2016	1513	1172	341	29
		2017	1624	1289	335	26
Eustats, Comext, EU trade by SITC	Raw Materials 28 METALLIFEROUS ORES AND METAL SCRAP(1988-2500)	2015	287	2546	-2259	787
		2016	276	2405	-2129	771
		2017	274	3194	-2920	1066

\* 44 WOOD AND ARTICLES OF WOOD; WOOD CHARCOAL(1988-2500) & 45 CORK AND ARTICLES OF CORK(1988-2500) & 47 PULP OF WOOD OR OF OTHER FIBROUS CELLULOSIC MATERIAL & 48 PAPER AND PAPERBOARD; ARTICLES OF PAPER PULP

\*\* Agri-Food Trade Statistical factsheet European Union - Canada,  
[https://ec.europa.eu/agriculture/sites/agriculture/files/trade-analysis/statistics/outside-eu/countries/agrifood-usa\\_en.pdf](https://ec.europa.eu/agriculture/sites/agriculture/files/trade-analysis/statistics/outside-eu/countries/agrifood-usa_en.pdf)

\*\*\* Professional Services: Architecture, engineering & scientific (SJ31) & professional and management consulting (SJ2) (aggregated)

Table 7 Cross-case analysis, overview of the trade flows for the seven cases

From this preliminary overview, 5 sectors among 7 are characterized by asymmetric trade flows, namely MVs, GI, Pharma, Forest and Biotech. This could imply that in these 5 sectors, there are risks of “hold-up” due to the relative higher ability of certain countries’ firms to enter the market of their counterparts. Indeed, for countries with trade surplus, liberalization through a reduction

of regulatory barriers, for instance, facilitates existing exports and increases their firms' market share in the country of import. In other words, regulatory cooperation acts as an accelerator or an intensifier of existing trade patterns. If a sector is characterized by an unequal trade pattern, this one will reinforce itself with the conclusion of the agreement (Osgood et al. 2016; Melitz 2003; Melitz and Ottaviano 2008; Baier and Bergstrand 2003).

Consequently, in sectors where import-competing firms are already in weaker position, they might face increased competition in case of long-term regulatory adjustments towards foreign regulations. Cooperation in a sector implies that the weaker firms of this sector will see their position become even more precarious and might end up in a "hold-up" situation. For instance, a long-term cooperation scheme with Europe in Motor Vehicles could provide the European car industry an increased access to Canadian market. Canadian firms might thus face increased competition within their own domestic markets, while remaining still unable to enter the European one. Therefore, the export surplus just described would indicate a potential risk of "hold-up" for all the five sectors of activities.

Nevertheless, before concluding the presence of high hold-up in all the five sectors with unbalanced trade flows, other indicators need to be considered. To accurately identify potential risks of "hold-up", the assessment must be enriched by other information, notably in terms of the goods/services traded across borders and GVC integration types. This would provide a more nuanced analysis of the trade structure in all these sectors. The next section will thus compare four sectors, which are all characterized by the presence of a high risk of shirking due to regulatory divergences but variation in terms of "hold-up" risks, namely: GIs, MVs, Pharma and PQ. It will go beyond the overall description of trade flows provided earlier by providing additional economic data. This supplementary source of data will be particularly helpful in clarifying the variation of economic structure between the two groups of cases (GI/MVs & Pharma/PQ), and the reasons why GIs and MVs feature a high risk of "hold-up" contrary to Pharma and PQ.

### **Hold-up or not hold-up? Comparison Type 1 (GIs, MV) with Type 2 (Pharma, PQ)**

Following the overall presentation of results in Table 6, this section and the following broke down the results in the two cross-sectoral variation mechanisms observed, namely High/Low "hold-up" and High/Low Shirking. First, this section focuses on the "hold-up" variation comparing four cases (GIs, MV Pharma and PQ), which vary in "hold-up" results but remain constant in

“shirking” (Table 8). The three remaining cases (Biotech, Forest and Raw) were not selected as they have different shirking values and would interfere with the comparison. The constant value of Shirking is especially important as it prevents the interference of this factor in the comparative analysis. This section’s analysis can thus focus on the value’s variation of “hold-up” risks, and its relationship with Ex-ante/Ex-post design.

<i>Regulatory Design</i>	<b>Type 1</b> <b>Hard/Ex-ante</b>	<b>Type 1</b> <b>Hard/Ex-ante</b>		<b>Type 2</b> <b>Hard/Ex-post</b>	<b>Type 2</b> <b>Hard/Ex-post</b>
	Geographical Indications	Motor Vehicles		Pharmaceutical products	Professional Qualifications
<i>Risk of Hold-up</i>	High	High	Variation	Low	Low
<i>Risk of shirking</i>	High	High	Same and constant	High	High

*Table 8 Cross-case analysis of "hold-up" risk*

As stated earlier, MVs, GIs and Pharma, and to a lesser extent PQ, all have asymmetric trade flows, characterized by the EU export surplus. Nevertheless, and Contrary to MV and GIs, the type of drugs produced and traded in Pharmaceuticals are similar between the EU and Canada trade flows. Indeed, the five leading pharmaceutical products in Canada are all authorized in the EU and similarly commercialized (Table 22, Appendix V). The same types of medications are thus equally present in both regulatory areas. This is especially key within the Pharmaceutical sector as medications need to follow extensive approval processes in all jurisdictions. In addition, the five leading firms in Canada are all multinationals exporting and producing around the world, with production facilities in multiple countries. Most of them are either European or American by origin, with a manufacturing or commercial presence in Canada. It is thus not clear that the main benefits of liberalization would be in the advantage of the EU per se. This absence of clarity on potential unilateral gains plays a role in the two countries’ assessment of risks. The multi-nationality and global integration of all firms in the sectors renders unilateral “hold-up” decision more difficult to take. As costs/benefits and related risks are distributed along the value chains irrespective of firms’ countries of origins, it becomes particularly difficult to assess the consequences of taking hostage the entire GVC. The risks of “hold-up” in Pharma, a sector characterized by this global integration, appear thus not as clear as trade flows would imply.

On the contrary, MV and GIs are either local firms, e.g. the Prosciutto di Parma consortium, or integrated in a local supply chain with most production facilities concentrated within national borders, such as the German car industries (see Chapter 6). Contrary to Pharma, none of these firms have production centers in Canada and their products are only available through exports. Export facilitation is thus a key concern for representatives of the industry lobbying the European Commission (Industry C7-C5-C6-C2-C1, interview in Brussels). In this case thus, the market gains of the EU could easily result in increased competition for Canadian firms without them being able to enter European markets. The prospects for the smaller and more parts-production focused Canadian firms to successfully enter the European market, considering the preexisting vast regional manufacturing networks already on European soil, are grim. On the contrary, for the Pharma industry, market access is not as meaningful as product approval (Industry A6, interview in Ottawa). Benefits for product approval cooperation notably can actually be to both sides' advantages in an equal manner, and do not have an inherently strong bias in favor of European firms (see chapter 7).

A similar pattern is also visible for professional qualification with some nuances. In contrast to pharmaceuticals, trade in services flows between the EU and Canada are relatively equal. Despite exporting relatively more, the EU trade surplus in PQ is actually the lowest of all the four sectors and just reaches a threshold of 25% for 2017 (Table 7). There is some level of difference between the two countries' specialization in professional skills. Canadian services firms focus more in business management/advertising services while the Europeans are stronger in legal/accounting/engineering. However, almost no professions were singled out during the negotiation.

Architecture is the sole exception, even though its MRA was signed after the negotiation and was not negotiated within CETA<sup>61</sup>. With the exception of this single case, no particular exporting services firm emerged from the empirical analysis. No data could be found either, allowing the identification of the firms exporting services in Canada. Interviews with Canadian and European officials similarly confirmed: no service providers manifested their interests during the negotiation or were mentioned (officials D6-B6, interviews in Brussels and Ottawa). While

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<sup>61</sup> Architects' Council of Europe (ACE), "Mutual Recognition Agreement of Professional Qualifications between The Architects' Council of Europe (ACE) and The Canadian Architectural Licensing Authorities (CALA)" [https://www.acecae.eu/fileadmin/New\\_Upload/\\_14\\_International/MOUs/ACE-CALA\\_MRA\\_\\_180409\\_v16\\_FINAL.pdf](https://www.acecae.eu/fileadmin/New_Upload/_14_International/MOUs/ACE-CALA_MRA__180409_v16_FINAL.pdf), accessed the 16<sup>th</sup> August 2019.

architecture did voice its interests, it does not seem that it has impacted the choice of design during the negotiation. It is possible to assume that the Big Four accounting firms (EY, KPMG, Deloitte and PWC) and the three big Consulting firms (McKinsey, BCG and Bain) could have played some role in potential accounting and management services exports. No additional empirical sources could confirm this though. In addition, no specific services suppliers based on either side could be identified with interests in exporting in the other market. Therefore, the choice of Type 2 seems to reflect the relative equilibrium economic relations between both sides. The absence of big groups of exporters or other economic actors eager to exploit future economic relations avoided the emergence of a potential “hold-up” issue.

The relatively equal distribution and specialization of professional skills between the two parties also seem to have played a role. As countries focus on their own area of specialty, the lack of substitutability between the services provided, for example between legal and advertisement services, also reduced the risks that one of the countries could take the others hostage by threatening to change its suppliers. This has thus encouraged both Canada and the EU to use an open-ended framework (Ex-post). The lack of strategic importance of certain specific assets and the relative equivalent economic distribution channels in Pharma and PQ, thus creates different regulatory challenges for states compared with the one in MV and GIs.

European GIs and MVs firms rely on the export of specialized products (premium products in cars and fine food). Exporting firms need a regulatory format that recognizes the technical specificities of their commodities. As they have a precise list of specific goods that they currently export, they pushed for a design that would list them and recognize their special status. This is especially the case for GIs. Indeed, the EC has preexisting lists of GIs that are more or less adapted according to their partners. As explained during several interviews, the purpose for European negotiators is to obtain the recognition of as many GIs’ as possible (Official D7, interview in Brussels). This is equally the case for UNECE motor vehicles regulations (Official D1, interview in Brussels). These lists of regulations correspond to the commodities exported. Therefore, to promote its exports, the EU is incentivized to obtain as much regulatory alignments as possible from its partner. This makes sense from a trade liberalization point of view as it would allow for the reduction of regulatory costs for a substantial share of bilateral trade.

This is probably where the risks of “hold-up” is the most expressed and determined the choice of Type 1 instead of Type 2. For European exporting firms in GIs and MVs, regulatory cooperation is particularly beneficial as it facilitates their market access within Canada. This can

problematic for Canada as the goods produced by the Europeans are relatively substitutable to Canada's own products, namely cars and cheese. While quality perception varies, the products from both sides can enter into competition with each other. Furthermore, Canadian firms are more inwards oriented or centered on the North American market, which has fundamentally different standards than the European one, rendering exports in the EU is unrealistic. While worried about potential rising European exports within Canadian market, both Canadian officials and industry stressed that the recognition of limited GIs and UNECE regulations as they are designed in CETA do not significantly affect Canadian producers and would not result in a conversion of production towards European standards (official and industry A1-A3-A4-A5-B2-B4, interviews in Ottawa).

The design chosen reflects thus the awareness of Canadian negotiators towards potential European competition on Canadian soil. They attempted to limit their cooperation with the EU in these two sectors, as not to undermine their domestic production systems (e.g. Canadian milk sector - chapter 6) or their regional integration (Canadian automobile industry – Chapter 6). Canadian actors appeared not to be willing to make significant new investments that would be needed to export by extensively regulatory aligned with European standards. The perspective of eventual new gains by exporting in Europe were considered elusive by the actors and did not convince the negotiators (Industry A3, interview in Ottawa). The design decided in CETA served thus at achieving the market access requested by the Europeans but importantly at preventing the latter to use the design to deepen Canadian firms' integration into European economic networks. This could have made Canada particularly vulnerable to further EU requests, forcing Canadian firms to pay the biggest share of regulatory adjustments. Furthermore, there was a significant risk that further integration with European lines of production could jeopardize the North American automobile value chain. Products listed were thus strictly limited and the regulatory adjustments would be restricted to the time of the negotiation but not open to future adjustments.

Pharma follows a different logic. As medications traded on both sides are relatively similar, parties are incentivized to avoid any form of discrimination against one another. This even more the case, as the pharmaceutical companies are multinationals with production units across the globe, e.g. Novartis, Sanofi. Consequently, for these firms their interests rely more on streamlining approval of manufacturing and batch certificates in both countries, instead of obtaining special recognition of their drugs. As said earlier, these drugs are similarly authorized in the EU and Canada. This absence of differences in specialization thus pushes states to focus their regulatory efforts on administrative costs carried by all parties of the sector, and not on specific drugs. Negotiators did not attempt to create special limited statuses for medications, as

the risks of “hold-up” was absent. Indeed, as the identities of the firms in both sides are similar (chapter 7), the risks of future exploitation are quite limited. Instead, they intensified their collaboration through an Ex-post mechanism.

CETA laid out the conditions for the mutual recognition of Good Manufacturing Practices (GMP) and facilities inspections. GMP and facilities inspections aim at guaranteeing the safety of medicinal products by establishing standards for all the phases of production<sup>62</sup>. Facilities inspections fulfill the same objective by focusing on the location of production and equipment. These costs are carried by all pharma firms when attempting to introduce a new product into the market. Without cooperation, product testing, and facilities inspections need to be replicated by both jurisdictions. These requirements can be also burdensome for public administration with limited resources as they must review results and conduct inspections (Industry A6, interview in Ottawa). To facilitate cooperation, negotiating states decided to create a framework that would allow future mutual recognition without specifying any drugs or standards.

A similar logic is present in the sector of professional qualifications. Due to the relative symmetry of trade flow between the two countries, the possibility for one party’s exports to overwhelm the other country’s market is quite limited. Contrary to MV and GIs, rising services exports and potential competition for local firms were not a concern (Officials D6-B6, interviews in Brussels & Ottawa). Parties thus used an Ex-post design to cooperate in this sector. In the absence of a professional service or a localized firm singling itself out during the negotiation, which could have become a threat to one or the other party, Canadian and European negotiations adopted an equally non-discriminatory regulatory framework. They did not prioritize market access issues and instead developed a more open-ended cooperation scheme. Specifically, they established a committee to oversee negotiations of MRAs between professional associations.

Overall, the choice of states in creating an open mechanism, instead of agreeing on ex-ante equivalencies is directly caused by the relative equal distribution of specific assets, observed in bilateral trade flow. The variation of bargaining positions between the four sectors, has led states to adapt the design type. As liberalization priority varies, market access vs regulatory approval, states decided to use Type 1 and Type 2 accordingly. While in GIs and MVs, the main preoccupation was the superior export capacity of the EU and its potential ability in overwhelming Canadian production, In Pharma and PQ, Canada and the EU were either equal in terms of traded

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<sup>62</sup>International Society for Pharmaceutical Engineering, “Good Manufacturing Practice (GMP) Resources”, <https://ispe.org/initiatives/regulatory-resources/gmp#>, accessed the 16th August 2019.

goods/services and no new significant investment would have put any of the two states in a more vulnerable position than before. This explains why in one case (GIs & MV) parties decide to curtail the existing “hold-up” risk through an Ex-ante design, and in the other (Pharma, PQ), where it was absent, they chose a more open-ended mechanism for long-term collaboration.

In conclusion, this preliminary comparison seems to show that when one country can benefit more from regulatory cooperation, reflected by un-balanced trade flows, due to its strong industrial base (e.g. German car industry) states privilege an Ex-ante design feature. This design reflects the underlying “hold-up” risks that un-restricted regulatory cooperation could carry, especially for States in an inferior economic position. By stimulating and facilitating existing exports, trade liberalization reinforces the dominant firms, which can then overwhelm local competition in their market of destination. For the latter, reducing this risk by reducing in time the extent of the cooperation design is of paramount importance to protect its own firms.

When a situation of relative economic symmetry exists between the two countries, states preferred instead Type 2. When trade balance is relatively equal (PQ), countries are specializing in non-substitutable assets (Pharma), and firms are either globally integrated or locally inward oriented (Pharma, PQ) parties of a negotiation choose an Ex-post design instead of an Ex-ante one. As illustrated by Pharma and marginally by PQ, looking at overall trade number alone is not enough to assess distribution of assets and “hold-up risks”. Specializations and GVC type of integration are also key in explaining the High or Low level of “hold-up” risks and negotiators decision in design type.

As introduced earlier, the second question looks at the divergence between hard and Soft obligations. Elements of explanations are present in the High/Low level of “shirking” risk due to the differences of regulatory framework between MV/GIs and Forest/Raw. These sectors were selected as they have the same value in “hold-up” (Low) but vary in shirking. Biotechnology is an exception in this framework as the state of its regulatory framework does not correspond to the expected hypotheses. This deviant case is discussed later.

### **Hard or soft due to shirking risk? Comparison Type 2 (Pharma, PQ) with Type 4 (Biotech, Forest and Raw)**

As introduced in the theoretical chapter, this research argues that the High or Low level of shirking risk in a given sector does matter. The assumption is made that when parties have diverging regulatory framework, this risk is more prone to happen, and parties use Hard obligation provisions. This is caused by the increased possibilities provided by a fragmented regulatory environment to use regulatory barriers for protectionist purposes. Additional barriers can also allow to protect import-competing firms by even further reducing market access of foreign firms. As mentioned previously the MV sector is plagued by a high risk of shirking in addition of “hold-up”. As described in section 5.2, Article 4.2 of the MV Annex 4-A of CETA states:

Canada shall continue to recognize the relevant United Nations Regulations, unless doing so would provide for a lower level of safety than the amendments introduced, or would compromise North American integration<sup>63</sup>.

The last addition of the sentence “*or would compromise North American integration*” is particularly illustrative of this risk of shirking. Canada recalls here its rights to end the recognition of UNECE standards. It does so because most of its regulations follow the U.S. standards system for Motor Vehicles, which is divergent from the UNECE one. This fragmentation encourages thus Canada to consider at any time the possibility to end its recognition of UNECE, especially in order to protect its car parts producing firms that are deeply integrated within U.S. automobiles value chain (see chapter 6). Contrary to this case, convergence implies that firms active in a sector followed jointly similar technical requirements. They benefit thus from coordination gains and would be less interested in protectionist measures that would upset their regulatory environment. The Raw Materials and Cleantech sectors are instances of this configuration. Due to the dependency of the clean technology firms towards supply in certain rare earth, both suppliers and consumers of these materials have an interest in collaborating together for mutual benefit. This case is further described later in the section and in Chapter 8.

The choice of design is thus made accordingly. To mitigate the opportunistic use of regulatory divergences, states use Hard obligations to obtain strict legal commitments that could result in sanctions in case of breaches. In other terms, they use hard commitments to ensure strong enforcement. Furthermore, Hard obligations also guarantee regulatory recognition or equivalence in both systems. This is necessary as, without these legal constraints, domestic regulatory

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<sup>63</sup> Council of the European Union website, “Comprehensive Economic and Trade Agreement between Canada”, “Annex 4-a cooperation in the field of motor vehicle regulations: Article 4”, <http://data.consilium.europa.eu/doc/document/ST-10973-2016-ADD-3/en/pdf#page=10>, accessed the 29th May 2020.

authorities on both sides might use regulations for protectionist grounds, for instance by not extending these recognitions to foreign regulations or products. These Hard obligations act *in fine* as guarantee for both parties that each of them commits to cooperate and adopt necessary measures to bridge their regulatory differences. They provide the necessary legal commitments language that could result in activating sanction mechanism in case of violation.

However, the absence of shirking risks due to existing and preexisting converging regulatory frameworks changes the negotiating logic. The absence of major trade distortion due to regulatory differences does not require major change in each party's regulatory system. On the contrary, the convergence of the systems creates a dynamic of confidence and cooperation between the parties. It reduces thus the fears from either side, that one of the parties will renege on its obligations. Furthermore, the two parties' allies might develop joint norms which can compete with third parties. Soft obligations become in this case an appropriate design as it encourages cooperation without requiring strictly binding commitments. The soft regulatory mechanisms present in PTAs act as an additional channel for preexisting cooperation. They support administrative actions and procedures that are required for administrating free trade. Without them, the flow of trade/services becomes more difficult to manage and identify. Both Soft and Hard obligations thus fulfill a different liberalization function. Soft regulatory cooperation in trade agreements follows a logic of continuity in cooperation efforts due to mutual confidence, while Hard provisions correspond rather to a situation of distrust, requiring a design prone to allow subsequent sanctions if need arises.

This cleavage is particularly explicit when comparing Pharma and PQ with Raw and Forest. A comparison of these four sectors illustrates why the low level of shirking risk led Canadian and European states to adopt soft provisions and a regulatory design of Type 4 for Raw & forest (Soft/Ex-post). To underline this logic, this section of the analysis contrasts this choice with the one made for Pharma & PQ. It also explains how the high level of shirking risk in these sectors convinced states to use hard provisions and a design of Type 2 (hard/Ex-post). To proceed with this comparison, data were collected from regulatory documents available to look at the divergence or convergence of regulatory systems, through the analysis of international and domestic regulatory documents.

<i>Regulatory Design</i>	Type 2 Hard/Ex-post	Type 2 Hard/Ex-post	Type 4 Soft/Ex-post	Type 4 Soft/Ex-post	Type 4 Soft/Ex-post
	Pharmaceutical products	Professional qualifications	Raw materials	Forest products	Biotechnology
<i>Risk of Hold-up</i>	Low	Low	Same and constant	Low	Low
<i>Risk of shirking</i>	High	High	Low	Low	High*

Variation ← →

*\* Deviant case,  
discussed further*

*Table 9 Cross-case analysis of shirking*

Pharma and PQ in the EU and Canada diverge on several points. First, both regulatory areas are deeply fragmented at the international level. Starting with Pharma, there are several regulatory harmonization initiatives that juxtapose and overlap with each other: The Good Manufacturing Practices (GMP) of the WHO adopted in 1968<sup>64</sup>, the Good Manufacturing Practices (GMP) of the EU developed in 1989<sup>65</sup>, the Pharmaceutical Inspection Co-operation Scheme PIC/S established by the European Free Trade Association (EFTA) in 1970<sup>66</sup>, the International Council for Harmonization (ICH)<sup>67</sup> founded in 1990 and the “International Pharmaceutical Regulators Programme (IPRP)” created in 2018<sup>68</sup>. Each of these different organizations or regulatory initiatives developed a wide range of regulations pertaining to production conditions, facilities inspections and conformity assessments methods of pharmaceutical products. While equivalences between these regulations exist, in practice national administrative authorities tend to have their own interpretation of the regulations and the establishment of equivalences<sup>69</sup> (Industry A6, interview in Ottawa).

Such a fragmented picture is not without consequences on the domestic approval system of pharmaceutical products and public regulations. Health Canada and the European Medicines

<sup>64</sup> WHO, “Good Manufacturing Practices”, [https://www.who.int/biologicals/vaccines/good\\_manufacturing\\_practice/en/](https://www.who.int/biologicals/vaccines/good_manufacturing_practice/en/), accessed the 8<sup>th</sup> August 2019.

<sup>65</sup>Ibid., “publications”, <https://www.picscheme.org/en/publications?tri=gmp>

<sup>66</sup>Pharmaceutical Inspection Co-operation Scheme (PIC/S), <https://picscheme.org/en/about>, accessed the 8<sup>th</sup> August 2019.

<sup>67</sup>International Council for Harmonisation (ICH), <https://www.ich.org/about/history.html>, accessed the 9<sup>th</sup> August 2019.

<sup>68</sup> International Pharmaceutical Regulatory programme (IPRP), “History”, <http://www.iprp.global/page/history>, accessed the 9<sup>th</sup> August 2019.

<sup>69</sup> Swissmedic, “Good Manufacturing Practice (GMP)”, <https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/good-manufacturing-practices-gmp-vorgehen-abweichungen-zwischen-eu-und-pics-gmp.html>, accessed the 9<sup>th</sup> August 2019.

Agency (EMA) have their own procedures, guidelines, and directives. In Canada, approval procedures are regulated by the Food and Drugs Regulations, notably Division 1a – *Establishment licences*<sup>70</sup> and Division 2 – *Good manufacturing practices*<sup>71</sup>. In Europe, compliance controls follow Directive 2001/83/EC<sup>72</sup> and Directive 2003/94/EC<sup>73</sup> laying out GMP requirements in EU legislation. Inspections are conducted respectively by Health Canada through its Regulatory Operations Enforcement Branch (ROEB)<sup>74</sup> and the EMA in their respective jurisdiction<sup>75</sup>. While an MRA for GMP has been in place between Canada and the EU since 1998, notably in recognizing each regulatory authorities' inspections<sup>76</sup>, it did not establish a sufficiently binding cooperative framework to facilitate cooperation (Industry A6, interview in Ottawa). As a consequence, significant duplicative regulatory requirements were still present and incur pharmaceutical companies significant administrative burdens in their requests for drug approval on both sides of the Atlantic.

The Professional Qualification sector shares similar features as in Pharma. The minimal existing global regulatory framework is the General Agreement on Trade in Services (GATS)<sup>77</sup>, notably Article VI on *Domestic Regulation* and article VII on *Recognition*. In parallel, several other

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<sup>70</sup> Government of Canada, Justice Laws Website: “Food and Drug Regulations (C.R.C., c. 870) Division 1”, [https://laws.justice.gc.ca/eng/regulations/c.r.c.\\_c.\\_870/page-110.html#h-575903](https://laws.justice.gc.ca/eng/regulations/c.r.c._c._870/page-110.html#h-575903), accessed the 9<sup>th</sup> August 2019.

<sup>71</sup> Government of Canada, Justice Laws Website: “Food and Drug Regulations (C.R.C., c. 870) Division 2”, [https://laws.justice.gc.ca/eng/regulations/c.r.c.\\_c.\\_870/page-114.html#h-576174](https://laws.justice.gc.ca/eng/regulations/c.r.c._c._870/page-114.html#h-576174), accessed the 9<sup>th</sup> August 2019.

<sup>72</sup> EUR-Lex, Official Journal of the European Communities, “Directive 2001/83/ec of the European parliament and of the council of 6 November 2001 on the Community code relating to medicinal products for human use” <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF>, accessed the 9<sup>th</sup> August 2019.

<sup>73</sup> EUR-Lex, Official Journal of the European Communities, “Commission directive 2003/94/ec of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use”, [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir\\_2003\\_94/dir\\_2003\\_94\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2003_94/dir_2003_94_en.pdf), Accessed the 9<sup>th</sup> August 2019.

<sup>74</sup> Health Canada, “Regulatory Operations and Enforcement Branch”, <https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/regulatory-operations-enforcement-branch.html>, accessed the 29<sup>th</sup> May 2020.

<sup>75</sup> European Medicines Agency, 18<sup>th</sup> February 2014, “Mandate, objectives and rules of procedure: GMP/GDP inspectors working group (GMDP IWG)”, [https://www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-gmp/gdp-inspectors-working-group-gmdp-iwg\\_en.pdf](https://www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-gmp/gdp-inspectors-working-group-gmdp-iwg_en.pdf), accessed the 9<sup>th</sup> August 2019.

<sup>76</sup> EC DG Health & Government of Canada, “Sectoral annex on good manufacturing practices (GMP)” [https://ec.europa.eu/health/sites/health/files/files/international/doc/mraeccan\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/international/doc/mraeccan_en.pdf), accessed the 9<sup>th</sup> August 2019.

<sup>77</sup> WTO, “The General Agreement on Trade in Services (GATS): objectives, coverage and disciplines “, [https://www.wto.org/english/tratop\\_e/serv\\_e/gatsqa\\_e.htm](https://www.wto.org/english/tratop_e/serv_e/gatsqa_e.htm), Accessed the 9<sup>th</sup> August 2019.

international agreements exist but without the same membership range. The Washington agreement of 1989 for the recognition of engineering qualifications<sup>78</sup>, the European Network for Engineering Accreditation (ENAE) <sup>79</sup> and the *Convention on the Recognition of Qualifications concerning Higher Education in the European Region* (ratified by Canada post CETA in 2018)<sup>80</sup>. Bilateral agreements are also present between European countries and Canadian provinces, notably several mutual recognition agreements (MRA) of professional qualifications between Québec and France since 2008<sup>81</sup>. As in pharma, the multiplication of these initiatives and the lack of a general framework rationalizing the regulatory requirements of this sector create the emergence of multiple difficulties for services suppliers to obtain recognition of their qualifications abroad (e.g. lawyers, engineers, etc.) (see Chapter 7).

This regulatory fragmentation is not exclusive to the international sphere, however. In both geographical zones, professional qualifications are member states' and provinces' prerogatives. Consequently, several federal (Canada) and European legislations exist to bridge the divergences of practices within internal jurisprudence themselves. The Canadian Free Trade Agreement (CFTA) plays an important role in Canada, regulating domestic labor mobility and professional qualifications recognition<sup>82</sup>. In Europe, it is the Directive 2005/36/EC<sup>83</sup> that fulfills this purpose. Nevertheless, noticeable discrepancies in the regulation of professional qualification still exist within Canada and the EU. For instance, not all EU member states regulate similarly the

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<sup>78</sup> International Engineering Alliance, “Washington accord”, <https://www.ieagreements.org/accords/washington/>, accessed the 9<sup>th</sup> August 2019.

<sup>79</sup> European Network for Accreditation of Engineering Education (ENAE) website, “ENAE Member Organisations”, <https://www.enae.eu/members/>, accessed the 29<sup>th</sup> May 2020.

<sup>80</sup> Council of Europe, “Details of Treaty N°. 165”, <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/165>; The Canadian Information Centre for International Credentials, “The Lisbon Convention”, <https://www.cicic.ca/1398/an overview of the lisbon recognition convention.canada>; accessed the 9<sup>th</sup> August 2019.

<sup>81</sup> « Entente entre le Québec et la France en matière de reconnaissance mutuelle des qualifications professionnelles » <http://www.mrif.gouv.qc.ca//Content/documents/fr/2008-12.pdf>, accessed the 10th August 2019.

<sup>82</sup> “Canadian free trade agreement”, 2017, <https://www.cfta-alec.ca/wp-content/uploads/2017/06/CFTA-Consolidated-Text-Final-Print-Text-English.pdf>, accessed the 10th August 2019

<sup>83</sup> EUR-Lex, Official journal of the European Union, “Directive 2005/36/ec of the European parliament and of the council of 7 September 2005 on the recognition of professional qualifications”, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005L0036&from=EN>, accessed the 9<sup>th</sup> August 2019.

profession of architect<sup>84</sup>. Similar variation can be found likewise in Canada, resulting in a deeply fragmented regulatory environment, both internationally and domestically.

In sum, while numerous regulatory instruments can be found in both sectors, significant regulatory barriers still exist incurring significant recognition and compliance costs to cross-border economic activities. The cooperative instruments existing before the conclusion of CETA were not able to strongly commit parties to recognize each other products requirements, inspections and professional qualifications. This resulted in costly regulatory adjustments for producers/suppliers as well as significant loses in market access. Combined with an Ex-post design detailed previously, Canada and the EU used provisions with Hard obligation to establish equivalence between Canadian/European GMP and Professional recognition authorities. Without this constraining legal format, the Ex-post mechanism would not have been enabled to bridge the pre-existing regulatory divergences. This was especially the case as the cooperation previously in place, especially GMP, was already voluntary and non-binding. CETA attempt to change this state of action by strongly committing both parties. Without such a level of “hardness” in legal provisions, risks would be particularly high that one of the parties decides to stop recognizing foreign rules. As said, both countries have their own domestic regulatory systems, with their own regulatory requirements, not always equivalent to each other. The tendency is thus high for domestic authorities to end recognition and re-impose their own rules.

Pharma and PQ are thus two cases where diverging regulatory frameworks required the use of binding provisions to obtain regulatory recognition for products exchanged. Raw Materials and Forest Products illustrate instead two cases with converging regulatory frameworks. Indeed, according to the OECD inventory of export restrictions<sup>85</sup> on industrial raw materials, neither Canada nor the EU have export restriction measures in place, as of 2017<sup>86</sup>. To note that this

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<sup>84</sup>EC DG Growth, “Mutual evaluation of regulated professions: Overview of the regulatory framework in the business services sector by using the example of architects”, p. 5, <https://ec.europa.eu/docsroom/documents/16684/attachments/1/translations/en/renditions/native>, accessed the 9<sup>th</sup> August 2019.

<sup>85</sup> Export restriction OECD definition: “export taxes, prohibitions, licensing requirements and other measures by which governments regulate the export of industrial raw materials including minerals, metals and wood. It records measures known to restrain export activity from 2009-2017 at the 6-digit level of HS2007 classification., <https://www.oecd.org/trade/topics/trade-in-raw-materials/>, accessed the 21<sup>st</sup> August 2019.

<sup>86</sup>OECD, “Trade in raw materials”, <https://www.oecd.org/trade/topics/trade-in-raw-materials/>, accessed the 21<sup>st</sup> August 2019.

database includes minerals, metals and wood<sup>87</sup>. Trade flows of raw materials appear thus unhindered by regulations. This was also confirmed by industries associations in Forest Products and Raw Materials (Industry A2-C3-C4, interviews in Brussels and Ottawa). The only regulatory point of discord appears to be mining permit licenses in certain cases. Nevertheless, mining permits are a competence of EU member states and Canadian provinces. Neither the European Commission nor the Canadian federal government have legal competencies on this issue, and they cannot thus negotiate on their own authority<sup>88</sup>. Besides this matter, all interviewed states concurred that trade flows in Forest Products or Raw Materials between the EU and Canada did not face any regulatory barriers when entering the European and Canadian markets.

In addition, the EU and Canada in their conformity assessment for minerals both follows *OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Rise Areas*<sup>89</sup>. Their joint adhesion to this standard and the *OECD Guidelines for Multinational Enterprises*<sup>90</sup> predated the conclusion of CETA, and it is no surprise that these guidelines are explicitly mentioned. CETA's regulatory design reflects thus preexisting cooperation and the use of voluntary standards to regulate trade relation. The common adhesion of both regulatory areas to the same standard is not negligible as it contributes to the governance of the global supply chain (Ponte and Gibbon 2005). When listing these standards in their cooperation, states fulfill their role as regulatory "orchestrators" of global economic activities (Abbott and Snidal 2009, 2010).

Besides conflict related issues with minerals, raw materials are also a key subject within the UN Sustainable Development Goals (SDGs), especially Goal 12 *Responsible Consumption and Production* and Goal 9 *Industry, Innovation and Infrastructure*<sup>91</sup>. Among many objectives, these

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<sup>87</sup> OECD, "Export restrictions on Industrial Raw Materials", [https://qdd.oecd.org/subject.aspx?Subject=ExportRestrictions\\_IndustrialRawMaterials](https://qdd.oecd.org/subject.aspx?Subject=ExportRestrictions_IndustrialRawMaterials), accessed the 21<sup>st</sup> August 2019.

<sup>88</sup> OECD Working Party of the Trade Committee, "Local content policies in minerals-exporting countries, case studies", [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=TAD/TC/WP\(2016\)3/PART2/FINAL&docLanguage=En](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=TAD/TC/WP(2016)3/PART2/FINAL&docLanguage=En), accessed the 21<sup>st</sup> August 2019.

<sup>89</sup> OECD, "OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas", <https://www.oecd.org/corporate/mne/mining.htm>, accessed the 21<sup>st</sup> August 2019.

<sup>90</sup> OECD, "2011 Update of the OECD Guidelines for Multinational Enterprises", <https://www.oecd.org/daf/inv/mne/oecdguidelinesformultinationalenterprises.htm>, accessed the 21<sup>st</sup> August 2019.

<sup>91</sup> SDG resources Centre, "Critical Raw Materials", <https://sdgresources.relx.com/special-issues/critical-raw-materials>, accessed the 21<sup>st</sup> August 2019; Columbia Center on Sustainable Investment, "Mapping

goals also address sustainability issues related to the extraction and consumption of raw materials. Likewise, raw materials also play a key role for new technologies and future industry. Both from an extraction point of view and their use in clean-tech, the regulation of the Raw sector is included by the SDGs. As both countries are part of the UN process, Canada and the EU have also adapted initiatives on their own to contribute to sustainable mining. In 2008, the EU adopted its Raw Materials Initiative (RMI), which included among its priority the “fair and sustainable supply of raw materials from global markets”<sup>92</sup>.

For Canada, as a major producer, the issue is less about sourcing and more about extracting. Therefore, the government requires that its firms follow Corporate Social Responsibility principles in their extraction activities. In addition, the main mining companies’ association in Canada, the Mining Association of Canada (MAC)<sup>93</sup>, has developed since 2004 a “Towards Sustainable Mining” (TSM) initiative<sup>94</sup>. This TSM initiative includes 6 protocols<sup>95</sup> related to sustainability in mining activities. It includes 23 indicators, which are certified by a neutral third party aiming at measuring and assessing the compliance of firms to sustainable principles<sup>96</sup>. Fulfilling the role of a standard in the sector, TSM is mandatory for all MAC members and has started to be exported abroad, notably in Europe. Spain and Finland have adopted TSM and integrated it into their regulatory frameworks, with certain adjustments due to particular local conditions<sup>97</sup>.

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<sup>91</sup> Mining to the Sustainable Development Goals”, July 2016, [https://www.undp.org/content/dam/undp/library/Sustainable%20Development/Extractives/Mapping\\_Mining\\_SDGs\\_An\\_Atlas\\_Executive\\_Summary\\_FINAL.pdf](https://www.undp.org/content/dam/undp/library/Sustainable%20Development/Extractives/Mapping_Mining_SDGs_An_Atlas_Executive_Summary_FINAL.pdf), accessed the 21<sup>st</sup> August 2019.

<sup>92</sup> European commission DG GROWTH, “Policy and strategy for raw materials”, [https://ec.europa.eu/growth/sectors/raw-materials/policy-strategy\\_en](https://ec.europa.eu/growth/sectors/raw-materials/policy-strategy_en), accessed the 21<sup>st</sup> August 2019.

<sup>93</sup>The Mining Association of Canada (MAC), <https://mining.ca/>, accessed the 21<sup>st</sup> august 2019.

<sup>94</sup> MAC, “Understanding the TSM assessment protocols” <https://mining.ca/wp-content/uploads/2019/02/Understanding-the-TSM-Protocols.pdf>, accessed the 21<sup>st</sup> August 2019.

<sup>95</sup> 1. Aboriginal and Community Outreach  
2. Crisis Management Planning  
3. Safety and Health  
4. Biodiversity Conservation Management  
5. Tailings Management  
6. Energy Use and Greenhouse Gas Emissions Management

<sup>96</sup> MAC, “TSM Guiding Principles”, <https://mining.ca/towards-sustainable-mining/tsm-guiding-principles/>, accessed the 21<sup>st</sup> August 2019.

<sup>97</sup> MAC, “Spain adopts Canada’s Towards Sustainable Mining initiative”, <https://mining.ca/press-releases/spain-adopts-canadas-towards-sustainable-mining-initiative/>, accessed the 21<sup>st</sup> August 2019; SITRA, “Bringing Towards Sustainable Mining (TSM) to Finland”, <https://www.sitra.fi/en/blogs/bringing-towards-sustainable-mining-tsm-finland/>, accessed the 21<sup>st</sup> August 2019; Kaivosvastuu, “Active work required on energy transition and raw materials supply”, [https://www.kaivosvastuu.fi/app/uploads/2017/03/Kaivosvastuujarjestelma\\_EN\\_13-03-17.pdf](https://www.kaivosvastuu.fi/app/uploads/2017/03/Kaivosvastuujarjestelma_EN_13-03-17.pdf), accessed

The TSM case is particularly interesting as it illustrates, prior to CETA, the regulatory convergence between EU requirements of sustainable sourcing and Canadian efforts in sustainable extracting. This convergence is strategic as Canada has the ambitions to become a major supplier of raw materials to the EU by using sustainable sourcing as its main selling argument (Official B1, interview in Ottawa). The EU is equally interested in this prospect and officials have stressed during interviews the interest of the EC in integrating some elements of the TSM into their next regulations on sustainable mining (official D2, interview in Brussels). Instead of regulatory conflict, the raw materials sector shows thus a case of preexisting regulatory convergence, conducted partly by the previous externalization of a Canadian standard.

Concerning Forest, it is useful to recall that forest products are also part of the EU Raw Materials Initiative (RMI). Thus, requirements for sustainable sourcing are equally valid for wood products. Moreover, the EU has also adopted an EU timber regulation, No 995/2010, for the purpose of countering the trade of illegally harvested timber and timber products<sup>98</sup>. Regarding both issues, illegal logging and sustainable sourcing, Canada is again convergent with the EU in terms of regulation. The exemplarity of Canada for illegal logging is acknowledged by the EU as Canada is not targeted by the Forest Law Enforcement Governance and Trade (FLEGT) Action Plan<sup>99</sup>. To ensure the sustainability of its products, Canada has developed a complex regulatory system helped by its provinces to ensure the sustainability of its traded forest products<sup>100</sup>. Relying on third party certification, this system ensures the compliance with the following standards: *Canadian Standards Association (CSA), the Forest Stewardship Council (FSC) and the Sustainable Forestry Initiative (SFI)*<sup>101</sup>. The sustainability and conformity of Canadian forest products with EU legislation is also confirmed by the absence of regulatory issues with Canadian exports to the EU.

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the 21<sup>st</sup> August 2019 ; The main protocol altered was by Finland on “1. Aboriginal and Community Outreach” due to a divergence with Finnish approach towards aborigines’ relations

<sup>98</sup>EUR-Lex, “Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market” <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32010R0995>, accessed the 21<sup>st</sup> August 2019.

<sup>99</sup>European commission DG Environment, [https://ec.europa.eu/environment/forests/illegal\\_logging.htm](https://ec.europa.eu/environment/forests/illegal_logging.htm), accessed the 21<sup>st</sup> August 2019.

<sup>100</sup>Government of Canada Natural Resources Canada, “Canada’s Forest laws: legality and sustainability”, <https://www.nrcan.gc.ca/our-natural-resources/forests-forestry/sustainable-forest-management/canadas-forest-laws/legality-and-sustainability/13303#section-2>, accessed the 21<sup>st</sup> August 2019.

<sup>101</sup>Canadian Council of Forest Ministers, “Statement on Forest Certification Standards in Canada”, [https://www.sfmcanada.org/images/Publications/EN/CCFM\\_StatementCertif\\_EN.pdf](https://www.sfmcanada.org/images/Publications/EN/CCFM_StatementCertif_EN.pdf), accessed the 21<sup>st</sup> August 2019

Both in Raw Materials and Forest Products, these two sectors are characterized by the absence of shirking risks between the EU and Canada. Both used similar international standards to ensure compliance with sustainability requirements. This context of regulatory convergence explains thus why states privilege the choice of a soft design in CETA. In the absence of regulatory conflicts, the similarity of their regulatory approaches and the use of preexisting standards by actors in the two sectors' supply chains, the risk that one of two country suddenly change its approaches and adopt technical barriers that would harm also its industry is low. This is even more the case that the preexisting system already facilitate the free flow of goods between firms on both sides. A soft mechanism can contribute to the "orchestration" of the sector by offering additional channels of cooperation and voluntarily expending the existing regulatory foundation through adding new subjects to be discussed.

Biotechnology is a more controversial case in CETA. The establishment of a biotechnology dialogue between the EU and Canada was a WTO requirement in order to solve a previous dispute: *European communities–Measures Affecting the Approval and Marketing of Biotech Products WT/DS292*<sup>102</sup>. Unlike Forest Products and Raw Materials, this dialogue was established due to the divergence of regulatory frameworks between the EU and Canada. Indeed, five EU regulations restricted the production of Genetically Modified Food within the EU, and their imports in the common market: *Directive 2001/18/EC on the deliberate release of GMOs into the environment*, *Regulation (EC) 1829/2003 on genetically modified food and feed*, *Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory*, *Regulation (EC) 1830/2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms*, *Directive 2009/41/EC on contained use of genetically modified micro-organisms*. *Regulation (EC) 1946/2003 on trans-boundary movements of GMOs*.

The European Food Safety Authority (EFSA) oversees the compliance of biotech products with the previous regulations and thus organizes and manages the product approval process. Despite the resolution of the WTO case, Canada continued to express its concerns regarding the length

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<sup>102</sup> WTO DSB, "DS292: European communities – Measures Affecting the Approval and Marketing of Biotech Products", [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds292\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds292_e.htm), accessed the 16th August 2019.

and complexity of European risk assessment<sup>103</sup>. For Canada, European product approval remains problematic and restricts market access for a series of products of interest for Canadian exporters. The risk that the EU adds new regulatory requirements preventing even further imports of Canadian biotech products is particularly high. Therefore, the use of Soft obligation does not correspond to the theoretical expectation of this research. Several explanations can be formulated to explain this deviant case.

First, Biotechnology in the European context is a highly political issue, which seems to go beyond questions of trade liberalization and market access. Concerns voiced by several NGOs over the sanitary and contamination risks of Genetically Modified Organisms (GMOs) were already present during the TTIP debate<sup>104</sup>. It would be possible to argue counter-factually that without this domestic political opposition, the EU and Canada would have decided on another regulatory design. For instance, Canada could have required Hard obligations such as in MVs and GIs, two sectors where shirking risks were also present. Indeed, a Hard obligation provision might require making regulatory adjustment in domestic regulatory framework, especially in the European one. This possibility would face significant political opposition within the EU though. It is thus plausible that states might have preferred to use a Type 4 design to accommodate Canadian exports' interests without affecting EU regulatory framework. This possibility is discussed further in the next section 5.4 on alternative explanations.

Compared with Biotechnology, Forest Products and Raw Materials situations stand in stark contrast. Instead of a confrontational relation between Canada and the EU, in Forest and Raw regulatory cooperation was predominant. Neither Forest Products nor Raw Materials were subject to export restriction measures from the EU or Canada. On the contrary, interviews with multiple stakeholders (official & industry A2-B1-C3-C4-D2, interviews in Ottawa & Brussels) confirm the absence of concerns on potential future shirking issues. The existence of a symbiotic regulatory environment decreased the chance that one country could decide suddenly to add regulatory barriers.

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<sup>103</sup>EC CETA, «meeting of the dialogue on biotech market access issues, videoconference, 26 April 2018», [http://trade.ec.europa.eu/doclib/docs/2018/july/tradoc\\_157100.04.2018%20-%20COM%20report\\_FINAL.pdf](http://trade.ec.europa.eu/doclib/docs/2018/july/tradoc_157100.04.2018%20-%20COM%20report_FINAL.pdf), accessed the 21<sup>st</sup> August 2019.

<sup>104</sup> Ecologist, “TTIP could open EU to ‘new biotech’ GMO seeds and foods”, <https://theecologist.org/2015/jul/07/ttip-could-open-eu-new-biotech-gmo-seeds-and-foods>, accessed the 21<sup>st</sup> August 2019.

On the other hand, in Pharma and PQ, concerns on shirking were particularly high. Not only the international regulatory environment of these two sectors is deeply fragmented, but Canada and the EU themselves have significant diverging points in their regulatory approaches. These divergences could be then subsequently exploited by any parties to restrict bilateral trade. Each using diverging versions of the same standard (GMP), conformity assessment procedures and authorities (Health Canada vs EMA), and domestic regulatory approaches, the EU and Canada were at regulatory odds with one another. This was not without consequences as these divergences impede trade and act as a Damocles sword on trading actors. It serves as a reminder that the regulatory cooperation designed in CETA could easily be called into question and each state could revert to its own regulatory system. It is this possibility that motivated the parties to use Hard obligations to bridge the regulatory divergences (see chapter 7 for details).

In these four cases (Pharma, PQ, Raw, Forest), the Low/High level of shirking risk has incentivized Canada and the EU to adopt different regulatory designs. While states privileged Hard obligations provisions for Pharma and PQ, they resorted to soft legal obligations instead in Raw and Forest. This variation of design is to be found in the risk of propensity of opportunistic use of regulatory divergences for economic gains, which was function of the pre-existing and existing state of both countries' regulatory frameworks. Indeed, while the EU and Canada follow significantly different regulatory requirements in Pharma and PQ, in Raw Materials and forest products regulations they converge. Thus, although a design of Type 2 for Pharma and PQ was particularly necessary to discourage any of the parties to subsequently call into question the mutual recognition of products and thus impede trade, this was not necessarily the case for Raw and Forest. As both countries recognized similar international standards, a Type 4 institutionalized and expanded the cooperation without requiring Hard obligations to facilitate sanctions in case of future violations.

### **The absence of Type 3 (Ex-ante/Soft) and its related risks configuration (High level of “Hold-up” / Low level of Shirking)**

The absence of Type 3 calls for reflection. To recall, this thesis could not perform a complete analysis of sectors potentially covered by CETA. It focuses only on sectors covered by the new agreement and for which a regulatory cooperation mechanism was designed and selected through an inductive ad hoc approach. This choice was due to nomenclature issues as discussed in section

4.1 of the methodology. This limited scope precludes thus this thesis to fully investigate the mechanism through in-depth case study as with the other sectors.

The concomitant absence of cases with the presence of “hold-up” risk but the absence of shirking risk seems to confirm the theoretical relation suggested earlier in section 2.2. The question remains if states deliberately decided to exclude sector with this type of features from the agreement or simply that sectors with this risk configuration do not exist in the CAN-EU relations. From the data compiled of the CETA negotiation, it does not appear that specific sectors were intentionally excluded by parties of the agreement. This eventuality was not mentioned in the different position papers consulted and other official declarations. It is also difficult to infer that the nature of the Canadian and European economic relations precludes per se the existence of this type of risk configuration. The impossibility to investigate systematically all relevant sectors for EU-CA relations prevents this option.

Consequently, the results from the cross-sector comparison tend to indirectly support the proposition that states used “voluntary” (soft) but technically detailed and limited cooperation mechanism (Ex-ante) to address risks originating from “hold-up” in a context of regulatory convergence. Cooperation schemes of Type 3 provide useful means for states to cooperate without engaging in a long-term regulatory mechanism that could create situation of dependencies. Indeed, even if voluntary standards and standardization processes can be quite powerful tools to harmonize regulations, even on a consensual basis. Therefore, there might be some interest for a state to choose specifically which standards/rules to abide and which to exclude. This allows to avoid committing to a full standardization process that can be resource intensive to influence and difficult to defect from once engaged.

This scenario would also explain why CETA might not have been chosen unintentionally to design cooperation mechanisms with this type of case features. PTAs remain a type of instrument largely dominated by states and which belong to the more traditional toolbox of public authorities. This is what Abbott and Snidal described as the “International Old Governance” (Abbott and Snidal 2010, 2009). On the contrary, Soft obligation appears to have been developed as an alternative to the “traditional” state dominated form of governance (Abbott and Snidal 2010, 326). The latter is more characterized by voluntary regulatory processes, such as standardization, which

can take place in International Organizations such as ISO<sup>105</sup>. The opposition between “old” and “new” forms remains an ideal type. Instances of hybridization between both can be found.

What this absence shows is rather the incongruity of specifically including Soft Ex-ante rules in PTAs. It is perhaps not clear for states why they should spend time and energy to negotiate provisions with Soft obligations. Soft obligation does not require states to commit to the cooperation and can appear “too weak” for bringing meaningful results to the cooperation. Furthermore, new forms of governance take place in various fora outside of trade negotiations and it is not necessary for states to integrate it into their trade agreements in order to pursue their informal cooperation. Type 4 (Soft/Ex-post) is less problematic in this logic as it leaves open the exact voluntary standards or technical requirements to be adopted, which can be decided outside PTAs. For states, voluntary Ex-post regulatory schemes can thus institutionalize a cooperation mechanism, the exact technical details of which could be discussed in another fora.

Nevertheless, this remains conjectures that might need to be verified through in-depth analysis of instances of design Type 3 outside PTAs. It would provide additional information on the reasoning behind the use of this design Type 3 and a potential definite confirmation of the theoretical proposition formulated in this thesis.

### *5.3. Alternative explanations*

Following the cross-sectoral analysis of the 7 cases, performed following Rational Institutionalist premises, there are merits in proceeding with a control test of this analysis. To do so, this section uses constructivist-inspired explanations and mainly checks two alternative options: treaty replication and Civil Society. Treaty replication assesses whether this design variation is unique to CETA or is reproduced similarly in other trade agreements. Civil Society investigates the potential influence of Civil Society mobilization to explain the design-deviant case of Biotech, belonging to Type 4 instead of Type 2 contrary to theoretical expectation. This latter argument looks at whether this factor could likewise explain the choices of Type 4 for Raw and Forest, also similarly designed.

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<sup>105</sup> To recall, according ISO terminology the different between “standards” and “regulations” is that the former is voluntary while the latter is compulsory

## **The complex relation between treaty replication and rational assessment**

As reviewed in Chapter 2, constructivism-inspired explanations argue that designs of trade agreements are the result of previous European and Canadian collaboration in international fora, such as in UNECE and WTO/WIPO. These high-level exchanges result in the development and the adoption of a joint legal template that fit with existing international regulatory regimes, such as UNECE agreements and the TRIPs. A complementary argument would add that due to path dependency and replication of existing practices, negotiators do not adapt their legal design according to local and domestic conditions. They simply replicate already existing legal templates that were used in the past by themselves or third actors. Thus, design between trade agreements vary mostly between the two most prominent PTA models currently: U.S. and EU (Acharya 2016). While significant variation could be found between the two models, each internal difference should be minimal. Variation is possible between the trade agreements of the EU, but all of them should follow a similar regulatory approach (Young 2015b).

This interpretation quickly suffers some shortcomings though. In GIs states are members to the same international agreements (WIPO, TRIPS) and in Motor Vehicles they are bitterly divided between UNECE 1958 and UNECE 1998 agreements. Nevertheless, a similar design type (Hard/Ex-ante) was chosen for both sectors. International emulation logic alone seems thus unable to explain this similarity. Instead, it appears rather that states rationally assess their own economic structure and use international agreements as instruments for their own interests. It is even more apparent when international regulatory decisions are put into context. The reasons for the EU to promote the recognition of GIs at WTO/WIPO originates from its internal efforts to reform its Common Agriculture Policy. In fact, and as mentioned previously, the introduction of the GIs system at the European level through the Council Regulation No 2081/92<sup>106</sup> was concomitant with the reform of CAP in the same year, 1992<sup>107</sup>. In the preamble of the Council regulation, it is furthermore stated:

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<sup>106</sup> EUR-Lex, Official Journal of the European communities, “Council regulation (eec) no 2081/92 of 14 july 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs”, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31992R2081&from=EN>, accessed the 8<sup>th</sup> July 2019.

<sup>107</sup> European Parliament, “The common agricultural policy – instruments and reforms”, <http://www.europarl.europa.eu/factsheets/en/sheet/107/the-common-agricultural-policy-instruments-and-reforms>, accessed the 8<sup>th</sup> July 2019.

[...] as part of the adjustment of the common agricultural policy the diversification of agricultural production should be encouraged [...]<sup>108</sup>

The GIs system was thus elaborated as one pillar of the European response to reform the CAP. It was meant to compensate producers for the reduction of subsidies that the policy shift would incur. It is prior to this regulatory change of the Europeans in 1992, that GIs would be incorporated in WTO legal corpus through the adoption of the TRIPS in 1994<sup>109</sup>. Following a causal logic, it was the EU's decision to use GIs as income loss mitigators that started work at WTO and subsequent EU efforts to integrate GIs into trade agreements.

In its current efforts, the EU strives in its PTAs to encourage its partners to completely adopt its domestic GI legislation (official D7, interview in Brussels). The legal design found in these trade agreements result from the compromise made with partners that have diverging regulatory and trade structure. For instance, the EU Korea trade agreement scheduled a specific working group on Geographical Indications (art 10.25)<sup>110</sup>, which has competence to add or remove new GIs as well as further cooperation. On the contrary, this possibility is strictly limited in CETA. Only the CETA joint committee has the competence to do so (art. 20.22.1), which is also strictly limited by the formulation:

A geographical indication shall not in principle be added to Part A of Annex 20-A  
[...] (Article 20.22.2)<sup>111</sup>.

According to officials involved in the negotiation, the formulation “in principle” was added as a compromise language, in light of Canadian opposition to add more GIs to the list in the future (official D7, interview in Brussels). This ambiguous language aimed at reassuring Canada that

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<sup>108</sup> EUR-Lex, Official Journal of the European communities, “Council regulation (eec) no 2081/92 of 14 july 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs”, 1p., <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31992R2081&from=EN>. accessed the 8th July 2019

<sup>109</sup> ENAVENTE, Daniela. Chapter 1 – Introduction to Geographical Indications: Origin and Characteristics In: The Economics of Geographical Indications [en ligne]. Genève: Graduate Institute Publications, Disponible sur Internet: <http://books.openedition.org/iheid/>, accessed the 25th July 2019.

<sup>110</sup>EUR-Lex, Official Journal of the European Union, Volume 54, 14 May 2011, “COUNCIL DECISION of 16 September 2010 on the signing, on behalf of the European Union, and provisional application of the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part” <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2011:127:FULL&from=EN>, accessed the 7<sup>th</sup> July 2019.

<sup>111</sup> European Commission, Joint statement Canada-EU Comprehensive Economic and Trade Agreement (CETA), Monday, 29 February 2016, [http://trade.ec.europa.eu/doclib/docs/2016/february/tradoc\\_154330.pdf](http://trade.ec.europa.eu/doclib/docs/2016/february/tradoc_154330.pdf), accessed the 2nd May 2019.

the EU would not attempt to further expand the lists and that the 143 GIs it accepted, will remain as such. This divergence between EU-KR and CETA is also visible for motor vehicles, where the former also scheduled comprehensive working groups aimed at furthering harmonization of regulations between the two partners (Article 9.2 .(b)). On the contrary, CETA schedules only a bilateral dialogue to facilitate exchanges of information' around the list of UNECE regulations that Canada recognized (Annex 4-A; Article 4.6).

As a further illustration, the EU-Japan agreement, signed after CETA, also regulates the sectors differently. While the international regimes remain the same, the EU-Japan treaty does not include a chapter on PQ MRA, nor a specific annex protocol for GMP mutual recognition<sup>112</sup>. In Pharma-GMP, the parties decided to extend only the numbers of products covered by their existing MRA. While it falls outside the scope of this research to determine why such choices were made in EU-Japan, this quick overview demonstrated that regulatory approaches in PQ and Pharma do vary between agreements. As in GIs and MV, parties do adapt their regulatory approaches to their trade partners and do not simply replicate a regulatory template.

These illustrations do not signify that no instances of imported language cannot be found. These examples mentioned are meant only to showcase that CETA is not the mere replication of existing trade agreements but has unique particularities that deserve a unique study of their own. Indeed, these differences in terms of sector design justify looking at the features of countries' sectors to explain design variation. These treaties are thus not simply replicated but also vary in small but crucial features that significantly affect their effects on trade patterns.

Even if different trade agreements share 90% of a same template, the 10% remaining might include the most relevant or binding provisions. Therefore, while an approach based on a large database can identify patterns of variation between international instruments, this large population approach may also run some risks. By aggregating large amounts of data from different sources, it might underplay subtle design variations that have crucial consequences for actors on the ground. This is even more sensitive in a time where small regulatory issues can have major political repercussions, as illustrated by the chlorinated chicken controversy for TTIP<sup>113</sup> or the

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<sup>112</sup> EC, “EU-Japan EPA – The Agreement in Principle”, [https://trade.ec.europa.eu/doclib/docs/2017/july/tradoc\\_155693.doc.pdf](https://trade.ec.europa.eu/doclib/docs/2017/july/tradoc_155693.doc.pdf), accessed the 10<sup>th</sup> August 2019.

<sup>113</sup> Benjamin Fox, Euractiv, “The return of the chlorinated chicken”, <https://euobserver.com/brexit/138650>, accessed the 30<sup>th</sup> July 2019.

more recent debate around beef flour protein in CETA<sup>114</sup>. The empirical evidence presented in this chapter supports the claim that looking sector by sector can shed valuable light on the choices made during the negotiation. The unearthed causal mechanism in this chapter was made possible due specifically to the choice of using a disaggregated unit of comparison. As seen, these variations have dramatic implications for the firms involved in these sectors of activities as well as political actors. States can hardly afford to simply replicate regulatory design, but rather must endure comprehensive costs and benefits. By conducting an analysis sector by sector, they are then able to determine which will suit their sectors best. As demonstrated in earlier sections, this variation can be explained by the strategic calculation of countries in specific sectors.

### **Civil Society, an intervening factor ?**

Another potential objection to this argument could be the role of other non-strategic factors, such as civil society mobilization for the case of Biotech in CETA. The potential influence of Civil Society Organizations was already discussed in the context of WTO failure at Seattle in 1999 (Walter 2001; Gantz 2000; Bayne 2000). Debates remain within the scientific literature on the capacity of NGOs to derail trade negotiations at that time, this possibility was raised and discussed again on the occasion of the TTIP negotiation (De Ville and Siles-Brügge 2017, 2016; De Bièvre and Poletti 2016; Young 2016). In these two instances, scholars discussed the reality of the causal effects of Civil Society Mobilization in the collapse of the trade negotiations. Some scholars argued that TTIP and Seattle instances do show a consistent pattern revealing the rising influence of civil society in trade policy, and its impacts on the negotiation itself (Gheyle and De Ville 2017; De Ville and Siles-Brügge 2016, 2017). In response, other researchers objected that it was rather the clash of economic interests that explain countries' inability to achieve trade liberalization (De Bièvre and Poletti 2016; Young 2016). In the case of CETA, the refusal of the regional Walloon government to ratify the agreement, in a context of civil society mobilization and demonstrations, has reiterated researchers' interests in civil society impacts on trade policy.

In 2017, The Journal of European Integration dedicated an entire issue to this “new type” of trade politics, labelling it as “contentious market regulation” (Dominguez 2017; Laursen and Roederer-

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<sup>114</sup> Maxime Vaudano, Le Monde, 22nd July 2019, «CETA et farines animales : comment le gouvernement s'est trompé » [https://www.lemonde.fr/les-decodeurs/article/2019/07/22/farines-animales-et-ceta-comment-le-gouvernement-a-t-il-pu-se-tromper\\_5492248\\_4355770.html?fbclid=IwAR26-qhmRpW0F2xkN\\_k09daqQ5fyhFo-yGrG-gC6WLzKg\\_UFwQy3O424pc](https://www.lemonde.fr/les-decodeurs/article/2019/07/22/farines-animales-et-ceta-comment-le-gouvernement-a-t-il-pu-se-tromper_5492248_4355770.html?fbclid=IwAR26-qhmRpW0F2xkN_k09daqQ5fyhFo-yGrG-gC6WLzKg_UFwQy3O424pc), accessed the 30th July 2019.

Rynning 2017; Young 2017; Buonanno 2017; Pelkmans 2017; Suzuki 2017). The main argument of these authors is that “deep” trade liberalization “challenges entrenched domestic norms of public policy and law-making and regulatory institutions and processes”. As a consequence, we should expect “a new range of actors to mobilize in trade policy, alongside the traditional state executives and special economic interest groups”, in particular “citizen groups and parliamentary actors” (Laursen and Roederer-Rynning 2017, 764). Thus, the pursuit of regulatory cooperation by States has resulted in a change of nature between “old generation of trade agreements, which was the “domaine reserve” of executive actors and economic lobby groups”, and the “new-generation trade agreements” that are “more broadly politicized and contested” (Laursen and Roederer-Rynning 2017, 764–65). According to Hübner, Deman and Balik (2017, 845), the mobilization of Civil Society during the TTIP had a “critical” influence in the CETA negotiation. In this framework, CETA negotiation’s results are thus also the consequence of rising Civil Society mobilization in the EU since the TTIP.

This implies that the choice of Type 4 could have been a result of Civil Society Mobilization for the sectors regulated under this type. Beyond the case of Biotech, Forest and Raw are also potential sectors where past civil society mobilizations were important. The adoption or amendments to regulate these sectors resulted also from the mobilization of civil society groups, such as for Canadian Whitehorse Mining Initiative in Raw (see Chapter 8). Compared with Type 1 and Type 2 it could be argued that design Type 4 is the less ambitious mechanism. Not only are its regulatory effects delayed (Ex-post) but cooperation does not entail any form of legal obligation (Soft). In this regard it is a relatively modest cooperation scheme that has limited effects for Canada or the EU. On the contrary, Type 1 and 2 have more potential regulatory adjustments effects as will be seen in Chapter 6, 7. An alternative explanation for Type 4 could be thus formulated as such: because of the presence of Civil Society Mobilization in certain sectors, countries decided to use the less stringent regulatory cooperation type available: Type 4 (Ex-post/Soft).

It remains to be determined whether this mechanism could explain Type 4 in CETA for all three sectors. Empirical evidence remains mixed. EU civil society mobilization against Biotech is not new and remains constant. Starting in Denmark and Germany during the 80s (Falkner 2007, 514), opposition to Biotech has been widespread over the years. This movement of contestation among EU member states increased in the 90s, including Austria, France, Greece, Belgium, and Luxembourg among the countries in 1999 calling for a moratorium on Biotech approbation

(Falkner 2007, 518)<sup>115</sup>. While the moratorium ended in 2004, opposition remained strong, with 19 EU member states calling to officially ban genetically modified crops<sup>116</sup>. The scientific literature acknowledged on several occasions the role that civil society organizations played in convincing EU public opinion and member states to oppose the approbation of Biotech products (Falkner 2007; Buonanno 2017). As of today, and on CETA itself, it is still possible to see calls to opposition against Biotech products on the websites of different EU civil society organizations. On the website of the Green/EFA Group of the European Parliament dedicated to opposing the TTIP, 12 reasons are exposed to explain opposition to CETA since January 2017. Reason 5 mentions directly CETA: “Because it pressures Europe to change its bio-technology and GMO rules”<sup>117</sup>. While this list was posted after the adoption of CETA in October 2016, other older publications by various organization included similar criticism on Biotech negotiation within CETA<sup>118</sup>. Overall, it appears clearly that Civil Society Mobilization on Biotech in Europe was very much present and was able over the years to build a powerful front regrouping several organizations and member states. This coalition is hence able to oppose any ambitious regulatory mechanism on Biotech in PTAs.

It could be argued that the opposition of EU member states were the only factor mattering and this opposition was driven by economic interests. Nevertheless, opposition between member states based on diverging trade interests is not exclusive to Biotech, such as opposition between French and German automakers during EU-Korea negotiation (Elsig and Dupont 2012). Nevertheless, unlike automobile sectors, free-trade coalition in Biotech was not able to overcome opposition in its case. A strong majority of EU member states keep holding hostile views towards

<sup>115</sup>FT, “Timeline: The EU’s unofficial GMO moratorium”, <https://www.ft.com/content/624a88c6-97db-11da-816b-0000779e2340>, accessed the 28<sup>th</sup> August 2019.

<sup>116</sup>Coghlan Andy, NewScientist, 5<sup>th</sup> October 2015, “More than half of EU officially bans genetically modified crops”, <https://www.newscientist.com/article/dn28283-more-than-half-of-european-union-votes-to-ban-growing-gm-crops/>; European Commission DG Environment, “Several European countries move to rule out GMOs”, <https://ec.europa.eu/environment/europeangreencapital/countriesruleoutgmos/>; both accessed the 28<sup>th</sup> August 2019.

<sup>117</sup> The Greens/European free Alliance, “12 reasons the green/efa group is opposed to ceta”, <https://ttip2016.eu/blog/id-12-reasons-the-greenefa-group-are-opposed-to-ceta.html>, accessed the 28<sup>th</sup> August 2019.

<sup>118</sup> Berit Thomsen, “CETA’s threat to agricultural markets and food quality”, <https://euagenda.eu/publications/ceta-s-threat-to-agricultural-markets-and-food-quality>; Dario Sarmadi, Euractiv, “German Environment Ministry seeks unconditional GMO ban”, 14<sup>th</sup> June 2015, <https://www.euractiv.com/section/agriculture-food/news/german-environment-ministry-seeks-unconditional-gmo-ban/>; Greenpeace & IATP & CCPA, “CETA, regulatory Cooperation and Food Safety”, 2017, [https://trade-leaks.org/wp-content/uploads/2017/09/1-CETA\\_Regco-factsheet\\_sept17\\_05w.pdf](https://trade-leaks.org/wp-content/uploads/2017/09/1-CETA_Regco-factsheet_sept17_05w.pdf) ; Friends of the Earth Europe, “GM food and the EU-US trade deal”, September 2014, [http://www.foeeurope.org/sites/default/files/gm\\_food\\_eu-us\\_trade\\_deal.pdf](http://www.foeeurope.org/sites/default/files/gm_food_eu-us_trade_deal.pdf) ; all accessed the 28<sup>th</sup> August 2019.

the sector, despite potential economic interests in facilitating biotech products approval. Civil Society Mobilization in the Biotech sector and within the context of CETA is thus confirmed, which is in line with findings of previous scientific contributions (Buonanno 2017). Contrary to Biotech, the same organizations surveyed did not mention Forest and Raw sectors. As an illustration, neither Greenpeace<sup>119</sup> nor the CNCD-11.11.11<sup>120</sup> an umbrella organization comprising 90 NGOs based in Brussels, mention these sectors in their opposition to the agreement. From a preliminary review and according to the empirical data available, it does not appear in any instances that Civil Society expressed its worries concerning regulatory negotiations between the EU and Canada on the Raw or Forest sectors.

In sum, while clear evidence supports the role of Civil Society Mobilization within the Biotech sector, this was not the case for Forest and Raw. The choice of design Type 4 in Raw and Forest cannot be thus attributed to the role of Civil Society Mobilization. The causal impact of Civil Society on design Type 4 appears thus uncertain. None of the empirical findings in Civil Society Organizations' publications gave insights into the choice of design they would privilege for cooperation. On the contrary, they advocated for the exclusion of these subjects from CETA, which they did not obtain in the end.

#### *5.4. Conclusion*

At first, this chapter proceeded with a textual analysis of the seven sectors describing the three types of regulatory design present in CETA. While, Geographical Indications (GIs) and Motor Vehicles (MV) contain Hard obligations and an Ex-ante mode of decision, featuring a regulatory design of Type 1, Pharmaceutical Products (Pharma) and Professional Qualification (PQ) integrate instead an Ex-post mechanism of Type 2. Raw Materials (Raw), Forest Products (Forest) and Biotechnology (Biotech) feature Soft obligation provisions and an Ex-post mechanism, categorizing them in Type 4. As mentioned in theory parts, no Type 3 regulatory design (Soft/Ex-ante) were found in CETA. As argued in section 5.3, this can be attributed to the incongruity of integrating detailed voluntary standards in a highly legalized text such as a PTA. Following the

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<sup>119</sup>Greenpeace, "Press release: CETA threatens food safety even before national parliaments sign off", <https://www.greenpeace.org/eu-unit/issues/democracy-europe/880/ceta-threatens-food-safety-even-before-national-parliaments-sign-off/>, accessed the 28<sup>th</sup> August 2019.

<sup>120</sup> Arnaud Zacharie, CNCD 11.11.11, « Les déséquilibres du CETA » <https://www.cncd.be/Les-desequilibres-du-CETA>, accessed the 28th August 2019.

design description, a cross-sectoral analysis compares the seven sectors with the help of two explanatory variables: presence/absence of “hold-up” and “shirking” risks. Data from trade statistics and regulatory documents were harnessed to measure them.

The overall comparison (Table 10 below) reveals that Canada and the EU cooperation was plagued by a high risk of “hold-up” and “shirking” for GIs/ MV, low “hold-up” risks in Pharma and PQ but high “shirking” risk, and both low risks in Raw, Forest. Biotech is the exception with a high shirking, but low “hold-up” risk, contrary to theoretical expectations.

		<i>Risks of "Hold-up"</i>	
		High	Low
<i>Risks of Shirking</i>	High	<b>Geographical Indications, Motor Vehicles</b>	<b>Pharmaceutical products, Professional Qualifications, Biotechnology*</b>
	Low	<b>None</b>	<b>Forest Products and Raw Materials</b>

\*To recall, Biotech is a deviant case

*Table 10 Risks results by cases and design types*

As reviewed, in Pharma and PQ, contrary to GIs and MV and despite the EU’s export surplus, Canada and the EU have similar economic footings as they are exchanging relatively similar medications, their exporting firms are globally integrated (Pharma) and similarly localized (PQ and Pharma). There are thus fewer possibilities for a potential risk of “hold-up” to take place in the future compared with GIs and MVs, explaining the choice of a regulatory design of Type 2. Raw and Forest share a similar trade flow profile than Pharma and PQ, however the risk of shirking is absent compared to the latter. Regulatory frameworks of Canada and the EU in Raw and Forest are converging instead of diverging. Canada and the EU use similar international standards and there are no regulatory barriers to bilateral exchanges.

To note that Biotech seems to be an outlier in this comparison and does not correspond to the expected with the explanatory factors. Despite being regulated in CETA with a design of Type 4, a strong risk of shirking between Canada and the EU characterized Biotech. It appears thus as a

deviant case, which does not correspond with the theoretical premises formulated earlier. One potential explanation could be the exceptional political sensitivity of Biotech in the European context and the role of past Civil Society Mobilization, which prevents a traditional trade liberalization approach. This argument was investigated and discussed in section 5.4, resulting in mixed results.

This cross-sectoral comparison illustrates the dilemma faced by countries when deciding between different regulatory designs to cooperate. Many other details and information also explain the choices made in CETA, when looking within the types. Comparing sectors belonging to the same types offers another perspective on the negotiation, as well as explicating even further the causal relationship between a sector's features and its type of design. Chapter 6 performs this in-depth analysis for GIs and MV within Type 1, Chapter 7 does the same for Type 2 with Pharma and PQ, and Chapter 8 concludes with Type 4 and Raw, forest and Biotech

## Chapter 6. In-depth case studies (Type 1): Geographical Indications & Motor vehicles

Section 5.2. described the design Type 1 used for Geographical Indications and Motor Vehicles. Following the theoretical framework formulated earlier, this type of design is chosen by states when the sectors they want to regulate are characterized by a high level of hold-up and shirking risks. This chapter is an in-depth case analysis of the internal mechanism between these variables results and the choice of regulatory design. Section 6.1 investigates the risk of “hold-up” in GIs and MVs. It looks at how the trade structure between the EU and Canada in these sectors led the negotiators to take into consideration a high risk of “hold-up” and design their cooperation Ex-ante instead of Ex-post. Section 6.2 looks at the risk of shirking in GIs and MVs. It examines how the divergence of regulatory framework between the EU and Canada pushes their representants to use Hard obligation design features instead of Soft ones.

This chapter finds that in GIs and MVs the Ex-ante feature chosen aimed at mitigating the risks for Canadian firms that cooperation with the Europeans would entail. By keeping the regulatory equivalences to the Europeans limited and short-term, Canadian negotiators provided increased market access to European firms while reducing the impact of increased competition in its domestic markets. Ex-ante was more appropriate for this purpose, as even if Ex-post would have been less painful at first, it could have had significant disruptive consequences for Canadian structures.

Indeed, the Canadian structure in these two sectors is fundamentally different than that of Europe, which disadvantages Canadian firms in an un-restricted liberalized environment. Prior to CETA Canadian firms have not been able to access the EU market as extensively as the European entered the Canadian market. Canadian value chains are furthermore inwardly oriented (GIs) or integrated with a third country (MVs) such as the US. Their relatively more upstream position in the value chains compared with the Europeans, also plays a role in making them more dependent on external firms. In sum, the Canadians were concerned that these characteristics made them less competitive compared to the Europeans in case of un-restricted liberalization.

Second, the deep regulatory fragmentation at the international level intensified the possibility that one of the parties decides to end recognition of foreign equivalences. This possibility is particularly high with Canada, which aligns with U.S. standards for motor vehicles rather than

UNECE and uses a trademark approach to regulate GIs. The analysis shows that the possibility of shirking was particularly high considering previous regulatory conflicts between them. In this instance, Hard obligations were especially necessary to bridge the regulatory gaps and provide European firms the means to litigate in case of violation of Canadian equivalences commitments.

Before proceeding directly with the analysis briefly summarized, it is useful to recall what are the type of economic activities is covered by these sectors. As a group of products, Geographical Indications includes a certain subset of food or drinks, traded across the border. They are agricultural goods, destined only for household consumption such as specific meats, cheese or wine products. Even if it is not a commonly used “sector” in existing nomenclature, this research considers it as a “regulatory sector” for different reasons. The actors involved in this branch of activities need to follow specific rules of production. Regulations and technical requirements on production are not the same compared with other agri-food products, including the procedure for conformity assessment.

It is thus a branch of activity that is hence submitted to unique regulations and technical requirements. This uniqueness is also supported by the decision of states to specifically dedicate certain provisions of CETA to GIs, and to create a specific mechanism for cooperation, as seen in previous chapters. Motor Vehicles is a more commonly used denomination, which includes a large set of industrially produced wheeled vehicles with their equipment and parts<sup>121</sup>. Passenger cars belong to the category, but also motorcycles and other motor vehicles.

### *6.1. Hold-up*

The first element to look at to assess the role of potential “hold-up” during the negotiation is the structure of trade exchanges for these two sectors. It provides a first image of the production and trading features of the sectors, notably potential asymmetric interdependence that could result or be intensified by liberalization through regulatory cooperation. The economic implications of regulatory cooperation considered during the negotiations are especially crucial to re-construct the strategic logic that led the states to adopt a design feature. This section focuses thus its research

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<sup>121</sup> UNECE, “Agreement Concerning the Establishing of Global technical regulations for Wheeled vehicles, Equipment and Parts Which can be Fitted and/or be used on wheeled vehicles”, <https://www.unece.org/fileadmin/DAM/trans/main/wp29/wp29wgs/wp29gen/wp29glob/tran132.pdf>, accessed the 1<sup>st</sup> August 2019.

efforts on the respective position of Canada and the EU in the two sectors here investigated, their relative trade positioning in terms of flows direction, production structure and integration in value chains. The purpose is to use economic indicators to understand the “hold-up” risk that regulatory cooperation poses to parties, especially to Canada, and their role of the design feature to mitigate it as it will be discussed now.

As displayed in Table 7, European firms have a net export surplus in these two specific sectors, according to data compiled from the EU Comtrade database. In 2017, the year in which CETA was concluded, European exports to Canada were 58.15% higher than Canada’s exports to Europe in Food Products, and 614.5% in Motor Vehicles. Moreover, this trade imbalance constantly increased during the years of negotiations, further reinforcing EU trade surplus. In absolute numbers and within these two sectors, EU firms appear to have a larger share of cross-border trade compared with Canada’s own firms. This dynamic holds in both the short and long run.

This surplus of the Europeans could be explained by Europe’s superior market size. As they proportionally have more capacity and means to produce and export, this should be reflected in trade imbalances. Nevertheless, these exports surplus are larger than the average of the EU-CA relations (av 25% see Table 23, Appendix V), indicating that they are two sectors where the EU have disproportionately larger share in bilateral trade. Theories of comparative advantage can explain why the Europeans would be advantaged in certain sectors, and the Canadian in others, according to the domestic embodiments of factors of production. Irrespective of the causes, these are two sectors where the Europeans do have a larger presence than the Canadians. This is not without implications, as liberalization can have for effects to reinforce the firms already exporting, which are more productive than their import-competing one (Melitz 2003; Melitz and Ottaviano 2008). Therefore, illimited regulatory cooperation in such sectors includes the risks that the Canadian industry become hostage of the Europeans leaders, and forced by their competition to align their production towards the European model.

This risk is well grounded in the realities of the sectors, as European firms in both sectors are occupying a different segment of the market, notably a higher one, by exporting “fine” food and “premium” cars”, which remains substitutable. From several interviews with different industry active in these two sectors, it appears that the European firms privilege the exportation of “premium” products (Industry C1-C5-C6, interview in Brussels). According to the interviewees, the regulatory frameworks designed in CETA, UNECE for Motor Vehicles & GIs for Agrifood, were meant to facilitate market access for these European specialized goods. Indeed, the Canadian

regulatory framework tended to penalize European cars, as it required additional costs to adapt the cars to North American requirements. For GIs, producers were complaining that misuse of geographical indications and symbols in Canada were harming their brands and restricted their access to Canadian market. The regulations adopted in CETA were thus aimed at solving these issues. Regulatory cooperation was thus supported by the actors of the European industry, especially as it could provide supports to a specific list of goods, considered politically important. As discussed now, this specialization in high quality goods plays an important role in explaining the regulatory conflicts between the Europeans and Canadians, and their related choices of design types.

### **The strategic importance of specific goods**

In CETA, GIs provisions in the agreement contain a comprehensive list of goods, notably cheese, which is recognized by both parties. UNECE regulations appear to be more generic, although they remain essential to produce specific cars. UNECE regulations listed in CETA targets certain technical features that relate to technology or design embedded in high-end cars' models, such as brake lights of the Mercedes A-class<sup>122</sup>. Statistical information also reflects the importance of these specific products. As presented at the Table 15 (appendix V), Europe's exports of Agrifood products are destined for household consumption, with the most important items being: wine, spirits<sup>123</sup>, beer, pasta & pastry, chocolate & ice-cream, cheese, olive oil and canned vegetables. By contrast, Canada's exports are concentrated mostly on four commodities: wheat, cereals, soybeans and vegetables, which are used as raw materials for food preparation, animal foodstuffs or other types of prepared foods. This dependency of Canada towards the exports of inputs or bulk Agri-food products is not without risks for Canada. As an illustration, the outside GIs case of the conflicts between Canada and Italy on Italian COOL (Country of Origin Labelling) requirements for durum wheat, post-CETA conclusion, is a good instance of such potential dependencies<sup>124</sup>. Canadian wheat producers saw one of their market of exportation suddenly

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<sup>122</sup> Lisa Monforton, The Globe and Mail, 27st February 2014, "Why we can't buy some popular European cars in Canada" <https://www.theglobeandmail.com/globe-drive/news/tale-of-the-red-tape-in-the-car-industry/article17119866/>, accessed the 1<sup>st</sup> August 2019.

<sup>123</sup> As Wine and Spirits were already covered by a previously concluded EU-Canada agreement in 2003, these commodities were not discussed during the CETA negotiation

<sup>124</sup> Amanda Stephenson, Calgary Herald, 17<sup>th</sup> July 2019, "Agriculture groups urging Europe to live up to CETA obligations as exports to EU fall", <https://calgaryherald.com/business/local-business/ag-groups-urging-europe-to-live-up-to-ceta-obligations-as-exports-to-eu-fall>, accessed the 30<sup>th</sup> May 2020.

closed due to a regulatory divergence, resulting in significant costs for them. This case is illustrative of the strategic role that specific commodities play in trade and regulatory negotiations and design choice.

The European specialization in the goods mentioned – mostly high-end transformed products - explain why the EU supported an ambitious regulatory harmonization mechanism that would recognize the higher quality of its exports and reinforce even further its competitive advantages in these two sectors. Acting as a label, Geographical Indications can help further European products to compete with other foreign products. The design choice of Type 1 reflects this preference. It allows the listing of specific commodity that will benefit extra legal protection. It was intentionally chosen as a privileged legal format to protect key products that are particularly significant for EU exporters, notably from a situation of hold-up as it took place, illustratively, for Canadian durum wheat exports to Italy.

In CETA, it was cheese that had a particularly strategic role, being the most cited item (57) among the 143 GIs contained in the list, followed by meat (34), and oil (21)<sup>125</sup>. This is not surprising as European cheese remains one of the most exported Agrifoods to Canada (Table 15: 4,5%) and benefitted within CETA from an additional Tariff-Rate-Quota (TRQs) of 16'000 tons<sup>126</sup>. The integration of GIs cheese into CETA, enable producers to increase their prices due to the improvement of quality perception by Canadian consumers (Duvaleix-Tréguer et al. 2018). The inclusion of Meat GIs into CETA appears odd, especially in light of the quasi absence of meat imports or exports from Canada<sup>127</sup>. Furthermore, European meat producers were rather worried that CETA offered potentials for Canadian producers to export to Europe<sup>128</sup>. The explanation could be that GIs are used also for defensive reasons, to compensate for the attribution to Canada of higher Tariff-Rate-Quota (TRQs) in meat products (60'790 tons for beef, and 80'000 tons for pork). The role of GIs as defensive shield from foreign imports was notably discussed at the

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<sup>125</sup> CETA, EC DG TRADE, [http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc\\_152806.pdf](http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf), p. 516-525 (counted manually) accessed, the 1<sup>st</sup> August 2019.

<sup>126</sup> Global Affairs Canada Notice to Importers, <https://www.international.gc.ca/controls-controles/prod/agri/dairy-laitiers/notices-avis/909.aspx?lang=eng>, accessed the 1<sup>st</sup> August 2019.

<sup>127</sup> Eurostats, Comtext, EU trade by SITC, Agri-Food Trade Statistical Factsheet: European Union – Canada, [https://ec.europa.eu/agriculture/sites/agriculture/files/trade-analysis/statistics/outside-eu/countries/agrifood-canada\\_en.pdf](https://ec.europa.eu/agriculture/sites/agriculture/files/trade-analysis/statistics/outside-eu/countries/agrifood-canada_en.pdf), accessed the 1<sup>st</sup> August 2019

<sup>128</sup> Liz Newmark, GlobalMeatnews, 1<sup>st</sup> November 2016, “EU meat industry voices concern over CETA”, <https://www.globalmeatnews.com/Article/2016/11/01/EU-meat-industry-concerned-by-CETA>, accessed the 21<sup>st</sup> May 2020.

European Parliament and was subsequently confirmed in writing by the European Commission<sup>129</sup>. In fact, the listed meat GIs would prevent Canadian meat producers to usurp the denomination and mix their exports with other similar products produced in Europe<sup>130</sup>. This is another instance of European attempts to use specialization with the purpose of keeping an edge over their potential Canadian competitors.

Coming back to the role of cheese, to understand the significance of this commodity the Canadian perspective must be included. Contrary to European firms' export ambitions, the Canadian dairy industry focused on the management of domestic production, which is centered around the domestic production of milk<sup>131</sup>. This supply management system has two main pillars: support prices and market sharing quota<sup>132</sup>. At the heart of it, the Canadian Dairy Commission acts as an umbrella organization for milk producers and processors, represented by provincial organization (e.g. "les producteurs de lait du Québec"). This commission negotiates collectively to fix prices, quantity and general production conditions at the provincial level<sup>133</sup>. On the other hand, this centralized system limits the specialization of dairy products. After production, the milk is transported into a provincial centralized center, from which it is distributed towards the different dairy actors<sup>134</sup>. This centralized milk collection renders more difficult the task to separate different types of milk to produce specialized food (Industry A3, interview in Ottawa). Stored and mixed together, the milk originating from different producers becomes undistinguishable. Consequently, the Canadian dairy production is not characterized by high quality and limits the ability of the industry to compete against EU exports. In addition, it is to be recalled that since the resolution of the WTO dispute DS103 *Canada - Measures Affecting the Importation of Milk and the*

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<sup>129</sup> Government of Canada, "True or false? Facts and myths about CETA", [https://www.canadainternational.gc.ca/belgium-belgique/bilateral\\_relations\\_bilaterales/Myths\\_and\\_Realties\\_CETA\\_mythes\\_et\\_Realites.aspx?lang=eng](https://www.canadainternational.gc.ca/belgium-belgique/bilateral_relations_bilaterales/Myths_and_Realties_CETA_mythes_et_Realites.aspx?lang=eng), accessed the 2<sup>nd</sup> August 2019.

<sup>130</sup> Miguel Viegas MEP, European Parliament, Parliamentary question : CETA and meat import quotas, 29 September 2016, [http://www.europarl.europa.eu/doceo/document/E-8-2016-007239\\_EN.html?redirect](http://www.europarl.europa.eu/doceo/document/E-8-2016-007239_EN.html?redirect), accessed the 2<sup>nd</sup> August 2019.

<sup>131</sup> Government of Canada, Canada's Dairy Industry at a Glance: [https://www.dairyinfo.gc.ca/index\\_e.php?s1=cdi-ilc&s2=aag-ail](https://www.dairyinfo.gc.ca/index_e.php?s1=cdi-ilc&s2=aag-ail), accessed the 5<sup>th</sup> July 2019.

<sup>132</sup> Canadian Dairy Commission, <http://www.cdc-ccl.gc.ca/CDC/index-eng.php>, accessed the 6<sup>th</sup> July 2019.

<sup>133</sup> Les producteurs de lait du Québec, « La gestion de l'Offre » <http://lait.org/leconomie-du-lait/la-gestion-de-loffre-et-la-mise-en-marche-collective/>, accessed the 6<sup>th</sup> July 2019.

<sup>134</sup> Ibid, « Les producteurs de Lait du Québec » <http://lait.org/notre-organisation/les-producteurs-lait-du-quebec/>, accessed the 6<sup>th</sup> July 2019.

*Exportation of Dairy Products* with the mutually agreed solution with US, Canada is not allowed to export dairy products that benefitted from its supply management system<sup>135</sup>

Therefore, for Canada the possibility for its industry to export in the EU is simply legally prohibited. That does not mean that an industry outside the supply management system specialized in high end products could not appear in Canada. Nevertheless, such as shift from the current industry structure as just described would be particularly costly and would imply competing with already well-established European competitors. Cooperation is thus not without problematic implication from a Canadian perspective. Very substantial risks existed for Canada that the Europeans exploited in the future the cooperation mechanism to even further reinforce their advantage in the Canadian market.

The choice of design type in GIs appears thus as a balance exercise for states, between the export and defensive interests of different European and Canadian firms. Indeed, the Europeans were also worried that Canadian meat producers would exploit the TRQs to obtain new market share in the EU. A compromise needed thus to be found between the wishes of the Europeans to obtain recognition for a certain number of specific goods while reducing the scope of this cooperation to avoid a hold-up situation against Canadian interests. The design provides thus a limited list of goods protected by CETA, while restricting the possibility to extend this list beyond the compromise achieved in CETA.

As explained by a European negotiator (Official D7, interview in Brussels), the GIs system is a cornerstone of the European agriculture sector. For any trade agreement to be accepted internally, it is imperative that the European Commission includes in the treaty sufficient safeguards that would protect and promote key commodities for European member states (e.g. Parmigiano Reggiano, see further) (Industry C1, interview in Brussels). This explains the choice of the design Type 1. It reflects the limited and specificity of European interests, *in fine* concentrated in a small sub-set of food commodities. At the same time, its limited Ex-post revision clause is explained by Canadian difficulties in adapting to such a fundamentally different economic structure as explained in later parts.

This situation is found similarly within the Motor Vehicles sector. According a report published by the Canadian Centre for Policy Alternatives (CCPA), it affirmed that Europeans export mostly

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<sup>135</sup> WTO, Dispute Settlement, “DS103: Canada — Measures Affecting the Importation of Milk and the Exportation of Dairy Products”, [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds103\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds103_e.htm), accessed the 20<sup>th</sup> May 2020.

assembled vehicles to Canada<sup>136</sup>. The models exported are concentrated in the “high-end segment” of the market, which is summarized to mainly four different brands: Mercedes/Daimler, BMW, Volkswagen, and Audi<sup>137</sup> (Table 16, Appendix V). In contrast, Canadian manufacturers export mostly auto parts to the EU, with a small number of assembled units being shipped. Canada remains one of the largest importers of cars globally, with 78% in 2012 of all their total sales originating outside its borders, while Europe imports marginally from outside the continent (14% of global sales in 2012) (Thelle et al. 2014). From secondary accounts, it seems that before the entry into force of the agreement Canada was exporting more or less 10,000 vehicles a year (baseline 2012)<sup>138</sup>, predominantly lower end vehicles of the brands Ford, Honda and Toyota<sup>139</sup>. Interviews with Canadian officials and European industry confirmed this overall picture of a European continent specialized in the export of high-end cars, counterbalanced by a Canadian regional hub focusing on assembling producing motor vehicle parts and lower end cars (Industry & Officials A1-B2-B4-C6, Interviews in Brussels & Ottawa).

Once again, the market segments mainly occupied by European firms in these two sectors are different from Canadian producers. This implies that not only European firms export more products, but also more valuable goods than Canadian producers. Canadians on their side are in a more precarious position, occupying an upstream segment of the value chains and highly integrated within intermediary phase of the value chains. This made them more sensitive to supply chain disruptions and thus more prone to be subject of hold-up threats from the U.S. but also from the EU in case of wide regulatory changes towards the European system. Europeans are less vulnerable to this possibility due to the intra-European nature of their value chain segment. The MV sector shares thus the same characteristics as the GIs, with two sectors where one of the actors has an advantage in terms of specialized commodities and occupies a segment of the value

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<sup>136</sup> Jim Stanford, Canadian Centre for Policy Alternatives, “CETA and Canada’s Auto Industry Making a Bad Situation Worse”, 27<sup>th</sup> May 2014, p. 10: “<https://www.policyalternatives.ca/publications/reports/ceta-and-canada%E2%80%99s-auto-industry>”, accessed the 21st May 2019.

<sup>137</sup> Ibid., 13p.

<sup>138</sup> Bill Curry, Barrie Mckenna, the Globe and Mail, 18<sup>th</sup> October 2013, “Canada’s auto industry faces sweeping change with EU trade deal”, <https://www.theglobeandmail.com/report-on-business/international-business/canadas-auto-industry-faces-sweeping-change-with-europe-trade-deal/article14925024/>, accessed the 6<sup>th</sup> July 2019; Department of Foreign Affairs, Trade and Development, “Technical Summary of Final Negotiated Outcomes,”: [https://archive.org/stream/812782-ceta-final-negotiated-outcomes/812782-ceta-final-negotiated-outcomes\\_djvu.txt](https://archive.org/stream/812782-ceta-final-negotiated-outcomes/812782-ceta-final-negotiated-outcomes_djvu.txt), accessed the 6<sup>th</sup> July 2019.

<sup>139</sup> Jim Stanford, Canadian Centre for Policy Alternatives, “CETA and Canada’s Auto Industry Making a Bad Situation Worse”, 27th May 2014, p. 15: “<https://www.policyalternatives.ca/publications/reports/ceta-and-canada%E2%80%99s-auto-industry>”, accessed the 21st May 2019.

chain less vulnerable to “hold-up” attempts. On the contrary, their negotiating counterpart produces fewer specific “commodities” and is more vulnerable to foreign competition.

Similarly to the case of GIs, experts from both sides adopted in the agreement a design type that reflected the specificity of the commodities produced by one country (EU), while limiting the extent of the cooperation to avoid a future “hold-up” situation. The design included a clear list of jointly recognized and enforceable regulations, which explicitly targets these specialized goods from the EU (Industry C6, interview in Brussels ). It provides a legal format sufficiently detailed to identify and include specific regulations. This is beneficial for the Europeans as the Canadian regulatory framework tended to impose significant regulatory adjustments on European cars to be able to enter the Canadian market. The same issue was present for GI as European food producers were not able to defend misuse of geographical indications and symbols (e.g. the Italian flag) and were sometimes prevented from entering the Canadian market.

States representatives were aware of these issues and as more thoroughly discussed in the next section 6.2 on shirking risk, design the bilateral cooperation through binding obligation, requesting Canadian and European regulators to recognize and accept the exact product concerned by the regulations. This is particularly the case of UNECE regulations, as both sides established a joint list of recognized regulations. This joint approach is less visible in GIs as Canada has let empty its section dedicated to the GIs it could have asked the EU to recognize. Nevertheless, in both cases the design contains a highly precise list of products and regulations to be jointly recognized by both parties.

Even though UNECE regulations’ focus on parts instead of finished products such as in GIs, the regulations they list are essential and reflect the specificity of the vehicles produced by European car manufacturers<sup>140</sup>. In fact, they target certain types of technology or components embedded in more high-end cars’ models, such as brake lights in Mercedes A-class<sup>141</sup>. Divergence in light technologies between US and the EU on headlight technology was a long-standing issue between the two regulatory regimes, which added regulatory costs to premium European car exports<sup>142</sup>.

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<sup>140</sup> European Automobile, Manufacturers Association website (ACEA), ACEA guidelines for FTAs: <https://www.acea.be/news/article/acea-guidelines-for-ftas>, accessed the 2 July 2019.

<sup>141</sup> Lisa Monforton, The Globe and Mail, “Why we can’t buy some popular European cars in Canada”, <https://www.theglobeandmail.com/globe-drive/news/tale-of-the-red-tape-in-the-car-industry/article17119866/>, accessed the 6<sup>th</sup> July 2019

<sup>142</sup> Center for Automotive Research, “Potential Cost Savings and Additional Benefits of Convergence of Safety Regulations between the United States and the European Union”, <https://www.autonews.com/assets/PDF/CA106125713.PDF>, p. 14, accessed the 6<sup>th</sup> July 2019.

Indeed, the U.S. standard FMVSS 108, equivalent in Canada with the standard CMVSS 108<sup>143</sup>, prevented the use of this type of technology (adaptive driving beam headlight), which is commonly integrated in high-end cars produced in Europe, for instance Audi<sup>144</sup>. Following CETA equivalences between CMVSS 108 and UNECE regulation No 98, 112, 113, this regulatory burden was however removed<sup>145</sup>.

To understand how states from both sides were able to come up jointly in designing this cooperation, especially in light of Canadian producers' vulnerability, it is key to stress a few facts. Europeans focus on specific market "niches", where brands and specific labels could provide their producers premiums in pricing. Second, European firms' large exports imply that Canadian consumers are demanding these types of products<sup>146</sup>. From a dyadic perspective, higher exports equate higher demand and reflects consumers' decision to consume more of certain products. The role that Canadian demands are playing is also illustrated by the decision of the Canadian government to attribute 50% of import quota to cheese retailers and distributors despite the Canadian dairy industry's opposition<sup>147</sup>. This allowed Canadian retailers to import highly demanded European cheese and catch part of the profit resulting from the sale of European products in Canada<sup>148</sup>. In fact, retailers can profit from consumer demand by profiting from the surge of product arrival. A similar logic can be applied to motor vehicles, where concerns are raised among retailers and some parts producers over the lack of access or price differences on certain premium cars<sup>149</sup>. In its response to the request for submission from the Canadian

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<sup>143</sup>Cornell Law School. Legal Information institute, "49 CFR § 571.108 - Standard No. 108; Lamps, reflective devices, and associated equipment", <https://www.law.cornell.edu/cfr/text/49/571.108>, accessed the 6<sup>th</sup> July 2019.

<sup>144</sup>Larry p. Vellequette, Automotive News, "NHTSA's proposed rule change should help tame headlights", <https://www.autonews.com/article/20181029/OEM03/181029812/nhtsa-s-proposed-rule-change-should-help-tame-headlights>, accessed the 5<sup>th</sup> July 2019.

<sup>145</sup> Eric A. Taub, The New York Times, "Smart Headlights Inch Closer to American Roads", <https://www.nytimes.com/2018/11/21/business/headlights-adb-high-beams.html>, accessed the 5<sup>th</sup> July 2019.

<sup>146</sup> Susan Greer, "Cheese, please: Canada's artisanal cheese market small yet growing", <https://globalnews.ca/news/1281438/canadas-artisanal-cheese-market-small-yet-growing/>, accessed the 5<sup>th</sup> July 2019.

<sup>147</sup>Dairy Processors Association of Canada, Canada-EU Comprehensive Economic and Tarde agreement (CETA): <http://www.dpac-atlc.ca/what-we-do/international-trade/ceta-trqs/>, accessed the 5<sup>th</sup> July 2019.

<sup>148</sup>CBC, 1<sup>st</sup> August 2017, Canada carves out more European cheese for retailers after EU concerns, <https://www.cbc.ca/news/politics/ceta-cheese-trqs-1.4230138>, accessed the 5<sup>th</sup> July 2019.

<sup>149</sup> Lisa Monforton, The Globe and Mail, "Why we can't buy some popular European cars in Canada", <https://www.theglobeandmail.com/globe-drive/news/tale-of-the-red-tape-in-the-car-industry/article17119866/>, accessed the 6<sup>th</sup> July 2019; CTV News, "How the trade agreement with the EU could benefit Canada", <https://www.ctvnews.ca/business/how-the-trade-agreement-with-the-eu-could-benefit-canada-1.3134117>, accessed the 6<sup>th</sup> July 2019.

government concerning the next meeting of the CETA Regulatory Cooperation Forum (RCF), Global Automakers of Canada, an association representing car equipment producers in Canada, stressed:

Current barriers exist to bringing current advanced propulsion technology vehicles to Canada from Europe due to the costs to homologate such vehicles for the Canadian CMVSS standards, particularly the costs associated with crash testing by Transport Canada, are prohibitively exorbitant, and this undermines any efforts by a Canadian entity to qualify such vehicles for Canada, when the anticipated sales volumes are small<sup>150</sup>.

Consumer demand played a significant role even though it did not express itself through collective organization and mobilization. It is an interesting component of the value chains (namely distribution phase) and the economic interdependence between the two countries. By focusing on the downstream part of the chain, European manufacturers are in a more favorable position to target consumers and obtain higher surplus through quality perception.

In both sectors, the fact that the demand was focused on specialized vehicles not produced in Canada appear to have played a significant role in states' decision to use a design Type 1. Canada's aim was to circumvent the regulatory implications of GIs and UNECE as much as possible to remove any threats for its own producers (Officials and Industry A1-A3-A4-B2-B4, interviews in Ottawa). An Ex-ante feature was more suited for this purpose than Ex-post. By keeping the regulatory harmonization short-term and unique, it offered concessions to the European and limits future danger for the local industry. Ex-post on the other hand would have been probably less painful at first but could have instead deeply disrupted the Canadian economic structure, fundamentally different from the European one. Post-CETA conclusion, this argument is corroborated by interviews with negotiators stressing how these regulatory changes in Type 1 will have a low impact in their own production structure. Their comments reflected their main concerns during the negotiations. Canadian negotiators attempted to balance European requests for cooperation with Canadian producers' concerns that long term regulatory adjustment would upset their value chains and create undue competition on their soil. At the same time, they also

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<sup>150</sup> Submission in Response to the Canada Gazette Part 1 Notice Request for Stakeholder Comments on the Canada-European Union Comprehensive Economic and Trade Agreement Regulatory Cooperation Forum, Global Automakers of Canada, April 2018: <https://open.canada.ca/data/en/dataset/c45c4cdaf134-4e65-8e99-5214eb07bcf3>, p. 3, accessed the 6th July 2019.

took into consideration the consumer benefits that regulatory adjustments would provide, a consequence of the ongoing interdependent economic relations between the two countries.

As mentioned, the CETA GIs and Motor Vehicles cooperation schemes include only a few selected commodities and regulations, which had a strategic importance during the negotiation. This disproportionate role is not fortuitous. It is the result of a deep economic structure embedded in different types of complex value chains. This economic structure facilitated European firms in coordinating with each other and on agreeing on a list of common technical regulations and specific commodities. It provided them the ability to limit competition—especially regulatory competition—between them and obtain higher margin. As said earlier, cheese in GIs is one of the most important agri-food traded commodities across the two regions and one of the new and most cited commodities listed in the design Type 1 within CETA.

As mentioned during this sub-section, the European Commission has a list of goods, notably GIs, that are particularly politically sensitive and can derail the negotiation if mishandled. Considering that trade agreements need to be accepted and ratified by all member states, each country has a veto power on the whole trade agreement. They often intervene preliminarily in the negotiating mandate, constraining then the EC during the negotiation. The facilitation of market access for these commodities becomes a necessary condition for the negotiation to be then ratified by EU members and institutions. As seen, these types of specific commodities provide a substantial surplus for the firms trading them, advantaging the countries where these firms are located.

At the year of the conclusion of the agreement (2017) the most imported cheese from Europe, within Canada WTO and CETA TRQs, is “Parmesan cheese” with 4,164 tons being imported (Table 17). The second one is Gouda with 2,672 tons and the third Cheddar with 1,210 tons. By comparing the different imports from EU and Non-EU sources, Parmesan also appears to be a European exclusivity, as it is marginally sourced from Non-EU origins compared to Cheddar and Gouda. Italy being the largest exporter of dairy products to Canada<sup>151</sup>, parmesan is thus a key product for overall European dairy exports<sup>152</sup> with a particular important political dimension for domestic acceptability-.

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<sup>151</sup>EC, “The EU-Canada Comprehensive Economic and Trade Agreement (CETA): Opening up a wealth of opportunities for people in Italy”, [http://trade.ec.europa.eu/doclib/docs/2017/february/tradoc\\_155349.pdf](http://trade.ec.europa.eu/doclib/docs/2017/february/tradoc_155349.pdf), accessed the 6<sup>th</sup> July 2019.

<sup>152</sup> News Italian Food, “Parmigiano Reggiano, Exports Share Exceeds 40%”, <https://news.italianfood.net/2019/04/17/parmigiano-reggiano-exports-share-exceeds-40/>, accessed the 6<sup>th</sup> July 2019.

To understand how these commodities play such a significant role for their country of production, which justifies designing an entire and separate distinct regulatory mechanism, requires looking at the production structure and the value chains of these sectors. Even though the link between these production conditions and the design chosen in PTAs is less apparent, they established a fundamental background that explains the emergence of strategic commodities, which are then subjects of international negotiations.

### Comparing supply chains structure

At first, there are merits in looking at the production conditions of GIs, especially above mentioned “Parmigiano Reggiano”, the most exported European Cheese in Canada. “Parmigiano Reggiano” production is organized through a consortium of producers<sup>153</sup> located in the provinces of Parma, Reggio Emilia, Modena, Bologna (North Italy), all jointly following common chemical composition and processing requirements<sup>154</sup>. These technical characteristics are agreed among a small group of organized producers, which supports the implementation of the EU decision to recognize the GI: “Parmigiano Reggiano”<sup>155</sup>. The organization also specifies the rules of production required to receive the recognition of the indication<sup>156</sup>.

While this type of organization varies among commodities, Article 36 of the EU regulation 1151/2012 on quality schemes for agricultural products and foodstuffs requires that member states designate a competent authority to control product quality<sup>157</sup>. This condition reduces the possibility for fraudulent producers to enter the market and thus limits easy access for producers within the sector. Therefore, the production and export market are organized and concentrated

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<sup>153</sup> Consorzio del Parmigiano-Reggiano, <https://www.parmigiano-reggiano.it/>, accessed the 6<sup>th</sup> July 2019.

<sup>154</sup> Consorzio del Parmigiano-Reggiano, «scopri i valori nutrizionali del parmigiano reggiano», [https://www.parmiganoreggiano.it/come/caratteristiche\\_nutrizionali/scopri\\_valori\\_nutrizionali\\_parmigiano\\_reggiano\\_3.aspx](https://www.parmiganoreggiano.it/come/caratteristiche_nutrizionali/scopri_valori_nutrizionali_parmigiano_reggiano_3.aspx), accessed the 6<sup>th</sup> July 2019.

<sup>155</sup> Gazzetta ufficiale dell'Unione europea, « DOCUMENTO UNICO

“PARMIGIANO REGGIANO N. UE: PDO-IT-02202 – 14.11.2016 DOP ( X ) IGP”, <https://www.parmiganoreggiano.it/tma/disciplinare/Documento%20Unico%20Parmigiano%20Reggiano%20DOP.pdf>, accessed the 6<sup>th</sup> July 2019.

<sup>156</sup> “DISCIPLINARE DI PRODUZIONE DEL FORMAGGIO PARMIGIANO REGGIANO”, [http://www.parmiganoreggiano.com/download\\_20081223\\_disciplinare\\_esameue\\_parmigiano\\_reggiano.pdf](http://www.parmiganoreggiano.com/download_20081223_disciplinare_esameue_parmigiano_reggiano.pdf), accessed the 6<sup>th</sup> July 2019.

<sup>157</sup> EUR-Lex, “Regulation (eu) no 1151/2012 of the European parliament and of the council of 21 November 2012 on quality schemes for agricultural products and foodstuffs”, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R1151&from=EN>, accessed the 6<sup>th</sup> July 2019.

among a small group of firms, localized in the same region and following common minimal technical requirements. This does not imply that competition among themselves is absent but rather that it is organized within common regulatory frames, set by public and private actors.

This minimal common denominator allows producers of “Parmigiano Reggiano” to come up as a single group and provide EU member states a list of specific commodities that can provide significant surplus. In other words, this tightly locally coordinated network of producers allows the creation of specialized commodities that are similarly produced by several firms. It acts as a negotiating buff for European negotiators by creating an important coalition of export-driven firms that can consensually lobby for the same preferences. It explains why European negotiators had strong incentives to include these products in the agreement. For the EU, obtaining a GI recognized in the design Type 1 is not only beneficial for the industry but also to gather political support from member states for the approval of the agreement (Industry C1, interview in Brussels).

The state of the Canadian cheese industry contrast significantly with the European one. It appears at first glance to be localized and organized similarly. According to the government of Canada, 75% of the milk produced in Canada is processed by three large corporations: Saputo, Agropur and Parmalat<sup>158</sup>. 81% of Canadian dairy farms (total population: 11,280) are divided between two main provinces: Ontario and Quebec<sup>159</sup>. The industry produces 667 distinct varieties of Canadian cheese, 71.5% originating from Quebec and 18.7% from Ontario. In sum, the Canadian dairy industry is a tightly managed market, controlled by major corporations.

Nevertheless, there are fundamental nuances that explains Canadian positioning in the sector. Despite their sizes, none of these firms can claim control over a single product, unlike the holders of “Parmiggiano Reggiano” GI. While certain trademark requirements apply, each of these groups are free to marketize similar products under different brands in direct competition with each other. Furthermore, common technical requirements are not required, which implies that each firm is free to produce in the manner it wants if it respects the basic sanitary requirements of the Canadian government. The market remains fragmented between different competing brands, selling similar products. This is particularly visible when visiting the websites of the three main producers

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<sup>158</sup> Agriculture and Agri-Food Canada, “Canada’s Dairy Industry at a glance”, 2009, [https://www.dairyinfo.gc.ca/pdf/At\\_a\\_glance\\_e\\_2009.pdf](https://www.dairyinfo.gc.ca/pdf/At_a_glance_e_2009.pdf), accessed the 6<sup>th</sup> July 2019.

<sup>159</sup> Agriculture and Agri-Food Canada, “Canada’s Dairy Industry at a glance”, 2016, [http://publications.gc.ca/collections/collection\\_2017/aac-aafc/A71-25-2016-eng.pdf](http://publications.gc.ca/collections/collection_2017/aac-aafc/A71-25-2016-eng.pdf), accessed the 6<sup>th</sup> July 2019.

(Saputo, Agropur, Parmalat), all of which have developed different brands proposing different types of cheese<sup>160</sup>. Furthermore, the existence of alternative smaller dairy producers, even if marginal, provides some additional choices to consumers and retailers to source their products. Independent players can enter the market and propose their own version of the product.

Overall, the Canadian dairy market remains relatively geographically concentrated, not far from the European one. Nevertheless, this concentration is not organized around single products. Indeed, even if Canadian producers opposed GIs on principle, they did not agree on similar regulatory requirements that could have been integrated into the design of the cooperation. Members of Canadian associations are major dairy companies that are involved in all different sorts of products and in competition with each other. They do not have a strategy of exports around a limited number of specific items. On the contrary, an interview with a Canadian trade association reveals that they were resigned to the integration of GIs in CETA and did not have any interests other than defending the domestic supply management system they benefitted from it (Industry A3, interview in Ottawa). Consequently, the difficulties for Canadian firms, to organize their similarly located production around jointly agreed upon technical requirements, reduced Canada ability to integrate these interests into the regulatory cooperation scheme. On the contrary, the priority was to limit as much as possible long-term cooperation, which could extend GI protection to the wide range of dairy products and derivatives produced by the main corporations. Ensuring that the cooperation scope would be temporally and the smallest possible in terms of content was the main objective of the negotiators (officials B2-B4-D7, interviews in Ottawa & Brussels).

A counterfactual logic of reasoning would indicate that if the Canadian dairy Industry was able to organize themselves and start producing specific high-quality goods, states could have designed the cooperation differently through a more open-ended cooperation system, taking into consideration the differences of technical approaches between European and Canadian firms. This would have been even easier if Canadian firms were also exporting specific products with specific characteristics. An Ex-post design would have been ideal in this context as it would have made it possible to encompass all these divergences into an institutionalized mechanism. By providing a long-term mechanism, cooperation could have progressively led to another type of technical process during which products/regulations on both sides would have been recognized

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<sup>160</sup> Agropur, “our trusted brands”, <https://www.agropur.com/en/our-brands>; Saputo, “Canada sector”, <https://www.saputo.com/en/our-products/canada-sector>; Parmalat, “our brands” <https://parmalat.ca/our-brands/>, all accessed the 6<sup>th</sup> July 2019.

progressively, on a case-by-case basis. The absence of similar production structure in the Canadian side renders this mechanism less pertinent for the objective of liberalization resulting in risks of “hold-up”.

Indeed, the weakness of the Canadian system to produce specific high-quality goods and the highly competitive nature of their market, renders regulatory adjustment towards a GIs system particularly “contentious”. If Canada aligns its regulatory arrangement too close, especially without re-structuring its industry, its producers might get overwhelmed by European specialized products, potentially benefitting from a higher quality perception. Especially as its regulatory system is deeply divergent from the European one (see next section 6.2), the full replacement of Canadian corporations’ trademark rights by GIs for a certain number of foodstuffs products, popular among Canadians consumers, could put the industry in a precarious position. This is particularly the case as Canadian firms have rather invested in the expansion of their production capacity, notably with a focus on ensuring sufficient income to their milk producers, with a lesser focus on the downstream aspect of the value chain contrary to European producers. Reverting this path implies even more investment that could take the entire industry in hostage, especially if Europeans decide to nominate new GIs even before Canadian firms are able to nominate their own. The results might be the exclusion of an important number of Canadian players from the dairy market under drastic regulatory changes, with a few survivals for whom investments were successful.

A similar scenario is observable for MVs. Like GIs, the Motor Vehicle sector in Europe is also characterized by a strong geographic concentration of exporting firms. As seen previously, the EU mostly exports four brands of cars to Canada: Audi, BMW, Mercedes-Benz and Volkswagen. All these brands belong to German companies and are produced in Germany. In fact, according to Eurostat 55% of all the EU car exports to the world originate from Germany (Table 18). The second country far below is the UK with 17.3%. Such a concentration within German territory partly found its roots in the fact that the motor vehicle value chain remains largely a regional integration story (Sturgeon et al. 2009). Germany still has the largest concentration of Original Equipment Manufacturers (OEM) in Europe, with 40 sites within its borders<sup>161</sup>. The country also

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<sup>161</sup> GTAI, “the automotive industry in Germany”, [https://www.gtai.de/GTAI/Content/EN/Invest/\\_SharedDocs/Downloads/GTAI/Industry-overviews/industry-overview-automotive-industry-en.pdf](https://www.gtai.de/GTAI/Content/EN/Invest/_SharedDocs/Downloads/GTAI/Industry-overviews/industry-overview-automotive-industry-en.pdf), accessed the 7<sup>th</sup> July 2019.

produced 70% of all premium cars in the continent and remains one of the largest industries within the manufacturing sector in the country, notably leading in R&D investment<sup>162</sup>.

Domestic German suppliers are also responsible for 70% of the added value of the cars, while 78% of the cars produced in 2017 are destined for export markets<sup>163</sup>. Germany remains thus a localized manufacturing center, with a production oriented towards export markets. This feature was already identified in the literature. T.J. Sturgeon et al (Sturgeon et al. 2009, 9) noticed the overemphasis of the motor vehicle sector on regional/local integration rather than on global value chains as is the case with apparel and electronics. They explain this feature by political sensitivities around the car industry, which put pressure on manufacturers to keep their operation within the borders or at least close to their originating country (Sturgeon et al. 2009, 22). As production focused on the downstream segment, it is planned to respond to immediate demand instead of holding large stocks, privileging shorter production chains. It becomes then possible to check that imported parts and equipment corresponds to required technical characteristics, notably UNECE regulations required by EU motor vehicles regulations (discussed in later section). The German motor vehicle sector made the choice to privilege the integration of its production with Eastern Europe instead of massive outsourcing outside the continent. In 2014, the contribution of Easter European firms accounted for 10% of value added in the German motor vehicles & trailers sector<sup>164</sup>. Geographically, these Imports originate from Poland, Czech Republic, Slovakia, Hungary and Romania (Frigant and Zumpe 2017, 670).

For the European car industry, the downstream focus of the value chains explains partly why the recognition of specific and limited regulations as equivalent plays such an important role. As the manufacturing plants are all located in Germany and without plans to expand production activities in Canada (Industry C6, interview in Brussels), there are no real interests in full harmonization. Instead, the priority is rather promoting market access for specialized cars that are penalized by regulatory costs imposed due to specific foreign regulations. While complete recognition would potentially be welcome, political sensitivities prevent the realization of globalized integration that could be enabled by a common regulatory system. Limited regulatory adaptations are thus “enough” as long as they target specific technologies that are costly for particular types of cars.

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<sup>162</sup> Ibid.

<sup>163</sup>ibid, p. 6

<sup>164</sup> Global Economic Dynamics, “How the German Economy is Connected to Eastern Europe”, <https://ged-project.de/ged-blog/fostering-economic-integration-through-international-trade-investment/how-the-german-economy-is-connected-to-eastern-europe/>, accessed the 7<sup>th</sup> July 2019.

Type 1 is thus a reflection of this European car industry focus, especially in negotiation with Canada.

Canadian MV industry features also acted as a factor limiting thorough regulatory harmonization. Like Europe, North America is largely regionally integrated with 75% of all auto-parts sourced from within NAFTA<sup>165</sup>. However, and contrary to Germany, Canada does not have domestically owned OEM on its territory. Canadian MV firms are rather a network of upstream regionally active national suppliers. These suppliers are mostly integrated with large firms, notably GM, Ford and Fiat Chrysler Automobiles (FCA), located around the Great Lakes states (GLS) between Canada and the U.S. 65% of automotive parts exports are destined to these states, where most assembling operations are present<sup>166</sup>. In terms of light vehicle production, where Canada is an important player, FCA, Ford and GM produced 55.27% of production in 2019 with relatively equal shares<sup>167</sup>. This trend remains largely constant since 2012 and shows a certain level of concentration among these three firms. In terms of production and exports, Canada is estimated to have exported 85% of its production to the U.S.<sup>168</sup>. It is worth mentioning that the motor vehicle industry is a key sector for Canada's external trade, occupying the second rank of its global exports in 2017 with 14,8%<sup>169</sup>.

Overall, the Canadian auto industry is distributed geographically in four regions around the GLS. The country's automobile sector is deeply integrated into North American production chains, mostly dominated by U.S. firms (Ford, GM and FCA), with a sizeable Japanese presence (Toyota, Honda). Its networks of suppliers and specialized parts producers is concentrated around this regional hub, where they collaborate with these motor vehicle giants. While relatively concentrated geographically, it remains the case that the absence of a Canadian national OEM

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<sup>165</sup> John Holmes, CCPA, "The Future of the Canadian Auto Industry", <https://www.policyalternatives.ca/publications/reports/auto-future>, p. 10, accessed the 6<sup>th</sup> July 2019.

Ibid.. P. 10; This cluster around the GLS targets mostly activities centered on vehicle assembly, equipment parts, auto-related MTDM (Machine, tool, die and mold), AI and Connected Vehicle – Autonomous Vehicle. It regrouped an important grouping of different firms, which include cars giants such as FCA, GM and Toyota but also the Canadian technological firm Blackberry and other small tech companies. With this cluster, Ontario plays a particular role with several operating car and/or light truck assembly plants producing models for several of these big firms and others, including Toyota and Honda. Three other clusters are also present in the Canadian territory: Manitoba (Buses and Cold weather testing), Quebec (heavy truck, buses, light metals, electric vehicle components), and British Columbia (Fuel cell)<sup>166</sup>.

<sup>167</sup> Canadian Vehicle Manufacturers' Association, "Automotive Industry Statistics", <https://www.cvma.ca/fr/lindustrie/donnees-statistiques/>, accessed the 6<sup>th</sup> July 2019.

<sup>168</sup> John Holmes, CCPA, "The Future of the Canadian Auto Industry", <https://www.policyalternatives.ca/publications/reports/auto-future>, p. 6, accessed the 6<sup>th</sup> July 2019.

<sup>169</sup>OEC, « Canada », <https://atlas.media.mit.edu/en/profile/country/can/>, accessed the 6<sup>th</sup> July 2019.

encourages alignment with foreign regulatory requirements, as its networks of small firms remain dependent on the decisions taken by major foreign firms, notably in terms of investment for R&D and manufacturing plant<sup>170</sup>. Thus, while certain major Canadian suppliers distinguished themselves at the global level (e.g. Magna International, Linamar, Martinrea, Woodbridge)<sup>171</sup>, the country lacks domestically based manufacturer exporters selling finished products across the globe.

As it appears, the need for upstream Canadian industry to maintain its integration with U.S. firms has implications for the choice of legal design. Faced with European motor vehicle firms, Canada cannot pretend to export its own regulations as its networks of firms is tightly integrated with mostly Non-European manufacturers. It is neither in a position to align fully with the European system. For this cluster of loose firms, access to U.S. markets is a key necessity to survive. Thus, accepting UNECE regulations is possible only in a limited capacity, to eventually provide diversification avenues, while not compromising the regional production chains. In this context, it appears better for Canadian states to recognize a limited number of binding regulations instead of a more long-term mechanisms that might interfere with the North American supply chain, such as regulatory design of Type 2.

Regulatory design of Type 1 appeared to have been a strategically crafted compromise as in GIs. Not only does it improve market access for the tightly coordinated European exporters but also it does not put the production structure of Canadian manufacturers in danger of a European “hold-up” risk similar that the existing one in GIs. It limits the cooperation to a specific set of products and generally does not require Canada to convert its production systems towards the UNECE system. As described in the textual analysis of section 5.1, the cooperation scheme schedules only 17 regulations to be compulsorily legally recognized by Canadian authorities. Canada recognizes these limited regulations; it is free to continue using Canadian and U.S. standards for its production destined to its main U.S. market. This argument is indirectly supported by interviews with officials emphasizing that recognition of UNECE regulations or GIs in CETA remained limited and did not affect their supply chains (Officials B2-B4, interviews in Ottawa).

In sum, despite a certain level of consolidation in GIs and Motor Vehicles, Canadian producers do not have the same level of concentrated organization of firms dedicated to exports, as the

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<sup>170</sup> John Holmes, CCPA, “The Future of the Canadian Auto Industry”, <https://www.policyalternatives.ca/publications/reports/auto-future>, accessed the 6th July 2019.

<sup>171</sup> John Holmes, CCPA, p. 10 “The Future of the Canadian Auto Industry”, <https://www.policyalternatives.ca/publications/reports/auto-future>, accessed the 6th July 2019.

Europeans. Either Canada's sectors are composed of giant producers (Saputo, Agropur and Parmalat) oriented mostly towards the domestic market with few external interests; or are well integrated into regional & global supply chains but constitute rather a fragmented nexus of small firms (Ontario for Motor Vehicles). On the contrary, the Europeans have a limited number of firms, structured together to facilitate trade towards international markets. They are geographically strictly bounded (e.g. Germany for cars & North-Italian region for Parmigiano) and follow a similar production structure with tight coordination (Eastern-Europe integration, Consortium based). While competition remains, their specific exports dominate foreign markets (premium cars, cheese) allowing them to "share" external gains. This prevents them from excluding each other and enables them to adopt a limited competition model instead. On the contrary, Canadian producers are not able to present a united front on the matter of EU exports. Moreover, they are also unable to organize themselves when it comes to Canadian exports. Due to their fragmented structure and internal competition, these firms cannot prevent EU imports and the limited substitutability of quality European products renders the risks of "hold-up" for the Canadian government even more present. Canadian firm's inward orientation pushes them towards competition among each other, especially for dairy products.

This assessment of the trade flow between Canada and the EU have shown a domination from EU firms within these two sectors (GIs and Motor Vehicles). In fact, not only do European firms export more to Canada, but their exports are also of high-quality, substitutable, and made by a well-organized geographically concentrated group of firms, with a high focus on downstream parts of the value chains. This allows these firms to capture a disproportionate share of bilateral exchanges, without product rivalry or major competition. Furthermore, these firms exercise a higher trade flow in these fields of economic activities. Indeed, the German Car Industry and European GIs producers create market niche with no local competition and organize collectively to facilitate exports. Canadian companies instead were not able to export to Europe on comparative terms. Neither were they able to strategically position their products to create and satisfy European consumer demands. Furthermore, their production structure is either fragmented for motor vehicle or inward oriented for GIs. On the contrary, Europeans were able to place themselves in an advantageous position where Canadian consumers themselves are requesting access to their products with a lower cost.

These indicators prove that European producers are more able to dominate the market in terms of production and trade. During the negotiation of CETA, the Canadian government was thus faced with the reality that its firms were not having a sizeable share of the market. Un-restricted

regulatory cooperation would have been thus problematic as it would have forced Canadian industry to compete with a more productive industry, supply higher value goods. Cooperation within such sectors are problematic as extensive regulatory changes could have significantly impacted the industry. Aware of the Canadian firms' opposition towards extensive regulatory alignment to European regulations, the negotiators crafted the cooperation to limit the extent of the regulatory changes (interview B2-B4, interviews in Ottawa). This implied that Canada was in a high-risk situation of "hold-up" in these two sectors.

In fact, the absence of a similar level of exports coupled with the absence of similar premium production resulted in Canada's simply not having the adequate economic structure and capacity to compete on a similar level with the Europeans. Significant new investments would have been necessary to change this situation, under the risks that the EU could exploit this transition and these vulnerabilities to obtain even further costly regulatory adjustments from Canada. In fact, as mostly an importer, Canada's interests lie more in the reduction of regulatory barriers and less with externalization of its own regulations. Furthermore, as its level of concentration is less than the Europeans, producers in Canada had also more difficulties in creating a production structure corresponding to similar regulatory preferences.

Therefore, a regulatory design of Type 1 in fact corresponds to the production structure of the GIs and MVs sectors. When deciding to design the cooperation, states took this situation into consideration and adopted the most fitting design for liberalizing the sector. As European export interests were prominent in these two sectors, the liberalization of GIs and MVs required that regulatory adjustments be made to facilitate their flows (Official and Industry A1-A5-B2-B4-C1-C6, interviews in Ottawa and Brussels). Nevertheless, the clear disequilibrium in the relations between the EU and Canada resulted in the latter requesting safeguard to avoid or mitigate the risk of "hold-up" (Official D7, interview in Brussels). Type 1 was ideal in this context. Among the design types available, Type 1 reflected the importance of certain specific commodities for bilateral flows.

GIs in cheese are the most numerous and protect existing strategic European dairy exports to Canada. Similarly, UNECE regulations contain technical requirements that are key for premium car producers, the most exported type of brand. By obtaining recognition of these products through a predefined list with hard binding effects, European exporters benefit from enhanced market access. For Canada, Type 1 restricts the extent of the cooperation to the moment of the negotiation. It precludes the possibility for the Europeans to potentially exploit in the future

economic interdependence to obtain further regulatory concessions, such as more GIs or UNECE standards to be recognized. By recognizing a limited among of regulations corresponding to the reality of its imports from Europe, Canada was also able to answer its consumer demands while reducing regulatory costs. Even though it was not the major element in this choice, it showed that Canadian negotiators took into account the interdependent nature of their relations.

Nevertheless, the choice of a design of Type 1 (Ex-ante/Hard) instead of a Type 4 (Ex-post/Soft) would be incomplete if the second explanatory factor, regulatory framework, was not also assessed. As it is demonstrated next, the use of Hard binding legal language was necessary to fill existing regulatory lapses in these two sectors originating from divergences between Canadian and European regulatory frameworks.

## *6.2. Shirking*

Besides the risk of “hold-up”, states’ decision to cooperate is also contingent on the possibility for one the party to renege on its commitments after the conclusion of the agreement. Convergence or divergence of their respective regulations are important to understand how states’ choice of regulatory design attempted to mitigate or not this risk. Different sources of data help make this assessment: international treaties, IOs memberships, content of domestic regulatory, and conformity assessment methods. Participation to different treaties or membership in IOs affect regulations used in both parties through additional international conditions. Domestic legislation focuses on national requirements that could prevent cross-border economic activity. Conformity assessment is equally important as it includes testing method and inspection processes used by countries in their product approval system, which can create additional administrative burden. This assessment starts with the GIs sector, followed by Motor Vehicles.

## **Geographical Indications**

Concerning GIs, several key international texts exist and can help identify where Canadian and EU regulatory frameworks depart from each other. As members of the World Trade Organization (WTO), Canada and the EU are also signatories of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. Within part II of TRIPS, section 3 specifies the conditions

for the use and protection of GIs<sup>172</sup>. It is divided into three Articles<sup>173</sup>: Article 22 establishing minimal condition for protection at the discretion of States<sup>174</sup>, Article 23 adding supplementary protection for wines and spirits and Article 24 specifying the WTO's mandate for future negotiation on GIs. Wines and spirit additional protections result from an agreement found between WTO members at the Cancun 5<sup>th</sup> WTO ministerial conference in 2003<sup>175</sup>. In parallel with WTO discussions, EU and Canada negotiated and concluded a bilateral agreement on trade in wines and spirits drinks in 2003-2004<sup>176</sup>. This agreement allows the registration of Wines and spirits GIs in Canada, with additional recognition and trade facilitation measures. A comprehensive list of all the alcoholic drinks protected is also added to the agreement<sup>177</sup>. The existence of this agreement previous to the start of the CETA negotiation explains why GIs on wines and spirits were excluded from the discussion in this process. As an agreement was already in place, it was not necessary to regulate further.

Another key international instrument is the *Lisbon Agreement for the Protection of Appellations of Origin and their International Registration*, which includes 29 contracting parties, seven of them EU member states<sup>178</sup>. While the European Commission recommended the adhesion of the EU to the agreement in July 2018, as of today neither the EU, nor Canada are signatories of the treaty. Canada acceded in March 2019 to three key WIPO instruments<sup>179</sup>: *Madrid System for the International Registration of Marks*, the *Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks* and *Singapore Treaty on the Law of Trademarks*. While the EU is member of the Madrid system, only certain

<sup>172</sup>WTO, “Part II — Standards concerning the availability, scope and use of Intellectual Property Rights”, [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_04b\\_e.htm#3](https://www.wto.org/english/docs_e/legal_e/27-trips_04b_e.htm#3), accessed the 6<sup>th</sup> July 2019.

<sup>173</sup> Ibid.

<sup>174</sup> WIPO, “Geographical Indications Ongoing Negotiations/Discussions in the WTO”, [https://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=81754](https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=81754), accessed the 6<sup>th</sup> July 2019.

<sup>175</sup> WIPO, Worlwide symposium on geographical indications parma, 27-29 june 2005, presentation, [https://www.wipo.int/export/sites/www/meetings/en/2005/geo\\_pmf/presentations/ppt/wipo\\_geo\\_pmf\\_05\\_tranwasescha.ppt](https://www.wipo.int/export/sites/www/meetings/en/2005/geo_pmf/presentations/ppt/wipo_geo_pmf_05_tranwasescha.ppt), accessed the 6<sup>th</sup> July 2019.

<sup>176</sup>Global Affairs Canada, “Agreement Between Canada and the European Community on Trade in Wines and Spirit Drinks”, <https://www.treaty-accord.gc.ca/text-texte.aspx?id=104976>, accessed the 6<sup>th</sup> July 2019.

<sup>177</sup>Official Journal of the European Union, “Agreement between the European Community and Canada on trade in wines and spirit drinks”, [http://www.europarl.europa.eu/cmsdata/121890/Agreement\\_trade\\_wines\\_spirits\\_EU-Canada\\_2003.pdf](http://www.europarl.europa.eu/cmsdata/121890/Agreement_trade_wines_spirits_EU-Canada_2003.pdf), accessed the 6<sup>th</sup> July 2019.

<sup>178</sup>European commission, “EU to join the Geneva Act of the Lisbon Agreement to better protect GIs”, [https://ec.europa.eu/info/news/eu-join-geneva-act-lisbon-agreement-better-protect-gis-2018-jul-27\\_en](https://ec.europa.eu/info/news/eu-join-geneva-act-lisbon-agreement-better-protect-gis-2018-jul-27_en), accessed the 6<sup>th</sup> July 2019.

<sup>179</sup> WIPO, “Canada Joins Three Key WIPO Trademark Treaties”, 18<sup>th</sup> March 2019, [https://www.wipo.int/portal/en/news/2019/article\\_0012.html](https://www.wipo.int/portal/en/news/2019/article_0012.html), accessed the 6<sup>th</sup> July 2019.

European member states are part of the Nice and Singapore agreements. Disagreements exist between the EU and Canada, notably around amending the TRIPs agreement to extend GI protection to all WTO members<sup>180</sup> (EU TN/IPW11 proposal vs U.S., Canada, China TN/IP/W10/Rev4. Counterproposal). However, as members of TRIPs, they both recognized GIs for wine and spirits. Due to the key role of this agreement, the divergence in terms of membership to international legal agreements does not result in additional regulatory barriers between the EU and Canada. Therefore, the choice of Hard obligation cannot be solely attributed to international legal divergences. This is not the case for national regulations though, where significant differences stand between the two systems.

Prior to the signature of the CETA agreement (30 October 2016), four EU regulations were in force and pertained to Geographical indications: *EC regulation No 207/2009 on the community trade mark*<sup>181</sup>, *EU regulation No 1151/2012 on Quality schemes for agricultural products and foodstuffs*<sup>182</sup>, *Commission delegated regulation No 664/2014 for “the establishment of the Unions symbols[.]”*<sup>183</sup> and *Commission implementing regulation No 668/2014 for the implementation of regulation No 1151/2012*. On the Canadian side, the “Trade-marks Act”<sup>184</sup> remained the most important legislative vehicle for the use of protected designations. After the signature of the CETA and before its entry into force (30<sup>th</sup> September 2017), a revised version of the Trade-marks Act was adopted the 21<sup>st</sup> September 2017<sup>185</sup>. This new version made the necessary legislative

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<sup>180</sup> WTO, “trips: geographical indications: Background and the current situation”, [https://www.wto.org/english/tratop\\_e/trips\\_e/gi\\_background\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/gi_background_e.htm), accessed the 6<sup>th</sup> July 2019.

<sup>181</sup> Replaced the 30th September 2017 by the EU Regulation 2017/1001 “European Union trademark”: Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trademark, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R0207>, accessed the 6<sup>th</sup> July 2019.

<sup>182</sup> <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32012R1151>; previously Council regulation (EC) No 510/2006: protection of the geographical indications and designations of origin for agriculture products and foodstuffs <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32006R0510>, both accessed the 6<sup>th</sup> July 2019.

<sup>183</sup> EUR-Lex, Commission Delegated Regulation (EU) No 664/2014 of 18 December 2013 supplementing Regulation (EU) No 1151/2012 of the European Parliament and of the Council with regard to the establishment of the Union symbols for protected designations of origin, protected geographical indications and traditional specialties guaranteed and with regard to certain rules on sourcing, certain procedural rules and certain additional transitional rules, <https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32014R0664>, accessed the 6<sup>th</sup> July 2019.

<sup>184</sup> Minister of Justice Canada, “Trademarks Act R.S.C., 1985, c. t-13”, <https://laws-lois.justice.gc.ca/PDF/T-13.pdf>, accessed the 15th august 2019.

<sup>185</sup> Minister of Justice Canada, Archives version of document from 2017-09-21 to 2018-10-04: “Trademarks Act R.S.C., 1985, c. t-13”, <https://laws-lois.justice.gc.ca/PDF/T-13.pdf>, accessed the 15th august 2019.

adaptations to respect Canadian commitments made in CETA, notably to accommodate foodstuffs GIs.

Before these modifications, EU No 207/2009 and Canadian trade-marks regulations also diverge in content at numerous sensitive points. Among the main points of divergence, EU No 207/2009 offers the possibility for geographical indications to be recognized as “community collective marks” at Article 66. Consequently, it allows the registration of “signs or indications which may serve, in trade, to designate the geographical origin of the goods or services [and] constitute Community Collective marks [...].” Certain safeguards are scheduled to prevent undue prohibition of the geographical origins to a producer, who “uses them in accordance with honest practices in industrial or commercial matters” or is “entitled to use a geographical name”. This implies that if a producer or a group of producers follow similar production and trade practices, as well as has claims on the geographical location, the trademark rights can be attributed to the producer’s groups and legal protection extended to their products.

On the contrary, the Canadian Trade-marks Act considers that the proposed trademark targets only “persons”, which have proposed the registration of the trademark. In its list of definitions, the act specifies:

proposed trade-mark means a mark that is proposed to be used by a person for the purpose of distinguishing or so as to distinguish goods or services manufacturers [...] ;”

“person includes any lawful trade union and any lawful association engaged in trade or business or the promotion thereof, and the administrative authority of any country, state, province, municipality or other organized administrative area<sup>186</sup>.

Concretely this means that Canada devolves exclusive indication rights to individual firms or associations that make the request. The term “person” can include various actors similarly to the EU. However, the point of contention lies in the obligation contained in the EU regulation No 207/2009 to authorize the use of the GI trademarks by “any person whose goods or services originate in the geographical area concerned to become a member of the association which is the proprietor of the mark” (art. 67). Such obligation of extension is absent in Canadian legislation,

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<sup>186</sup> Ibid.

where the holder of the trademark can prevent the adoption of the trademark by subsequent producers, which may share similar geographical origin.

To illustrate this divergence, in the EU a new producer of Parma ham can apply to enter the consortium of Parma ham producers, which holds the GI. It can also create its own company and produce on its own. The only requirements it must fulfill is that it respects the GI specification and produces in the same geographical area. On the contrary, a newly created Canadian cheese producer situated in the province of Ontario cannot apply to use the designation “Cheddar Ontario” if another producer is already holding this designation. The EU system recognizes thus the collective rights of similarly located producers, irrespective of producers’ individual property rights. GIs act as a public good in the European system, open to all complying producers in the region (official D7, Interview in Brussels). Canada instead privileges individual holders’ rights by excluding other potential use of the brand. It follows a logic of “first in time, first in right” in all circumstances and dismiss the rights of subsequent producers<sup>187</sup>.

This divergence of “right” is the fundamental regulatory point of contention in the GIs sector. If GIs is considered as a private and not a public/collective right it can prohibit other producers from using it. Consequently, producers are not rewarded from following common and stringent regulatory requirements. They risk instead to be excluded from the market by legal proceeding, removing its means to distinguish its quality products from the remaining bulk one. This is a classic problem identified by Akerlof (1970) in its notorious lemon dilemma. In the long run, consumers are not in position to distinguish quality products from others due to the asymmetry of information between them and producers. Therefore, the risk is high that quality producers can be opportunistically excluded from the market by denying collective indication rights and favoring instead local corporation that were able to protect their trademarks before everyone else. Strong legally binding commitments are thus necessary to ensure the legal protection of these collective groups of producers based outside Canadian territory.

Indeed, in the EU these “producer organizations” or “inter-branch organizations” can also be in charge of controlling and enforcing the quality of the GI products, as indicated in Article 45 of EU regulation No 1151/2012. This supports the earlier point made that collective organizations and association have special prerogatives in the European context compared to the Canadian one.

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<sup>187</sup> Presentation from European commission DG Agri, “The relationship between geographical indications and trademarks in the bilateral agreements of the European Union” at the Conference, the 3-4th October 2018, Trademarks and geographical indications: future perspectives, organized by European Union Intellectual Property Office (EUIPO), Alicante, Spain.

The EU regulations specifically delegate them a certain level of monitoring and management powers on the GIs and their related intellectual property rights. There is no monitoring in Canadian legislation on quality requirements. Canadian rights holders can thus decide what will be the level of quality of their goods or the location of their production as long as it does not “mislead” consumers (art. 7)<sup>188</sup>. This stipulation has been broadly interpreted as the Canadian trademark system has allowed the firm Maple-leaf to use the denomination “PARMA” since 1971. Maple-leaf’s trademark rights allowed the company to prevent the entry into the Canadian market of products labelled “Prosciutto di Parma”, originating from firms belonging to the “Consorzio del Prosciutto di Parma”<sup>189</sup>. This conflict illustrates the large freedom devoted to the company holding the rights, irrespective of the accuracy of the origin of their products.

The interaction between the European regulatory system and the existence of an asymmetrically located group of producers explain partly how these actors were able to come up with a common list of indications. Indeed, the EU GI regulations encourage producers of similar products to join common associations and cooperate to protect their designation. There is also a congruence of interests between the producers to agree on common sets of standards that will be respected by all. As standards settings and monitoring is delegated to the producer’s association, they can easily coordinate with each other on common technical features. This being the case, it is in the interest of all the producers of the branch to promote a list of GIs. On the contrary, the Canadian trademark rather encourages competition and exclusion among the producers of similar goods. It is hence rather much harder for them to agree on a common list of demands.

Furthermore, in Canada the possibility for producers to see their trademarks being recognized is contingent upon the absence of opposition from other potential claimants. The Canadian Trademarks Act forces the authority to equally consider both the demand for GI recognition and potential opposition ((4) & (5)). It is required to justify both a positive and negative decision ((7)). No obligation is made on the authority to recognize the indication. In the European system as long as the producer fulfills the conditions specified in the Articles 36 & 37 of EU No 207/2009, the authority is forced to recognize the indications requested (art 68(3.)), even in the case of

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<sup>188</sup> Minister of Justice Canada, “Trademarks Act R.S.C., 1985, c. t-13”, <https://laws-lois.justice.gc.ca/PDF/T-13.pdf>, accessed the 15th august 2019.

<sup>189</sup> Ann Hui, The Globe and Mail, “A cured trademark dispute: After 20-year battle, Prosciutto di Parma name heads for Canadian shelves”, <https://www.theglobeandmail.com/news/national/trademark-dispute-prosciutto-di-parma-canadian-shelves/article37427226/>, accessed the 6<sup>th</sup> July 2019.

opposition. Therefore, the burden of proof is on the side of the authority or claimant, who attempts to deny the validity of the GI request.

EU producers are thus incentivized to produce specialized products. As the regulation favors the applicants of GIs, the latter are encouraged to link their production or create production lines that are geographically bound. This relative ease to submit applications pushes producers to specialize their production from other competitors through the GI system. This is also economically rational as GIs can provide economic benefits to their producers (Duvaleix-Tréguer et al. 2018). On the contrary, the Canadian system does not encourage this level of specialization. Indeed, the Canadian claimant would have relatively more difficulties to demonstrate that his production is unique and deserves special recognition. Opponents could easily object that the indication is generic and thus should not be recognized as it would result in unfair discrimination.

Driven by the incentives contained in the GIs regulations, over the years the EU has compiled an important list of specialized products (3400 GIs registered at the EU level)<sup>190</sup>, which it can push for recognition in foreign markets. This specialized nature of production coupled with the regulatory lapse explains hence why the choice was made of a Hard/Ex-ante design. As the Ex-ante mode of decision relies on an already agreed upon list of detailed regulations, this design is perfectly suited for GIs. Not only does it reflect the specialized nature of EU production, and subsequent “hold-up” risk for Canada due to its difficulty to compete within a fully liberalized framework, but it also takes into consideration the regulatory lapse by specifying precisely the products on and off the list. Canada is thus able to limit concessions and opt out or carve out products that are considered too controversial domestically, without rejecting the entire design. At the same time, the binding nature of the listed recognitions (Hard obligation) allows the European firms to be sure that their products are recognized by Canada even if the domestic legislation and authorities are hostile to food GIs. On the contrary, the Ex-ante design gave a guarantee to Canada that the list of GIs it accepted is definite and that Canada has no obligation to extend over the years. This condition was stressed by Canadian negotiators, who made it clear

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<sup>190</sup>EC, “New database for EU geographical indications aims to increase transparency and simplify search “, 1<sup>st</sup> April 2019, [https://ec.europa.eu/info/news/new-database-eu-geographical-indications-aims-increase-transparency-and-simplify-search-2019-apr-01\\_en](https://ec.europa.eu/info/news/new-database-eu-geographical-indications-aims-increase-transparency-and-simplify-search-2019-apr-01_en) ; European commission, “eAmbrosia – the EU geographical indications register”, <https://ec.europa.eu/info/food-farming-fisheries/food-safety-and-quality/certification/quality-labels/geographical-indications-register/> ; European IP Helpdesk, “Geographical Indications: Terms & Tools”, <http://www.iprhelpdesk.eu/ip-special-GIs-article-terms-tools>, all accessed the 8<sup>th</sup> July 2019.

that they refused to commit to a mechanism that would enlarge the list of 143 GIs (official D7, interview in Brussels).

The next point of divergence is the Canadian Trade-marks Act's restriction to recognize GIs for wine and spirits only. Its definition in the preamble of "geographical indications" includes wine and spirits with no mention of foodstuffs. Article 11.12. (1) to (3) also specifies that the list of GIs under the supervision of the public authority allows solely wines and spirits to be registered as such. Furthermore, following articles prohibiting third party use of a GI (Articles 11.14 to Article 11.15) only targets wines and spirits. Similarly, Article 12 (1) prevents the registration of trade-marks due to already existing GIs for wine and spirits. Overall, the previous Canadian Trade-marks Act did not consider the possibility for foodstuffs GIs and did not extend any special protections for them. Foodstuffs are supposed to be registered as a trademark like any other kind of product. This feature of the Canadian legislation resulted in European Parma ham producers being confronted with local Canadian production imitating Italian flags, using labels such as "authentic" and the use of the appellation "Parma"<sup>191</sup>.

In comparison to Canada, the EU follows a similar approach to trademarks but carves out special protection from its No 207/2009 trademarks regulation dedicated specifically to Geographical Indications within the EU No 1151/2012. Indeed, Article 14 of No 1151/2012 prevents the registration of a trademark if it refers to a geographical indication or similar product already registered. On this point, Canada and the EU share the principle of "first in time, first in right" embodied in the TRIPs agreement. Nevertheless, the EU can attribute additional protection for GIs, if the products of the previous trademark holders are not "reputed" in the market<sup>192</sup>. The question of the "reputation" of a trademark in EU jurisprudence is subject to multiple debates, which will not be explored further here<sup>193</sup>. It remains fair to say that a certain level of higher protection is extended to GIs, compared to normal trademarks in the EU and Canada. The

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<sup>191</sup> Presentation from Prosciutto di Parma Consortium at the Conference, the 3-4<sup>th</sup> October 2018: "Trademarks and geographical indications: future perspectives", organized by European Union Intellectual Property Office (EUIPO), Alicante, Spain.

<sup>192</sup> Presentation from European commission DG Agri, "The relationship between geographical indications and trademarks in the bilateral agreements of the European Union" at the Conference, the 3-4<sup>th</sup> October 2018, *Trademarks and geographical indications: future perspectives*, organized by European Union Intellectual Property Office (EUIPO), Alicante, Spain.

<sup>193</sup> Guidelines for examination of European union trademarks European union intellectual property office (euiipo),

[https://euiipo.europa.eu/tunnelweb/secure/webdav/guest/document\\_library/contentPdfs/law\\_and\\_practice/trade\\_marks\\_practice\\_manual/WP\\_1\\_2017/PartC/05part\\_c\\_opposition\\_section\\_5\\_trade\\_marks\\_with\\_reputation\\_article\\_8\\_5\\_eutmr/TC/part\\_c\\_opposition\\_section\\_5\\_trade\\_marks\\_with\\_reputation\\_article\\_8\\_5\\_eutmr\\_tc\\_en.pdf](https://euiipo.europa.eu/tunnelweb/secure/webdav/guest/document_library/contentPdfs/law_and_practice/trade_marks_practice_manual/WP_1_2017/PartC/05part_c_opposition_section_5_trade_marks_with_reputation_article_8_5_eutmr/TC/part_c_opposition_section_5_trade_marks_with_reputation_article_8_5_eutmr_tc_en.pdf), accessed the 8<sup>th</sup> July 2019.

regulation extends this protection to agriculture products and foodstuffs in Article 2, while Article 5 provides details on the requirements for the registration of GIs, which includes:

2. (a) originating in a specific place, region, or country,
- (b) whose given quality, reputation or other characteristics is essentially attributable to its geographical origin; and
- (c) at least one of the production steps of which take place in the defined geographical area<sup>194</sup>.

This absence of recognition for food products within Canadian trademark is an important explanatory factor in the choice of binding provisions. As the Canadian domestic system previously in place did not allow for registration nor schedule any forms of protection, legal constraints were necessary to protect European exporters. Indeed, due to wide divergence between the EU and Canadian frameworks, softer legal provisions would have been insufficient. Without binding obligations, Canada could have maintained its system as such, while doing the minimum in terms of regulatory cooperation. For European firms nothing would have changed in the sector and misuse of geographical indications would have continued. It was thus necessary for the EU to push for binding regulations to ensure protections for its exports.

From the Canadian perspective, the changes they had to make did not overturn their trademark regulation. Instead, they created a special avenue to protect GIs products while keeping the rest of the system in place. The changes extended legal protection to European GIs, allowing the possibility to sue in case of violation, without upsetting the frameworks for other producers. As was previously mentioned, the “grandfather rights” scheduled in the agreement guaranteed that Canadian producers active before 2013 would not be affected by the changes. Therefore, despite enacting some significant changes, Canada preserved its domestic constituents and satisfied the Europeans by extending its IPr protection to food GIs.

Overall, Canadian and European regulations diverge on four main points. First, previous Canadian trademark acts did not include foodstuffs and agriculture products in the list of protected geographical indications. Second, the burden of proof to justify the registration of a GIs is equally

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<sup>194</sup> EUR-Lex, “Regulation (eu) no 1151/2012 of the European parliament and of the council of 21 November 2012 on quality schemes for agricultural products and foodstuffs”, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R1151&from=EN>, accessed the 6th July 2019.

shared between the demanding producers and potential opposition. The administrative authority has to equally arbitrate between both to make a judgment. Within the EU as long as the producer respects the requirements specified in the regulations, there is no legal basis for the authority to deny the registration of the GI. Third, the Canadian system considers trademarks and GIs alike, while the EU provides supplementary protections to GIs. Lastly, Canada follows an individualistic understanding of GIs and Trademarks. It does not allow an organization to manage it and excludes extending the denomination to new producers even if their production and origin might be similar to those of the holders of the rights. The EU partly delegates the conformity assessment and management of the GIs to geographically located organizations which are required to accept new members if they are compliant with the technical characteristics specified by the association.

All these characteristics favor the use of a design of Type 1. In fact, the European system encourages the listing of designations agreed upon by all producers within a range of specific products. The European states can thus externalize this list and request that strong legal provisions ensure the protection of these specific products in foreign markets despite regulatory differences. This furthermore allows European firms the possibility to use Canadian legal systems against potential indications usurpers within Canadian territory. For Canada, its trademarks system does not encourage this approach to indications. Regulatory changes were accepted partly as they did not significantly disrupt the system in place for domestic producers. The reinforcing role of Ex-ante in curtailing potential European regulatory ambitions in the future is also noted, even if it was not the main factor explaining the divergence between Hard-Soft.

## **Motor Vehicles**

For motor vehicles, similar levels of divergence between the regulatory frameworks of Canada and the EU were present before the conclusion of the agreement. For Canada, the main legislative document is the Motor Vehicle Regulations<sup>195</sup>, which contains the legal and technical requirements for motor vehicles and their components. The EU relies on two regulatory pillars in this sector: the *Directive 2007/46/EC* and the UNECE regulations. While subsequent regulations

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<sup>195</sup>Government of Canada, Justice Law website, Archives version of document from 2016-12-28 to 2017-05-02: “Motor Vehicles Safety Regulations

C.R.C., c. 1038”, [https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.\\_c.\\_1038/20161228/P1TT3xt3.html](https://laws-lois.justice.gc.ca/eng/regulations/C.R.C._c._1038/20161228/P1TT3xt3.html), accessed the 8<sup>th</sup> July 2019.

were added to the directive, until its replacement by the *Regulation (EU) 2018/858*, it was during the time of the negotiation the main European legal instrument to refer for motor vehicle regulations<sup>196</sup>. The preamble to the regulation specifies its objective of harmonizing technical requirements for motor vehicles for European producers within the single market. As the Directive recalls:

- (2) For the purposes of the establishment and operation of the internal market of the community, it is appropriate to replace the Member States' approval systems with a Community approval procedure based on the principle of total harmonization<sup>197</sup>.

The directive establishes thus a Community framework, in which motor vehicles producers follow similar requirements and receive thus approbation for the whole single market. The EU used this regulation to “totally” harmonize the European motor vehicles sectors, with one of the objectives being the opening of the European market to producers of vehicles in small series (paragraph 6 of the Directive 2007/46). Therefore, the directive contains a sizeable list of annexes and appendices, which specify definitions (Annex II), models, conditions, and standards that producers need to comply with<sup>198</sup>. Nevertheless, besides listing this information, the directive also recalled the accession of the EU to the UNECE and its incorporation of UNECE Regulations in its regulatory corpus (paragraph 11 of the Directives Directive 2007/46).

The role of the UNECE regulations is specified in Article 34 *UNECE Regulations required for EC type-approval* and Article 35 *Equivalence of UNECE Regulations with directives or regulations*<sup>199</sup>. Article 34 requires EU member states to repeal or adapt any national legislation that is incompatible with the UNECE Regulation previously adopted at the Community level. Article 35 complements this obligation by establishing equivalences between UNECE regulations and European directives and regulations, forcing hence member states to recognize UNECE as equivalent. These two obligations enable thus the complete harmonization of national motor vehicles standards in Europe on UNECE regulations. The EU and UNECE frameworks create

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<sup>196</sup> EC DG GROWTH, “Technical harmonization in the EU”, [https://ec.europa.eu/growth/sectors/automotive/technical-harmonisation/eu\\_en](https://ec.europa.eu/growth/sectors/automotive/technical-harmonisation/eu_en), accessed the 7<sup>th</sup> July 2019.

<sup>197</sup> EUR-Lex, «Directive 2007/46/ec of the European parliament and of the council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles», <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007L0046&from=EN>, p. 1, accessed the 7th July 2019.

<sup>198</sup> Ibid., p. 24

<sup>199</sup> Ibid., p. 19

thus an imbricated regulatory area throughout the continent. The role that UNECE regulations play in the EU regulations partly explains why Europeans are so keen to externalize them. By using UNECE regulations to align national European regulations, the EU was able to build a single market for motor vehicles. These regulations played thus the role of regulatory common denominator for all European manufacturers. The latter are hence able to jointly support these detailed rules, despite their production systems and trade differences.

Compared to EU Directives 2007/46/EC, the Canadian Motor Vehicle Safety Regulations do not depart significantly in terms of format. Indeed, the Canadian regulations similarly lists its technical definition of vehicles and components within the text. It refers to Canadian standards or guidelines, e.g. test methods, that are part of the enlarged regulatory framework of the country. Notably, the act lists in Schedule III<sup>200</sup> Canada Motor Vehicle Safety Standards (CMVSS) that producers and importers need to comply with. This system is actually similar to the European one.

Where the Canadian Regulatory Act departs sensibly, is in the complete absence of references to UNECE agreements and regulations. In its stead, a specific section dedicated to the import of vehicles from the United States is present. This section specifies the conditions to be met for imports, notably compliance with U.S. regulation. Besides this section, the text contains also references to United States Federal Motor Vehicle Safety standards (FVMSS). In certain cases, it establishes equivalences between FVMSS and existing Canadian standards, and in other cases it directly incorporates the (US) standard. While these direct references remain limited, the Canadian ministry in charge of implementing the Motor Vehicle Safety Regulations, Transport Canada, also monitors FMVSS to assure regulatory alignment with U.S. standards<sup>201</sup>. Even if formally, Canada develops its own standards (CMVSS) these standards are often close to U.S. ones, with some potential adaptations to the Canadian market. Overall, the U.S. motor vehicle standards plays a similar role in Canada to the UNECE in the EU. Thus, Canadian manufacturers

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<sup>200</sup> Government of Canada, “Motor Vehicle Safety Regulations C.R.C., c. 1038”, [https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.\\_c\\_1038/20180901/P1TT3xt3.html](https://laws-lois.justice.gc.ca/eng/regulations/C.R.C._c_1038/20180901/P1TT3xt3.html); “Motor Vehicle Safety regulations: Schedule III Canada Motor Vehicle Safety Standards”, [https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.\\_c\\_1038/section-sched3.html](https://laws-lois.justice.gc.ca/eng/regulations/C.R.C._c_1038/section-sched3.html). For instance, the schedule contains CMVSS 102, which targets “transmission control Functions” for Bus, passenger car, truck.; all accessed the 8th July 2019.

<sup>201</sup>The Association for the Work Truck Industry (NTEA), “U.S., Canada and Eu certification: What’s the difference?”, [http://www.ntea.com/NTEA/Member\\_benefits/Industry\\_leading\\_news/NTEANewsarticles/U.S.\\_Canada\\_and\\_EU\\_certification\\_\\_What\\_s\\_the\\_difference\\_.aspx](http://www.ntea.com/NTEA/Member_benefits/Industry_leading_news/NTEANewsarticles/U.S._Canada_and_EU_certification__What_s_the_difference_.aspx), accessed the 18th August 2019.

do not have much influence on standards setting in the U.S. or in the UNECE, which is largely dominated by European states.

To understand this conflict between the North American standardization system and the European one, an investigation into the reasons for the emergence of these two competing international systems (UNECE, FMVSS/CMVSS) is needed. In fact, while in GIs there is a relative common adhesion to similar international treaties and regulations, in Motor Vehicles it is not the case. Both states diverge strongly in their international references, which define the technical contents of their domestic regulations. These divergences in terms of international instruments are such that it makes them incompatible.

To be more specific, the main point of contention is between two different UNECE agreements: the 1958 UNECE agreement<sup>202</sup> and the 1998 *Agreement Concerning the Establishing of Global Technical Regulations*<sup>203</sup>. The United States and Canada are members only to the 1998 agreement and not the 1958 agreement. On the contrary, the EU member states are signatories to both agreements. Two tracks of standardization are thus possible at UNECE, discussed within one institution: The World Forum for Harmonization of Vehicle Regulation (WP.29)<sup>204</sup>. The legal framework of this forum includes three UN agreements (the 1958, the 1997 and 1998), which create three different types of regulations. The 1958 agreement produced UN regulations concerning safety and environmental aspects, as re-transcribed in EU regulations and CETA. The 1997 agreement is responsible for the development of UN rules, which include periodical technical inspections. The 1998 agreement oversees the elaboration of UN Global Trade Regulations (GTR), which aims at harmonizing performance-related requirements and test procedures. This divergence of regulations process is not benign and has economic and political implications. In fact, as noticed by Lori Wallach:

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<sup>202</sup> Whole name is : “Agreement concerning the Adoption of Harmonized Technical United Nations Regulations for Wheeled Vehicles, Equipment and Parts which can be Fitted and/or be Used on Wheeled Vehicles and the Conditions for Reciprocal Recognition of Approvals Granted on the Basis of these United Nations Regulations”, the text is available at : [https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg\\_no=XI-B-16&chapter=11&clang=en](https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=XI-B-16&chapter=11&clang=en), accessed the 8<sup>th</sup> July 2019.

<sup>203</sup> Whole name: Agreement concerning the Establishing of Global Technical Regulations for Wheeled Vehicles, Equipment and Parts which can be fitted and/or be used on Wheeled Vehicles, the text is available at: [https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=XI-B-32&chapter=11&lang=en](https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XI-B-32&chapter=11&lang=en), accessed the 8<sup>th</sup> July 2019.

<sup>204</sup> UNECE, “Vehicle Regulations”, <https://www.unece.org/trans/main/welcwp29.html>, accessed the 8<sup>th</sup> July 2019.

The dual venues for auto standards create an interesting situation where industry could try to play one forum off of the other, or forum shop for the more amenable institution. If, for example, the United States blocks the development of a global auto standard under the 1998 Agreement that NHTSA [(National Highway Traffic Safety Administration)] believes would unacceptably lower existing U.S. standards, industry could try and get the same standards passed in the European auto standards body, thus placing the higher U.S. standard at risk for a WTO challenge as a technical barrier to trade (Wallach 2002, 860).

As previously mentioned, the NHTSA produces its own standards (FMVSS)<sup>205</sup>, which are then integrated into Canadian regulations as CMVSS<sup>206</sup>. Interviews with trade representatives on both sides revealed that producers acknowledge that the UNECE 1958 and FMVSS/CMVSS differ significantly in several elements (Industry A1-C6, interviews in Brussels and Ottawa). This results in additional costs and sensibly limits bilateral trade between the two regulatory areas. Notably, certain Canadian manufacturers make the argument that the North American system remains more stringent than the UNECE one, which implies that harmonization efforts should be made on North American basis to avoid a downgrade of protection level<sup>207</sup>. Europeans have a different stance and their producers rather support an alignment on both the UNECE 1958 and 1998 agreements<sup>208</sup>.

The differences between UN regulations and GTR do not relate only to the contents of regulations but also to the difference between systems of product approval. Indeed, while North America follows a “self-certification” process, Europe uses rather a “type-approval” one. In fact, Transport Canada’s “guidelines on compliance and enforcement” for the Motor Vehicle Safety Act schedules a self-certification regime to demonstrate vehicle compliance with the Canadian

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<sup>205</sup> National Highway Traffic Safety Administration, “Regulations”, <https://www.safercar.gov/laws-regulations/fmvss>, accessed the 8<sup>th</sup> July 2019.

<sup>206</sup> [http://www.ntea.com/NTEA/Member\\_benefits/Industry\\_leading\\_news/NTEANewsarticles/U.S.\\_Canada\\_and\\_EU\\_certification\\_\\_What\\_s\\_the\\_difference\\_.aspx](http://www.ntea.com/NTEA/Member_benefits/Industry_leading_news/NTEANewsarticles/U.S._Canada_and_EU_certification__What_s_the_difference_.aspx), accessed the 8<sup>th</sup> July 2019.

<sup>207</sup> Nantais, Mark A., President, Canadian Vehicle Manufacturers’ Association, February 10, 2018 *Canada Gazette Part I Canada-European Union Comprehensive Economic and Trade Agreement Regulatory Cooperation Forum – Request for stakeholder comments*: <https://open.canada.ca/data/en/dataset/c45c4cd-7134-4e65-8e99-5214eb07bcf3>, accessed the 8<sup>th</sup> July 2019.

<sup>208</sup> ACEA, website, ACEA guidelines for FTAs, “FTAs should secure the elimination of non-tariff barriers (NTBs), and in particular, promote the recognition and deployment of the UNECE Regulations (1958 and 1998 Agreements)”: <https://www.acea.be/industry-topics/tag/category/acea-guidelines-for-ftas>, accessed the 8<sup>th</sup> July 2019.

regulatory act<sup>209</sup>. All vehicles circulating in Canada, produced nationally or imported, need to receive a National Safety Mark (NSM) obtained through the self-certification regime<sup>210</sup>. This system requires that manufacturers demonstrate proof of compliance by performing additional tests on their vehicles according to prescribed minimal performance levels scheduled in CMVSS<sup>211</sup>. Companies are not required to test all their vehicles but can extend test results to vehicles belonging to a certain class of products and sharing common technical features<sup>212</sup>. Furthermore, companies are responsible for performing their own testing according to required standards and sending tests results to Transport Canada. The latter will then judge conformity according to the results received, and the respect of methodologies scheduled in the standard.

The main particularity of this system is that manufacturers are directly in contact with the government, can proceed themselves to the tests and can test only a representative sample of vehicles. On the contrary, the EU “type-approval” certification system follows a different process. This system is present in both the UNECE 1958 agreement and the *Directive 2007/46/EC* and aims at establishing a mutual recognition of approvals recognized in the whole EU<sup>213</sup>. This system requires systematic testing of vehicles by third party-party assessment, designated by governments<sup>214</sup>. Compared to Canada, it is a more government driven system based on systematic testing and mutual recognition of certification throughout Europe. Both regulatory areas diverge sensibly in their type of conformity assessment system, restricting bilateral flows of goods on both sides.

These divergences are important factors to explain why a design of Type 1 was chosen for Motor Vehicles. As Canada does not refer to 1958 UNECE regulations, it was necessary to use binding language to ensure that they will be recognized. Like GIs, the divergence of systems required a

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<sup>209</sup> Transport Canada, “Motor vehicle safety oversight program guidelines on compliance and enforcement”, <https://www.tc.gc.ca/media/documents/roadsafety/Guidelines-Compliance-Enforcement-October-2015.pdf>, accessed the 8<sup>th</sup> July 2019.

<sup>210</sup>; Government of Canada, “Motor Vehicle Safety Act”, <https://laws-lois.justice.gc.ca/eng/acts/M-10.01/page-1.html#h-353347>, accessed the 8<sup>th</sup> July 2019.

<sup>211</sup>Government of Canada, “Motor Vehicles Safety Oversight Program: Guidelines on Enforcement and Compliance Policy”, <https://www.tc.gc.ca/eng/motorvehiclesafety/tp-tp12957-menu-173.htm#demo>, accessed the 6<sup>th</sup> July 2019.

<sup>212</sup> ibid.

<sup>213</sup> EC DG GROWTH, “Technical harmonization in the EU”, [https://ec.europa.eu/growth/sectors/automotive/technical-harmonisation/eu\\_en](https://ec.europa.eu/growth/sectors/automotive/technical-harmonisation/eu_en), accessed the 7th July 2019.

<sup>214</sup>Verband der TÜV e.V., “Regulatory remarks concerning the EU-Commission’s position on motor vehicle and type-approval process”, [https://www.vdtuev.de/dok\\_view?oid=525769](https://www.vdtuev.de/dok_view?oid=525769), accessed the 20 August 2019.; EC DG GROWTH, “Technical harmonization in the EU”, [https://ec.europa.eu/growth/sectors/automotive/technical-harmonisation/eu\\_en](https://ec.europa.eu/growth/sectors/automotive/technical-harmonisation/eu_en), accessed the 7th July 2019.

framework that would provide effective recognition instead of soft provisions calling for cooperation, with a potential option for sanctions in case of non-recognition. UNECE and GIs follow the same logic on these aspects. The EU needs strong commitments from Canadian authorities that despite the divergence of systems in GIs and Motor Vehicles, European products will be recognized in the Canadian regulatory environment. These legal obligations provide the Europeans the legal means to potentially initiate a violation procedure, internationally but also domestically namely in front of Canadian courts. For Canada this was possible as it could select the exact regulations it would agree to recognize and consider equivalent to its own, especially for UNECE. This possibility to carve out gave enough assurance to Canada that its system and value chains would not be compromised by recognizing some UNECE regulations (Industry C6, interview in Brussels).

Furthermore, the difference of conformity assessment systems is also key to explain the choice of an Ex-ante design. As the two systems, self-certification & type approval, differ sensibly, a long-term mechanism (Ex-post) would have been particularly difficult to reach. Indeed, either Canada or the EU would have to completely alter its own system and align with the other. In light of Canadian integration with the US and its relatively small number of exports to Europe, this possibility was even more unlikely. The economic asymmetry between both partners and the divergence of systems encouraged the use of limited binding recognitions that would satisfy European exporters without compromising Canadian production presently and in the future. These regulatory and trade features explain thus why a Hard/Ex-ante design was better suited to liberalize the Motor Vehicles sector in CETA.

From this analysis it appears clearly that the EU and Canadian regulatory frameworks for MVs diverge sensibly. The adhesion to different UNECE agreements and the inherent regulatory logic of each region, faced with its own technical and coordination challenges between producers, resulted in two different systems in contradiction with each other. This is also the case for GIs, where even if both actors belong to the same international agreements, their domestic trademarks and GI regulations diverge sensibly. Their respective systems of product approval also contain also significant variation, as the EU provides more avenues for collective holding of IPRs for GIs, especially for consortia and producers associations. On the contrary, Canada used to follow a more individualistic interpretation of IPR with exclusive rights for holders even vis-à-vis similarly located producers.

As demonstrated throughout the text, this divergence, coupled with asymmetry of trade flow, can explain why states privilege a design Type 1 for both sectors. In fact, neither Type 2 nor Type 4 were adequate to achieve liberalization, as it would not protect the specific goods exchanged nor address the deep regulatory divergences between the two systems. As Canada was not able to export similarly in the EU, it could not commit further than a list of limited regulations presents in the agreement. Doing otherwise would jeopardize its industry, as the EU could have taken Canadian industry hostage through the interdependence of its economic linkages. This Ex-ante format allowed states to select precisely which regulations to recognize and which to not. It limits the temporal extent of the cooperation and reduces the risk of “hold-up”. Reciprocally, European exporters could also be satisfied as some of the regulations that affected their exports were included, reducing their trade disruptive costs. Legal provisions with Hard obligations were also necessary for the Europeans as their exports are sent to a different regulatory framework. To ensure recognition and gains from regulatory cooperation, strong commitments from Canada were necessary. Likewise, Canada could agree to this disposition as it would not affect its own production while facilitating access for its consumers to cheaper European products.

### *6.3. Conclusion*

Throughout this chapter, the sectors of Geographical Indications and Motor Vehicles in both Canada and the EU were investigated. The assessment looked at the two explanatory factors, “hold-up” and shirking risks, for both sectors. It found that both explanatory frameworks vary similarly in both sectors. Table 11 under summarize the empirical findings of these two sectors, corresponding in the emergence of both risks in these two sectors. These features resulted in the choice made by states to use a Type 1 (Ex-ante/Hard) to design cooperation.

<b>Geographical Indications</b>	<b>Motor Vehicles</b>
Asymmetric trade flows with European export surplus, higher EU firms' ability to access Canadian market than Canada one	Asymmetric trade flows with European export Surplus, higher EU firms' ability to access Canadian market than Canada one

	EU specialization in high-end, compared with Canada focus on bulk products	EU specialization in high-value premium cars, compared with Canada focus on cars parts and light-vehicles
	Higher coordination and agreement between European consortium producers, compared with Canadian competitive market	European Original Equipment Manufacturers (OEM) (Germany), compared with Canadian SMEs parts-producing focused and integrated with U.S. firms
<i>Risk of "Hold-up" assessment</i>	Due to European trade advantage and specialization, un-restricted cooperation could intensify competition within the Canadian market entailing a high "hold-up" risk for Canada especially considering its firms' difficulties to compete with EU counterparts, access the EU markets and the subsequent investment costs it would require to survive	Due to European trade advantage and premium focus, un-restricted cooperation could intensify competition within the Canadian market entailing a high "hold-up" risk for Canada especially considering its deep integration with U.S. value chains, parts focused industry and lack of OEM. Competing in EU firms in similar footings would require thus subsequent investments to survive
	Adhesion to similar treaties (e.g. TRIPS) and IOs (WIPO, WTO)	International environment divided between European UNECE motor vehicles Standards and North America CVMSS/CVMSS/FMVSS standards
	Divergent regulatory systems: EU collective rights, compared with Canadian private rights' holders and "first in time, first in right" principle	Lack of foreign standards recognition and equivalences within domestic regulations, notably between UNECE and CMVSS
	EU protection of GIs, compared with Canadian prevalence of claimant's responsibility to demonstrate rights' validity	Diverging conformity assessment methods: EU Type-Approval system versus North America self-certification

<i>Risk of Shirking assessment</i>	High risk of shirking due to deep divergences between EU GIs and Canadian trademarks principles. Pre-CETA, Important risks of non-recognition of EU GIs' holders' rights	High risk of shirking due to divergences between the UNECE and FMVSS/CMVSS systems. High risks by Canada to end equivalences with UNECE to protect integration with U.S.
<i>Regulatory Design</i>	Type 1 (Ex-ante/Hard) includes specific European goods, protects long-term Canadian industry and bridge regulatory divergences between GIs and Trademarks	Type 1 (Ex-ante/Hard) includes specific standards keys for EU cars, limits temporally cooperation to protects Canada industry, and establishes binding equivalences between CMVSS and UNECE

*Table 11 GIs & MVs empirical results of the in-depth analysis*

Indeed, the economic advantages that the EU enjoys in terms of high-quality goods, distribution and GVC integration within its sectoral bilateral relations with Canada, is an important element to understand the choice to use an Ex-ante design. It showcases a structural competitive strength of the EU industry compared with its Canadian counterparts. Liberalization through regulatory cooperation provide thus these highly productive EU firms advantages within the Canadian market, without Canadian firms being able to reciprocate in EU market. In such scenario, Canadian firms must make significant investment to compete equally with European firms notably in adapting their regulatory frameworks to the new market structure. Regulatory design safeguards are thus necessary, to protect Canadian import-competing firms.

This design enables the EU to list the specialized goods it exports to Canada within CETA while allowing Canada to limit the extent of this cooperation, especially future additional requests. In these two cases, Canada does not export the same type of agri-food or motor vehicles as the EU. It focuses rather on less specialized goods, notably bulk products such as wheat or motor vehicle parts as well as cheap light cars. Therefore, Canadian producers are not producing high-value goods compared the EU one and occupies rather an upstream segment of the value chain. On the contrary, the EU is highly specialized in premium finished products with an important focus on

the downstream segment of the market. For Canada the use of Ex-ante design has thus major advantages, such as adding exceptions for its producers, notably to avoid committing in the future to a binding mechanism that would add more GIs to the list. Empirical evidence presented earlier shows thus that Canada supported the Ex-ante design, instead of the Ex-post option, to avoid any future commitments.

To add that the choice of Ex-ante also found its justification in the organization of the industry. The production of GI foodstuff as well as the car industry is essentially locally or regionally integrated in Europe. GIs are structured around local consortia, which detailed the exact specification of the products, jointly produced by all the members of the production association. The motor vehicle industry is characterized by the overwhelming importance of German car producers, which still produce 70% of cars' added value in Germany. This concentration explains the ease with which these producers organize themselves around common regulatory preferences, integrated within CETA in Ex-ante design.

Contrary to the EU, Canadian producers could not present a similar united front. Concerning GIs, especially cheese, a very important commodity in Canada and during the negotiation, Canada had a different industry structure. Although, Canada has major producers, such as Saputo, Agropur or Parmalat, these firms are in competition with each other on the same products. They do not jointly organize the production of certain commodities around similar specifications. In Motor Vehicles, Canadian firms are organized in clusters around the Great Lake region, strongly integrated with mostly U.S. car producers. They are mostly fragmented networks of small firms, dependent on major foreign producers, such as Ford or General Motors.

The second part of the puzzle, the review of the EU and Canada's regulatory framework has shown how the existence of regulatory barriers between the two areas required the use of Hard obligations to mitigate the shirking risk within these two sectors. Although Canada and the EU are both members of the TRIPS agreement, which recognized GIs for wine and spirits, they depart significantly in domestic regulations. While Canada follows a "trademark" driven approach, where the principle "first in time, first in right" applies without exception, the EU has chosen a different approach. It curtails trademark rights by a series of EU regulations, which aim at giving extra rights to producers located in a specific area. These producers can use geographical indications to bypass trademark rights. This particularity was not recognized in Canada for food products.

Within the Motor Vehicles sector, regulatory divergences emerge due to the differences of international reference points between Canada and the EU. While the EU relies on UNECE regulations for its automotive producers, Canada instead follows U.S. standards for motor vehicles safety (FMVSS) and integrates them into its own standards (CMVSS). Furthermore, the EU and Canada also follow different conformity assessment procedures, “type-approval” in Europe and “self-certification” in North America. These divergences significantly restrict flows of goods between the two regions, as they require extensive regulatory adjustments.

To remove these regulatory barriers due to preexisting regulatory divergences, the parties of the negotiations have used binding commitments through Hard obligations. These commitments ensured the legal recognition of listed foreign products/regulations in both jurisdictions, and potential legal means for producers to go in domestic courts in case of violation. The use of Hard obligation finds its justification in the restriction that firms faced in their cross-border flows and was largely supported by the industry for this purpose. Overall, this chapter has confirmed the causal links between “hold-up” and Ex-ante, as well as shirking risks and Hard obligations. By reviewing the trade and regulatory features of both sectors, as well as collecting insights and information on the negotiation process, it is possible to confirm the verification of hypothesis Type 1 (Ex-ante/Hard & High level of Hold-up and Shirking). The next chapter will proceed similarly with the two following sectors, Pharmaceutical Products (Pharma) and Professional Qualification (PQ), both using a design of Type 2 (Ex-post/Hard).

## Chapter 7. In-depth case studies (Type 2): Pharmaceutical Products & Professional Qualifications

In CETA, Pharmaceutical Products (Pharma) and Professional Qualifications (PQ) are regulated through an Ex-post/Hard design. In both cases, states did not include a precise list of products/regulations. They jointly created a framework for their future cooperation. To recall, CETA establishes a mutual recognition scheme for Good Manufacturing Practices (GMP) for Pharma, specifically on the mutual recognition of certificates, batches and facility inspection. Concerning PQ, a joint committee responsible for the negotiation of a Mutual Recognition Agreement (MRA) is in place. Both mechanisms contain hard commitments to accept and recognize the equivalences of products/regulations.

As theorized earlier, this type of mechanism is favored by the High level of shirking risks and the Low level of “hold-up” one. The following chapter investigates these two sectors and demonstrates the causal links between factors’ features and the Type 2 design used. Section 7.1. looks first at the risks of “hold-up” in PQ and Pharma. To do so it investigates the bilateral trade relations in these two sectors, mobilizing economic data to evaluate potential risks of one state taking the others hostage in case of regulatory cooperation. Section 7.2. investigates instead the possibility of states shirking their commitments, by making opportunistic use of preexisting and existing regulatory divergences to create new additional technical barriers for protectionist grounds. The last section 7.3. summarizes the findings of the chapter notably the links between “hold-up”/Shirking risks and Design Type 2.

Similarly, like the previous Chapter 6, this chapter looks at the bilateral trade flows and structure in the two specific sectors under investigation. It found that contrary to GIs and MVs, the EU and Canadian industry entertain a relatively more equal economic relations in Pharma and PQ. Indeed, in the former significant concerns were raised by Canadian firms that extensive regulatory cooperation would intensify European competition within the Canadian market and jeopardize the domestic industry. Notably, this does not apply to the sectors here investigated. First of all, investigation shows that in Pharma the sector is globally integrated, with similar firms present all around the world, sending components and drugs to their manufacturing and distribution centers based abroad.

In this context, the differences of drug approval processes were considered a more significant issue than cross-border market access. While specialization exists between firms with different drug patents, differences between countries were not considered significant. Indeed, both Canada and the EU recognized their joint junior partner in this sector compared to the U.S. and attempted to use their cooperation to mutually improve their innovation capacity. In this context, the use of Ex-post was particularly welcome as it provides a long-term institutional format that support Canadian and EU attempts to improve their global profile for the launching of new products. In PQ, while some differences in terms of skills' specialization exist between the EU and Canada, concerns of foreign competition was completely absent. In addition, the investigation reveals that the interests for European or Canadian firms to engage in cross-borders activities were also significantly low. The industries from both sides are all inwards oriented and domestically focused, with few interests to take the opportunity of liberalization through regulatory cooperation to enter foreign markets. Ex-post was also a more appropriate design feature, as no specific professions expressed an interest to obtain its recognition Ex-ante.

In sum, in both PQ and Pharma the risk of "hold-up", namely that regulatory cooperation would result in a "hostage" situation by a country with more productive firms was particularly low. This encouraged parties to institutionalize their cooperation in the long run through an Ex-post design. On the contrary, the risk of Shirkung was considered particularly plausible. Due to global fragmentation of international regulations, standards and treaties in both sectors, significant regulatory gaps exist. This has enabled domestic authorities in both cases to either re-interpret existing international standards by adding new domestic requirements (Pharma) or diverging significantly in their requirements for mutual recognition (PQ). In both cases, the use of Hard obligations was thus particularly necessary to ensure the recognition of equivalences in both countries, and provide means to firms or professionals to litigate in case of violation.

Pharma in CETA includes all types of goods related to the production of medications and drugs, including chemical compounds. Pharma also encompasses regulations, product approval processes and other unique regulatory requirements that are used in this field. PQ targets certain type of services activities, which are recognized by states as regulated professions or "professional services". This can include a large variety of services, notably law practice or architecture. The common denominator is the requirements to fulfill a certain number of conditions to be authorized to practice the profession. The fulfillment of conditions is assessed and certified by recognized authorities, either public or private. The regulatory activities that can be subject to states'

cooperation include detailed curriculum requirements, procedure for qualification approval and practice requirements.

### *7.1. Hold-up*

Recalling the overall trade figures description in Table 6 presented in section 5.2, during the three years preceding the conclusion of CETA (2015-2017) the EU enjoyed a large trade surplus with Canada in Pharma, exporting 266% more than Canada in 2017. According to Eurostat, while Canada exported 1,266 Billion Euro in 2017, the EU's exports reached a level of 4,645 billion Euro the same year. In PQ, the flows are more balanced. In 2015, the EU only exported 10% more than Canada. This European trade surplus rose to 29% in 2016, while experiencing a slight decrease to 25% for 2017. It should be further noted that between the 7 sectors analyzed, PQ is the sector where the EU has the smallest trade surplus of all. In absolute numbers, the EU exported 1,518 billion Euro in professional services in 2015, while Canada's exports amounted to 1,373 billion Euro. In 2017, EU cross-border services supplied equaled 1,624 billion Euro and Canada 1,289 Billion Euro.

This first overview indicates thus a clear trade flow asymmetry in Pharma at the benefit of the EU, and a more symmetrical relationship with Canada in PQ. As mentioned in the theoretical and methodological parts, according to the firms heterogeneity theory and works around “super-star” exporters, such results would indicate that European firms are more productive than Canadian ones in Pharma (Melitz 2003; Melitz and Ottaviano 2008; Osgood et al. 2016). This should thus result in a high level of “hold-up” risk and the use of Ex-ante to mitigate it. However, this trade flow asymmetry did not result in the same choices of design Type 1 (Ex-ante/Hard), as in MVs or GIs. Risk of “hold-up” seems thus not to have worried the negotiating parties in these two sectors. Other data sources might inform of the reasons behind this apparent discrepancy, notably explaining why Canadian negotiators were less concerned of European competition in Pharma than in GIs and MVs. Pharma appears a case, where despite trade flow asymmetry, the EU and Canada's industries shares more common interests than in GIs and MVs.

Importantly, in this sector countries do not distinguish themselves by exchanging different types of goods, but rather exchange similarly approved drugs. Indeed, the same manufacturing firms are similarly present in both territories and are integrated in the same value chain. The distinction takes thus place between multinationals rather than between domestically based firms. Canada

appears less vulnerable to the consequences of regulatory cooperation than in GIs and MVs. In PQ, trade relations with the EU are also complex and requires further details to explain the choice of using a Type 2 to design cooperation. As seen later, in PQ both countries specialize in different services skills. The industries on both sides are inward oriented, which explains the lack of interests from trade associations in supporting a list of professions jointly recognized, through an Ex-ante design. Concerns on differences in the level of competitiveness between Canadian and European firms were overall absent. To explain that, other factors might have also intervened such as the role of “Servification” and immigration.

## Pharmaceutical Products

This empirical investigation attempts to assess the possibility of a “hold-up” risk in case of cooperation in Pharma. This required using a wider range of data than overall trade statistics, with the purpose of looking at products exchanged and the type of value chain integration. While trade flows were easily accounted for, it remains unclear what were the products exchanged on both sides. The first issue encountered was the inability to use Eurostat data to identify the products, neither at HS6 level nor SITC grouping. Indeed, medicinal products are listed in the database according to their chemical composition<sup>215</sup>. This does not say much about the type of pharmaceuticals exported and it is even more difficult to determine whether the products are chemical compounds or finished products. While the chemicals used has an impact in the type of medication produced, it is important to stress that the economic value is not derived from the production itself or the chemical composition but the intellectual property which is attached to the medication. In fact, productions are identified through their brand names or the type of disease they address<sup>216</sup>.

Industry emphasized that exports or imports are not important for cross-border activity (Industry A6, interview in Ottawa). According the same expert interviewed, product approval is much more

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<sup>215</sup> For instance, 54141 Alkaloids of opium and their derivatives

<sup>216</sup> This lack of information was persistent, despite using different empirical sources, such as interviews with industry (Industry A6, interview in Ottawa) and publicly accessible websites (EC, Global Affairs Canada, Health Canada, Innovative Medicines Canada, EFPIA). When asked this question, the industry indicated that EU exports include “finished products and active pharmaceutical ingredients”. This includes parts and finished products and does not say anything about the composition of the flows, nor the share of parts/finished products. It renders the identification of a specific commodity or asset more difficult. Here it should be pointed out that this difficulty to gather this type of data, is a deviant case in this research. Indeed, except Pharma, data on goods/services were found for the 6 other sectors.

relevant to understand the economic interests of Canada and the EU. This feature of Pharma is particularly important as it implies that market access for exports does not play a role. The sector's economic features seem to depend instead on product approvals process and potential dependency towards a third-party R&D. The question lies if the two parties involved in the negotiation (EU-Canada) have the means to hold each other hostage through these means? According to a report on the state of Canada's Pharmaceutical Industry and Prospects, published by the Canadian government in 2013<sup>217</sup>, Canada has significant concerns regarding its industry competitiveness related to the launch and approval of new products<sup>218</sup>. In Europe similar reports express the same worries for the Europeans, notably the necessity for the continent to compete with other countries by promoting product innovation<sup>219</sup>. The European Federation of Pharmaceutical Industries and Association (EFPIA) notices in its 2019 report on the Pharmaceutical Industry that "65.2% of sales of new medicines launched during the period 2013-2018 were on the US market, compared with 17.7% on the European market (top 5 markets)"<sup>220</sup>.

In terms of Pharma innovation, the EU is hence a junior player compared with the United States, despite its market size and GDP. CETA is thus an occasion for the EU industry to collaborate with a like-minded partner on shared issues. In fact, neither Canada nor the EU industries association see each other as rivals and entertain rather a complementary relationship (Industry A6, interview in Ottawa). The two states appear thus not to have considered the risk of "hold-up" in their cooperation. As both are jointly confronted by a larger competitor, the U.S, EU-Canada cooperation is a means to mitigate the "hold-up" risk posed by this third-party. Even while the size difference remains between the two markets, in Pharma the economic features of the sector show that their size discrepancies are not as meaningful as they should be.

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<sup>217</sup> Government of Canada, "Canada's pharmaceutical industry and prospects", <https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/hn01768.html>, accessed the 30<sup>th</sup> July 2019.

<sup>218</sup> Ibid. "These factors include record levels of loss of exclusivity for major brand products, a lack of new blockbuster products, sluggish uptake of new products, a slowdown in new product approvals and longer processing time to access public formularies." P. 7,

<sup>219</sup> IQVIA,"2018 and Beyond: Outlook and Turning Points", p. 3, <https://www.iqvia.com/en/institute/reports/2018-and-beyond-outlook-and-turning-points>: "Relatively weak economic growth in the region, combined with budget concerns arising from adopting and paying for recent innovations, will encourage European payers to be more cautious in adopting newer medicines in the future. Mechanisms to control price and/or access to innovative drugs continue to be the main tools used by European governments to manage spending on medicines and will limit spending growth through the forecast period. As a result, fewer new launches in Europe are achieving price premiums, as few medicines are considered breakthroughs while the remainder are subject to more stringent levels of price limitations at launch.", accessed the 1<sup>st</sup> August 2019.

<sup>220</sup> EFPIA, "The Pharmaceutical Industry in Figures Key Data 2017", p. 4, <https://efpia.eu/publications/downloads/>, accessed the 1<sup>st</sup> August 2019.

To illustrate, Canada and the EU are relatively on the same footing in Pharma. Table 22 in Appendix V lists the 5 most sold pharmaceutical products in Canada. All of them are approved by the European Medicines Agency (EMA) and commercialized in Europe<sup>221</sup>. Notably, medications on both sides are among the most sold globally<sup>222</sup>. However, this information only looks at domestic consumption and does not indicate whether the medications are imported or exported. It is nevertheless an indication that if there are specialization differences, they took place between Multinational Enterprises (MNEs), each holding the patent of a different medication approved and commercialized globally. The differences between states – the EU and Canada – appear less relevant as the one between these MNEs. These firms produce and sell medications across the worlds and make product approval requests everywhere they are eligible.

This is corroborated when looking at the identity of the main firms on the two sides and the structure of the value chains. According to the Canadian government (Table 22, Appendix V), the 5 leading firms in Canada are: Johnson & Johnson/Actelion, Novartis, Merck/Cubist, Apotex and Pfizer/Hospira. All of them are multinationals operating globally, with diverse national origins: J&J, Pfizer and Merck<sup>223</sup> are originally American, Novartis is from Switzerland, and Apotex is Canadian. None of these multinationals' groups are from the EU but rather North America. A similar picture is visible concerning the most sold medications, which are all produced by American companies, except for one product developed by Bayer & Regeneron (German & American). Note that each of these companies has activities all around the world and are globally integrated. In fact, when comparing the memberships of the two main industry association on both sides (EFPIA & IMC), most of the members are the same and are part of the two

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<sup>221</sup> To note that due to high prevalence in inflammatory bowel disease, Humira and Remicade are the most sold medications in Canada. The EU top sold drugs has a different ranking but share similarities for certain products. LaBiotech.eu, « The 5 Best-Selling European Drugs of 2017 », <https://labiotech.eu/tops/best-selling-drugs-europe-2017/>, accessed the 8<sup>th</sup> July 2019; Crohn's and Colitis Foundation of Canada, “The impact of

inflammatory bowel disease in Canada 2012 Final Report and Recommendations”, [http://www.crohnsandcolitis.ca/Crohns\\_and\\_Colitis/documents/reports/ccfc-ibd-impact-report-2012.pdf](http://www.crohnsandcolitis.ca/Crohns_and_Colitis/documents/reports/ccfc-ibd-impact-report-2012.pdf), accessed the 2<sup>nd</sup> August 2019.

<sup>222</sup>Creative Biolab, “Prediction of the World’s Top 10 Best-selling Drugs in 2018”, <https://www.creative-biolabs.com/blog/index.php/prediction-top10-best-selling-drugs/>, accessed the 3<sup>rd</sup> August 2019.

<sup>223</sup> Not too confuse with Merck in Germany, The company is called MDS globally, with the exception of Canada and the U.S. where the appellation is only “Merck”, <https://www.merck.com/about/home.html>, accessed the 5<sup>th</sup> August 2019.

associations<sup>224</sup>. They all have a commercial, research and/or manufacturing presence in both the EU and Canada<sup>225</sup>.

Therefore, and contrary to Geographical Indications and Motor Vehicles, the firms active in cross-border economic activities are the same on both sides. This is not without negotiation implications, as the possibility for one country to unilaterally take hostage the value chain is less plausible. This corresponds to the shifting pattern of Pharma firms towards an increasing integration into Global Value Chains since the adoption of the TRIPS agreement in 1995 (Haakonsson 2009). This global integration of Pharma firms explains why the EU export surplus numbers, obtained from Eurostats and publicized by the EC<sup>226</sup>, appear to be misleading<sup>227</sup> and fail to raise worries in Canada on potential EU exploitation of the trade relation.

In sum, this pattern explains why a design of Type 1 would make little sense in this context. As both Canada and the EU approved the same medications, there is no need to list the products. The EU is facing no market access issues and its exports are equally present in Canada. While no data were found that the EU is exporting these specific medications, it does not seem that its exporters faced any regulatory challenges that would require an Ex-ante legal design. In addition, this specialization between MNEs instead of territorially based, and the shared trade position in global trade of both countries, significantly reduce the risk of “hold-up” in future relation. In other words, while cooperation with the U.S. for any of the two countries would probably pose this type of risks, the EU and Canada do not fear similar issues due to their both junior position in global market. As seen later, the importance of the global market is an important feature of the Pharma sector and is a result of the Globalized nature of its value chain. Overall, this absence of “hold-up” risks in future regulatory cooperation seems to make Type 2 a more suited design for Pharma.

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<sup>224</sup> EFPIA, “EFPIA corporate members”, <https://efpia.eu/about-us/membership/>, accessed the 5<sup>th</sup> August 2019; Innovative Medicines Canada, “Members Companies”, <http://innovativemedicines.ca/about/member-companies/>, accessed the 5<sup>th</sup> August 2019.

<sup>225</sup> Government of Canada, “Pharmaceutical Industry profile”, [https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h\\_hn01703.html](https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html), accessed the 20th September 2019.

<sup>226</sup> EC DG TRADE, “Canada”, <https://ec.europa.eu/trade/policy/countries-and-regions/countries/canada/>, accessed the 6<sup>th</sup> August 2019.

<sup>227</sup> “Trade statistics can only provide a minor part of the evidence needed to understand how this industry has become globalized post-TRIPs. The value of traded pharmaceuticals does not indicate the types and quantities of products exported, and whether they are high-value or low-value products”(Haakonsson 2009, 81)

As advocated by EFPA and Innovative Medicine Canada (IMC) in a factsheet, CETA is seen mostly as a means to improve innovation in both countries<sup>228</sup>. As reviewed in section 5.2, CETA's Protocol on GMP within design Type 2 aims at facilitating product approval. By collaborating in the long run with each other and recognizing each other's inspection and certificates, the EU and Canada aim at making it easier for their firms to submit their product approval requests. Furthermore, both parties stand to benefit additionally as product approval in one jurisdiction could be extended to the other with reduced costs. These measures offer a sort of institutionalized "fast-track" process to get products approved jointly in Canada and the EU. This Ex-post design in CETA hence improves the competitiveness of the two countries in the launch and commercialization of new products. The delayed nature of Ex-post is particularly adequate to fulfill this role as it targets mostly new products and rather than those which have been already approved. The absence of the possibility for any party to use this mechanism to its advantage by promoting its specialized drugs instead of its partners, explains the possible joint commitments of both parties to a long-term mechanism.

This is not a coincidence especially regarding the role that GMP plays in product approval process. Instead of market access for specific drugs, innovation, translated into the development of new patented products, became the main catalyst of the negotiation around CETA within Pharma. This is reflected in numerous documents, including a letter from Health Canada to the European Medicines Agency of December 7<sup>th</sup>, 2007, which calls to increase regulatory cooperation between the two agencies expecting that cooperation:

provide accelerated access of patients and animals to new and innovative therapeutic products as well as resources savings and improved regulatory performance and safety as a result of the involvement of the best regulatory expertise from both sides<sup>229</sup>.

As suggested in officials' documents and positions papers, Regulatory requirements for the approval of new products are heavy for both firms and regulators. Regulatory Cooperation can thus help regulators save resources by pooling their expertise as well as reducing duplications of

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<sup>228</sup> EFPIA, "CETA: A Step Forward to Benefit Patients and Innovation", <https://www.efpia.eu/media/26025/ceta-a-step-forward-to-benefit-patients-and-innovation.pdf>, accessed the 3<sup>rd</sup> August 2019.

<sup>229</sup> Letter from Health Canada, Meena Ballantyne Assistant Deputy Minister to the European commission and the European Medicines Agency, December 7, 2007

administrative requirements for firms<sup>230</sup>. What can be said from the information gathered, is that both the EU and Canadian government decided jointly to enshrine their cooperation into a long-term regulatory cooperation process.

As seen, when negotiating CETA the EU and Canada did not adopt a design that limited long-term regulatory adjustment. Instead of establishing a short-term list of products or regulations that could facilitate market access for specific exporters and drugs, they adopted a long-term Ex-post design. Empirical evidence explains this decision in a context where exports have reduced importance due to GVC integration. Priorities were focused instead on regulatory requirements faced by all firms when they desire to launch a new product. In fact, both Canada and the EU have similar concerns relative to their global competitiveness in the global market, notably in terms of new product launching. The risk that one of the two actors would exploit this situation was considered thus less important than the one caused by non-cooperation in front of their main real competitor, the U.S. This context explains thus why a design of Type 2 was privileged in CETA. Although, Professional Qualification (PQ) is a different story, it shares nevertheless similar results. In fact, despite the different context that characterized the negotiation of PQ, in this case states also decided to use an Ex-post design.

## **Professional Qualifications**

As briefly described earlier, the trade surplus of the EU with Canada for Professional Services raised from 10 to 26 % between 2015 to 2017 (Table 7). Despite this small EU trade surplus, it is thus reasonable to assume that Canada and the EU enjoy a relatively symmetrical trade relationship. Neither Canada nor the EU can argue that their exports require specific regulatory mechanisms in place to guarantee market access, contrary to GIs and MV. Furthermore, it does not preliminarily appear that one country has more productive firms than the others, which could dominate the sector. This absence of vested interests in regulatory cooperation is also noticeable in other data sources, as seen following. It is possible to wonder why the two actors would negotiate in this sector, despite neither one having strong export interests.

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<sup>230</sup> Canadian Association of Professionals in Regulatory Affairs, “Comprehensive Economic and Trade Agreement (CETA) and Canada’s Pharmaceutical Sector”, <https://capra.ca/en/blog/comprehensive-economic-and-trade-agreement-ceta-and-canadas-pharmaceutical-sector.htm>, accessed the 10<sup>th</sup> August 2019.

Among the potential explanatory factors, the traditional European immigration to Canada could be identified as one cause. Despite a relative decline in immigration from Europe over the years in terms of the share of overall immigration numbers<sup>231</sup>, European immigrants tend to have a similar employment rate to that of Canadians (85.7% in 2017). Combined with the fact that immigrants in Canada have a higher participation rate in professional, scientific, and technical services, this would explain the interests in professional qualification recognition on both sides. The activities covered range from legal services, accounting, architectural, engineering, and related services, computer systems design, management, scientific and technical consulting, as well as scientific research and development. There is thus a similarity between the composition of immigrant workers' occupations in Canada and the service activities covered by the PQ MRA. This link between immigration and the negotiation of the MRA in CETA should however not be overrated. Insights and opinions gathered from industry and officials gave a mixed picture. While cross-sector business organization from the Canadian side affirmed that they supported the inclusion of the MRA in CETA, as it would help support their activities, sectoral professional organizations on both sides appear to have been less enthusiastic (industry A5-D5, interviews in Brussels and Ottawa).

Furthermore, officials from both sides, while acknowledging the possible connection between immigration and professional qualifications, affirmed that immigration did not play a significant role during the negotiation (officials D6-B6, interviews in Ottawa & Brussels). Instead, they see the PQ MRA in connection with CETA Chapter 10 - *Temporary entry and stay of natural persons for business purposes*. The purpose of the integration of PQ in CETA was to support trade in services between the two regions, notably by favoring the accreditation of states on both sides (officials D6-B6, interviews in Ottawa & Brussels). Indeed, a lawyer who is a member of the Canadian and European bars does not need to live in Canada or the EU to provide legal services. The same could be said for other professionals, who can regularly cross borders on both sides without having to live in the place where they provide services. Qualification recognition for these people facilitates their ability to engage in economic activities in both regulatory areas, on their individual behalf or for the firms they work for. In sum, this cooperation scheme acknowledged the interdependent reality of their economic bilateral relationship, but also of the relative absence of a superior state relative to the other.

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<sup>231</sup> Government of Canada, “150 years of immigration in Canada”, <https://www150.statcan.gc.ca/n1/pub/11-630-x/11-630-x2016006-eng.htm>, accessed the 6<sup>th</sup> August 2019.

Besides looking at overall trade statistics, disaggregated data can indicate the sectors that could benefit the most from the CETA MRA. Table 25 (appendix V) shows a certain degree of sector specialization between Canada and the EU. While Canada enjoys a trade surplus in Business/management consulting and Advertising/market research/public opinion polling services; the EU trade imbalance is positive for engineering, accounting & auditing, legal services and architecture. Scientific services are more balanced between the two countries with the EU enjoying a limited trade surplus of 24% in 2017. Trade in services between the two parties appear thus to be characterized by a Canadian specialization in business management related services, while the EU focuses on “core” professional services such as engineering, accounting, and legal services.

Architecture in CETA is as of today the only sector where the respective professional organizations (Architects’ Council of Europe (ACE), Canadian Architectural Licensing Authorities (CALA)) signed an MRA following the signature of CETA<sup>232</sup>. No other professions appear to have followed the initiative of architecture, despite some preliminary exchanges in certain cases, notably for legal services (Industry and Officials D5-D6-B6, interviews in Brussels & Ottawa). It does not appear that “super-star exporters” were waiting for the conclusion of the agreement to expand their activities in foreign markets. Among the services traded, architecture numbers should call for caution especially due to the apparently low level of exchange between the two countries. Indeed, in 2017 the EU exported only 14 million Euro to Canada, while Canada’s exports reached 4 million. Compared with the other services, architecture exchange data seems particularly small. Unfortunately, no other data sources were available at this level of detail. As reviewed in previous sections, not all databases contain trade in services data.

In architecture, it is plausible that this low level of exchanges is the reason the agreement could be concluded. Seeing an opportunity to expand cross-country exchange without fear of foreign competition from more productive firms, the two trade associations used the opportunity of CETA to adopt a mechanism that would increase trade flows. In fact, MRA being a non-discriminatory mechanism, the actors of the sectors could decide to support it to reduce qualification barriers. At such low level of exchanges, the two parties consider their trade flow symmetrical, assess the risk of “hold-up” low, and agree to commit to an Ex-post mechanism to increase market access for both parties. This argument is however not confirmed by any other empirical sources and could

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<sup>232</sup> Architects’ Council of Europe, “Press Release”, 23<sup>rd</sup> April 2018, <https://mailer.acae.eu/en/public/webview/show/128/6>, accessed the 6<sup>th</sup> August 2019.

be only circumstantial. The existence of a previous agreement between the “Ordre des Architectes du Québec” (OAQ) and the “Conseil national de l’Ordre des architectes français”, signed in 2009<sup>233</sup> could explain it. The role of this previous agreement is discussed further, when looking at Pharma and PQ’s preexisting regulatory framework.

The absence of other sectors’ MRAs remains puzzling, as well as the lack of interest of other trade associations to follow the architecture association. According to Canadian and European officials, with the exception of architecture, no other sectors’ associations expressed interest during the negotiation (officials D6-B6, interview in Brussels & Ottawa). The states were not aware of particular sectoral interests to defend. While there was a shared will on both sides to engage in cooperation to facilitate the supply of cross-border services, this did not originate from the defense of specific interests. The overall trade balance between Canada and the EU might be a cause for this approach to cooperation. States establish a long-standing framework, which can be mobilized if there are interests in cooperation from actors on the ground. They reflect this state of symmetry by designing a mechanism for liberalization for the long term. Specifically, the MRA mechanism in CETA puts into place a mechanism that is at the disposition of professional associations without determining the content of the cooperation. The associations are free to decide the rules to be followed, e.g. number of required years of professional experience. It is thus a technical process of cooperation, where the concerned actors can initiate a procedure to solve technical issues progressively.

Another cause could be the degree of fragmentation of professional services on both sides. In fact, the division of professional organizations along provincial and national lines results in more difficulties to coordinate and create a single common front. In Europe, although the EU has several directives forcing national organizations to recognize other Europeans’ professional qualifications, a certain level of diversity among national practices remains. For instance, Sweden, Denmark, Finland and Estonia do not regulate the profession of architect<sup>234</sup>. In Canada, professional qualifications are a provincial competence and are self-regulated as detailed later (official B6, interview in Ottawa).

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<sup>233</sup> Ordre Des Architectes, « Signature d’un accord de reconnaissance mutuelle entre la France et le Québec », <https://www.architectes.org/actualites/signature-d-un-accord-de-reconnaissance-mutuelle-entre-la-france-et-le-quebec>, accessed the 7th August 2019.

<sup>234</sup> EC DG GROWTH, “Mutual evaluation of regulated professions: Overview of the regulatory framework in the business services sector by using the example of architects”, p. 5, <https://ec.europa.eu/DocsRoom/documents/13382/attachments/1/translations/en/renditions/native>, accessed the 7<sup>th</sup> August 2019.

This results in a situation where professional organizations are dispersed in both territories, at the local level, and have difficulties to organize collectively as a group of exporters. Their different technical requirements within the EU and Canada, prevent them from coming up with a joint list of requirements they could integrate within CETA (Ex-ante). It is thus a situation where the same firms are equally present on both sides, organized in a decentralized manner without coordination on technical requirements, and without specific interests to defend. The consequence of such a pattern, is the almost complete absence of a “hold-up” risk by one of the negotiating party. As none have specific commodities to use opportunistically, neither are in a particularly advantageous situation in bilateral economic relations, they will not be in capacity to use in the future the economic interdependence – particularly limited in this case – to obtain further specific regulatory concessions.

This level of internal variation within the EU and Canada might explain even further the choice of Type 2 as the most feasible considering the complex variation of regulatory approaches within Canada and the EU. Faced with such diversity of practices it is particularly complicated to select specific professions. For instance, while Swedish architecture services might be fine with recognizing Canadian qualifications Ex-ante, it might be different for other countries with a different process. Delaying cooperation through a stable mechanism appears thus as the best choice for liberalization in light of such complexities. Ex-post design also has the advantage of keeping the content of the regulatory cooperation open and thus letting local actors decide *in fine* if they want to adopt new regulations or not.

This line of argument however poses another question: isn’t the fragmentation of regulatory framework ultimately responsible for the choice of Ex-post? To which extent is the choice of Ex-post due to presence of “hold-up” risk and not the technical difficulties resulting from the regulatory divergences and fragmentation—typical of shirking risk situation—between the EU and Canada? To answer this question requires us to look at another similar case in CETA, Government Procurements, which in Canada is similarly regulated in a fragmented way, belonging to the provincial competence. However, in this case, this fragmentation did not prevent Canada and the EU from including in Annex 19-2 of CETA a comprehensive list of services and provincial/municipal authorities subjected to government procurement rules as established in chapter 19 – *Government procurement*.

As provincial and municipal authorities were involved in the government procurement negotiation<sup>235</sup>, it was thus counterfactually possible for states to include professional organization to their technical talks in order to come up with a comprehensive list of requirements. What significantly differentiates Government procurement from PQ was the strong asymmetric interest of the EU in opening Canadian procurement markets to European firms<sup>236</sup>. In PQ, the absence of offensive export interests from both sides, as industries and officials stated cited earlier, appears thus as the significant factor that affected the design feature Ex-ante/Ex-post. The absence of interests from either side, and thus of major “hold-up” risk, has led the negotiating states not too include any specific profession’s rules but adopt instead an open-ended mechanism.

Additional evidence of the absence of “hold-up” risk to explain the use of the Ex-post mechanism is the conviction from both sides of economic gains through cooperation. According a Canadian “Report of the Standing Committee on International Trade” presented at the House of Commons in 2012:

The Committee was told that Canada is well positioned in terms of trade in services with the EU in light of its trade surplus with the EU in professional services, which include primarily legal, architectural and engineering services. Increased access to the European marketplace could help strengthen Canada's existing position<sup>237</sup>.

Although the export surplus of Canada is only present for Business/advertising services and not engineering, legal and architectural service (even in 2012)<sup>238</sup>, this Canadian confidence in their ability to compete in trade service might have helped European negotiators to convince their Canadian counterparts to commit to an MRA mechanism in PQ. The Canadian commercial services’ sector is indeed an important acknowledged trade interest of the country and is thus part of Canada's trade policy<sup>239</sup>. For the Europeans, the small trade surplus and their advantages in

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<sup>235</sup> House of Commons Canada, “Negotiations toward a comprehensive economic and trade agreement (ceta) between canada and the european union: Report of the Standing Committee on International Trade”, p. 5, <https://www.ourcommons.ca/Content/Committee/411/CIIT/Reports/RP5431905/CIITrp01/ciitrp01-e.pdf>, accessed the 8<sup>th</sup> August 2019.

<sup>236</sup>Ibid, p. 19

<sup>237</sup>Ibid., p. 13

<sup>238</sup> Eurostat, International trade in services (BPM6); to note that Canadian statistics sources concurred with Eurostats, <https://www.international.gc.ca/economist-economiste/statistics-statistiques/bip-bdp.aspx?lang=eng>; [https://www.international.gc.ca/gac-amc/campaign-campagne/ceta-aecg/year\\_one-premiere\\_annee.aspx?lang=eng](https://www.international.gc.ca/gac-amc/campaign-campagne/ceta-aecg/year_one-premiere_annee.aspx?lang=eng), accessed the 8<sup>th</sup> August 2019.

<sup>239</sup> “Commercial services exports (total services less travel, transportation, and government services) are the most important and fastest growing sector of services exports for Canada, creating high-paying jobs in

other service sectors appear to have been sufficient motivations to commit to the mechanism. Thus, the available declaration and official statements and reports seem to indicate that joint perception of equal shared relative benefits played a role in establishing the mechanism. Two facts appear thus to have acted jointly in determining the choice of Ex-post. One, no specific professional association or service suppliers from either side appear to have come forward and asked for integration of specific qualifications directly in the treaty recognition rules. This apparent restraint from domestic actors appears to have convinced states to delay cooperation. This would make sense as it would allow professional associations to seize the mechanism if specific economic interests finally emerged. States thus designed the MRA as a voluntary instrument, but with compulsory consequences, that can be seized at any moment. Second, both countries' expectations of relatively symmetrical mutual gains appear also to have played a significant role. As both were convinced, as expressed in official reports and statements, that they are well placed in trade in services, states could design a delayed mechanism for a progressive long-term liberalization of the sectors.

### **Pharma and PQ, cooperation without “hold-up” threat**

In sum, the trade position of the EU and Canada for Pharma and PQ appears to explain the use of an Ex-post mode of decision and a regulatory design of Type 2 (Ex-post/hard). In these two sectors, none of the parties were able to advance specific export interests they could integrate into CETA's regulatory design. Despite the EU's large trade surplus in Pharma, the global integration of pharmaceutical companies tones down the importance of exports. As reviewed, product approval for new pharmaceutical drugs plays a larger role in countries' international competitiveness. In this aspect, the EU and Canada share a similar position, recognizing similar medications and both being a secondary place for the launching of new products compared to the USA. CETA Pharmaceuticals provisions aimed thus at improving the global status of these two countries. Interestingly, while the negotiation of the protocol of conformity assessment for GMP witnessed an important level of engagement from both sides, resulting in an equilibrium, the PQ sector achieves a similar result from a different context. Indeed, the actors concerned with the negotiation of the PQ MRA mechanism are divided along national and provincial lines and did

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knowledge-intensive industries such as management, architectural, engineering, research and development, and financial services.” <https://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/services/canada.aspx?lang=eng>, accessed the 8 the August 2019.

not mobilize significantly for the negotiation, except for architecture. This decentralized geographical presence and organization of services suppliers limited the ability for all parties involved, industry and states, to come up with a precise list of specific professions jointly recognized by the two countries.

In sum, what explains PQ design is the relatively similar gains expectations on both sides. This conjunction of interest in liberalizing trade in services encourages states to choose a long term, comprehensive mechanisms instead of immediate market access concessions. They choose to delay technical cooperation as the relative symmetry in trade flow did not result in singling out specific services. The absence of specific exports interests from either side, reassured them on the future possibility of “hold-up” and led the states to choose a more open-ended approach to liberalization.

In Pharma, the global integration of economic activities has reduced the need to adopt product level regulations. Trade surplus loses its importance because of the presence all around the world of firms active in all sorts of activities, e.g. production, R&D, commercialization. As products can be manufactured and accessible all around the world, the chance of unilaterally exploiting this relation is meagre. This is even more the case considering that the value of pharmaceuticals products does not derive from the production process as such or its chemical components, but regulatory approval, so downstream segment of the value chain. In fact, as seen earlier product approval is a major concern for both the EU and Canada, which share similar weakness in this downstream part of the global pharmaceutical sector. It explains their Ex-post choice of design to cooperate in the long run, for the purpose of improving their competitiveness and reducing regulatory costs. Overall, the choice of Ex-post design by states appears to have been motivated by states’ preferences in establishing a long-standing mechanism where they could address joint regulatory concerns and work to address technical details on a case-by-case basis.

Preliminarily addressed in this section, regulatory requirements have a particularly acute importance for PQ and Pharma. The next section looks at the regulatory frameworks of both countries. It also looks at how, from this state of regulatory divergences, states decided how to choose a specific design feature, notably Hard obligations, in these two cases.

## 7.2. *Shirking*

Following the adoption of the WTO TRIPS agreement in 1995, concomitant with the establishment of the WTO, the value chains of pharmaceutical products have radically changed (Haakonsson 2009). Global integration has resulted in a deep restructuring of pharmaceutical activities all around the world. One of the implications of this reorganization is the emergence of new regulatory challenges, particularly sensitive due to the nature of Pharma products. For Professional Services, it becomes possible to witness a current global “servification”<sup>240</sup> of international trade. This phenomenon results in the rising integration of a series of professions (consultants, lawyers, engineers, scientists) within trade value chains. Consequently, an increasingly higher share of export or import value is attributed to the role of these services<sup>241</sup>. At the same time, trade in services is restricted by domestic regulations, which significantly impedes cross border services supply (Lianos and Odudu 2012, 1). This state of fact is acknowledged by the WTO, which includes Domestic Regulations (DomReg) as one of its main pillars for negotiation on services liberalization<sup>242</sup>. Professional services have a particular significance in this context as they include services with important added value (engineering, business consultants, lawyers), which can be heavily regulated in different domestic environments. These requirements significantly restrict services supply, often for safety reasons and consumer protection.

Previously belonging solely to the domestic sphere, Pharma and Professional Services regulations have now taken on an inescapable global dimension. The integration of these issues into the CETA cooperation framework corresponds thus to a witnessed global trend. How these cooperative schemes are designed remains however to be explored. This is particularly the case as CETA did not initiate regulatory cooperation in these sectors, but rather places itself in the continuation of preexisting regulations, some of them at the global level. Existing global regulations can potentially play an important role in designing sectors’ cooperation in CETA. As proposed in the theoretical part and preliminarily observed in the cross-sector Chapter 7, existing

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<sup>240</sup> Servification is a concept that acknowledged the growing share of services inputs into manufacturing process of goods. The EC and DG trade chief economist, Lucian Cernat took stock of this trend and published a series of papers on the “servification” of manufacturing and the rise of a new mode of services supply (M5) (Antimiani and Cernat 2017; Cernat and Kutlina-Dimitrova 2014)

<sup>241</sup> UNCTAD, “The Servicification of Global Value Chains: Evidence and Policy Implications”, [https://unctad.org/meetings/en/Presentation/c1mem5\\_2017\\_124\\_S3\\_Miroudot\\_2.pdf](https://unctad.org/meetings/en/Presentation/c1mem5_2017_124_S3_Miroudot_2.pdf), accessed the 8th August 2019.

<sup>242</sup> WTO, “WTO negotiations on domestic regulation disciplines”, [https://www.wto.org/english/tratop\\_e/serv\\_e/dom\\_reg\\_negs\\_e.htm](https://www.wto.org/english/tratop_e/serv_e/dom_reg_negs_e.htm), accessed the 8th August 2019.

and preexisting regulatory divergences in Pharma and PQ could explain the use of legal provisions with Hard obligations instead of soft ones. This chapter thus investigates this possibility, by looking in priority if this divergence could result in future or presently to any parties attempting to stop/limit recognition of products, or shirking risk. The use of Hard obligation is also assessed in their legal constraining effects to force recognition and potentially provide sanctions possibilities in case of commitments' violation.

To proceed to this assessment, data from international regimes, domestic regulation and conformity assessment methods are gathered. The empirical observation will help testing the causal link between presence of shirking risk and the use of Hard obligation.

### **Pharmaceutical Products (Pharma)**

As introduced, a sizeable number of global rules and regulations are already existing for producing and commercializing pharmaceutical products. This international cooperation often includes safety related rules, also labelled as pharmacovigilance (Pezzola and Sweet 2016, 2). This cooperation is especially crucial due to the outsourcing by pharmaceutical multinationals of certain activities, notably manufacturing, to countries outside of the jurisdiction of the surveillance authority. Due to limitation in administrative resources, controls are difficult to perform particularly considering the complex international imbrication. To give an illustration, citing a U.S. government report in 2010, the Council on Foreign Relations recalls:

it would take the FDA [(Food and Drug Administration)] eighteen years to inspect all registered manufacturing firms in China just once. This point underscores the fact that most foreign facilities have never received a single inspection from the FDA, and never will, if the status quo persists. Tackling these concerns requires strong multilateral cooperation among national regulatory agencies<sup>243</sup>.

The Pharma sector is thus characterized by numerous layers of regulations and standards used globally, for all activities related to R&D, approval, production and commercialization of Pharma products. These rules are however complex and can be interpreted differently according to

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<sup>243</sup> Council of Foreign Relations, “Designing a Global Coalition of Medicines Regulators”, 19<sup>th</sup> August 2014, p. 2: <https://www.cfr.org/report/designing-global-coalition-medicines-regulators>, accessed the 8th August 2019.

countries' regulatory preferences. Among these existing regulations, Good Manufacturing Practices (GMP) are particularly important. Initially introduced by the World Health Organization (WHO) in 1968, GMP were part of a WHO Certification Scheme on the quality of pharmaceutical products moving in the global market<sup>244</sup>. It is:

a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product<sup>245</sup>.

Since then, GMP benefitted from an extension in 1991 by the Expert Committee on Biological Standardization (ECBS) in the form of a new annex, extending its products scope to new medications such as vaccines<sup>246</sup>. Adopted by 100 countries, mostly developing countries, these GMP guidelines are a minimally required quality threshold for manufacturing. In parallel with the early development of the GMP, the Pharmaceutical Inspection Convention (PIC) was adopted in 1970 by the European Free Trade Association (EFTA). The PIC was re-labelled as the Pharmaceutical Inspection Co-operation Scheme PIC/S in 1995, following its establishment as a non-profit organization<sup>247</sup>. Its purpose in short is to provide guidelines on facilities inspection for the good implementation of the GMP<sup>248</sup>. It is thus a corollary of the GMP standards. Its membership is more restricted than WHO (45 regulatory authorities' participant), with a predominance of European countries and important pharmaceutical players such as the U.S.A., Canada, Argentina, Australia, South-Africa, Japan and other south-east Asian countries<sup>249</sup>. The EU departed from the PIC/S original guide, based on WHO GMP of 1968, to develop its own GMP guide, finally adopted in 1989<sup>250</sup>. While the two documents are considered equivalent, it nevertheless represents a first expression of EU regulatory autonomy. In fact, the rising role of

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<sup>244</sup> WHO, “Good Manufacturing Practices”, [https://www.who.int/biologicals/vaccines/good\\_manufacturing\\_practice/en/](https://www.who.int/biologicals/vaccines/good_manufacturing_practice/en/), accessed the 8<sup>th</sup> August 2019.

<sup>245</sup> WHO, “GMP Question and Answers”, [https://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/gmp/en/](https://www.who.int/medicines/areas/quality_safety/quality_assurance/gmp/en/), accessed the 8<sup>th</sup> August 2019.

<sup>246</sup> WHO, “WHO good manufacturing practices for biological products: Annex 2”, [https://www.who.int/biologicals/areas/vaccines/Annex\\_2\\_WHO\\_Good\\_manufacturing\\_practices\\_for\\_bio logical\\_products.pdf?ua=1](https://www.who.int/biologicals/areas/vaccines/Annex_2_WHO_Good_manufacturing_practices_for_biological_products.pdf?ua=1), accessed the 8<sup>th</sup> August 2019.

<sup>247</sup> Pharmaceutical Inspection Co-operation Scheme (PIC/S), <https://picscheme.org/en/about>, accessed the 8<sup>th</sup> August 2019.

<sup>248</sup> PIC/S aims at harmonizing inspection procedures worldwide by developing common standards in the field of GMP and by providing training opportunities to inspectors., <https://picscheme.org/en/about>

<sup>249</sup>Ibid., “members”, <https://picscheme.org/en/members?payselect=NL>

<sup>250</sup>Ibid., “publications”, <https://www.picscheme.org/en/publications?tri=gmp>

the European Medicinal Agency (EMA) has pushed the EU to pursue a standardization role on its own. This has two results. First, despite being considered equivalent, the PIC/S and EU GMP are still not identical, which can create some level of discrepancy and complicate GMP implementation and compliance<sup>251</sup>. This strengthens the EU's regulatory position for certain states that share regulatory alignment with Europe, e.g. Switzerland, as its regulations tend to be issues earlier than the one of PIC/S.

Besides PIC/S and WHO GMP, another international organization was also established in 1990: “the International Council for Harmonization (ICH)”<sup>252</sup>. An international organization since 2015, the ICH was founded to “rationalize and harmonize regulation”, producing guidelines on safety, quality and efficacy since 1990. In 2000 it developed its Q7 guidelines on “Good manufacturing practice guide for active pharmaceutical ingredients”<sup>253</sup>, quickly adopted by the regulatory authorities of the EU, the U.S., Canada, Japan and Switzerland. These guidelines were more recently updated in 2015, notably to further harmonize facilities inspections<sup>254</sup>. In addition to the ICH, the “International Pharmaceutical Regulators Programme (IPRP)” was created, in 2018, as a successor to the “Regulators Forum” established in 2008<sup>255</sup>. It acts as a forum for regulators with the purpose of promoting “convergence of regulatory approaches for pharmaceutical medicinal products for human use”<sup>256</sup>. Contrary to ICH, IPRP membership extends to a larger group of countries, including developing ones.

This overview of existing international standards and organizations currently in place presents a picture of a complex regulatory network in charge of regulating pharmaceutical products. Despite the use of numerous international standards, evidence presented during this short history of the GMP shows the presence of regulatory discrepancies within the international Pharma regime. Calls to improve Pharma regulatory cooperation and fill the policy gaps are echoed by prominent

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<sup>251</sup> Swissmedic, “Good Manufacturing Practice (GMP)”, <https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/good-manufacturing-practices-gmp-vorgehen-abweichungen-zwischen-eu-und-pics-gmp.html>, accessed the 9<sup>th</sup> August 2019.

<sup>252</sup> International Council for Harmonisation (ICH), <https://www.ich.org/about/history.html>, accessed the 9<sup>th</sup> August 2019.

<sup>253</sup> Ibid., “Guidelines quality”, [https://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Quality/Q7/Step4/Q7\\_Guideline.pdf](https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q7/Step4/Q7_Guideline.pdf), accessed the 9<sup>th</sup> August 2019.

<sup>254</sup> International Council for Harmonisation (ICH), <https://www.ich.org/about/history.html>, accessed the 9<sup>th</sup> August 2019.

<sup>255</sup> International Pharmaceutical Regulatory programme (IPRP), “History”, <http://www.iprp.global/page/history>, accessed the 9<sup>th</sup> August 2019.

<sup>256</sup> Ibid., “Mission”, <http://www.iprp.global/page/mission>, accessed the 9<sup>th</sup> August 2019.

think-tanks, such as the Foreign Relations Council<sup>257</sup>. It remains however difficult for regulatory authorities to solve these regulatory conflicts due to Pharma's global integration. Pharma GVC puts a significant strain on regulatory authorities' resources, notably for countries with less administrative resources at their disposal. Deploying inspectors around the world is expensive and difficult, especially considering the number of facilities to visit and control. The conclusion of MRAs by States around the world aims at countering these effects, notably by encouraging the mutual recognition of inspection results. This type of scheme can save needed resources, by allowing public authorities to rely on inspections and controls performed by other countries' regulatory bodies. Nevertheless, this requires that all bodies' inspection guidelines and standards follow a similar threshold level, and legally binding obligation requires each authority to recognize their foreign counterparts inspection's results. As shown by the decision of the EU to adopt its own GMP regulation guide and the recent creation of the ICH, it remains difficult to rationalize existing international standards and convince states to collaborate with each other.

Despite the establishment of equivalences between standards, such as PIC/S-EU GMP, the process of compliance appears to be particularly complex and difficult. According to an industry, this complexity is due to the tendency of national regulatory authorities to add unique regulatory requirements to existing international standards (Industry A6, interview Ottawa). ICH standards remain voluntary and are reinterpreted by domestic authorities according to their needs. This implies that even if the same standard is used "formally" on both sides, it does not equate with a harmonized regulatory environment. As the Swiss Agency for Therapeutic Products expresses it: "equivalence" between guidelines (EU - PIC/S) does not imply they are "identical"<sup>258</sup>. Manufacturers are expected to comply with both guidelines and to the most stringent conditions where differences between guidelines exist.

However, firms are not passive in the face of these regulatory lapses between countries. For instance, the currently growing marijuana industry in Canada is looking at EU-GMP certification

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<sup>257</sup> Patrick M. Stewart & Jeffrey Wright, Council on Foreign Relations, "Designing a Global Coalition of Medicines Regulators", 19<sup>th</sup> August 2014: <https://www.cfr.org/report/designing-global-coalition-medicines-regulators>, 8<sup>th</sup> August 2019.

<sup>258</sup> Swissmedic, "Good Manufacturing Practice (GMP)", <https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/good-manufacturing-practices-gmp-vorgehen-abweichungen-zwischen-eu-und-pics-gmp.html>, accessed the 9<sup>th</sup> August 2019.

to enter the European market<sup>259</sup>. While Directive 2001/83/EC<sup>260</sup> allows for cannabis production as an active pharmaceutical ingredient (API), Directive 2003/94/EC<sup>261</sup> lays down the principles and guidelines of GMP with respect to *medicinal products for human use* and *investigational medicinal products for human use*. These requirements are considered higher than Canadian standards for licensed Canadian firms’ (“Good Production Practices (GPP)”)<sup>262</sup> and more harmonized than US standards. Firms are thus interested in getting certified to the most stringent regulations, in this case the EU one, as it would facilitate subsequent regulatory compliance in Canada. Regulatory competition between different versions of the GMP is present internationally and is fueled by the various interpretations that domestic authorities have of the standard. There are thus strong interests to establish a legally binding framework that allows mutual recognition. The purpose would be to integrate both into a common regulatory framework that would be mutually beneficial. Indeed, following similar technical requirements saves significant regulatory and compliance costs.

As said earlier, the purpose of GMP is to demonstrate that production followed safety and quality requirements. To obtain recognition however, the products and facilities need to be regularly inspected. Health Canada specifies the inspection guidelines as well as its requirement to issuing conformity certification. These procedures are compulsory in order to assure compliance with Canada Food and Drugs Regulations, notably Division 1a – *Establishment licences*<sup>263</sup> and

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<sup>259</sup> Marijuana Business Daily, “In race to win Europe, Aurora Cannabis and other Canadian companies pursue EU-GMP”, <https://mjbizdaily.com/race-to-win-europe-aurora-cannabis-other-canadian-companies-pursue-eu-gmp/>, accessed the 9<sup>th</sup> August 2019.

<sup>260</sup> EUR-Lex, Official Journal of the European Communities, “Directive 2001/83/ec of the european parliament and of the council of 6 November 2001 on the Community code relating to medicinal products for human use” <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF>, accessed the 9<sup>th</sup> August 2019.

<sup>261</sup> EUR-Lex, Official Journal of the European Communities, “Commission directive 2003/94/ec of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use”, [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir\\_2003\\_94/dir\\_2003\\_94\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2003_94/dir_2003_94_en.pdf), Accessed the 9<sup>th</sup> August 2019.

<sup>262</sup> CCI, “Application of gmp in the cannabis industry”, <https://www.cannabiscomplianceinc.com/application-of-gmp-in-the-cannabis-industry/>, accessed the 9<sup>th</sup> August 2019.

<sup>263</sup> Government of Canada, Justice Laws Website: “Food and Drug Regulations (C.R.C., c. 870) Division 1”, [https://laws.justice.gc.ca/eng/regulations/c.r.c.\\_c.\\_870/page-110.html#h-575903](https://laws.justice.gc.ca/eng/regulations/c.r.c._c._870/page-110.html#h-575903), accessed the 9<sup>th</sup> August 2019.

Division 2 – *Good manufacturing practices*<sup>264</sup>. In the EU, guidelines and related documents are provided by the European Medicines Agency (EMA), which has a function of coordination and ultimate guarantor of the uniform application of GMP across the continent<sup>265</sup>. As mentioned earlier, the EMA is also responsible for controlling the conformity with Directive 2001/83/EC and Directive 2003/94/EC laying out in EU legislation GMP requirements. In the EU, member states provide the related expertise and personal responsibility for GMP inspection<sup>266</sup>. To note that it is the EMA, who is in charge in implementing MRA of inspection<sup>267</sup>. In Canada, it is Health Canada through its Regulatory Operations Enforcement Branch (ROEB), which oversees MRA implementation.

An MRA for GMP has existed between Canada and the EU since 1998, operationalized in 2003. This MRA established mutual recognition between regulatory authorities on both sides. This implies that both parties recognized that regulatory authorities from both sides have equivalent GMP requirements and compliance programs (art. 2)<sup>268</sup>. While the same articles require GMP measures to lead to similarity of results but not to be “identical”, a certain leeway of interpretation remains. Complete recognition of equivalence remains thus conditional on the degree of confidence that both regulatory authorities entertain with each other. This should not be assumed as natural, especially taking into consideration the existing regulatory variations and discrepancies between regulators compliance expectations. Following the conclusion of CETA, the MRA is integrated into the treaty and replaced by the “Protocol on the Mutual Recognition of the Compliance and Enforcement Program regarding Good Manufacturing Practices for Pharmaceutical Products”. According to the industry, this protocol goes further than the previous MRA by aiming to remove “duplication and reduce/eliminate unnecessary differences between the two regimes (for the same activity).” This includes the possibility of active review of existing

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<sup>264</sup> Government of Canada, Justice Laws Website: “Food and Drug Regulations (C.R.C., c. 870) Division 2”, [https://laws.justice.gc.ca/eng/regulations/c.r.c.\\_c\\_870/page-114.html#h-576174](https://laws.justice.gc.ca/eng/regulations/c.r.c._c_870/page-114.html#h-576174), accessed the 9<sup>th</sup> August 2019.

<sup>265</sup> European Medicines Agency, “Good Manufacturing practice”, <https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice>, accessed the 9<sup>th</sup> August 2019.

<sup>266</sup> European Medicines Agency, “GMD/DGP Inspectors Working Group”, <https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/gmpgdp-inspectors-working-group#governance-section>, accessed the 9<sup>th</sup> August 2019.

<sup>267</sup> European Medicines Agency, 18<sup>th</sup> February 2014, “Mandate, objectives and rules of procedure: GMP/GDP inspectors working group (GMDP IWG)”, [https://www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-gmp/gdp-inspectors-working-group-gmdp-iwg\\_en.pdf](https://www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-gmp/gdp-inspectors-working-group-gmdp-iwg_en.pdf), accessed the 9<sup>th</sup> August 2019.

<sup>268</sup> EC DG Health & Government of Canada, “Sectoral annex on good manufacturing practices (GMP)” [https://ec.europa.eu/health/sites/health/files/files/international/doc/mraeccan\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/international/doc/mraeccan_en.pdf), accessed the 9<sup>th</sup> August 2019.

requirements to align requirements and/or processes, but also early discussion during the development of new regimes (Industry A7, interview in Ottawa).

CETA positions itself in the continuation of states ongoing cooperation in the field of GMP MRA. By strengthening joint commitments, the purpose is to create a regulatory area where regulatory compliance is facilitated. The use of Hard obligation in this context is logical as the MRA aims at constraining regulatory authorities to accept the requirements and documentations of both sides. Indeed, national divergence between official forms alone can make compliance more difficult as it duplicates administrative work for firms. Therefore, explicit obligations to accept batch or GMP certificates can remove significant regulatory hurdles. Soft regulations alone, such as international standards, already exist and fail to reduce regulatory divergences between countries. It is the failure of this soft type of design that prompted States to commit formally to cooperation in MRA and later in CETA. Hard obligations are thus designed so as to constrain recognition by the regulatory authorities, enabling states to potentially enact violation mechanisms if batch or GMP certificates are not recognized.

Their motivation originates partly from the role that GMP plays in the approval of new pharmaceutical products notably at the “marketing authorization” stage within the centralized procedure of the EMA<sup>269</sup> and Health Canada approval procedure<sup>270</sup>. GMP goes beyond the approval of new products, as it includes all facilities manufacturing pharmaceutical products. Nevertheless, the importance of GMP in the launching of new products is not to be neglected, especially in the context of international regime fragmentation. Through creating a common regulatory area for this standard, the EU and Canada can benefit from a comparative advantage for the launching of certain medicinal products, as the case of marijuana illustrated previously. By removing regulatory divergence and facilitating compliance with international requirements, both countries can gain some market attractiveness.

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<sup>269</sup> European Medicines agency, “From laboratory to patient: the journey of a centrally authorized medicine”, p. 10, [https://www.ema.europa.eu/en/documents/other/laboratory-patient-journey-centrally-authorised-medicine\\_en.pdf](https://www.ema.europa.eu/en/documents/other/laboratory-patient-journey-centrally-authorised-medicine_en.pdf), Accessed the 9<sup>th</sup> August 2019.

<sup>270</sup> Government of Canada, “Good Manufacturing Practices”, <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices.html>, access the 9<sup>th</sup> August 2019.

## Professional Qualifications

The WTO General Agreement on Trade in Services (GATS) lays out the foundation for the regulations of services, including professional ones, at the international level<sup>271</sup>. Two GATS articles are particularly relevant for Professional Qualifications: Article VI – *Domestic Regulations* and Article VII – *Recognition*. Article VI specified the conditions that States need to respect when developing service regulations, notably to avoid unfair discrimination towards foreign suppliers (National Treatment). These disciplines are to be negotiated at WTO within the DDA, which includes regulations on domestic qualifications<sup>272</sup>. Article VII focuses on the recognition of licenses or qualifications of services suppliers and details the conditions for recognitions that states need to abide by. These two articles act as a minimal threshold for the recognition of domestic qualifications but leaves an important margin of appreciation to regulators, notably which qualifications to recognize and under which conditions. The unsuccessful bid to conclude the DDA left this question un-resolved multilaterally. The attempt to provide an answer through the Trade in Services Agreement (TiSA) also fails for the time being, negotiation being suspended since November 2016<sup>273</sup>.

Besides GATS, few international instruments exist that handle the question of professional qualifications, especially across different professions. The Washington agreement of 1989 for the recognition of engineering qualifications establishes a mutual recognition mechanism with minimal threshold for the profession of engineers<sup>274</sup>. The USA and Canada are part of the agreement, but the UK remains the only European member of the treaty<sup>275</sup>. European engineering association and accreditation bodies are part of the European Network for Engineering Accreditation (ENAE), a non-profit organization that does not count Canada or the USA among its membership (Russia and Switzerland are full-fledged members). Canada is however part of the *Convention on the Recognition of Qualifications concerning Higher Education in the*

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<sup>271</sup> WTO, “The General Agreement on Trade in Services (GATS): objectives, coverage and disciplines “, [https://www.wto.org/english/tratop\\_e/serv\\_e/gatsqa\\_e.htm](https://www.wto.org/english/tratop_e/serv_e/gatsqa_e.htm), Accessed the 9<sup>th</sup> August 2019.

<sup>272</sup> Ibid.

<sup>273</sup> EC, “Trade in Services Agreement”, <https://ec.europa.eu/trade/policy/in-focus/tisa/>, accessed the 9<sup>th</sup> August 2019.

<sup>274</sup> International Engineering Alliance, “Washington accord”, <https://www.ieagreements.org/accords/washington/>, accessed the 9<sup>th</sup> August 2019.

<sup>275</sup> Ibid., “Signatories”, <https://www.ieagreements.org/accords/washington/signatories/>, accessed the 9th August 2019.

*European Region*, signed in 1997<sup>276</sup>. The agreement specifies rules for the recognition of academic credentials. To note however that for many professional services, such as lawyer, additional exams and professional experience requirements are necessary to practice in a foreign territory, e.g. the bar exam. To note that Canada was only a signatory of the treaty, which it formally ratified the 1<sup>st</sup> August 2018<sup>277</sup>. Significant regulatory fragmentation exists thus multilaterally. States created different limited clusters-groups of countries recognizing qualifications recognition. The case of engineers as mentioned is particularly illustrative, between the countries following the 1989 Washington agreement (Anglo-saxon mostly) and the ones belonging to the ENAEE (continental Europe). To bridge such a diverging regulatory environment, Hard obligations are necessary to commit parties to recognize professionals originating from countries outside a cluster.

Multilateral agreement are not the only legal instruments though. Certain bilateral agreements for the mutual recognition of PQs were anterior to CETA. Notably, an agreement on the mutual recognition (MRA) of professional qualifications was signed between the province of Québec and France since 2008<sup>278</sup>. An important number of sectoral MRAs between French and Québec professional organizations are also in place since, including law practices, architecture, nursing etc.<sup>279</sup>. Despite the extent of this cooperation, it remains geographically limited to France and Québec. Therefore, this does not resolve significantly the legal rift between Canada and the EU.

This rift is even more significant when taking into consideration the geographical fragmentation within regulatory areas (EU, Canada). Indeed, the organization of regulated professions is a strict provincial competence, within Canada (official B6, interview in Ottawa). Main internal legal instrument on this sector, the Canadian Free Trade Agreement (CFTA) between federal,

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<sup>276</sup> Council of Europe, “Details of Treaty N0. 165”, <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/165>; The Canadian Information Centre for International Credentials, “The Lisbon recognition Convention”, [https://www.cicic.ca/1398/an\\_overview\\_of\\_the\\_lisbon\\_recognition\\_convention.canada](https://www.cicic.ca/1398/an_overview_of_the_lisbon_recognition_convention.canada), accessed the 9<sup>th</sup> August 2019.

<sup>277</sup> Council of Europe, “Chart of signatures and ratifications of Treaty 165”, [https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/165/signatures?p\\_auth=v8ZTr5W0](https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/165/signatures?p_auth=v8ZTr5W0), accessed the 9th August 2019.

<sup>278</sup> « Entente entre le Québec et la France en matière de reconnaissance mutuelle des qualifications professionnelles » <http://www.mrif.gouv.qc.ca//Content/documents/fr/2008-12.pdf>, accessed the 10th August 2019.

<sup>279</sup> Ministère des relations Internationales et de la Francophonie Québec, «Liste des professions pour lesquels un arrangement de reconnaissance mutuelle (ARM) des qualifications professionnelles a été signé », [http://www.mrif.gouv.qc.ca/content/documents/fr/LIS\\_professions\\_ARM.pdf](http://www.mrif.gouv.qc.ca/content/documents/fr/LIS_professions_ARM.pdf), accessed the 10th August 2019.

provincial and territorial governments, updated in 2017, regulates labor mobility inside Canada (Chapter 7), including the recognition of professional qualifications and certifications<sup>280</sup>. Since the update, procedures have been established by professional organizations to facilitate competences recognition across Canada<sup>281</sup>. Professional organizations nevertheless keep their rights to impose certain minimal permissible requirements for recognition.

Within the EU, Directive 2005/36/EC<sup>282</sup> regulates the recognition of professional qualifications across the union. Article 10 of the Directives lays out a general system of recognition. The process is generic and the Article 10 set out the process to handle the recognition of qualifications. The system constrains European states to respect the procedure and treat all European professionals equally (art. 12) under some conditions (art. 13). Nevertheless, Europeans states' obligations are clearly stated. Article 16 also requires EU members to recognize experience of a non-national professional as sufficient proof of qualification. Several other provisions dedicated to certain professions, such as medical professions, also establish the frame of recognition within the EU. Overall, the EU system forces member states to recognize the qualifications and experience of European professionals.

Nevertheless, this harmonized version of qualification recognition in the EU and Canada should not be overstated. EU member states remain competent to decide whether their professions are regulated or not. Licenses to practice is also a member state's prerogative. This can create a noticeable variation inside the EU. As mentioned earlier, some European member states do not regulate the profession of architect<sup>283</sup>. This variation can be also present in Canada, where the provinces decide similarly how they regulate their professions. Conformity assessment of qualifications is also decentralized to the associations, which can specify the conditions of recognition. To note that the EU Directive requires equality of treatment but does not specify the condition for each profession. For instance, the Belgian bar association can require 3 years of

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<sup>280</sup> “Canadian free trade agreement”, 2017, <https://www.cfta-alec.ca/wp-content/uploads/2017/06/CFTA-Consolidated-Text-Final-Print-Text-English.pdf>, accessed the 10th August 2019

<sup>281</sup> Labour mobility, “A Guide for Regulatory Authorities”, <http://workersmobility.ca/wp-content/uploads/2018/03/2A50-GDL-FinalRevisedChecklist-E-20170715.pdf>, accessed the 10<sup>th</sup> August 2019.

<sup>282</sup> EUR-Lex, Official journal of the European Union, “Directive 2005/36/ec of the European parliament and of the council of 7 September 2005 on the recognition of professional qualifications”, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005L0036&from=EN>, accessed the 9<sup>th</sup> August 2019.

<sup>283</sup> EC DG Growth, “Mutual evaluation of regulated professions: Overview of the regulatory framework in the business services sector by using the example of architects”, p. 5, <https://ec.europa.eu/docsroom/documents/16684/attachments/1/translations/en/renditions/native>, accessed the 9<sup>th</sup> August 2019.

experience while the French only 2. However, the Belgian association needs to recognize the professional experience of French lawyers if they want to register in the bar association.

In sum, while Professional Qualifications are relatively harmonized within Canada and the EU, at the international level recognition of qualifications remains incomplete. Regulatory gaps within the global framework are widespread and cooperation is rather case by case, instead of being systematic. Despite the vanguard's role of previous bilateral agreements, such as between Québec and France, their scope is limited. Furthermore, the considerable autonomy that professional organizations enjoy internally is not without consequences. This freedom of action can result in the emergence of significant regulatory barriers for foreign professionals, who do not perfectly comply with local regulations. This can take the form of special certifications to pass. In fact, recognition of qualification does not equate to licensing and a right to work. Professional organizations still have important leeway in this aspect and the possibility of shirking recognition obligation is thus very high.

For the states involved in CETA, the purpose of cooperation was to address part of these gaps through a formalized framework. It was essential that this framework was “binding” to assure equal treatment to foreign professionals (officials B6-D6, interviews in Brussels and Ottawa). This cooperation was not meant to be voluntary but to ensure that once an MRA is in place, it will be respected by all related actors. In this context, the use of Hard obligation provision is not surprising. In the context of regulatory fragmentation, characterized by the important power of local organizations, it is essential for states to ensure that recognition could not be watered down locally. The opposite would defeat the liberalization aim of regulatory cooperation. Hard obligations constrain states externally and internally as they are internationally responsible if the agreements are not respected. Therefore, an MRA with hard design gave the legal basis for states to force potential local reluctance in recognizing foreign qualifications.

### *7.3. Conclusion*

Throughout the empirical analysis (Table 12), it appeared that economic relations between the EU and Canada are relatively symmetrical in Pharma and PQ sectors. While the EU had an export surplus in Pharma, the commodities it trades are approved and available on both sides of the Atlantic. Due to the global integration of Pharma firms around the world, these companies have dispersed units of production and R&D. The promotion of pharmaceutical product exports has

thus less importance compared with the development of new products, including the product approval requirements that come with. The development and authorization of new products are indeed key to firms global competitiveness in the sector, impacting countries' level of innovation. Consequently, the regulatory design for Pharma used an Ex-post design with the aim of reducing administrative burdens and regulatory duplications between the EU and Canada, especially in the area of Good Manufacturing Practices (GMP). By facilitating the mutual recognition of GMP and related inspections, the purpose of states from both sides was to facilitate the launching of new products in both jurisdictions. This binding scheme is particularly necessary as the global regime of Pharma is characterized by fragmentation between various standards and organizations, such as WHO, PIC/S and ICH. Furthermore, countries tend to adapt these standards to domestic particularities, which limits the establishment of equivalence between states' regulations.

#### **Pharmaceutical Products**

Asymmetric trade flows with European  
export Surplus

Trade flows have less economic  
importance than product approval. Similar  
drugs and medications are approved  
between EU and Canada.

Firms from both sides are Multinationals  
firms globally integrated. Specialization  
takes places between them. EU and  
Canada are similar junior partners globally  
in launching new products

*Risk of  
"Hold-up"  
assessment*

EU export surplus is not as relevant as  
Canada and the EU shared similarly a  
junior position in global market. "Hold-  
up" risk is seen less present between them  
than in their relations with the U.S., world  
leader in new products development

#### **Professional Qualifications**

Symmetric trade flows, with marginal EU  
export surplus.

Professional skills specialization within  
cross-borders services supplied, Canada  
focusing on Business and consultancy  
services, while EU on engineering and  
legal services

Absence from both sides of clusters of  
services suppliers interested in cross-  
border activities. General lack of interest,  
coupled with preferences on inwards  
domestic markets rather than international  
one.

Symmetric trade flows and the lack of  
exports interests from firms located in both  
sides, explain the low level of "hold-up"  
risks. This relative equal lack of interest  
explains the absence of majors concerns  
on potential opportunistic use of the  
mechanism

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	Deep international fragmentation between multiple regulatory initiatives and organizations without a coherent rationalizing general framework (e.g. WHO, PIC/S, ICH)	Thin international common denominator (GATS) and multiplication of various clusters of international agreements in opposition with each other (e.g. Engineering: Washington 1989 Versus ENAEE)
	Divergent domestic procedures and authorities ( Health Canada; European Medicines Agency) for products approval. Tendencies of these authorities to add "national" requirements.	Multiplication of limited bilateral MRA (Québec-France) without general framework. Delegation of accreditation and recognition procedure to provincial authorities and EU member states
	Voluntary legal nature of MRA concerning inspection equivalences and other administrative process. Lack of binding commitments for mutual recognition	Divergences in the requirements between national/professional/provincial authorities, within and across borders (e.g. architecture).
<i>Risk of Shirking assessment</i>	High risk of shirking due to international fragmentation, the lack of a commonly accepted framework and national tendencies to add specific regulatory requirements	High risk of shirking due to international and domestic fragmentations of recognition procedure. Lack of jointly accepted requirements. High tendencies for accredited authorities to revert towards internal practices

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<i>Regulatory Design</i>	Type 2 (Ex-post/Hard) allows the institutionalization of a long-term mechanism that facilitates and bind countries in the mutual recognition and equivalences establishments of administrative procedures for cross-borders products approval	Type 2 (Ex-post/Hard) allows the institutionalization of a long-term mechanism that establishes binding MRA between authorities. Rationalize the existing international framework by putting existing bilateral MRA within CETA
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Table 12 Pharma and PQ, results of the in-depth analysis

For Professional Qualifications, the aim pursued by the states is to facilitate trade in services between the two continents. Having relatively symmetrical flows of trade, Canada and the EU chose a design of Type 2. Several reasons can be attributed to this decision. One was the lack of interests on the part of professional associations to integrate a list of recognized professions in the agreement. The absence of concentrated specific economic interests centered around the supply of specialized services might explain this absence of firms' mobilization. At the same time, the role of EU-Canada immigration might have encouraged the establishment of a general framework for professions moving to Canada. This was not the heart of the EU-Canada trade negotiation though, as acknowledged by negotiators themselves. Other explanations might be found around the transformative role that "servification" plays in global trade.

The rising integration of a wide range of services into the global trade in goods might render it difficult to identify specific professions *a priori*. Thus, to address regulatory barriers to trade in services, an open-ended framework (Ex-post) is more suited to reflect the integration of services into global production and trade. In terms of regulatory barriers, the main issue faced by PQ is the absence of a multilateral treaty regulating the recognition of qualifications across the globe. The failure to conclude the DDA and TiSA has allowed a regulatory gap to open between countries with divergent domestic requirements. Furthermore, the important autonomy and diversity of local professional organization is another challenge for the establishment of a joint regulatory framework. Hard obligations are necessary to ensure that the MRA concluded will be respected by all actors and not remain a best endeavor clause. This point was emphasized by negotiators, which were committed to the establishment of a binding cooperative scheme that could result in the possibility to activate a sanction mechanism (internationally or in front of domestic courts).

Chapter 6 and Chapter 7 both looked at sectors using a Hard obligation design. The next chapter will focus on three other sectors that were regulated instead through Soft obligation provisions. As recalled in theoretical parts, the design of Type 4 relies on an Ex-post mode of decision and Soft obligations. It was used to design cooperation in three sectors Biotechnology (Biotech), Forest Products (Forest) and Raw Materials (Raw). Chapter 8 investigates these three sectors through the same method used until now. It looks at the presence/absence of "hold-up" or shirking risks. This chapter tests the causal mechanism between these explanatory factors and the design Type 4 used.

## Chapter 8. In-depth case studies (type 3): Biotechnology, forest products & raw materials

Among the sectors covered in CETA, states decided to design their cooperation in Biotechnology (Biotech), forest products (Forest) and raw materials (Raw) through an Ex-post/Soft mechanism. This design of Type 4 delays cooperation and does not contain a binding regulatory mechanism. Instead, it sets a framework for cooperation through “soft” provisions to encourage joint regulatory efforts. In terms of activities covered, Biotech includes the production, distribution, importation and exportation of genetically modified organisms (GMOs), mainly foodstuffs. This scope reflects the type of products and activities covered by the Biotech bilateral dialogue. Forest includes similar economic activities centered around the production and trade of woods or wood-based products, such as roundwood, sawn wood, plywood, papers, etc. Raw instead focuses on the economic activities and regulatory issues around the extraction and commercialization of minerals (e.g. copper, gold) and transformed minerals or metal based products (steel, glass).

This chapter finds also that two sectors where Canada is a major exporter in the EU, Forest and Raw, did not result in the emergence of “hold-up” risks for the Europeans. In Raw, the EU was interested in diversifying its raw materials supply, notably reducing its exposure towards China rare earth. Both parties were thus interested in increasing Canadian exports in the EU. This was especially key as the EU lacks in its soil specific minerals that are needed for its clean tech industry, a key component of its climate change strategy. The risk of “hold-up” with Canada was considered thus non-existent, despite Canadian firms’ dominant role in the sector. On the contrary, mutual interests led negotiators to institutionalize in the long run their cooperation for increasing Canadian exports in Europe.

In Forest, the European industry did not see Canada as a potential rival in the market, notably as the European industry is closely connected to local supply chains and produces goods that are not substitutes for Canadian ones. Furthermore, for the EU supply in forest products by Canada was considered beneficial for the EU, especially considering the stringency of Canadian regulatory systems. Last but not least, in Biotech a similar picture emerged. Canada supplies mostly animal feeds to the EU (e.g. canola, soya), which are considered necessary by the European meat sector. At the time of the negotiation, the Canadian supply was not considered problematic potentially because the EU biotech sector is simply non-existent. While competition could have emerged with European non-genetically modified farmers, this did not rise potentially because of the needs

of animal feeds for the European meat sector. In all these instances, the complementary of the economic relationship between European and Canadian firms reduced again the risks of “hold-up”, despite the overwhelming productivity advantage that Canadian firms enjoyed in these tree markets.

Secondly, this chapter also notices that in Forest and Raw, the EU and Canada share similar regulatory objectives and abide to the same regulatory principles. They also use closely connected regulatory instruments, such as international standards, conformity assessment methods that are widely used on both sides and/or recognized. For the EU, the supply of raw materials that respect a certain number of social and environmental criteria is a key component of its regulatory approach towards the Raw and Forest sectors. Canada has developed over the years certification and assessments systems that comply with the EU stringent requirements (e.g. Towards Sustainable Mining). This complementary nature of the two systems creates thus a relatively harmonized regulatory environments with low risks of commitments’ defection from both sides. In such context, the use of Soft obligation to design the cooperation appears in light with the joint commitments to “orchestrate” the sectors.

On the contrary, the Biotech case is more controversial. Still as of today, the EU and Canada continues to have deeply diverging approval system and requirements. Before CETA a dispute emerged between the EU and Canada on the European moratorium of approval for new Biotech products. Even though a solution was found with the creation of a bilateral dialogue, technical barriers remain present for Canadian firms. The investigation finds that the design of Soft obligation is thus probably a legacy of the resolution of the WTO dispute case DS292, which was then integrated within CETA as such without changes. The solution of this bilateral dialogue is potentially considered by both parties as a “good enough” solution for the time being, considering that the WTO case already clarified partly the issue in the sector and the decision of the EU to end its moratorium earlier.

This chapter is structured as follows. Section 8.1 looks at the low level of “hold-up” risks for the three sectors, and through an in-depth analysis illustrates in more details its link with Ex-post design. Section 8.2 follows a similar objective between the low level of shirking risk and Soft obligation design. As discussed in Chapter 5, Biotech is a deviant case among the 7 cases discussed. The potential role of Civil Society was scrutinized in section 5.4 to explain this discrepancy, with mix results. By investigating this case further, section 8.2. argues that the role of the WTO dispute settlement mechanism could explain better the choice of Soft obligation

instead of hard one for Biotech, notably the role of DS292 European Communities — Measures Affecting the Approval and Marketing of Biotech Products. Last, section 8.3. summarized the findings of this chapter.

### *8.1. Hold-up*

Biotech, Forest and Raw share one main common denominator. They are all sectors characterized by a Canadian trade surplus with the EU. From export surplus statistics displayed earlier in Table 7, Forest and Raw are characterized by an unequal trade relationship between the two parties. In 2017, Canada exported 141% Forest Products and 1065% Raw Materials more than the EU. This superiority is present in the two previous years and can be qualified as a stable trade trend in these two sectors. Concerning Biotech, available trade statistics (Eurostats, UnComtrade, OECD TiVA) do not provide a sufficient level of details to determine the share of Biotech products in Canadian agriculture exports to the EU. Aggregated trade data does not distinguish goods according to production process and are thus not usable to assess Canadian biotech exports to the EU. Table 15 comparing EU-CAN agri-food exports can provide some substitute information to solve these limitations in existing database.

In all these three cases, Canada is exporting different products than EU exports. Furthermore, its exporters produce within the Canadian territory itself, and export to the EU from Canada. Biotech, Raw and Forest export patterns are relatively similar to MV and GIs. The question is thus: why did parties not choose a design Type 1 (Ex-ante/Hard) to regulate these three sectors? Part of the answer lies in studying more in-depth the trade relations between them.

### **The Canadian Biotech industry**

The trade composition between the two countries described in Table 15 (Appendix V) shows that the EU does not export any agri-food commodities that used available genetically modified technology. To recall, according to a report from the Canadian Biotechnology Action Network (CBAN) four GM crops are used for 99% of worldwide GM crop hectares: soy, corn, cotton and

canola<sup>284</sup>. None of these four commodities are present in main EU exports to Canada. On the contrary, the third and fourth most agri-food exported by Canada to the EU are soybeans (14.5% of all AG exports) and non-soya oilseeds (7.5%) (Table 15, Appendix V). From figures found in the same report, these commodities are mostly produced as GM in Canada, especially for canola<sup>285</sup> (used as oilseeds) and soybeans. Among Canadian oilseed exports to the EU, canola takes the biggest share as showed by comparing oilseed numbers in the report. To note that GM wheat and cereals are not allowed in the EU<sup>286</sup> and at least not commercialized in Canada<sup>287</sup>. While the picture remains mixed, it seems fair to assume that Canada has some significant trade interests in assuring and promoting market access of specific Biotech-Agri products in the EU. The European Food Safety Authority does allow the commercialization of certain GM soybeans and oilseeds, under the requirements that exporters label their products when entering the European market<sup>288</sup>. The possibility for a “hold-up” risk to emerge due to European dependency towards Canadian imports is thus theoretically possible.

Canada was the 4<sup>th</sup> country with the largest land use for GM crops in 2016 and 2017<sup>289</sup> with 13.1 million hectares exported. Most of the crops planted at these times currently produce Canola with

<sup>284</sup>Canadian Biotechnology Action Network (cban), “Where in the world are GM crops and foods?”, P. 5, <https://gmoinquiry.ca/wp-content/uploads/2015/03/where-in-the-world-gm-crops-foods.pdf>, accessed the 15<sup>th</sup> August 2019.

<sup>285</sup> Canola is not labelled as such in HS6. Nevertheless, it is partly capture with the tariff line 120510 Low erucic rape or colza seeds "yielding a fixed oil [...], the most traded between the EU and Canada, WTO, “Revised Draft Modalities for Agriculture”, p. 84, [https://www.wto.org/english/tratop\\_e/agric\\_e/agchairopt\\_may08\\_e.pdf](https://www.wto.org/english/tratop_e/agric_e/agchairopt_may08_e.pdf), accessed the 15<sup>th</sup> August 2019.

<sup>286</sup> EC DG Health and Food Safety, “EU Register of authorized GMOs”, [https://webgate.ec.europa.eu/dyna/gm\\_register/index\\_en.cfm](https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm), accessed the 15<sup>th</sup> August 2019.

<sup>287</sup>Canadian Biotechnology Action Network (cban), “Wheat”, <https://cban.ca/gmos/products/not-on-the-market/wheat/>, It remains unclear if GM wheat are authorized or not in Canada. While certain reports and newspaper claims that GM wheat are not authorized globally, in reality Canadian authorities approved certain Wheat GM in 2006 requested by the firm BASF Canada, Government of Canada Health Canada, “Approved products”, <https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html>, Canadian Food Inspection Agency, “DD2007-64: Determination of the Safety of BASF’s Imidazolinone-Tolerant Clearfield™ Durum Wheat Events DW2, DW6, and DW12”, <https://www.inspection.gc.ca/plants/plants-with-novel-trait/approved-under-review/decision-documents/dd2007-64/eng/1310920922697/1310921004894>; all accessed the 15<sup>th</sup> August 2019. ; It is possible that despite the authorization by the Canadian Food Inspection Agency the products were either prevented later for commercialized or are considered under the “novelty” threshold to be qualified as GM. Further investigations could bring more lights about GM Wheat around the world. Overall, it remains fair to say that available data does not reveal if GM Wheat in Canada plays a big role in exports.

<sup>288</sup> Canadian Canola Council, “Canadian canola biotechnology”, p. 23, <https://biotech.canolacouncil.org/files/Canola-Biotech-Report.pdf>, accessed the 15<sup>th</sup> august 2019.

<sup>289</sup> International Service for the Acquisition of Agri-biotech Applications (ISAAA), “Brief 53 Global Status of Commercialized Biotech/GM Crops in 2017: Biotech Crop Adoption Surges as Economic Benefits Accumulate in 22 Years”, p. 6, <http://www.isaaa.org/resources/publications/briefs/53/default.asp>, accessed the 15<sup>th</sup> August 2019.

67% of all land utilization, the second largest is soybeans with 19%, followed by maize with 13.5%<sup>290</sup>. Canada occupies the first rank for the production of canola in the world, exporting 90% of its production<sup>291</sup>. In terms of domestic economic value, the sector of canola production is the top source of farm crops income in Canada, totaling CAD \$8 billion in 2015<sup>292</sup>. Producers are organized through the Canola Council of Canada, which also represent their interests<sup>293</sup>.

In retrospect, it is possible to affirm that Biotech exports for Canada, especially Canola, is one of the country's major trade interests. On the contrary, EU agriculture areas dedicated to GM production are marginal if not absent compared with Canada or other major players. The union relies mostly on imports to satisfy its needs (soybeans, corn and rapeseed) and does not export its production<sup>294</sup>. For instance, the EU imports 95% of its soya bean consumption, Canada being a significant supplier for the continent<sup>295</sup>. The EU's restrictive regulatory framework in place for GM is often considered responsible for the lack of development of the sector and the importance of foreign sourcing in this sector<sup>296</sup>. The impact of EU regulatory frameworks is further discussed in the following section 8.2.

Bilateral trade in Biotech appears thus to be largely dominated by Canadian exports to the EU, notably by a concentrated group of nationally based producers of canola and soybeans. There are thus valid objective reasons to consider that a "hold-up" risk could emerge, especially in light of the European import dependencies towards Canadian exports. From a European perspective, there are significant interests as the continent is already using the crops imported for animal feed and

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<sup>290</sup> Ibid., p. 25, <http://www.isaaa.org/resources/publications/briefs/53/default.asp>, accessed the 15th August 2019.

<sup>291</sup> Canadian Biotechnology Action Network (cban), "Where in the world are GM crops and foods?", P. 16, <https://gmoinquiry.ca/wp-content/uploads/2015/03/where-in-the-world-gm-crops-foods.pdf>, accessed the 15th August 2019.

<sup>292</sup> Canadian Canola Council, "Canadian canola biotechnology", p. 5, <https://biotech.canolacouncil.org/files/Canola-Biotech-Report.pdf>, accessed the 15th august 2019

<sup>293</sup> Canadian Canola Council, "Board of Directors", <https://www.canolacouncil.org/what-we-do/board-of-directors/>, accessed the 15<sup>th</sup> August 2019.

<sup>294</sup> USDA Foreign Agriculture Service, "EU-28 Agricultural Biotechnology Annual", p. 10, [https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual\\_Paris\\_EU-28\\_12-14-2018.pdf](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_12-14-2018.pdf), accessed the 15th August 2019.

<sup>295</sup> EuropaBio, «The EU Protein Gap: facts and Figures», p. 9, [https://www.europabio.org/sites/default/files/EU\\_protein\\_GAP\\_WCover.pdf](https://www.europabio.org/sites/default/files/EU_protein_GAP_WCover.pdf), accessed the 15th August 2019.

<sup>296</sup> USDA Foreign Agriculture Service, "EU-28 Agricultural Biotechnology Annual", p. 17, [https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual\\_Paris\\_EU-28\\_12-14-2018.pdf](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_12-14-2018.pdf), accessed the 15th August 2019.

opened the possibility in 2017 to use canola oil as biofuel<sup>297</sup>. There are also some possibilities for the EU to shift its current supply in palm oil from ASEAN countries to soybean and canola, which could also be sourced in Canada<sup>298</sup>. Nevertheless, certain factors interfere in this structure notably the type of value chains (upstream), discussed in later parts that explain why countries concluded that the sector had a low level of “hold-up” and used an Ex-post design feature.

### The Forest sector, a strong Canadian asset

As shown by overall trade data, Canada is a leader the “Forest” sectors. According to Table 7, Canada enjoyed a trade surplus between 170% and 141% in its trade relation with the EU, around the years 2016 and 2017. In terms of products exchanged, Table 21 (Appendix V) revealed a specialization of Canada in the export of sawnwood coniferous, while the EU specialized instead in the exportation of plywood and veneer sheets. To note that this differentiation is not perfect as both are exporting newsprint, and Germany as well as Sweden are also exporting non-coniferous and coniferous sawnwoods. The same Table 21 reveals nevertheless, that Canadian exports remain largely superior to EU, its 7<sup>th</sup> export in value of importance (10'3336'000 US\$) corresponds to three times the highest EU export (3'750'000 US\$).

In terms of the three top products exchanged<sup>299</sup>, by aggregating numbers of the top seven markets of exports, Canada exports 101,646,000 US\$ of sawnwood, 92,242,000 US\$ of Newsprint and 10,336,000 US\$ of sawnwood, non-coniferous. On the contrary, the EU exports 10'115'000 US\$ of plywood, 2,599,000 US\$ of newsprint and 2'210'000 US\$ of veneer sheets. In aggregating numbers by commodities, Canadian export superiority is clear and its specialization in sawnwood appears more visible. The EU instead seems to focus on the exports of plywood to Canada. To note that in retail prices, products made of sawnwood tend to be described of higher quality and more expensive than plywood. Indeed, plywood is often produced by compressing lower quality

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<sup>297</sup> Canola Council of Canada, “Canola Council secures continued access to European Union Biofuel Market”, <https://www.canolacouncil.org/news/canola-council-secures-continued-access-to-european-union-biofuel-market/>, accessed the 15<sup>th</sup> August 2019.

<sup>298</sup> Farmlead, “APRIL 6 – “Why does the EU hate palm oil and can it help canola?”, <https://farmlead.com/blog/graincents/palm-oil-europe-imports-canola-prices/>, accessed the 15<sup>th</sup> August 2019.

<sup>299</sup> These three types of wood commodities (sawnwood, plywood and newsprint) were the only commodities with significant numbers reported by the FAO database (Table 21).

residue of wood, including remains of sawnwood, aiming at producing thin sheets of veneer<sup>300</sup>. A specialization pattern seems thus to appear, where Canada focuses on exporting quality wood products to the EU, while the EU exports lower quality products made of wood residues. Nevertheless, this specialization results in the exports of non-comparable and non-integrating products. In other terms, the two countries belong to different value chains with little imbrication with each other. An industry indeed informed that the trade relation with Canada is neither seen as a threat nor as an important partner (Industry C4, interview in Brussels). There is thus a juxtaposition of the flows of goods without integration.

A comparison of the two-industries' structures supports this argument. In Canada firm size varies according to the region. In the North of the country and British Columbia, big firms dominate the sector of wood exploitation, in Quebec and Ontario it is rather a landscape of small firms (officials B1, interview in Ottawa). In general, in harsh climate conditions, big firms tend to be more present as they have the required capital available to invest for exploitation in hostile territories. Furthermore, while small firms tend to focus on the production of crafted high added value products, big firms produce rather bulk wood products. From the patterns of exports of sawnwood timber described earlier, it appears thus that Canadian firms tend to export this type of commodity the most to the EU. Among the multiple existing industry associations<sup>301</sup>, the export interests of the forest industry in Canada are defended by the "Forest Products Association of Canada" (FPAC/APFC)<sup>302</sup>. Regrouping important producers of the sector, it also entertains partner relationships with several public and private organizations, including Natural Resources Canada and the Canadian chamber of Commerce<sup>303</sup>. Canadian firms are thus divided but with certain level of internal coordination among groups of producers.

In contrast, industry and officials from both sides acknowledged that the European industry is rather inward oriented instead of exports driven (Industry & officials B1-C4-D2, interviews in Ottawa & Brussels). The European sector serves first and foremost the European market and rather aims at rendering the continent autonomous. Their value chains are rather local and close to the distribution point. While the sector does export extra-EU, the number remain lower than intra-

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<sup>300</sup> FAO, "Yearbook of Forest Products Definitions", <http://www.fao.org/waicent/faostat/forestry/products.htm>, accessed the 15<sup>th</sup> August 2019.

<sup>301</sup> Canadian Forests Website, "Industry Associations", <https://www.canadian-forests.com/industry-associations.html>, accessed the 16<sup>th</sup> August 2019.

<sup>302</sup> Forest Products Association of Canada (FPAC), "Economy and Trade", <https://www.fpac.ca/advocacy/economy-trade/>, accessed the 16th August 2019.

<sup>303</sup>Ibid., "Partners", <https://www.fpac.ca/about-forest-products/partners/>, accessed the 16th August 2019.

European trade and Canada is totally absent from its list of export market destinations<sup>304</sup>. The number of firms is also particularly high, counting 170,000 firms for the whole sector, including 33,000 for the sawmill industry and 96,000 firms for the other sub-sectors<sup>305</sup>. These absolute numbers reflect the larger size and decentralized nature of the European market, which also impacts the industry's ability to coordinate across the multiple EU member states. This data gives thus the picture of a highly performing Canadian sectors, with strong export interests. The European sector belong to a different value chain than the global one where Canada is a big actor. Thus, while the EU sources itself from Canada this lack of common integration limits the ability of the Canadian industry to opportunistically use the apparent "dependency" towards Canadian export. Furthermore, the products specialization of the two countries reduces if not remove potential competition between actors, and potential use of barriers for protectionist gains. The risks of "hold-up" were thus judged low by both states.

The case of raw is then discussed, followed by another section looking at the three sectors. This sub-section demonstrating how the difference of value chain integration with MV and GIs reduce in fact the risk of "hold-up" in these three cases, as briefly shown with the Forest sector.

### **Canadian Raw Materials extraction and exports**

Concerning Raw Materials, the Eurostats database indicates that Canadian exports were superior by 771% in 2016, reaching the level of 1065% export surplus in 2017 (Table 7). Canada's overall export surplus seems beyond discussion and is confirmed by multiple sources, including the "facts & Figures 2017" report of The Mining Association of Canada<sup>306</sup>. While Eurostats' definition of Raw Materials include mostly tariffs lines related to "metalliferous ores and metal scrap", the report is more comprehensive and includes a larger panel of minerals and raw materials commodities. According the report, for the year 2016, Canada exported 19.208 mil US\$ of commodities to Europe, while the EU exported 6,378 mil US\$ to Canada. Canada's trade surplus

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<sup>304</sup> European Confederation of the Woodworking Industries (CEI-Bois) <http://www.cei-bois.org/the-wood-industry-in-numbers/trade/>, accessed the 16th August 2019.

<sup>305</sup>Ibid., "Enterprises", <http://www.cei-bois.org/the-wood-industry-in-numbers/enterprises/>, accessed the 16th August 2019.

<sup>306</sup> The Mining Association of Canada, "Facts And Figures 2017", [https://mining.ca/wp-content/uploads/dlm\\_uploads/2019/02/Facts-and-Figures-2017.pdf](https://mining.ca/wp-content/uploads/dlm_uploads/2019/02/Facts-and-Figures-2017.pdf), accessed the 16th August 2019.

remains largely superior to the EU even if it is nuanced as the EU has its key commodity of exports to Canada, as revealed by the report.

Table 19 (Appendix V) describes the trade patterns between the EU and Canada. The top 5 exports of Canada to the EU are: Gold (11.336 mil US\$), Iron ore (1.827 mil US\$), Nickel (1.353 mil US\$), Diamonds (1.094 mil US\$) and Cooper (538 mil US\$). EU top 5 exports to Canada are: Iron and steel (2.219 mil US\$), Silver (507 mil US\$), Aluminum (345 mil US\$), Clay and clay products (312 mil US\$), Glass and glassware products (292 mil US\$).

Gold export has a disproportionate share in Canadian raw material exports to the EU. This commodity is imported by the U.K, which hosts the London Metals exchange, an important hub for gold trading in the world<sup>307</sup>. This demand for gold is mostly driven by financial motives, as gold is often used as a reserve asset for investors held by public and private financial entities, such as central banks. Except for gold, Canada seems to specialize in the exports of iron ore, diamond, nickel and copper. The EU has major exporting commodities: transformed iron products, notably iron and steel, silver, aluminum and clay/clay products. Canada appears to focus on the extraction and export of “raw” mineral components while the EU exports “transformed” or partially “transformed” raw materials. This differentiation is however not perfect, as numbers reveal that the EU is also an exporter of Nickel and Copper to Canada, even if estimated values of exchange are lower. In terms of industry concentration, Canada remains a global leader in the extraction of raw materials in its territory, well beyond the EU. In fact, according to Table 20 (Appendix V), for the commodities traded with the EU, Canada is globally the third most important producer of gemstones (18.3% global production), the second most important producer for nickel (11.4%), the third in aluminum and the fifth for gold (5.5%) and diamonds (9.2%). There are thus significant evidence to showcase the trade advantage of Canada in this sector. Not only does it produce more products but also specialized one. On the contrary, the EU is completely absent from all the top ranking of minerals producers.

To note that in terms of Canadian firms mining commodities across the globe, Canadian firms have a secondary presence in the EU, concentrating most of their activities in Canada, the USA,

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<sup>307</sup>Maclean's, “The British are coming—for our gold”, <https://www.macleans.ca/economy/business/the-british-are-coming-for-our-gold/>; Commodity.com, “Canada's Top 5 Commodity Exports”, [https://commodity.com/canada/#Canadas\\_Top\\_5\\_Commodity\\_Exports](https://commodity.com/canada/#Canadas_Top_5_Commodity_Exports)”, Both accessed the 17<sup>th</sup> August 2019.

Argentina and Chile<sup>308</sup>. While many members of the Canadian Mining Association are multinationals active globally, such as ArcelorMittal or Glencore, their investments in the EU remain marginal compared with other regions of the world. Their activities are thus mostly concentrated in North America and particularly in Canada, where stands the largest concentration of mining companies (1176 companies) and investment (88.3 bil US\$). The Canadian mining industry appears thus to be largely concentrated in the territory. This stands in contrast with the previously seen pharmaceutical sectors. While in both the Raw and Pharma, MNEs play an important role in the sectors, in Raw the sectors are more locally based than globally distributed. In addition to the numbers just provided, membership between The Mining Association of Canada (MAC) and the European mining association diverge sensibly. Members in IMA-Europe and Euromines appear to be nationally related in contrast with the international orientation of MAC memberships<sup>309</sup>. This is not surprising in light of Canada's top global ranking in the production of certain commodities.

Overall, the Canadian Raw sector seems thus a straightforward case of High “hold-up” risk. Nevertheless, by looking jointly with Biotech and Forest, further analysis on the value chain will demonstrate why it is not the case.

### A potential Canadian “Hold-up” risk ? Comparing results in the three sectors

As revealed by these descriptions of the Forest, Biotech and Raw sectors just below, Canada entertains an asymmetric trade flow relationship with the EU, in its advantage. Not only does it export more in value than the European continent, but its production within the sector is specialized so as not to compete with European production. This complementarity relationship is present especially in Raw and Biotech where the EU largely imports what it needs and does not produce itself. In Forest, this “EU dependency” is less pronounced, but the investigation confirms that the EU and Canadian industries do not see each other as competitors in the European or

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<sup>308</sup> The Mining Association of Canada, “Facts and Figures 2017”, p. 67; 79, [https://mining.ca/wp-content/uploads/dlm\\_uploads/2019/02/Facts-and-Figures-2017.pdf](https://mining.ca/wp-content/uploads/dlm_uploads/2019/02/Facts-and-Figures-2017.pdf), accessed the 16th August 2019.

<sup>309</sup> Most of the largest mining company active in Canada are members to The Canadian Mining Association: The Northern Miner, “Top 10 Canadian-based mining companies”, <https://www.northernminer.com/news/top-10-canadian-based-mining-companies/1003797700/>; The Mining Association of Canada, “Our Members”, <https://mining.ca/members-partners/our-members/>; IMAEurope, “Membership”, <https://www.ima-europe.eu/about-ima-europe/associations> ; Euromines, “members”, <http://www.euromines.org/who-we-are/members>, all accessed the 16<sup>th</sup> August 2019.

Canadian market (Industry & officials B1-C4-D2, interviews in Ottawa and Brussels). To note though that the EU has expressed its interest in improving its efforts to guarantee a sustainable supply of forest products and timbers<sup>310</sup>. As shortly viewed in section 5.3 and reviewed thoroughly by the next section on shirking risk, collaboration with Canada in this matter can be mutually beneficial as the country has one of the strictest certification mechanisms for its timber production in the world. While it was not expressed formally by any of the actors, there are obvious opportunities for the EU and Canadian forest industry to increase Canadian exports to serve the European market. While some rivalry seems to be present between Europeans and Canadian firms in the U.S. market (Industry C4, interview in Brussels), none of the actors see each other as competitors within their own markets.

Low risks of “Hold-up” and mutual interest in increasing Canadian exports to the EU appears to go beyond the Forest sector. As mentioned earlier, the EU recently authorized (2017) the use of canola oil for biofuels. While this does not imply that the EU actively encourages this particular flow, new opportunities seem to be present. In the Raw sector, interviews with officials and industry reveal that the EU is interested in increasing its sourcing of minerals and raw materials from Canada (officials & industry A2-C3-B5-D2, interviews in Brussels and Ottawa). Indeed, interviewees stressed that the Canadian level of exports were considered relatively low in key rare earth. Both on the European and Canadian sides, there are interests in increasing European supply from Canada in these key commodities, notably to offset existing European dependence towards imports of rare earth minerals from China. This interest increased recently as China considered cutting off its exports of rare earths to other countries, notably the U.S.<sup>311</sup>. The possible weaponization of rare earth supply appears to have encouraged both parties to intensify their collaboration in the Raw sector.

In sum, for each of the three sectors reviewed, they are characterized by a trade flow asymmetry at the advantage of Canada. Nevertheless, this flow asymmetry resulted in Europe encouraging instead further supply from Canada. In these three cases, the EU directly or indirectly aimed at increasing or facilitating its supply from Canada. While this intention was not expressly formulated during the negotiation for the Forest and Biotech sectors, this was clearly stated by

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<sup>310</sup>European Commission, “Communication from the commission [...]: Stepping up EU Action to Protect and Restore the World’s Forests {SWD(2019) 307 final}”, [https://ec.europa.eu/info/sites/info/files/communication-eu-action-protect-restore-forests\\_en.pdf](https://ec.europa.eu/info/sites/info/files/communication-eu-action-protect-restore-forests_en.pdf), accessed the 16<sup>th</sup> August 2019.

<sup>311</sup> FT, “China rare earth stocks surge after export ban threat “, <https://www.ft.com/content/d7890d7e-81ba-11e9-b592-5fe435b57a3b>, accessed the 17<sup>th</sup> August 2019.

the states involved in Raw negotiation. In these sectors, the situation could be described as mutual dependency. The European market is considered valuable for Canada. It is supported by the existing trade, but mainly by the attempts of the Canadian firms and government to get more products approved and improve overall market access within the European continent. There is thus a congruence of interests between the Canadian export interests and European sourcing needs.

The different occupation of value chain segments also plays a role. Canada occupies an upstream segment of GVC, while the EU is focused again in downstream namely the consumption of raw materials (rare earth, forest products, biotech products). This has a reductive threat effect on Canadian superior production and export capacities. For the EU, potential future dependency towards Canadian sourcing did not worry EU negotiators, quite the opposite. The current dependency of the EU towards Chinese raw materials clearly encouraged the European negotiators to diversify the sources by cooperating with Canada.

From a strategic point of view, cooperation with Canada does not entail a “hold-up” risk for its industry, but rather an opportunity to mitigate one already existing with Chinese suppliers. It thus encourages cooperation with Canada and taking into consideration their product approval requests so as to preserve and even increase Canada sourcing share in Europe. The logic of a long-term mechanism, institutionalizing this long-term cooperation is thus justified. A counterfactual logic would entail that Ex-ante would have privileged if Canadian producers were located rather in more a downstream phase of the value chains, especially if they were entering in direct competition with European producers. This was however not the case for the three sectors. None of the European industry and officials interviewed were worried about Canadian increased market access in European markets (Industry & Officials C3-D2-D4, interview in Brussels). A mutual beneficial understanding of this complementary relation between upstream (Canada, e.g. rare earth) and downstream segment (EU, e.g. clean tech) of the value chain predominated.

Nevertheless, from interviews with officials (official D3, interview in Brussels) and the legal design of the cooperation itself, it seems that Biotech stands apart from the two others. According to European sources, the bilateral dialogue for Biotech products was included into CETA only due to WTO obligations resulting from the dispute case *European Communities – Measures Affecting the Approval and Marketing of Biotech Products WT/DS292*. This dialogue was established on 15 July 2009, following the mutually agreed upon solution between Canada and the EU (art.25.2).

The EU appears very reluctant to satisfy Canadian states' wishes though, especially on genetically modified agri-food. According to minutes from the 10<sup>th</sup> and 11<sup>th</sup> meeting of the bilateral dialogue on Biotech products, Canadian states repeatedly expressed their concerns on the delay and process of biotech product approval<sup>312</sup>. This issue was already addressed by the WTO DSB during the DS291 and DS292 cases but appears to remain problematic<sup>313</sup>. Biotech product approval continues to be a pending regulatory issue. Further investigation and analysis are thus necessary, especially focusing on comparing the EU and Canadian regulatory frameworks of these three sectors.

## 8.2. *Shirking*

According to my analytical proposition, the factor “shirking risk” is a necessary condition to determine when parties decide to use soft or Hard obligations. The theoretical expectation is that a converging regulatory framework reduces this risks and act as an incentive for states to design sectoral cooperation through “soft” provisions instead of “hard” ones. On the contrary, a diverging regulatory framework increase the chance of countries “shirking” their commitments and encourages consequently the use of Hard obligations to mitigate this risk under and violation/sanction mechanisms. Further investigations of Forest and Raw in these sections appear to confirm these theoretical expectations. Canadian negotiators intentionally agreed to use “soft” provisions taking in consideration the congruence of regulatory approaches between them and the EU. They thus did not consider likely that the EU would renege their commitments in these sectors. Possibility of future joint regulatory cooperation plays a positive reassurance role. The use of “soft” provisions is thus shown to be a direct consequence of existing and preexisting regulatory alignments between the two countries.

An additional point to raise, the analysis of Forest and Raw shows that the use of “soft” obligations in CETA was meant to support the governance of the value chains. States designed

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<sup>312</sup> EC-Canada, “meeting of the dialogue on biotech market access issues, videoconference, 26 April 2018: report”, [https://trade.ec.europa.eu/doclib/docs/2018/july/tradoc\\_157100.04.2018%20-%20COM%20report\\_FINAL.pdf](https://trade.ec.europa.eu/doclib/docs/2018/july/tradoc_157100.04.2018%20-%20COM%20report_FINAL.pdf); “11th meeting of the bilateral dialogue on biotech market access issues 4 march 2019 in brussels and by videoconference: joint report”, [https://trade.ec.europa.eu/doclib/docs/2019/september/tradoc\\_158341.pdf](https://trade.ec.europa.eu/doclib/docs/2019/september/tradoc_158341.pdf) ; all accessed the 16<sup>th</sup> August 2019.

<sup>313</sup> WTO, “DS291: European Communities — Measures Affecting the Approval and Marketing of Biotech Products”, [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds291\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm), accessed the 17<sup>th</sup> August 2019.

these cooperative mechanisms with the intent of “orchestrating” the value chains (Abbott and Snidal 2010, 2009). In exception to these findings, Biotech seems to contradict these expectations. Far from being convergent, several regulatory points of discontent exist between the EU and Canada. Significant regulatory barriers seem to impede Canada’s exports to the EU and bilateral trade flows overall. Therefore, it seems that the opposite result of the factor regulatory frameworks resulted in the same results (soft design). This deviant case appears nevertheless to be removed once the role of the WTO dispute mechanism is considered, especially regarding the resolution of the dispute DS 292 between the EU and Canada.

## **EUTR, FLEGT and Forest private certification**

In the EU, the main specific legislation on the import and production of wood products is the EU Timber Regulation (EUTR), Regulation (EU) No 995/2010<sup>314</sup>, in force since March 2013. It relies on three main requirements: the prohibition of illegally harvested timber, the requirement for timber operators to exercise “due diligence” and their obligation to keep records of the transactions<sup>315</sup>. Fulfillment of “Due diligence”, implies access to information on the source of the timber (species, origin of wood and compliance with national laws and regulations). Risks assessment and risks mitigation are also required, notably concerning the presence of illegal timber on European markets<sup>316</sup>. Within the EU, each member state has a competent authority<sup>317</sup> designated to monitor the implementation of the regulation, more specifically implementing the Forest Law Enforcement, Governance and Trade (FLEGT) Action Plan<sup>318</sup>. The FLEGT includes a series of measurements aimed at “tackling illegal logging in the world’s forests”. Pertinent to this research, it includes the promotion of legal timber, as well as technical support to demonstrate

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<sup>314</sup>EUR-Lex, “Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market”, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010R0995>, accessed the 16<sup>th</sup> August 2019.

<sup>315</sup> EUFLEGT, “What are the requirements for operators?”, <http://www.euflegt.efi.int/what-are-the-requirements-for-operators->, accessed the 17<sup>th</sup> August 2019.

<sup>316</sup> European commission DG Environment, “Timber Regulation”, [https://ec.europa.eu/environment/forests/timber\\_regulation.htm#diligence](https://ec.europa.eu/environment/forests/timber_regulation.htm#diligence), accessed the 18<sup>th</sup> August 2019.

<sup>317</sup> European commission, “Nominated Competent Authorities For implementation of the Regulation EU 995/2010 (EUTR)”, [https://ec.europa.eu/environment/forests/pdf/list\\_competent\\_authorities\\_eutr.pdf](https://ec.europa.eu/environment/forests/pdf/list_competent_authorities_eutr.pdf), accessed the 20th august 2019.

<sup>318</sup> EUFLEGT, “What is the EU FLEGT Action Plan?”, <http://www.euflegt.efi.int/flegt-action-plan>, accessed the 20th august 2019.

supply-chain compliance by private actors. Among the tools mobilized to implement the regulation outside its borders, the EU initiated and signed a series of “Voluntary Partnership Agreements” (VPAs) with timber-producing countries, including African, Asian and few South American countries<sup>319</sup>. These agreements provide further specifications to support the implementation of the FLEGT as well as to assure compliance of local producers in foreign territories (Fishman and Obidzinski 2015). Within the UN Sustainable Development Goals (SDGs), the EU frames its FLEGT action plan in line with its efforts to achieve the Goal 15<sup>320</sup>, in combination with initiative REDD+ fighting deforestation<sup>321</sup>.

In sum, the EU regulatory framework is thus based on two pillars. One is the FLEGT certification and compliance system inside the EU borders, which control and assure compliance with the EUTR. The second is the conclusion of VPAs outside its border to establish regulatory equivalences with foreign producers, exporting to the EU market. This system establishes requirements for importers and exporters to demonstrate the source of products as well as its compliance with the legislation. It relies on a licensing scheme, which aims at assuring the traceability and transparency of the timber supply chain. The overall purpose is the fight against illegal logging outside the EU and the subsequent import of illegally harvested timbers.

Notably, the regulation does not impose a definition of “illegal logging” but refers instead to foreign countries’ domestic legislation (14)<sup>322</sup>. A definition is rather provided in the VPA that the EU signed with partner countries, such as the one with Vietnam, entered into force in June 2019<sup>323</sup>. These VPAs contain extensive details on the production and commercialization of wood products, including a precise definition of illegal logging according to the country’s legal definition (Annex II)<sup>324</sup>. In this context, the definition of “illegal logging” is probably the result

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<sup>319</sup> EUFLEGT, “Voluntary Partnership Agreements”, <http://www.euflegt.efi.int/vpa>, accessed the 19<sup>th</sup> August 2019.

<sup>320</sup> Goal 15: Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss

<sup>321</sup> European commission, “The Sustainable Development Goals”, [https://ec.europa.eu/europeaid/policies/sustainable-development-goals\\_en](https://ec.europa.eu/europeaid/policies/sustainable-development-goals_en), accessed the 20<sup>th</sup> August 2019.

<sup>322</sup> EUR-Lex, Official Journal of the European Union, “Regulation (eu) no 995/2010 of the european parliament and of the council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market”, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010R0995&from=EN>, accessed the 20<sup>th</sup> August 2019.

<sup>323</sup> EUFLEGT, “Vietnam”, <http://www.euflegt.efi.int/vietnam>, accessed the 20<sup>th</sup> august 2019.

<sup>324</sup> EUFLEGT, “Voluntary partnership agreement between the european union and the socialist republic of vietnam on forest law enforcement, governance and trade”, [https://ec.europa.eu/environment/forests/pdf/11\\_05\\_2017\\_EU\\_Vietnam\\_VPA.pdf](https://ec.europa.eu/environment/forests/pdf/11_05_2017_EU_Vietnam_VPA.pdf), accessed the 21<sup>st</sup> August 2019.

of a negotiation between the EU and Vietnam, used by the Union to ensure that the country of export (Vietnam) provides a similar level of ambition in its domestic regulations. While further investigation on VPAs cannot be pursued in this research as it falls outside of its scope, it remains an interesting vehicle of regulatory externalization with some similarities with the type of legal design used here (Overdevest and Zeitlin 2018).

While Canadian imports are subjected to the requirement of the EUTR, the EU and Canada did not sign a VPA. One of the main reasons is that Canada has developed a comprehensive system of certification that complies fully with EUTR. This feature played a key role during the negotiation, notably on the design of the cooperation. According Canadian sources, concerns were voiced at the initial steps of the negotiation regarding the implementation of the EUTR (official B1, interview in Ottawa). Canadian provinces were worried that the implementation of the EUTR would result in the creation of new regulatory barriers for Canadian products that could impede market access. In other words, Canadian negotiators were afraid that EUTR would have provided EU officials the means to shirk from their commitments. These concerns pushed the Canadian side to initially request “more binding” and detailed legal provisions to ensure market access of their products. Nevertheless, according to the interviewed official, subsequent information exchanges convinced both representatives that regulatory systems of both sides were compatible notably with the new requirements of EUTR. At the same time, the EU provided reassurance that the Canadian regulatory system would be recognized in the EU, ensuring Canadian access to the European common market. The FLEGT license is not the only certification recognized. The EUTR also recognized permits from the Convention on Illegal Trade in Endangered Species (CITES)<sup>325</sup>. The two different regulatory systems recognize thus both their audit performances and each state’s conformity assessment systems.

An important fact for the Canadian Forest framework is that 90% of forest lands in Canada are owned by provinces and territories, 6% by private agents and 4% by the federal government<sup>326</sup>. The provincial and territorial authorities are thus the most relevant actors for the regulation of forest lands and their exploitation. Although federal laws are in place on endangered species (fisheries, migration birds and plant protection), provincial law and regulations remain the main

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<sup>325</sup> EUFLEGT, “What is the EU FLEGT Action Plan?”, <http://www.euflegt.efi.int/flegt-action-plan>, accessed the 20th august 2019.

<sup>326</sup> Government of Canada Natural Resources Canada, “Forest Land Ownership”, <https://www.nrcan.gc.ca/our-natural-resources/forests-forestry/sustainable-forest-management/forest-land-ownership/17495>, accessed the 21<sup>st</sup> august 2019. Canada's forest laws

regulations for the production and commercialization of timber and related products<sup>327</sup>. Each province adopted a series of acts and legislations that regulate wood exploitation activities in their territories. While a province might allow firms to exploit forest for commercial activities, their approval is conditioned by the issuing of a permit by provincial authorities (official B1, interview in Ottawa). For instance, the *Forest Act* of British Columbia states that “before any logging can begin on public lands, a company must be issued a cutting permit by government [...]”<sup>328</sup>. The British Columbia Forest Act specifies the detailed technical requirements that firms need to respect in order to obtain permission for exploitation. To demonstrate compliance with provincial regulations and requirements, these legislations often require firms to be certified by third party certification organization<sup>329</sup>.

While this fragmented regulatory framework could have caused issues for the cooperation, as in PQ, in Forest it acted at the opposite. This system made of Canada “the largest area of third-party independently certified forests in the world”, with 148 million hectares certified, followed by the USA with 49 million and Russia with 31 million hectares<sup>330</sup>. This high rate of certification plays an instrumental role in demonstrating to European negotiators the compatibility of the Canadian certification system with the EUTR.

Indeed, different comprehensive forest certification systems are used in Canada, belonging mostly to three organizations: the Canadian Standards Association (CSA), the Forest Stewardship Council (FSC) and the Sustainable Forestry Initiative (SFI)<sup>331</sup>. The CSA and SFI are both recognized internationally by the Program for the Endorsement of Forest Certification (PEFC)<sup>332</sup>.

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<sup>327</sup> Government of Canada Natural Resources Canada, “Forest Land Ownership”, <https://www.nrcan.gc.ca/our-natural-resources/forests-forestry/sustainable-forest-management/canadas-forest-laws/17497>, accessed the 21st august 2019. Canada's forest laws

<sup>328</sup> British Columbia, “Province of British Columbia”, [https://www.sfmcanada.org/images/Publications/EN/BC\\_info\\_Province\\_and\\_territories\\_EN.pdf](https://www.sfmcanada.org/images/Publications/EN/BC_info_Province_and_territories_EN.pdf), accessed the 22<sup>nd</sup> August 2019.

<sup>329</sup> Québec, “Province of Québec”, p. 2, [https://www.sfmcanada.org/images/Publications/EN/QC\\_info\\_Provinces\\_and\\_territories\\_EN.pdf](https://www.sfmcanada.org/images/Publications/EN/QC_info_Provinces_and_territories_EN.pdf), accessed the 22nd August 2019.

<sup>330</sup> Forest products association of Canada (FPAC), “Forest certification in Canada”, p. 8, [https://www.fpac.ca/publications/FPAC\\_ForestryCertification-Similarities\\_EN.pdf](https://www.fpac.ca/publications/FPAC_ForestryCertification-Similarities_EN.pdf), accessed the 21<sup>st</sup> August 2019.

<sup>331</sup> Government of Canada Natural Resources Canada, “Forest certification in Canada”, <https://www.nrcan.gc.ca/our-natural-resources/forests-forestry/sustainable-forest-management/forest-certification-canada/17474>, accessed the 21<sup>st</sup> August 2019.

<sup>332</sup> Sustainable Forest management in Canada, “Canada: Embracing Third-Party Forest Certification”, <https://www.sfmcanada.org/en/sustainable-forest-management/embracing-third-party-certification>, accessed the 21<sup>st</sup> August 2019.

The FSC is an international non-profit organization, setting standards for forest management<sup>333</sup>. It includes environmental groups (the WWF for e.g.), businesses as well as forest owners. The SFI is an “independent body of states” composed of external states from multiple organizations, private and public<sup>334</sup>. SFI is also a standard setter for multiple forest standards and establishes the conditions for accreditations to certify its standards<sup>335</sup>. The CSA is a private standard-setter, accredited by the Standards Council of Canada (SCC – the official national standardization body), driven by firms and members of the industry<sup>336</sup>. The CSA launched its own Forest Management System standards in 1996, which fulfill the same function as the other standards described before.

Compared with the EU system, the Canadian regulatory system relies mostly on private certification and standards to achieve regulatory requirements. Canadian public authorities use their ownership of the land to set similar high regulatory requirements as the Europeans, while delegating certification and conformity assessment to private actors. This enables them to provide a similar level of stringency in their regulations, without having to resort to a national legislation and a centralized system of licensing, such as the FLEGT. This is possible as compliance with the EUTR can be demonstrated with certification to certain private standards, notably the PEFC of the FSC. A convergence between the two systems can hence be witnessed. The Canadian regulatory systems easily provide what European regulations required for their sourcing of forest products: proofs of legal logging, traceability of the supply chain and regulatory threshold for sustainability. Furthermore, Canada being a signatory member of CITES, firms in its territory must respect the convention in their activities<sup>337</sup>. Canada is also committed to orient its Forest strategy in line with the accomplishments of the SDGs<sup>338</sup>. Besides alignments in domestic regulations and conformity assessment procedures, the regulatory frameworks of Canada and the EU are also convergent within the international Forest regime. The mutual recognition of

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<sup>333</sup>The Forest Stewardship Council (FSC), “Who We Are”, <https://ca.fsc.org/en-ca/about-us>, accessed the 22<sup>nd</sup> August 2019.

<sup>334</sup> Sustainable Forestry Initiative, “External Review Panel (ERP)”, <https://www.sfiprogram.org/erp/>, accessed the 21<sup>st</sup> August 2019.

<sup>335</sup> Sustainable Forestry Initiative, “Independent Certification Bodies”, <https://www.sfiprogram.org/independentsertificationbodies/>, accessed the 21<sup>st</sup> August 2019.

<sup>336</sup> Standards Council of Canada, “Canadian Standards Association (or CSA Group)”, <https://www.scc.ca/fr/agl-csa>, accessed the 21<sup>st</sup> August 2019.

<sup>337</sup> Government of Canada Natural Resources Canada, “5 ways Canada prevents illegal logging”, <https://www.nrcan.gc.ca/our-natural-resources/forests-forestry/sustainable-forest-management/canadas-forest-laws/5-ways-canada-prevents-illegal-logging/17479>, accessed the 21<sup>st</sup> August 2019.

<sup>338</sup>Government of Canada, “Canada’s Forest-related Contributions to the Sustainable Development Goals Under Review in 2018: A Report to UNFF” [https://www.un.org/esa/forests/wp-content/uploads/2018/03/Input\\_SDGs2018\\_Canada.pdf](https://www.un.org/esa/forests/wp-content/uploads/2018/03/Input_SDGs2018_Canada.pdf), accessed the 22<sup>nd</sup> august 2019.

international standards and conventions by both sides pushes both countries towards regulatory alignment, while using different regulatory systems.

The regulatory convergence between Canada and the EU had an important impact during the negotiation and choice of design. As noted earlier, the Canadian side had concerns regarding the entry into force of the EUTR. In addition, the Belgian and Dutch governments' reforms of their environmental supply legislation were feared to create additional certification requirements (official B1, interview in Ottawa). This would have been particularly costly for small firms in Canada, which already must comply with provincial requirements and get certified. Fearing that other European countries would adopt similar reforms and that the EUTR could create additional barriers to trade in the future, Canadian negotiators were originally in favor of requesting "hard" provisions to mitigate this "shirking" risk from the EU (official B1, interview in Ottawa). These concerns were particularly present during the early days of the introduction of the EUTR as it was not clear how compliance could be achieved within this new system. Nevertheless, information exchanges between states reassured the Canadian side that its products would not face any discriminations. This was possible as Canadian states were also able to demonstrate to their European counterparts that their third-party certification system could achieve a similar level of stringency. Subsequently the risks of "shirking" from both parties were considered low. On the contrary, willingness to institutionalize a long-term cooperation was very much welcome.

The purpose of the dialogue was to establish a formal channel of communication with the relevant European agencies responsible for managing trade and production of Forest Products. As illustrated by the minutes of the first bilateral dialogue, the main cooperation activities scheduled within the framework are information exchanges<sup>339</sup>. The range of issues is however wide, including bioeconomy, deforestation, climate mitigation, transition to a circular, low carbon economy, H2020 work program, collaboration at the UNECE, etc. The ambition of the dialogue seems to be supporting the management of the sector and collaborating with each other for the development of the Forest sector within the context of joint international commitments made for mitigating climate change.

From this comparison between the European regulatory system and the Canadian one, it appears that the convergence of regulatory frameworks contributed significantly to reducing the risk of

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<sup>339</sup>EC-Canada, "comprehensive economic and trade agreement (ceta) meeting of bilateral dialogue on forest products 24 may 2019 by videoconference joint report", [https://trade.ec.europa.eu/doclib/docs/2019/july/tradoc\\_158172.pdf](https://trade.ec.europa.eu/doclib/docs/2019/july/tradoc_158172.pdf), accessed the 22<sup>nd</sup> August 2019.

shirking and thus the choice of soft design language. As attested by the Canadian side, the decision to design a long term but soft cooperation scheme was motivated by the reassurance obtained from the EU on the regulatory implication of the EUTR. Being able to solve regulatory concerns from both sides (market access for Canada and sustainable sourcing for EU), the states took the decision to use Soft obligation to design their mechanism. The purpose of the cooperation aims at supporting the management of Forest value chains and the extension of Forest related economic activities within climate change efforts from both sides. In addition, the design of the VPA for the European FLEGT could deserve future exploration. A preliminary analysis seems to indicate an interesting case of a cooperation scheme that could correspond to this research typology of design types. Overall, it appears that the theoretical expectations formulated in Chapter 2 are verified for the Forest sector.

## **Raw Materials and the TSM initiative**

The origin of Raw material regulations in Canada began with the Whitehorse Mining Initiative (WMI), adopted in 1994 by all Canadian provincial governments, joined by the mining industry, labor unions, Aboriginal peoples, and the environmental community<sup>340</sup>. Although the EU already had two directives in place since 1992, Directive 92/91/EEC and Directive 92/104/EEC<sup>341</sup>, both focused on the safety and health of workers within the mineral-extracting industries. They do not address the extraction and commercialization of raw materials themselves. Canada was thus a pioneer in the regulation of Raw Material, reflecting its profile as a global leader in minerals extraction. The WMI's focus is on the social, economic and environmental sustainability of the mining industry. It was initiated by the Mining Association of Canada (MAC), which aimed at responding to the rising debate on the sustainability of mining within Canada since the 80s (Fitzpatrick, Fonseca, and McAllister 2011, 377). The initiative sets a list of principles and goals for the achievement of sustainable mining. It institutionalizes the issue by establishing the “Whitehorse Mining Initiative Leadership Council Accord”, as well as multi-stakeholder working

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<sup>340</sup> Government of Canada Natural Resources Canada, “Whitehorse Mining Initiative”, <https://www.nrcan.gc.ca/mining-materials/mining/minerals-and-metals-policy/whitehorse-mining-initiative/8698>, accessed the 22<sup>nd</sup> August 2019.

<sup>341</sup> European Agency for Safety and Health at Work, “Directive 92/91/EEC - mineral-extracting industries – drilling”, <https://osha.europa.eu/en/legislation/directives/11>; “Directive 92/104/EEC - mineral-extracting industries”, <https://osha.europa.eu/en/legislation/directives/12>; all accessed the 22<sup>nd</sup> August 2019.

groups on finance/taxation, environment, land access and workforce/workplace/community<sup>342</sup>. Serving as a benchmark, the Whitehorse frameworks aimed at harmonizing sustainable mining approaches in Canada (Fitzpatrick, Fonseca, and McAllister 2011, 378).

Despite the good intentions of the WMI, the framework did not produce many results and several failures appear in compliance with the guiding principles (Industry A2, interview in Ottawa). As risks of losing permits of exploitation were looming, the MAC decided in 2004 to launch the program “Towards Sustainable Mining” or TSM. TSM is described as a “performance system that helps mining companies evaluate and manage their environmental and social responsibilities”<sup>343</sup>. It is not a certification nor a conformity approval system but rather a standardized benchmark of best practices (Industry A2, interview in Ottawa). It is composed of six performance protocols:

- Aboriginal and Community Outreach
- Crisis Management Planning
- Safety and Health
- Tailings Management
- Biodiversity Conservation Management
- Energy Use and GHG Emissions

Each protocol has its own sets of indicators, which are all graded through a rating scale from C (worst) to AAA (Best). Evaluation is performed through a mix of self-assessment and a third-party certification system. It is compulsory for all full members of the MAC to participate in the TSM and thus to be evaluated. The purpose of the program is that all facilities of the MAC membership reach at least a level A for all protocols<sup>344</sup>. Overviewing the program, the Community

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<sup>342</sup> CSD-6 Follow-Up, “Initiative: Whitehorse (Canada) Mining Initiative”, [https://sustainabledevelopment.un.org/content/dsd/dsd\\_aofw\\_mg/mg\\_VIA/vaprofiles\\_Canada\\_Mining.htm](https://sustainabledevelopment.un.org/content/dsd/dsd_aofw_mg/mg_VIA/vaprofiles_Canada_Mining.htm), accessed the 22<sup>nd</sup> August 2019.

<sup>343</sup> The Mining Association of Canada (MAC), “Towards sustainable mining 2016: Progress Report”, p. 3, <https://mining.ca/wp-content/uploads/2019/02/TSM-Progress-Report-2016.pdf>, accessed the 22<sup>nd</sup> August 2019.

<sup>344</sup> The Mining Association of Canada (MAC), “Towards sustainable mining 2016: Progress Report”, p. 16, <https://mining.ca/wp-content/uploads/2019/02/TSM-Progress-Report-2016.pdf>, accessed the 22nd August 2019.

of Interests Advisory Panel (COI Panel) is a multi-stakeholder group including 12 to 15 individuals representing various actors, including aboriginal groups, NGOs, trade unions and financial organizations<sup>345</sup>. Overall, the TSM acts as an industry-driven harmonization program that establishes minimal a level of regulatory stringency for all members of the industry. As mentioned earlier, the MAC is the largest mining industry association in Canada and includes most players in the sector. Consequently, the TSM program covers largely the Canadian mining sector.

The TSM initiative should be seen in the context of the proliferation of various international standards and initiatives that aim similarly at regulating mineral extracting activities. In 1999, the Global Reporting Initiative Framework was created to produce global standards for sustainability reporting<sup>346</sup>. GRI collaborates with major international regulatory organizations, such as United Nations Conference for Trade and Development (UNCTAD), the International Finance Corporation, ISO and the OECD, to cite a few<sup>347</sup>. The mention of the OECD is not benign as the OECD has developed a series of Guidelines relevant for MNEs active in minerals extractions and trading, notably the *OECD Guidelines for Multinational Enterprises* and the *OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas*<sup>348</sup>. As reviewed in section 7.2 of Chapter 7, these two OECD guidelines are explicitly cited by the CETA bilateral dialogue on raw materials (art 25.4). Members of the OECD, Canada and EU countries' members approved both guidelines. These guidelines are part of a global regulatory regime in which both the EU and Canada co-participate. The mention by CETA of these OECD guidelines is not a novelty but rather a continuation with previous regulatory efforts.

In the Raw sectors, the regulatory initiatives mentioned (TSM, GRI and the OECD) act in complement with one another instead of being opposed. The OECD (BIAC<sup>349</sup>) Raw Materials Expert Group, which “advises on issues and policies related to and affecting the supply of industrial raw materials”, has for its chair the President and Chief Executive Officer of the

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<sup>345</sup> The Mining Association of Canada (MAC), “Community of Interest Advisory Panel”, <https://mining.ca/towards-sustainable-mining/community-interest-advisory-panel/>, accessed the 22nd August 2019.

<sup>346</sup>GRI, “About GRI”, <https://www.globalreporting.org/information/about-gri/Pages/default.aspx>, accessed the 22nd August 2019.

<sup>347</sup>Ibid., “GRI's alliances and synergies “<https://www.globalreporting.org/information/about-gri/alliances-and-synergies/Pages/default.aspx>, accessed the 22nd August 2019.

<sup>348</sup>OECD, “OECD Guidelines for Multinational Enterprises”, <http://mneguidelines.oecd.org/guidelines/>, accessed the 22<sup>nd</sup> August 2019.

<sup>349</sup>An international business network recognized at the OECD, which represent industry at the organization, Business at OECD, <http://biac.org/quick-facts/>, accessed the 22<sup>nd</sup> August 2019.

MAC<sup>350</sup>. According to interviews from the industry (industry A2, interview in Ottawa), while there is no direct relationship between the OCED guidelines and the TSM, the MAC was involved in the definition of the OECD guidelines. According to the representative, the TSM is one potential instrument to implement the OECD guidelines. TSM was developed in cooperation with local actors in order to be locally operationalized, through a performance measurement framework. In contrast, the OECD guidelines establish a general framework to achieve sustainable objectives set by the firms themselves. They follow the same requirements as ISO standard 14001: 2015 - *Environmental Management Systems*<sup>351</sup>. In other words, while OECD-ISO created the framework for sustainable management, TSM specifies the exact technical requirements and obligations (through performance indicators) that mining companies must comply with.

According to Canadian industry, there are significant interests in the EU for the adoption and diffusion of TSM within the continent (Industry & Officials B4-A2, interview in Ottawa). Within the EU, the Finnish Mining Association has developed a new standard for sustainable exploration, in 2015, based on the Canadian TSM<sup>352</sup>. In March 2018, it is the national mining association of Spain, CONFEDEM, which announces it will integrate the TSM into its Gestión Minero Metalúrgica Sostenible (GMMS) standard<sup>353</sup>. Currently Spain and Finland are the only two European countries that incorporated TSM into their own standards. TSM is however also used in other parts of the world, notably in Argentina, Botswana, Philippines and Brazil<sup>354</sup>. This international diffusion of TSM reflects the interests and intentions of the MAC to diffuse TSM globally and position it as a global benchmark for sustainable mining. These efforts are not without hurdles as significant adaptations are necessary according to local circumstances, such as was the case for the aboriginal protocol in Finland (Industry C3, interview in Brussels). TSM nevertheless becomes an increasingly attractive regulatory instrument. Admittedly, the EC sees it

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<sup>350</sup> Ibid, “raw Materials”, [http://biac.org/policy\\_groups/raw-materials/](http://biac.org/policy_groups/raw-materials/), Accessed the 22<sup>nd</sup> August 2019.

<sup>351</sup> ISO, “ISO 14001:2015(en) Environmental management systems”, <https://www.iso.org/obp/ui/#iso:std:iso:14001:ed-3:v1:en>, accessed the 22<sup>nd</sup> August 2019.

<sup>352</sup> Kaivosvastuu, “Network approves new standard for sustainable exploration”, <https://www.kaivosvastuu.fi/network-approves-new-standard-for-sustainable-exploration/>; MAC, “Finnish mining sector to adopt Mining Association of Canada’s Towards Sustainable Mining Initiative”, <https://mining.ca/press-releases/finnish-mining-sector-adopt-mining-association-canadas-towards/>, accessed the 22<sup>nd</sup> August 2019.

<sup>353</sup> MAC, “Spain adopts Canada’s Towards Sustainable Mining initiative”, <https://mining.ca/press-releases/spain-adopts-canadas-towards-sustainable-mining-initiative/>, accessed the 22<sup>nd</sup> August 2019.

<sup>354</sup> MAC, “Global Uptake of TSM”, <https://mining.ca/our-focus/international-csr/global-uptake-of-tsm/>, accessed the 22<sup>nd</sup> August 2019.

as an inspiration for its own efforts to develop an EU joint approach on sustainable mining (officials D2, interview in Brussels).

While Canada was commencing its regulatory initiative to shift its industry towards more “sustainable” practices”, the EU subsequently followed. In 2008, the EU adopted its Raw material initiative, composed of three pillars<sup>355</sup>:

- Fair and sustainable supply of raw materials from global markets
- Sustainable supply of raw materials within the EU
- Resource efficiency and supply of secondary raw materials through recycling

The purpose of the strategy is the establishment of sustainable supply lines of raw materials that are needed for the European industry. In this context, the negotiation of PTAs becomes a new regulatory instrument to promote “sustainable access to raw materials”:

The EU should promote new rules and agreements on sustainable access to raw materials where necessary and ensure compliance with international commitments at multilateral and at bilateral level, including WTO accession negotiations, Free Trade Agreements, regulatory dialogue and non-preferential agreements<sup>356</sup>.

The bilateral dialogue on raw materials within CETA is a direct consequence of this European imperative to establish new supply sources that respect a certain threshold of sustainability. From a dyadic perspective, the bilateral dialogue could be also seen as the conjunction of Canadian earlier regulatory efforts in sustainable mining and the EU increased prioritization in its regulatory efforts to ensure the sustainability of its raw materials supply. The implementation of this strategy is supported by the development of a European Raw Materials diplomacy within various OIs (UNECE, UNCTAD, OECD, World Bank, African Union)<sup>357</sup>. Various events and channels of

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<sup>355</sup>European commission “Policy and strategy for raw materials”, [https://ec.europa.eu/growth/sectors/raw-materials/policy-strategy\\_en](https://ec.europa.eu/growth/sectors/raw-materials/policy-strategy_en), accessed the 22<sup>nd</sup> August 2019.

<sup>356</sup>EUR-Lex, “Communication from the commission to the European parliament and the council: The raw materials initiative — meeting our critical needs for growth and jobs in Europe SEC(2008) 2741” p. 7, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52008DC0699&from=EN,%20p>, accessed the 22<sup>nd</sup> August 2019.

<sup>357</sup>European commission, “Communication from the commission to the European parliament, the council, the european economic and social committee and the committee of the regions: tackling the challenges in commodity markets and on raw materials”, p. 16-18, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011DC0025&from=EN>, accessed the 22<sup>nd</sup> August 2019.

communications are organized in order to raise this issue at the international level. In addition, the EU puts into place a new instrument: European Innovation Partnership on Raw Materials or EIP<sup>358</sup>. Although mostly oriented towards creating domestic coalitions of actors promoting innovation (EU member states, networks of research, NGOs, industries, etc.), EIP also put forwards the need to use trade policy and policy dialogues for international cooperation in multiple fora (Africa Union, World Bank, G20, bilateral relations and the OECD) (work package 5)<sup>359</sup>. Overall, this strategy of international engagement to sustainable raw materials sourcing is consistently pursued by the European Institutions<sup>360</sup>. Consistent with this overall effort, Canada was identified as a potential supplier during the negotiation<sup>361</sup>. Both within the 2008 communication on RMI and in a staff working document, the EC stressed the importance of certain “Critical Raw Materials”<sup>362</sup> to start the “technological” turn towards sustainability, within European industries. The potential role of Canada as a supplier was already identified since 2008:

The EU is highly dependent on imports of “high-tech” metals such as cobalt, platinum, rare earths, and titanium. Though often needed only in tiny quantities, these metals are increasingly essential to the development of technologically sophisticated products in view of the growing number of their functionalities. The EU will not master the shift towards sustainable production and environmental-friendly products without such high-tech metals<sup>363</sup>.

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<sup>358</sup> European commission, “communication from the commission to the european parliament, the council, the european economic and social committee and the committee of the regions making raw materials available for europe's future wellbeing proposal for a european innovation partnership on raw materials”, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012DC0082&from=EN>, accessed the 22<sup>nd</sup> August 2019.

<sup>359</sup>Ibid., p. 8.

<sup>360</sup>European Commission, “Report from the commission to the european parliament, the council, the european economic and social committee and the committee of the regions on the implementation of the raw materials initiative”, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013DC0442&from=EN>, accessed the 22<sup>nd</sup> August 2019.

<sup>361</sup>European commission, “Communication from the commission to the european parliament, the council, the European economic and social committee and the committee of the regions: On the review of the list of critical raw materials for the EU and the implementation of the Raw Materials Initiative”, p. 5, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0297&from=EN>, accessed the 22<sup>nd</sup> August 2019.

<sup>362</sup> Ibid.

<sup>363</sup>European commission, “communication from the commission to the european parliament and the council: The raw materials initiative — meeting our critical needs for growth and jobs in Europe”, p. 3, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52008DC0699&from=EN>, Accessed the 22<sup>nd</sup> August 2019.

First, they [“high-tech metals”] have a significant economic importance for key sectors, second, the EU is faced with a high supply risks, associated with e.g. very high import dependence and a high level of concentration in particular countries, and third, there is currently a lack of substitutes<sup>364</sup>.

The Commission has held discussions on raw materials with Canada’s Ministry of Natural Resources and took part in a workshop to exchange information on rare earth elements research and development in Ottawa in June 2013. As they have strong potential for mining rare earth elements and other critical raw materials, the Commission invited Canada to the workshop on critical raw materials with American and Japanese counterparts. [...]<sup>365</sup>.

Nevertheless, the real regulatory convergence was possible after the adoption of EU Communication on “European action for sustainability” (COM (2016))<sup>366</sup>. In this document, the EU enshrines the SDGs into its policy actions, and refers each SDGs to ongoing EU initiatives. Mining is mentioned at SDG 8: “Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all”. From this commitment towards the achievement of the SDG, the TSM scheme developed in Canada becomes an interesting tool for the EC. It can be used to demonstrate the fulfillment of sustainability requirements for raw materials supply. Furthermore, the TSM can also become a source of inspiration inside the EU to harmonize European mining regulations within the common market. This convergence between regulatory initiatives from both sides of the Atlantic played an important role to understand the choice of design in Raw. It fundamentally removes the risk of any party shirking its responsibilities and pursuing a regulatory path that would be incompatible with the other. On the contrary, it reinforced the coherence and complementary nature of both systems and removed the necessity of deploying more “binding” instruments.

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<sup>364</sup>European commission, “communication from the commission to the european parliament and the council: The raw materials initiative — meeting our critical needs for growth and jobs in Europe”, p. 3, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52008DC0699&from=EN>, Accessed the 22<sup>nd</sup> August 2019.

<sup>365</sup>European commission, “Commission staff working document on the implementation of the Raw Materials Initiative”, p. 5, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014SC0171&from=EN>, accessed the 22<sup>nd</sup> August 2019.

<sup>366</sup>European commission, “Communication from the commission to the European parliament, the council, the European economic and social committee and the committee of the regions: Next steps for a sustainable European future European action for sustainability”, [https://ec.europa.eu/europeaid/sites/devco/files/communication-next-steps-sustainable-europe-20161122\\_en.pdf](https://ec.europa.eu/europeaid/sites/devco/files/communication-next-steps-sustainable-europe-20161122_en.pdf), accessed the 23<sup>rd</sup> August 2019.

The bilateral dialogue adopted in CETA is a continuation of ongoing regulatory convergence between the two actors and is an additional channel of communication. For Canada, it gives the country a means to raise sensitive regulatory issues for its exports and influence European regulators. According minutes from the second bilateral meeting:

Both parties agreed to: [...] Identify opportunities to connect Canadian suppliers of critical raw materials with European manufacturers, including by exploring supply-demand dynamics, and opportunities to promote Canada as a responsible and sustainable source of supply at the 2019 EU Raw Materials week<sup>367</sup>.

The ability of Canada to position itself as a regulatory leader in sustainable mining, as well as to externalize its regulatory scheme to certain EU member states, were key to understand how the country succeeded to reassure the EU on its regulatory commitments towards sustainability in mining. From the EU perspective, the Canadian regulatory initiatives correspond well to the regulatory approach they are currently developing. Both parties did not have any “shirking” concerns that could have been caused by sudden regulatory upheaval. This possibility did not appear to have been considered by the negotiating parties. Cooperation in this instance shared the same features as in Forest. The purpose is to explore and extend economic activities through regulatory cooperation. As stressed by the minutes of the meeting and its agenda, the purpose of states is to develop the sector within the objective of liberalization and with the help of public regulators.

### **EU-CA Biotech product approval hurdles and WTO disputes**

For the Sector of Biotech, one of the most important documents to summarize the regulatory situation between Canada and the EU is the WTO panel reports relative to the dispute DS/291/292/293 - *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*<sup>368</sup>. Initiated in 2003, the dispute opposed Canada/USA/Argentina against the

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<sup>367</sup>EC-Canada, “Comprehensive economic and trade agreement (ceta) meeting of bilateral dialogue on raw materials 6 March 2019, Toronto joint report”, p. 2, [https://trade.ec.europa.eu/doclib/docs/2019/april/tradoc\\_157819.pdf](https://trade.ec.europa.eu/doclib/docs/2019/april/tradoc_157819.pdf), accessed the 23<sup>rd</sup> August 2019.

<sup>368</sup> WT/DS291/R; WT/DS292/R; WT/DS293/R European Communities - Measures Affecting the Approval and Marketing of Biotech Products - Reports of the Panel, WTO “database”, [https://docs.wto.org/dol2fe/Pages/FE\\_Search/FE\\_S\\_S006.aspx?Query=\(@Symbol=%20wt/ds293/\\*\)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20wt/ds293/*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#), accessed the 23<sup>rd</sup> August 2019

EC on the basis that the latter implemented a moratorium on the approbation of all new Biotech products since October 1998<sup>369</sup>. The three plaintiffs argued the *de facto* imposed moratorium was in violation with WTO SPS, TBT and Agriculture agreements. Specifically, the European procedure discriminated their Biotech products without any scientific basis to justify the refusal of approbation. In other words, by systematically refusing to approve new products, irrespective of the individual scientific assessment, the measures were discriminating products of export interests for these three countries. The conclusion of the panel report adopted in 2006 by the DSB, concurred with the existence of a de facto moratorium on the approbation of new products by the EC. It also follows the three complaining countries assertions that the EU's delay process for products approbation were “undue” and not based on scientific assessment.

The central point of the regulatory dispute in this case is related to the implementation of the EC Directive 2001/18 governing “the deliberate release into the environment of genetically modified organisms” and EC Regulation 258/97 regulating “novel foods and novel food ingredients”<sup>370</sup>. As such, these EU legislations are not put under question by the panels nor the plaintiffs. It is rather their implementation that is questioned, especially their conformity assessment processes<sup>371</sup>. The food approval procedures diverge strongly between the EU and the USA or Canada. As described thoroughly by Shaffer and Pollack (2000, 47), the EU approach to food approval follows a comprehensive approach, taking into consideration social, environmental, health and ethical concerns. Besides the approbation of the products themselves, the production process is also investigated. This approach contrasts with the North American perspective, focusing on the health and safety concerns for consumers only, evaluated by “scientific risks assessment”. This difference is embodied in the differences of institutional approaches. While the US and Canada delegate the competence of approval to a federal agency, the Food and Drugs Agency (FDA – US) and the Canadian Food Inspection Agency (CFIA), the EU shares the competences between

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<sup>369</sup> WTO, “DS292: European Communities — Measures Affecting the Approval and Marketing of Biotech Products”, [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds292\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds292_e.htm), accessed the 23<sup>rd</sup> August 2019.

<sup>370</sup> WT/DS291/R; WT/DS292/R; WT/DS293/R European Communities - Measures Affecting the Approval and Marketing of Biotech Products - Reports of the Panel, p. 3, WTO “database”, [https://docs.wto.org/dol2fe/Pages/FE\\_Search/FE\\_S\\_S006.aspx?Query=\(@Symbol=%20wt/ds293/\\*\)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20wt/ds293/*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#), accessed the 23<sup>rd</sup> August 2019

<sup>371</sup> Ibid., p. 11

different institutions: member states national agencies, the European Food Safety Agency (EFSA), the European Commission and member states' committees (comitology)<sup>372</sup>.

Specifically, in Canada, products that underwent genetical modifications need to pass a procedure of pre-market approval, performed by the Food Directorate of Health Canada and the CFIA respectively<sup>373</sup>. In its assessment, the directorate and CFIA follows a series of guidelines and standards publicly available<sup>374</sup>. Canada does not appear to have developed specific legislation for Biotech, but rather used a strict approval and conformity assessment system, more stringent than the US for instance (Howlett and Migone 2010, 5). Canadian agencies apply different legislations in their assessments, notably: The Food and Drugs Act (Health Canada), the Pest Control Products Act (CFIA), the Fertilizers Act (CFIA) and other relevant legislations also used for the approbation of non-biotech products<sup>375</sup>. Canada privileges a generic approach to Biotech products and treats them like any other products in its legislation. For instance, the Canadian Food and Drugs Act does not contain any mentions of “Biotech” or “Genetically modified”<sup>376</sup>. Compared with non-biotech products, divergences appear during the approbation and conformity assessment procedures followed for Biotech’s pre-market approval (more stringent). Further distinction with European approaches to conformity assessment, the CFIA “regulates novel agricultural products

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<sup>372</sup> European Commission, “GMOs: EU decision-making process explained”, [https://ec.europa.eu/food/sites/food/files/plant/docs/gmo\\_auth\\_decision-making-process.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_auth_decision-making-process.pdf); European commission. “GMOs: commission’s proposal on Food/Feed, Brussels 22<sup>nd</sup> April 2015”, [https://ec.europa.eu/food/sites/food/files/plant/docs/gmo\\_auth\\_decision\\_presentation\\_20150422.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_auth_decision_presentation_20150422.pdf); all accessed the 23<sup>rd</sup> August 2019.

<sup>373</sup> Government of Canada Agriculture and Agri-Food Canada, “Regulatory Readiness: A Decision Model for Canadian Food Products”, <http://www.agr.gc.ca/eng/industry-markets-and-trade/canadian-agri-food-sector-intelligence/processed-food-and-beverages/trends-and-market-opportunities-for-the-food-processing-sector/regulatory-readiness-a-decision-model-for-canadian-food-products/?id=1311966040606>, accessed the 23<sup>rd</sup> August 2019.

<sup>374</sup> Government of Canada Health Canada, “Guidance Document for Preparing a Submission for Food Health Claims”, <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidance-document-preparing-submission-food-health-claims-2009-1.html>, accessed the 23<sup>rd</sup> August 2019.

<sup>375</sup> Government of Canada Canadian Food Inspection Agency, “Regulating Agricultural Biotechnology in Canada: An Overview”, <http://www.inspection.gc.ca/plants/plants-with-novel-trait/general-public/overview/eng/1338187581090/1338188593891>, accessed the 24<sup>th</sup> August 2019.

<sup>376</sup> Government of Canada Canadian Food Inspection Agency, “Regulation of Agricultural Biotechnology in Canada”: The “CFIA regulates novel agricultural products including plants, livestock feeds, fertilizers and supplements, and veterinary biologics”, while Health Canada assesses “assessing the human health safety of novel micro-organisms and plants for food use, as specified under the Food and Drugs Act.”; Environment Canada and Health Canada also performed an assessment in light of the Canadian Environmental Protection Act,1999; [http://publications.gc.ca/collections/collection\\_2007/cfia-acia/A104-24-2007E.pdf](http://publications.gc.ca/collections/collection_2007/cfia-acia/A104-24-2007E.pdf), accessed the 24<sup>th</sup> August 2019.

based on their novelty, not on how they were produced”<sup>377</sup>. Production processes are thus excluded from the risk assessment, a significant point of departure from the EU’s Biotech process.

In Europe, risk assessment is a prerogative shared between the EFSA and member states<sup>378</sup>. The request for approval of a Biotech product is submitted first to member states, which proceed with their own scientific assessment<sup>379</sup>. The submission is then forwarded to the EFSA that also performs a scientific assessment of the products. Both member states and EFSA opinions are sent to the European Commission, which will propose a draft decision to be submitted to the relevant member states’ states committees. The committees vote at the qualified majority to decide if the product is approved or not, namely for cultivation and consumption within the European Union. Nevertheless, even if a product is approved by the committee and is authorized at the EU level, member states can restrict the geographical scope of the application to ensure that their territories are excluded from the authorization. They can also “prohibit or restrict the cultivation of the crop based on grounds related amongst others to environmental or agricultural policy objectives, or other compelling grounds such as town and country-planning, land use, socio-economic impacts, co-existence and public policy”<sup>380</sup>. Contrary to the centralized process of approval as used in Canada, the EU follows a more member states driven approach, where they retain until the end the last word on whether or not to authorize the products. Furthermore, the assessment of the products goes beyond its “novelty” or the safety of its intrinsic chemical or biological components. Risk assessment is based on a more comprehensive approach to safety, which include environmental and socio-economic concerns.

This extended approach of risk-assessment is embodied into EU law corpus through the “principle of precaution”, mentioned at the Article 191(2) in the Treaty on the Functioning of the European Union and during the Judgement of the European Court of Justice of 11 September 2002, Case T-13/99 Pfizer v. Council<sup>381</sup>. In light of this principle, the EU directive 2001/18/EC diverges from

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<sup>377</sup> Ibid., p. 13.

<sup>378</sup> European commission, “Fact Sheet: Questions and Answers on Eu’s Policies on GMOs”, [https://europa.eu/rapid/press-release\\_MEMO-15-4778\\_en.htm](https://europa.eu/rapid/press-release_MEMO-15-4778_en.htm), accessed the 22<sup>nd</sup> August 2019.

<sup>379</sup> European Commission, “GMOs: EU decision-making process explained”, [https://ec.europa.eu/food/sites/food/files/plant/docs/gmo\\_auth\\_decision-making-process.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_auth_decision-making-process.pdf); European commission. “GMOs: commission’s proposal on Food/Feed, Brussels 22nd April 2015”, [https://ec.europa.eu/food/sites/food/files/plant/docs/gmo\\_auth\\_decision\\_presentation\\_20150422.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_auth_decision_presentation_20150422.pdf); all accessed the 23rd August 2019.

<sup>380</sup> European commission, “Fact Sheet: Questions and Answers on Eu’s Policies on GMOs”, [https://europa.eu/rapid/press-release\\_MEMO-15-4778\\_en.htm](https://europa.eu/rapid/press-release_MEMO-15-4778_en.htm), accessed the 22<sup>nd</sup> August 2019.

<sup>381</sup> EUR-Lex, “Consolidated version of the Treaty on the Functioning of the European Union (TFEU)”, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT>; European court of Justice,

Canadian perspective as it requires comparing the “identified characteristics of the GMO and its use which have the potential to cause adverse effects [...] presented by the non-modified organism”<sup>382</sup>. On the relation between GMO and the environment, it remains more difficult to certify a divergence. The EU clearly embodied these aspects in its directives, the procedure of the CFIA noticeably takes into consideration the impact of the GMO in its environment<sup>383</sup>. Nevertheless, where the divergences stand is on the focus from the Canadian side on the “novelty” of the products’ characteristics. Regulatory reviews are triggered if the product is considered “novel” by the Canadian regulatory agencies. If it is found similar to already existing approved products by the authorities, it is presumed already compliant and exempted from the additional risks’ assessment procedures<sup>384</sup>. To note that non-genetically modified products can also be considered “novels” by the authorities and thus also follow extensive risk assessment<sup>385</sup>. Biotech is hence seen as one product type among others and Canadian risk assessment applies a similar process as with “traditional” non-genetically modified products. The EU takes a very different approach when GMOs are implicated. Instead of using the same process, the authority directly compares the GMO with its non-genetically modified alter-ego to determine approbation. This assessment is based on the social, cultural, economic and environmental criteria mentioned earlier. GMOs is thus presumed as a different class of products than other agri-food products and the firm applying for authorization is required to demonstrate the value and safety of its products.

Recalling the WTO DSB case, the adoption of the panel report in 2006 was followed by a significant evolution of the situation. The situation diverged according to the country’s plaintiff.

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“JUDGMENT OF 11. 9. 2002 — CASE T-13/99 Pfizer Animal Health VS Council”, <http://curia.europa.eu/juris/showPdf.jsf?docid=47642&doclang=EN>; both accessed the 24<sup>th</sup> August 2019.

<sup>382</sup> EUR-Lex, Official Journal of the European communities, “Directive 2001/18/ec of the European parliament and of the council of 12 march 2001 on the deliberate release into the environment of genetically modified organisms and repealing council directive 90/220/eec”, p. 19, [https://eur-lex.europa.eu/resource.html?uri=cellar:303dd4fa-07a8-4d20-86a8-Obaaf0518d22.0004.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:303dd4fa-07a8-4d20-86a8-Obaaf0518d22.0004.02/DOC_1&format=PDF), accessed the 25<sup>th</sup> August 2019.

<sup>383</sup> Government of Canada Canadian Food Inspection Agency, “Regulation of Agricultural Biotechnology in Canada”, p. 19, [http://publications.gc.ca/collections/collection\\_2007/cfia-acia/A104-24-2007E.pdf](http://publications.gc.ca/collections/collection_2007/cfia-acia/A104-24-2007E.pdf), accessed the 25<sup>th</sup> August 2019.

<sup>384</sup> Ibid.: The CFIA regulates novel agricultural products based on their novelty, not on how they were produced.

The decision to use a product-based approach was also based in part on the fact that the CFIA had several pre-existing product-based Acts (e.g. the Feeds Act, Seeds Act, and Fertilizers Act). Regulators saw new

biotechnology methods (e.g. genetic engineering) as other means of producing new lines of the same family of products

<sup>385</sup> ibid., p. 6.

While the matter remains unresolved with the USA, Canada and the EU established a bilateral dialogue on agricultural biotech market access as part of a mutually agreed solution in 2009<sup>386</sup>. Furthermore, during the WTO case the EU did approve a GE corn variety (Syngenta Bt-11) in 2004, putting an effective end to the moratorium<sup>387</sup>. Another consequence was the adoption of the Directive (EU) 2015/412 amending Directive 2001/18/EC, which gives the possibility for Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory<sup>388</sup>. This last change has allowed to resolve partially the WTO case, by putting an end to an all-products moratorium, incompatible with the WTO ruling, while preserving EU member's policy space in allowing or not Biotech in their territories.

Despite these regulatory changes and the establishment of the EU and Canada bilateral dialogue, it would be far-fetched to affirm that the regulatory frameworks of these two countries are convergent. As seen throughout this section, regulatory points of discontent remain numerous, even beyond this quick overview of the respective regulatory frameworks. Minutes of the two bilateral dialogues that followed the adoption of CETA testify to the continuation of regulatory conflicts between the two countries<sup>389</sup>. Canadian provinces continue to express their concerns relative to the EU's risk assessment procedure. The timeline for application is pointed at, especially in relation with the 10-years expiry of authorization and the retroactive application of EFSA guidance documents. Questions of labelling, traceability and the Low-Level Presence (LLP) of GM are all also part of the agenda. Nevertheless, the "solution" found in DS 292 remain still as today in action, the EU fulfilling its obligation of consultation as according to WTO DSB preceding requirements. In sum, while risks of "shirking" by the EU of its regulatory obligations to consider in a due process foreign product for approval are still present, they are mitigated by

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<sup>386</sup> WTO, "DS292: European Communities — Measures Affecting the Approval and Marketing of Biotech Products", [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds292\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds292_e.htm), accessed the 23rd August 2019.

<sup>387</sup> Congressional research Service, 8<sup>th</sup> April 2010, "Agricultural Biotechnology: The U.S.-EU Dispute", [https://www.everycrsreport.com/files/20100408\\_RS21556\\_90ae3bd461abd7d052d2e3dd5e1cdeb3b86a071f.pdf](https://www.everycrsreport.com/files/20100408_RS21556_90ae3bd461abd7d052d2e3dd5e1cdeb3b86a071f.pdf), accessed the 25<sup>th</sup> August 2019.

<sup>388</sup> EUR-Lex, Official Journal of the European Union, "Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory", <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015L0412>, accessed the 27<sup>th</sup> August 2019.

<sup>389</sup> EC-Canada, "Meeting of the dialogue on biotech market access issues, videoconference, 26 April 2018", [https://trade.ec.europa.eu/doclib/docs/2018/july/tradoc\\_157100.04.2018%20-%20COM%20report\\_FINAL.pdf](https://trade.ec.europa.eu/doclib/docs/2018/july/tradoc_157100.04.2018%20-%20COM%20report_FINAL.pdf); "11th meeting of the bilateral dialogue on biotech market access issues 4 March 2019 in Brussels and by videoconference", [https://trade.ec.europa.eu/doclib/docs/2019/september/tradoc\\_158341.pdf](https://trade.ec.europa.eu/doclib/docs/2019/september/tradoc_158341.pdf); both accessed the 27<sup>th</sup> August 2019.

WTO DSB decision. This can explain why this bilateral dialogue was integrated as such in CETA and did not result in a strengthening of legal obligations in the agreements, such as EU-CA GMP MRAs in Pharma.

### *8.3. Conclusion*

This chapter investigated the risks of “hold-up” and shirking of three sectors in CETA: Raw, Forest and Biotech. These three sectors were integrated in CETA through a design Type 4 (Ex-post/Soft). For all of them, the empirical findings confirm the theoretical expectation formulated in Chapter 2. In all these three cases, the risks of “hold-up” was absent. Canada’s trade surplus was not considered by the EU as a significant risk for the future of bilateral exchanges. At the opposite, the relation was considered complementary. While, Canada exports high quality coniferous sawnwood to the EU, the EU focuses rather on lower quality plywood, a cheaper manufactured combination of wood remains. Consequently, the European industry did not consider itself in competition with Canadian firms. The forest products sector is also composed of a mix between SMEs and MNEs, with a different degree of presence according to geographical region. The easier the logging, the more SMEs will predominate. The contrary is witnessed with the hostile region of Northern Canada.

The situation was similar in the raw material sector. Canada exports mostly gold, iron ore, nickel, diamond and copper to the EU and Europe sends iron steel, aluminum, clay and glass products, and magnesium. Overall, Canada exporters appear to supply mostly raw products to the EU, while the latter tends to send abroad semi-manufactured products, based on metal and other raw materials. While Canadian firms are mostly Multinationals, with international presences across the globe, they extract raw materials for exports within the Canadian territory. From there, they supply the world including the European continent.

The position of Canadian firms in the upstream segment of the value chains explains why the European firms despite being smaller did not see Canada as competitors. The downstream position of the Europeans cexplain this complementarity relations between raw material suppliers and transformed one (plywood, transformed minerals and clean tech). For the EU diversifying its supply was also a major interest and Canada appears as a practical option to do so, especially in Raw and Biotech. As expected, the EU and Canada’s regulatory convergences played an important role in removing the risks of “shirking”. Regarding the last case, Biotech remains an

ambiguous case, which can be explained by the solution found following the resolution of DS 292.

	<b>Raw Materials</b>	<b>Professional Qualifications</b>	<b>Biotechnology</b>
	Asymmetric trade flows with Canadian Export Surplus.	Asymmetric trade flows with Canadian Export Surplus	Asymmetric trade flows with Canadian Export Surplus
	Canada focused on the extraction and exports of minerals, while the EU is specialized in partially transformed materials and services. Production of the EU and Canada are thus non substitutable and not in competition	Canada focused on the extraction and exports of sawnwood (higher quality), while the EU is specialized in partially transformed forest materials such as plywood. Production of the EU and Canada are thus non substitutable and not in competition	Canada focused on the production of Canola and Soybean for animal feeds. European meat industry imports these inputs while European production is non-existent. Production of the EU and Canada are thus non substitutable and not in competition
	Canadian firms are Multinationals extracting mostly from Canada and exporting across the globe. Global leaders for several key minerals. EU firms are smaller and inward focused	Canadian firms are Multinationals extracting mostly from Canada and exporting across the globe. EU firms are smaller and inward focused	Canada is a global leader in the production and exports of Biotech products. EU is non-existent in the market and does not have any ambitions to join.
<i>Risk of "Hold-up" assessment</i>	Canadian exports are an opportunity for the EU to diversify its dependences on China. Furthermore, the upward segment of the Canadian value chain is seen as complementary with the European downstream	Canadian exports are an opportunity for the EU. The upward segment and specialization of Canadian firms is seen as complementary to European firms' downstream focused one.	Canadian exports are not a threat. Specialization of Canada is seen as complementary to the needs of EU meat industry. Interests of diversification from imports of South-East Asia palm oil.

focused one, especially for  
clean tech industry.

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Wide range of mutually supportive international standards, such as Sustainable development goals, OECD guidelines and Canadian Towards Sustainable Mining (TSM) scheme	Wide range of mutually supportive international standards and supportive schemes, such as Sustainable development goals, the Forest Stewardship Council (FSC) and the Sustainable Forestry Initiative (SFI)	International environment divided: Conflicts around the previous EU moratorium on approval of Biotech products (WTO case DS291)
Regulatory Complementarity between EU Raw Material Initiative and Canadian TSM scheme. The latter is seen as potential mean to implement EU regulatory ambition in the sector.	Regulatory Complementarity between EU Timber regulation and FLEGT scheme with Canadian provincial requirements for production. Canadian standards are compatible and supportive of EU requirements.	Divergence between Canadian federal approval system (Canadian Food Inspection Agency (CFIA)) and the European one, divided between: European Food Safety Agency (EFSA), the European Commission and EU Member states
Increasing numbers of European countries are using and integrating TSM into their Raw regulatory frameworks.	Self-certification schemes in Canada is widely accepted in the EU and used international standards recognized by authorities from both sides	Divergences in the conformity assessment methods: Canada follows a generic approach to Biotech as any "novel" products, while EU has in place separate process with more criteria for assessment

<i>Risk of Shirking assessment</i>	Low risk of shirking due to a wide range of mutually supportive international voluntary standards, complementarity between Canada and European regulatory ambitions and European imports of Canadian regulatory schemes.	Low risk of shirking due to a wide range of mutually supportive international voluntary standards, complementarity between Canada and European regulatory ambitions and European timber regulations.	High risk of shirking due to deep division between EU and Canada approval process, both in terms of methods, process and administrative structure in place
<i>Regulatory Design</i>	Type 4 (Ex-post/Soft) allows for the institutionalization of a long-term mechanism relying on existing voluntary standards, widely used and recognized in the sector. The design pursues previously existing cooperation .	Type 4 (Ex-post/Soft) allows for the institutionalization of a long-term mechanism relying on existing voluntary standards, widely used and recognized in the sector. The design pursues previously existing cooperation .	Type 4 (Ex-post/Soft) is a result of the resolution of WTO DS291. It is a minimal mechanism to reduce the existing regulatory divergences and does not reflect the state of the sector's regulatory framework.

*Table 13 Biotech, Forest and Raw, results of the in-depth analysis*

In Forest and Raw, regulatory systems are complementary and facilitate free flows of goods across borders. In Forest, states from both sides concluded that the Canadian third-party certification system for Forest Products and EU timber regulation were compatible and even mutually supportive. Conformity assessment in Canada was thus recognized and considered as equivalent by EU authorities. The use by Canadian firms and regional governments of international standardization and certification schemes has allowed producers to satisfy new European requirements. EU and Canadian SDGs commitments to emphasize sustainability into their Forest regulatory frameworks also contributed to their regulatory convergences.

For Raw, Canada was an early mover for this sector. Having adopted the Whitehorse Mining Initiative (WMI) in 1993, the Mining Association of Canada (MAC) extended these regulatory

schemes and re-labelled it: “Towards Sustainable Mining” (TSM). This initiative allowed Canadian mining firms to preempt rising European concerns over the sustainability of their raw materials imports. It also puts them into a favorable position to even export this scheme to some EU member states, notably Finland and Spain. Similarly, with Forest, Canadian and EU convergence in their regulatory systems has shifted the liberalization priority away from pure market access issues, to include a more all-encompassing approach to the sector, including sustainability and clean tech.

Therefore, the liberalization priorities of states in Raw and Forest were significantly different than with MV and GIs. Instead of focusing on market access issues, the priority for the negotiating states was to institutionalize their relationship through a long-standing mechanism and extend their cooperation to multiple regulatory subjects related to the two sectors. This mobilization of design Type 4 fulfills thus several key functions for the mutual interests of both parties. Compared with Raw and Forest, the case of Biotech is more complex to explain. Market access issue remains crucial for Canadian states, due to its prominent role as an exporter. Being a global player in the cultivation and export of Biotech products, Canada mostly specializes in the production of canola and soybeans. Most of its firms are based within the Canadian territory and export outside its frontiers. Interested in keeping its supply from Canada in terms of animal feeds, the EU remains interested in cooperation with Canada to potentially lessen its dependencies on other suppliers outside the agreement, notably ASEAN country palm oil suppliers.

Nevertheless, and contrary to Raw and Forest, the regulatory frameworks of the EU and Canada are diverging. These divergences found their roots in the difference of risk assessments methods between the two parties. While Canada only proceeds to an extensive risks assessment if the product is “novel” and treats Biotech and non-genetically modified alike, the EU follows a different approach. In Europe, the EFSA takes into consideration multiple criteria, notably production process and socio-economic impacts for the agri-food sector. Furthermore, Canada uses similar regulations for all its agri-food products, while the EU developed regulations specific to the Biotech sectors. In sum, both frameworks have significant points of departure, which creates important barriers to trade for Canadian exports. Nevertheless, this deviant case in terms of the Type 4 theoretical expectation can be explained by the solution found to create a bilateral dialogue, following the resolution of WTO dispute DS/292 initiated by Canada against the EU. Despite remaining regulatory divergences, EU’s respect for its legal commitments since seems to mitigate—even if not entirely solve—shirking risks by the Europeans.

This concludes the last empirical chapter of this thesis. As recalled, this chapter found that overall, the three cases confirm hypothesis 4, predicting that a Low risk level of “hold-up” and shirking would result in Type 4.

The following Conclusion summarizes the theoretical foundation of this research in Part I, as well as its methodological approaches from Part II. It also recalls the main empirical findings from this Part III. Finally, it will also provide some concluding remarks on the study of the legal design and regulatory cooperation in trade policy.

## Conclusion

By investigating the different formats of regulatory cooperation used in CETA and the cause for their variation across sectors, this thesis attempted to open the “black box” of this type of collaboration. It establishes a typology of different design types used by negotiators. By looking at which sectors were regulated through which design, it saw directly in which sectors the most significant regulatory adjustment occurred. In parallel, this research also investigated how sectors were regulated transnationally, and through which legal means and regulatory instruments states intended to contribute to the sector’s governance in their bilateral PTA.

This work contributes to the literature by providing further evidence of the fundamental differences between sectors’ regulations, which are the theatre of traditional inter-state strategic bargaining. Focusing on sectors allows for an understanding of the link between the domestic and international context in which both sides are embedded. This is particularly key in a context where domestic spheres and actors are not isolated from each other, such as firms exposed to global markets and macro-economic tendencies. By framing the explanation of design variation through interdependent risks, this thesis attempted to look at the sectors through a transnational lens. As investigated in this research, risks are managed strategically following the cost/benefits expectation of states when thinking about their mode of cooperation.

This strategic logic goes beyond assessing impacts by connecting the domestic sphere with the international one (Putnam 1988; Moravcsik 1997). Instead, it adopts a joint perspective of an interactive structure. Specifically, the analysis puts particular attention to how the domestic sphere imbricates itself within a complex international structure, and assesses what are the potential consequences (Lake 1999). In this context, strategic thinking guides the action of states attempting to mitigate the structural risks that come with international interdependence.

The empirical analysis portrayed the technical issues that states faced and linked them within the broader context of international negotiation processes. States choices during these processes took into consideration the variation of interdependent contexts that characterizes different forms of value chains across sectors (Eckhardt and Poletti 2018). In charge of liberalizing sectors through regulatory cooperation, they assess the economic and regulatory state of their trade relations and design their cooperation accordingly.

## **Findings' summary**

The empirical findings of this research found that in 6 cases out of 7, the hypotheses formulated were supported (see Table 6, Chapter 5 section 5.2). In GIs and MVs, a high level of “hold-up” and shirking risks did lead negotiators to use a design Type 1 (Ex-ante/Hard). In both cases, the joint presence of these risks did result in the decision of states to adopt a limited in time, highly binding, technically detailed regulatory design. Specific products were selected to be included when others were left out. Negotiating states took into consideration the sensitivities of locally based Canadian producers for specific products, e.g. certain type of cheese within listed GIs (grand-father rights) & producers of car parts and light vehicles.

Furthermore, the cooperation provided guarantees to Canada that its dairy and car industry will not be taken hostage to further regulatory changes due to European GIs and UNECE regulation. The use of Hard obligations is justified by the existing and pre-existing regulatory divergences between the EU and Canada. In fact, both the Canadian Trademark Act and CMVSS system for cars did prevent or incur sensitive costs for market access, notably for European fine food and car exports to the Canadian market. Regulatory adjustments were made within the Canadian regulations to allow the recognition of new products without altering the overall Canadian system. They included significantly binding language to prevent Canada from shirking its obligations in the future.

This research found that the “standards harmonization” scheme defined as the complete alignments of two countries on one set of standards is absent from CETA. Indeed, the regulatory adjustments mentioned instead create parallel systems of legal recognition for foreign products, without changing requirements for domestic producers within Canadian borders. This finding is particularly meaningful as it shows that even the most potent and immediate design type (Ex-ante/Hard) has strictly limited effects. Regulatory adjustments are restricted to easier market access conditions but do not alter pre-existing production systems. The ambition of regulatory externalization is thus significantly more limited than could have been expected. It remains for future researchers to assess the long-term effects of these immediate adjustments, including whether the latter did push domestic producers to use the new legal provisions to shift their production or not. Looking at the evolution of the GIs sector in Canada would be a promising case study in this regard to assess the effect and realities of EU efforts to externalize its indication system abroad.

According to the other mechanism used, states choose a design Type 2 (Ex-post/Hard) when a sector features a high risk of shirking but low risk of “hold-up”. In pharma, despite the EU trade surplus, empirical analysis found that specialization took place rather between multinational firms and not between countries. Firm’s integration into global value chain did reduce the risk of “hold-up” in the bilateral relation. This was especially the case as both the EU and Canada are junior players in new products launching compared to the U.S. Indeed, the global integration of production process renders exports promotion and requested regulatory changes for unilateral market access meaningless in these circumstances, while the development and approval process of new products gains a strategic importance.

Listing products into a design was considered thus less useful to address this type of issue than a more open-ended scheme that could tackle the lack of recognition of inspections – resulting in administrative duplication – for product approval across borders. Market access issues were hence not as prevalent in these two sectors, compared with MV and GIs. Indeed, the main regulatory barriers emerge due to the multiplication of international and domestic regulatory authorities and regulatory schemes with diverging technical requirements. Consequently, to design their cooperation states privileged an Ex-post design instead of an Ex-ante. Regulatory Cooperation in Pharma institutionalizes thus a long-term binding cooperation mechanism on GMP standards to reduce the divergences in product approval processes between the EU and Canada.

In PQ, the symmetry of exports on both sides and the inward orientation of both countries’ industry also pushed the states to use an Ex-post design. Except for architecture, no others professional services were found to be interested in establishing new immediate equivalences. The relative similar level of trade flows and economic structure in both sides appeared to have played a role. No risk of “hold-up” was thus reported from either side. Negotiators privileged a delayed mechanism that could be seized by professional associations in case of future interests to promote services exports. Furthermore, the Ex-post mechanism had the added advantage of potentially addressing immigration issues in the future, according to the flows of professionals’ in the aftermath of CETA’s implementation. States were nevertheless keen on assuring that their mechanism would be binding and on that it addresses the existing regulatory divergences between Canada and the EU on the mutual recognition professional qualifications.

Finally, this thesis found that for Raw Materials and Forest Products states did select a design Type 4 (Ex-post/Soft) when both risks of “hold-up” and shirking were low. It was not however the case for Biotech, a sector where the risk of shirking was high due noticeable regulatory

divergences between the European and Canadian regulatory frameworks, which are restricting Canadian market access in Europe. In Raw and Forest, states choose to extend their ongoing cooperation on subjects other than market access issues, contributing to the liberalization of the sector through other means. Nevertheless, in Biotech significant issues were raised as the EU's product approval process prevented exports from Canada. Investigating the factors that could explain this deviant case, this thesis found that civil society opposition to Biotech in Europe might have played a role within the overall negotiation but could not determine the design type choice. They would have rather preferred been an exclusion of Biotech from the agreement, but this was incompatible with the resolution of the WTO case DS292.

The resolution of this previous WTO dispute appeared thus to have played a more significant role in CETA, notably by leading to the inclusion of this bilateral dialogue (Type 4 Ex-post/Soft) into the agreement corpus. For Forest and Raw, the previous use and international diffusion by Canadian actors of private standards before the negotiation, such as TSM in mining and PEFC for forest products, did facilitate the recognition of Canadian products in the EU markets. States from both sides took stock of their respective system and decided to use Soft obligations to design their cooperation. Type 4 allows for the extension of cooperation beyond market access issues, such as climate change mitigation, sustainable sourcing, industrial development and technological innovations.

Overall, the explanatory framework proposed, suggesting linking design types to configuration of risks structures, has been able to explain the choice of states when designing sectoral cooperation. The aims of this research were also to demonstrate that a Rational Institutionalist framework comparing sectors instead of overall trade agreements can reveal the institutionalization variation within treaties. It makes it possible to link sectors' technical issues and intricacies with the strategic bargaining process taking places at the state level. As the empirical Part III. illustrates, the sectors' design is not the result of idiosyncratic features. It is the result of careful, calculated decisions of negotiating parties. They anticipate potential gains and losses, with the overarching objective of reducing barriers to trade as presented in the introduction.

## **Race to the bottom or SMEs' promotion ?**

This objective of liberalization through regulatory cooperation remains particularly important, as we saw that it can take different forms according to the state of the sector. In certain circumstances the priority is on removing barriers to facilitate market access (Type 1 in GIs and MVs). In others, liberalization can include product approval processes and promoting innovation (Type 2 in Pharma). It can also support and facilitate the recognition of certain professions that are key for added value in supply chains (Type 2 in PQ). In others, liberalization can extend to managing production, ensuring sustainability of sourcing, promoting technology, and providing administrative support to ongoing economic activities (Type 4 Raw and Forest). The empirical analysis of this research shows how design types are adapted according to the issues or objectives that states identified in each sector. As liberalization priorities vary so do design types.

This design investigation found nevertheless that among the liberalization priorities, regulatory dismantlement was not one of them. Overall, the risk of “Race to the bottom” resulting from international regulatory cooperation in CETA is generally unsupported. By emphasizing the role of explanatory factors such as trade flows and regulatory frameworks, this thesis has attempted to investigate whether negotiators did in fact remove regulatory requirements to facilitate cross-border trade. From the empirical analysis performed, this does not appear to be the case. In the GIs sector, the purpose was rather to introduce the GIs system, within the Canadian *Trademark Act*. In MVs, equivalence was established under the condition that a similar level of protection is guaranteed. The cooperation also schedules the possibility for Canada to remove the equivalence if it considers it necessary for consumer safety or to preserve its value chain integration with the U.S.

In the Pharmaceutical sector, risks of “Race to the Bottom” did not materialize either. The establishment of practical equivalences are particularly difficult as compliance with the more stringent requirements can be required by public authorities. The protocol of mutual recognition for Pharma GMP is a good illustration. The cooperation scheme does not list binding equivalences between ICH standards and/or specific products. Instead, it addresses issues related to facilities inspection and batch controls. The purpose appears to address the consequence of the Global integration of the pharmaceutical sectors, which renders inspection by domestic authorities particularly difficult outside national borders. Even though it aims at facilitating the product approval process, to compete with U.S. superiority, it does not do so by forcing the automatic recognition of standards/product equivalences. It creates a binding framework for the recognition

of inspection processes. In Professional Qualifications, the scheme leaves professional organizations free to decide if they are willing to engage in cooperation or not. Being the main regulators of the markets, these professions are also the first interested in avoiding “dumping” practices through overly lenient recognitions. For Biotech, Raw and Forest, the channel of cooperation is voluntary and does not entail any obligations for negotiating parties.

In sum, it seems difficult to see how regulatory dismantlement could happen through regulatory cooperation in CETA, particularly without passing through a domestic legislative process. At the same time, the original ambitions of regulatory cooperation to include SMEs excluded from the international markets seem also farfetched. Overall, the empirical analysis does confirm previous findings from the EU trade policy literature. PTAs follow a logic of protecting existing exports from discrimination (Dür 2007; Elsig and Dupont 2012). The purpose is less to create new avenues for exports rather than to protect and potentially reinforce existing ones. PQ and Pharma regulatory schemes are more nuanced cases as the link with the design and existing exports is less obvious. In fact, even in Pharma where the EU has a trade surplus, it does not appear that GMP cooperation between Canada and the EU would protect the EU's flows more than Canada's. The mechanism focuses on regulatory duplication and mutual recognition of inspection processes. This choice is understandable in light of the importance of the bilateral imbrication of the sectors and the importance to preserve consumers' safety.

Overall, the ability of trade liberalization and notably regulatory cooperation to fulfill its objective of improving SMEs market access appears uncertain. When looking at the regulatory schemes adopted within the seven sectors reviewed in this research, only two benefitted from immediate and binding regulatory adjustments (GIs, MV), two had binding but delayed mechanisms (Pharma, PQ) and three were voluntary schemes with no immediate rulemaking (Biotech, Forest & Raw). When looking at the economic consequences post-CETA implementation, it does appear that GIs and MV benefitted from these adjustments as exports in these two sectors rose significantly (e.g. EU cheese exports by 33%, CA exports motor vehicles parts by 100%)<sup>390</sup>. These rising exports do not solve the questions of internal distribution problems though, as it appears to

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<sup>390</sup> European commission, News archive, “EU–Canada Summit: strengthening the rules-based international order”, <https://trade.ec.europa.eu/doclib/press/index.cfm?id=2051>, accessed the 1<sup>st</sup> September 2019; A note of caution is necessary for MV as it remains open to determine whether Canadian Motor Vehicles exports are attributed to UNECE adjustments or from tariff reduction and the reduction of RoO requirements: The Canadian chamber of Commerce, “So what's in the Canada-EU Trade Agreement (CETA)?”, p. 3, [http://www.chamber.ca/membership/131018-So-whats-in-the-Canada-EU-Trade-Agreement-CETA/131018\\_CETA\\_Analysis.pdf](http://www.chamber.ca/membership/131018-So-whats-in-the-Canada-EU-Trade-Agreement-CETA/131018_CETA_Analysis.pdf), accessed the 1<sup>st</sup> September 2019.

rather reinforce existing exports than create new opportunities for exports for outside firms. This impact was already empirically established for GIs by the Centre d'Études Prospectives et d'Informations Internationales (CEPII) (Duvaleix-Tréguer et al. 2018).

### **The uneasy relation between trade and industrial policies**

Regulatory Cooperation in PTAs remains a problematic set of tools. Not only, does it continue to have difficulties to fulfill its objective of better integrating SMEs within international trade flows, but trade liberalization in itself is widely contested both in the EU and the USA. The World Trade Organization is itself facing some of the most vivid challenges of its history. It is to wonder whether we are witnessing a reversion of the previous substitution of industrial policy by trade policy, that took place in the 80s. At that time, the European public authorities replaced their direct intervention in the economy by regulatory tools (Majone 1994), privileging setting rules that organized markets rather than creating them directly.

It appeared retrospectively that trade policy and its regulatory instruments in PTAs were parts of this new toolbox, which adopted a “regulated” approach towards economic governance instead of direct intervention. The U.S. promotion of the “competitive liberalization” doctrine can be seen for instance as governmental economic management through trade liberalization (Evenett and Meier 2008). For the EU, this trend is particularly apparent with the rise of “Regulatory Europe”, a potential illustration of the link between public governance and regulatory externalization (Bradford 2015). As investigated and discussed in this research EU PTAs a similar function in acting as European external policy tools, through international regulatory cooperation. This was particularly apparent for EU GIs and Motor vehicles regulations.

These questions appear particularly relevant as free trade and current EU trade policy is increasingly under criticism from a range of different stakeholders (Dominguez 2017). Concomitant with this debate on the limits of the European “trade-regulatory” approach, several propositions are being voiced calling for a return of industrial policy. The economist Dani Rodrik has notably recently called for the re-appropriation by states of more direct forms of intervention, while taking into account the lessons of past failures<sup>391</sup>. These calls have found more attraction in

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<sup>391</sup> Dani Rodrik, VoxDev, “Where are we in the economics of industrial policies?”, <https://voxdov.org/topic/public-economics/where-are-we-economics-industrial-policies>, accessed the 28<sup>th</sup> August 2019.

light of increasing empirical evidence highlighting the increasing dualization of the economy between “low” and “high” productivity sectors within an overall economic context of secular stagnation (Gordon 2015; Storm 2017; Summers 2015). The “firm heterogeneity” theory (Melitz 2003; Melitz and Ottaviano 2008) already identified this dualization visible in international trade economics. As Krugman recalls, the International trade field economics toned down this dualization by emphasizing the overall welfare gains that liberalization provides<sup>392</sup>. The structural context of stagnation since 2008 and even global deflation due to the ongoing pandemic, probably contributed to the previous and current questioning of free trade merits by public opinion and policymakers.

The resurgence of industrial policy proposals might indicate that the use of trade liberalization as policy tool, especially PTAs, could have encountered certain limits. In this context, CETA might be seen as a zenith point for EU trade policy, especially in using regulatory cooperation as public policy tools. Standing as the gold standard for the new generation of trade agreements, CETA could remain the most ambitious regulatory agreement that the EU concluded in the current political era. This argument remains subject to caution, especially as the EU signed the EU-Japan trade agreement in 2018, shortly after CETA<sup>393</sup>. Nevertheless, both treaties share many similarities although EU-Japan is more ambitious in its inclusion of provisions relating to Corporate Social Responsibility and Climate Change<sup>394</sup>. As of now, it does reasonably appear that CETA corresponds to an upper limit in terms of regulatory cooperation ambitions. While it remains open to discussion whether or not it will last, domestic controversies that took place in Europe at the conclusion of CETA could have caused the EC to refrain from adopting more ambitious approaches.

The importance of trade liberalization for policymakers is often related to the rising function of trade policy as “jobs creators”. Stressed in numerous policy documents, the role of trade in creating jobs is often used as justification for the EU trade policy ambitions in the face of rising economic and social discontent in Europe. As stressed by several OECD policy

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<sup>392</sup> Paul Krugman, Bloomberg, “What Economists (Including Me) Got Wrong About Globalization”, <https://www.bloomberg.com/opinion/articles/2019-10-10/inequality-globalization-and-the-missteps-of-1990s-economics>, accessed the 28<sup>th</sup> August 2019.

<sup>393</sup> European council, “EU trade agreements”, <https://www.consilium.europa.eu/en/policies/trade-policy/trade-agreements/>, accessed the 1<sup>st</sup> September 2019.

<sup>394</sup> European parliament, “Study requested by the INTA committee: The EU-Japan Economic Partnership Agreement”, p. 26, [https://bruegel.org/wp-content/uploads/2018/10/EXPO\\_STU2018603880\\_EN.pdf](https://bruegel.org/wp-content/uploads/2018/10/EXPO_STU2018603880_EN.pdf), accessed the 1<sup>st</sup> September 2019

recommendations<sup>395</sup> cited in this thesis' introduction, and within the "Report on the Implementation of the Trade Policy Strategy Trade for All"<sup>396</sup>, published in 2017, the benefits of trade and noticeably of exports for jobs is clearly emphasized. While the report is not a binding document, the systematic integration of jobs metrics (numbers, salary) encouraged by IOs, like the OECD, can effectively impact how trade policy is defined by the EC and potentially impact its economic priorities.

Besides legitimacy, this type of questioning also relates to the overall role of states' interventionism in the economy. As jobs' creation prospects through liberalization are particularly dire in time of a global pandemic, the possibility for more "forceful" states' actions is to be seriously considered. This is especially worthy of discussion considering that the resurgence of industrial policies originated even prior to Covid-19. The "EU Green Deal" is an instance of this trend, but others are similarly taking place notably Made in China 2025 or recent efforts of the U.S. administration to promote their own digital technology. A potential option for regulatory cooperation to remain compatible with these recent evolutions might become the coordination of these industrial policies to reduce avoidable detrimental effects.

This thesis has attempted to show that regulatory negotiations are not just mechanical exercises. It is an exercise of managing risks and expectations on complex economic phenomena. The variety of interdependence integration played a major role in influencing how states cooperate with one another. States' cooperation is thus a reflection of the reality of transnationality in international politics. The ability for these sectors to cooperate on a wide variety of different issues while considering the interests and sensitivities of the other party, such as in CETA, is exemplary of global governance relevance. While not all issues can be addressed, CETA nevertheless established a foundational basis on which the EU and Canada can rely.

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<sup>395</sup> OECD, 2005, "OECD Guiding Principles for Regulatory Quality and Performance": <http://www.oecd.org/fr/reformereg/34976533.pdf>; OECD, 2012, "Recommendation of the council on Regulatory Policy and Governance": <http://www.oecd.org/gov/regulatory-policy/49990817.pdf>; OECD, OECD Legal Instruments, 1995, "Recommendation of the Council on Improving the Quality of Government Regulation, OECD/LEGAL/0278": <https://legalinstruments.oecd.org/public/doc/128/128.en.pdf>, all accessed the 28th May 2019.  
<sup>396</sup> European commission: "Report on the Implementation of the Trade Policy Strategy Trade for All: Delivering a Progressive Trade Policy to Harness Globalization", p. 3 & 5, [https://trade.ec.europa.eu/doclib/docs/2017/september/tradoc\\_156037.pdf](https://trade.ec.europa.eu/doclib/docs/2017/september/tradoc_156037.pdf), accessed the 28<sup>th</sup> August 2019.

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# **Appendix**

## **Appendix I**

### *Terms definition and coding process*

When is a legal provision included as Regulatory Cooperation?

- A legal provision is considered as belonging to regulatory cooperation activities when it specifies the technical requirement of a products and/or service; and prescribe or encourage its common use by the parties targeted by the legal text.
- Are also included convex activities leading indirectly to the production of joint technical requirements, which can include administrative task, process and criteria to be fulfilled.
- Technical requirements can include the technical characteristics of the product/service itself and/or its production process.
- Requirements are criteria that need to be fulfilled by the product/service to comply with the regulation specified.
- Activities of regulatory cooperation include the common development of standards and/or metrics to be fulfilled; whole or part of processes for conformity assessment; audit and/or accreditation.
- Cooperation between authorities, public or private bodies conducting just mentioned activities is also included in regulatory cooperation

How is a legal provision coded as a Regulatory Solutions?

Two steps are followed to code a legal provision identified in the legal:

- First, legal provisions pertaining to regulatory cooperation pertaining to the Regulatory Cooperation activities described upper are identified and listed. The coding follows an article-article process, which looked at each article of the entire CETA. In certain case, the article was referring to a protocol and/or annex. In this case, the entire annex and protocol was reviewed in relation with article.
- Then, the legal feature of the specific article is assessed according to the nature of the rules it produces. Are the results of its activity binding or voluntary? Are they directly implementable or delayed in time? This help to classify the article along the two dimensions: Obligation and decision. In case of annex and/or protocol, the same process was followed.

How economic Sectors are identified and defined?

From a legal provision, two steps are taken to associate them to an economic sector:

- To identify the products, services or actors targeted by regulatory cooperation activities. This is done by analyzing the provision to detect if a specific product/service or economic field of activity is explicitly mentioned.
- To classify the products/services and economic field into common label according to the level of similarity of their economic activities.
- To detect of other parts of the agreements referring to “sectors” as a separate entity, regulated under specific articles, annexes and/or protocols.

## **Appendix II**

### *Regulatory Sectors in CETA coding process*

#### Biotechnology

- Include activities related to the production, control and distribution of biotechnological goods
- Biotechnology goods refers here to genetically modified agri-food products.
- Articles referring to the regulation, technical regulation linked products approval, production, standardization of genetically modified products are classified under this sector

#### Forest Products

- Include activities related to the production, control and distribution of forest goods
- Forest goods refers here to goods made of woods, either raw woods material, partially or completely transformed.
- Articles referring to the regulation, technical regulation linked products approval, production, standardization of forest products are classified under this sector.

#### Geographical Indications

- Include activities related to the production, control and distribution of agri-food products identified as belonging to GIs according to classification of EU DG agri.
- Articles referring to the regulation, legal recognition, production process and technical regulations related of GIs are classified under this sector.

#### Motor Vehicles

- Include activities related to the production, control and distribution of automobile and motor vehicles.
- Include regulations, standards and technical requirements concerning the safety and quality of automobile and motor vehicles, including conformity assessment and audits processes.

## Pharmaceuticals

- Include activities related to the production, control, distribution and approval of pharmaceutical products
- Include regulations, standards and technical requirements concerning the safety and quality of pharmaceutical products, including conformity assessment and audits processes.

## Professional Services

- Include activities related to the supply, recognition and regulation of publicly and/or privately services.
- Include activities related to the recognition and equivalence of qualifications between professional organizations in respective parties.

## Raw Materials

- Include activities related to the production, control and distribution of raw material goods.
- Raw materials refer here to goods made of materials, either raw, partially or completely transformed (e.g. steel).
- Articles referring to the regulation, technical regulation linked products approval, production, standardization of raw materials products are classified under this sector.

## **Appendix III**

### Coding results – Regulatory Sectors in CETA

#### **Type 1**

##### **Ex-ante, Hard**

Art 20.18 & Annex 20 A	Geographical Indications
Annex 4-A	Automobile and motor vehicles

#### **Type 2**

##### **Ex-post, Hard**

Art 11.3.6	Professional Services
Art 11.3.1/.2/.3/.4/.5	Professional Services
Art 11.5.g, art.11.6	Professional Services
Annex 11-A	Professional Services
Art 4.5	Pharmaceuticals
Art 11.3	Professional Services
Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products	Pharmaceuticals

#### **Type 4**

##### **Ex-post, Soft**

Art 25.1	Biotech, forest product, raw materials
Art 25.2	Biotech
Art 25.3.1	Forest Products
Art 25.4	Raw Materials

## **Appendix IV**

### List of Interviewed Organization

Business Council of Canada

Canadian Chamber of Commerce

Canadian Federation of Agriculture

CEI-BOIS

CEN-CENELEC

Council of Bars and Law Societies of Europe (CCBE)

Dairy Processors Association of Canada

Directorate General Agriculture & Rural Development (DG AGRI)

Directorate General Internal Market, Industry, Entrepreneurship and SMEs (DG GROWTH)

Directorate-General for Trade (DG TRADE)

EUCOLAIT

European Automobile Manufacturers Association (ACEA)

European Dairy Association (EDA)

European Milk Board

EuroMines

Global Affairs Canada

Innovative Medicines Canada (IMC)

Natural Resources Canada

SpiritsEurope

Standards Canada Council (SCC)

The Mining Association of Canada (MAC)

Treasury Board of Canada

Table code of cited Interviews

Location of the actor	Type of actor	Code for the interviewee	Dates
Ottawa	Industry	A1	1st April 2019
Ottawa	Industry	A2	24th June 2019
Ottawa	Industry	A3	3rd April 2019
Ottawa	Industry	A4	3rd April 2019
Ottawa	Industry	A5	4rd April 2019
Ottawa	Industry	A6	2nd April 2019
Ottawa	Public Official	B1	19th September 2019
Ottawa	Public Official	B2	5th April 2019
Ottawa	Public Official	B3	2nd April 2019
Ottawa	Public Official	B4	5th April 2019
Ottawa	Public Official	B5	4th April 2019
Ottawa	Public Official	B6	10th July 2019
Brussels	Industry	C1	7th June 2019
Brussels	Industry	C2	15th March 2019
Brussels	Industry	C3	15th March 2019
Brussels	Industry	C4	16th March 2019
Brussels	Industry	C5	15th March 2019
Brussels	Industry	C6	16th March 2019
Brussels	Industry	C7	16th March 2019
Brussels	Public Official	D1	24th June 2019
Brussels	Public Official	D2	22nd July 2019
Brussels	Public Official	D3	15th March 2019
Brussels	Public Official	D4	16th March 2019

Brussels	Industry	D5	16th March 2019
Brussels	Public Official	D6	12th July 2019
Brussels	Public Official	D7	25th July 2019

## Appendix V

### Additional Figures & Statistics

From EU (28) to Canada  
Value in € EUR rounded to the Million

Motor vehicles, trailers and semi-trailers			
	2015	2016	2017
Gross Imports	329	506	673
Gross Exports	3879	4546	4809
<b>Gross Imbalance</b>	<b>3550</b>	<b>4040</b>	<b>4136</b>
	2017: surplus in % = 714.5		
Agri-Food			
	2015	2016	2017
Gross Imports	2238	2218	2251
Gross Exports	3419	3451	3560
<b>Gross Imbalance</b>	<b>1181</b>	<b>1233</b>	<b>1309</b>
	2017: surplus in % = 158.15		

Eurostats, Comtext, EU trade by SITC

*Table 14 Motor Vehicles and GIs Trade imbalances between EU and Canada, Eurostats, Comtext EU trade by SITC, Agri-Food Trade Statistical Factsheet: European Union – Canada*

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[https://ec.europa.eu/agriculture/sites/agriculture/files/trade-analysis/statistics/outside-eu/countries/agrifood-canada\\_en.pdf](https://ec.europa.eu/agriculture/sites/agriculture/files/trade-analysis/statistics/outside-eu/countries/agrifood-canada_en.pdf)

EU exports, superior to 3,5% share in all Agri-food in 2018

Name	Value Mio €	% Share
Cheese	167	4,5
Olive oil	133	3.6
Preparation of Vegetables, fruits or nuts	142	3.8
Wine. Vermouth, cider and vinegar	940	25.4
Chocolate, confectionery and ice-cream	282	7.6
Pasta, pastry, Biscuits and bread	226	6.1
Beer	211	5.7
Spirits and Liqueurs	344	9.3

EU Imports, superior to 3.5% share in all Agri-food in 2018

Wheat	278	14
Cereals	306	15.4
Soyabean	289	14.5
Oilseeds, other than soyabean	150	7.5
Vegetable, fresh, chilled and dried	229	11.5
Fruits, fresh or dried	86	4.3
Pet food	85	4.3

Eurostats, Comtext, EU trade by SITC

*Table 15 Agrifood Commodities export profile, Data extracted from Agri-Food Trade Statistical Factsheet European Union – Canada*

Source: [https://ec.europa.eu/agriculture/sites/agriculture/files/trade-analysis/statistics/outside-eu/countries/agrifood-usa\\_en.pdf](https://ec.europa.eu/agriculture/sites/agriculture/files/trade-analysis/statistics/outside-eu/countries/agrifood-usa_en.pdf)

	<b>Models (excerpt)</b>	<b>Quantity</b>
Damler AG (e.g. Mercedes Benz)	B-Class, C-Class, Maybach, Smart	29'688
BMW	1-Series, 3-Series, Mini Cooper	26'612
Volkswagen	CC, EOS, Golf, GTI	22'671
Audi	A3, A4, A5, A6	20'506
Jaguar/land Rover	F-Type, XF, XJ6/8, XK8	6'399

*Table 16 Types of EU vehicles exported to Canada*

*Source: EU vehicles exported to Canada, data found in Stanford, Jim. 2014. “CETA and Canada’s Auto Industry Making a Bad Situation Worse.” Ottawa, 13.*  
<https://www.policyalternatives.ca/publications/reports/ceta-and-canada%E2%80%98s-auto-industry>

Imported Cheese in Canada, by TRQs, 2017, superior at 600'000 kg

	WTO Tariff Rate Quota - EU Access Level: 14,271,832 kg	WTO Tariff Rate Quota - NON-EU Access Level: 6,140,034 kg	CETA Cheese Tariff Rate Quota Access Level: 5,333,000 kg
0406209100 GRATED OR POWDERED	38,961	617,684	584
CHEESE OF ALL KINDS,			
0406901100 CHEDDAR CHEESE AND CHEDDAR TYPES OF CHEESE	1,160,647	750,950	49,506
0406401000 BLUE- VEINED CHEESE	942,995	135,204	19,102
0406903100 BRIE CHEESE AND BRIE TYPES OF CHEESE	874,033	564	80,708
0406904100 GOUDA CHEESE AND GOUDA TYPES OF CHEESE	2,618,966	810,298	53,186
0406909300 PARMESA N CHEESE AND PARMESAN TYPES OF CHEESE	3,898,986	207,362	265,617

*Table 17 Quota : Cheese imports in Canada for 2017*

*Source: Global Affairs Canada / Affaires mondiales Canada, TRQ imports summary control year: 2018, [https://www.eics-scei.gc.ca/report-rapport/Arc\\_2017\\_APRMT61C-C.htm](https://www.eics-scei.gc.ca/report-rapport/Arc_2017_APRMT61C-C.htm)*

	Extra EU Trade (EUR Millions)			Share in EU trade (%)	
	Exports	Import	Balance	Share	Import
EU-28	127'745	46'212	81'533	100	100
Germany	70'251	12'965	57'286	55	28.1
United Kingdom	22'120	4166	17'954	17.3	9
Italy	6845	4260	2585	5.4	9.2
Slovakia	5164	37	5127	4	0.1
Spain	4284	3807	477	3.4	8.2

Table 18 Top 5 EU members exporting motor cars outside the EU for 2018

Source: Eurostats, [https://ec.europa.eu/eurostat/statistics-explained/index.php?title=File:Extra\\_EU\\_trade\\_in\\_motor\\_cars\\_by\\_Member\\_State,\\_2018.png](https://ec.europa.eu/eurostat/statistics-explained/index.php?title=File:Extra_EU_trade_in_motor_cars_by_Member_State,_2018.png)

Canada	Exports to the EU	
	Gold	11,336,003,725
	Iron ore	1,827,360,919
	Nickel	1,353,375,996
	Diamonds	1,094,709,626
	Copper	538,451,261
	Uranium and thorium	498,688,076
	Vanadium	231,963,680
	Iron and steel	212,295,647
	Aluminum	169,321,049
	Niobium	105,633,027
Imports from the EU		
	Iron and steel	2,219,756,109
	Silver	507,900,253
	Aluminum	345,968,142
	Clay and clay products	312,655,149
	Glass and glassware products	292,761,510
	Magnesium and magne Nickel	179,293,608
	Copper	176,465,671
	Abrasives	163,251,287
	Graphite	105,005,655
		101,786,113

*Table 19 imported and exported between Canada and the EU*

Source: Facts and figures 2017 of the Canadian mining industry, the mining association of Canada, Annex 9 & 10, <https://mining.ca/documents/facts-and-figures-2017/>

Canada's rank among world producers, EU absent among the 5th biggest producers for all minerals

Uranium (metal content) (2015)	t	13325
mine production	% world total	22
	Rank	2
Niobium (metal production) (2015)	t	5800
mine production	% world total	9.1
	Rank	2
Gemstones	t	13000
	% world total	18.3
	Rank	3
Nickel	t	256
	% world total	11.4
	Rank	2
Aluminium	t	3250
	% world total	5.6
	Rank	3
Gold	t	170
	% world total	5.5
	Rank	5
Diamonds	t	11.677
	% world total	9.2
	Rank	5
Copper	t	NA
	% world total	NA
	Rank	Absent among the 5th most producers
Iron Ore	t	NA
	% world total	NA
	Rank	Absent among the 5th most producers

*Table 20 Canada's ranks among world producers for most minerals exported to the EU*

*Source: data extracted from: Facts and figures 2017 of the Canadian mining industry, the mining association of Canada, Annex 4, <https://mining.ca/documents/facts-and-figures-2017/>*

**Canada exports to the EU** Value (2016), Unit 1000 US\$

Sawnwood, coniferous	101646
Newsprint	92242
Sawnwood, non-coniferous	10336

**EU exports to Canada**

Plywood	10115
Newsprint	2599
Veneer sheets	2210
Sawnwood, non-coniferous	1314

*Table 21 EU-Canada trade exchanges of forest products, classified by countries of exports/destination and commodities*

Source: Data extracted from FAO, <http://www.fao.org/faostat/en/#data/FO>

**Pharmaceutical sector in Canada, leading products and firms**

2017 Leading Pharmaceutical Products in Canada

1	Remicade	Anti-arthritis	Merck	American	<a href="https://www.ema.europa.eu/en/medicines/human/EPAR/remicade">https://www.ema.europa.eu/en/medicines/human/EPAR/remicade</a>
2	Humira	Anti-arthritis	AbbVie	American	<a href="https://www.ema.europa.eu/en/medicines/human/EPAR/humira">https://www.ema.europa.eu/en/medicines/human/EPAR/humira</a>
3	Epclusa	Liver health	Gilead	American	<a href="https://www.ema.europa.eu/en/medicines/human/EPAR/epclusa">https://www.ema.europa.eu/en/medicines/human/EPAR/epclusa</a>
4	Eylea	Ophthalmology	Bayer/Regeneron	German/American	<a href="https://www.ema.europa.eu/en/medicines/human/EPAR/eylea">https://www.ema.europa.eu/en/medicines/human/EPAR/eylea</a>
5	Enbrel	Anti-arthritis	Amgen	American	<a href="https://www.ema.europa.eu/en/medicines/human/EPAR/enbrel">https://www.ema.europa.eu/en/medicines/human/EPAR/enbrel</a>

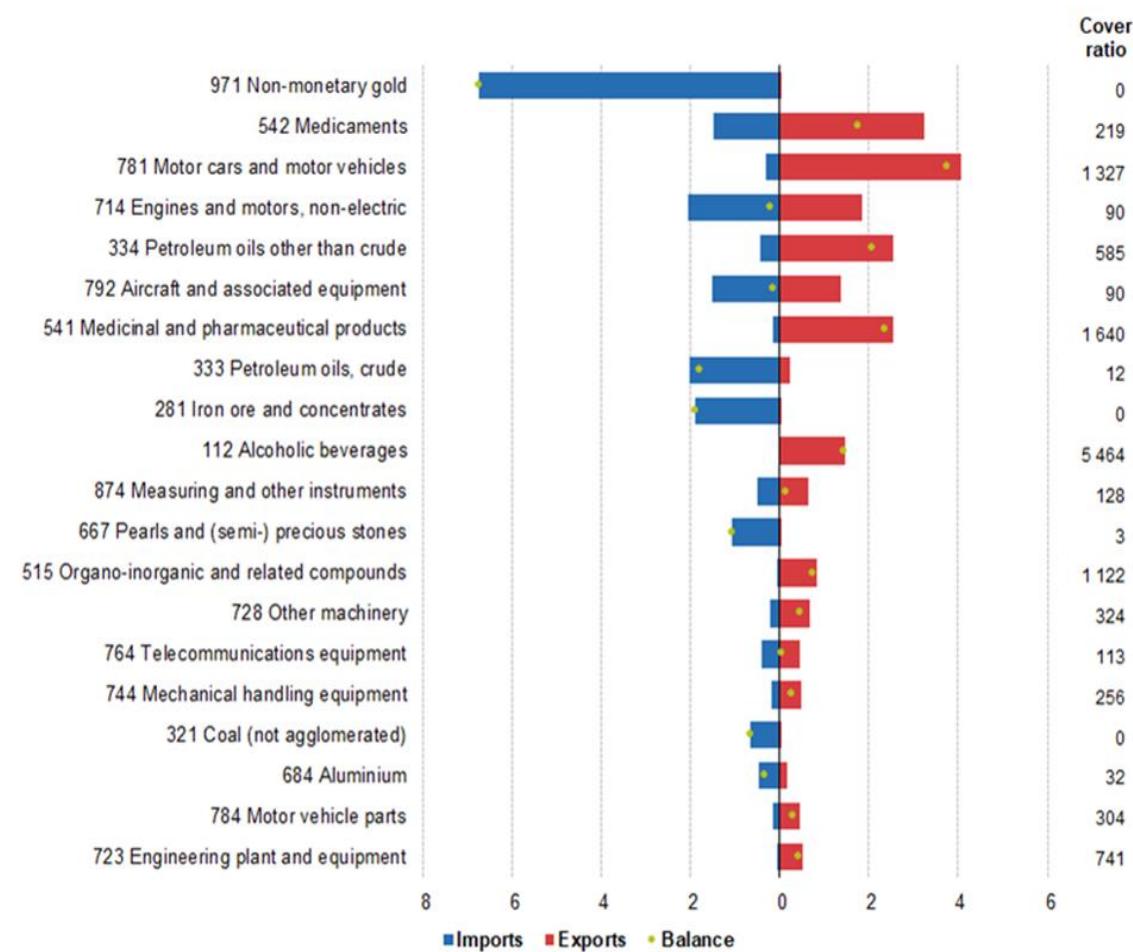
Leading Pharmaceutical Companies in Canada in 2017

1	Johnson & Johnson/Actelion	American	<a href="http://www.jnj.ch/en/about-us/who-we-are.html">http://www.jnj.ch/en/about-us/who-we-are.html</a>
2	Novartis	Swiss	<a href="https://www.novartis.com/news/novartis-corporate-fact">https://www.novartis.com/news/novartis-corporate-fact</a>
3	Merck/Cubist	American	<a href="https://www.merckgroup.com/en/worldwide.html">https://www.merckgroup.com/en/worldwide.html</a>
4	Apotex	Canadian	<a href="http://www1.apotex.com/global/about-us">http://www1.apotex.com/global/about-us</a>
5	Pfizer/Hospira	American	<a href="https://www.pfizer.com/general/global_sites">https://www.pfizer.com/general/global_sites</a>

*Table 22 Pharmaceutical products authorized in Canada & Leading pharmaceutical companies in Canada in 2017*

Source: Government of Canada website, [https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h\\_hn01703.html](https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html)

**Most traded goods between EU-28 and Canada, top 20 of SITC level 3 products, 2018**  
 (EUR billion)



Note: While the trade balance provides information on the absolute value of trading positions, the cover ratio provides a relative measure that is based on the ratio (expressed in percentage terms) between the value of exports and the value of imports; if exports are higher than imports then the cover ratio will be above 100.

Source: Eurostat (online data code: DS-018995)

eurostat

*Table 23 Data from Eurostats on exports ratio and trade imbalances*

Source: data from Eurostats, [https://ec.europa.eu/eurostat/statistics-explained/index.php/Canada-EU-international\\_trade\\_in\\_goods\\_statistics#EU\\_and\\_Canada\\_in\\_world\\_trade\\_in\\_goods](https://ec.europa.eu/eurostat/statistics-explained/index.php/Canada-EU-international_trade_in_goods_statistics#EU_and_Canada_in_world_trade_in_goods)

Bilateral export relation EU-Canada	EU	Canada	Export surplus (%)
2015	35137878898	28020237264	25.40179
2016	35227817776	29034305476	21.3317
2017	37702891161	3151468411	19.63593
2018	41419992006	31000750417	33.60964
Surplus Average from 2015 - 2018			24.99477

Table 24 : Bilateral export flows from 2015-2018 and average of export surplus

Source: Eurostat, Comext database

largest Services Exported							
Country of Surplus	Top Services Traded			EU	Canada	Balance (EU)	Export differences in %, rounded to 1 decimals
Canada	1	Business and management consulting and public relations	2015	525	722	-197	-27.3
			2016	495	541	-46	-8.5
			2017	710	562	148	26.3
EU	2	Engineering	2015	315	102	213	208.8
			2016	431	121	310	256.2
			2017	304	133	171	128.6
Canada	3	Advertising, market research, and public opinion polling services	2015	142	279	-137	-49.1
			2016	148	292	-144	-49.3
			2017	181	333	-152	-45.6
EU	4	Legal Services	2015	213	75	138	184
			2016	214	71	143	201.4
			2017	178	97	81	83.5
EU	5	Scientific	2015	214	159	55	34.6
			2016	127	99	28	28.3
			2017	123	99	24	24.2
EU	6	Accounting, auditing, bookkeeping, and tax consulting services	2015	103	37.6	65.4	173.9
			2016	87	46.3	40.7	87.9
			2017	116	56	60	107.1
EU	7	Architecture	2015	7	1	6	600
			2016	10	1	9	900
			2017	14	4	10	250

Table 25 : bilateral exports flows of professional services

Source: Comext database

## Appendix VI

### Consent forms for Interviews



### REGULATORY COOPERATION DESIGN In PREFERENTIAL TRADE AGREEMENTS STUDY INFORMATION SHEET

#### Study Title

Regulatory cooperation design in preferential trade agreements

#### Principal Investigator

Kevin Kalomeni, Ph. D. Candidate  
Political Science Department, LUISS Guido Carli  
Political Science Department, Université Laval

#### Ph. D. Supervisors

Arlo Poletti, Ph. D.  
Associate Professor, Department of Sociology and Social Research at the University of Trento  
Louis Bélanger, Ph. D.  
Professor, Department of Political Science at the Université Laval

#### Background and Purpose of Research

This academic research looks at the legal design of Regulatory Cooperation provision in trade agreements. The specific objectives of this study are as follows:

- i. To identify and categorize the different types of regulatory design found in trade agreements;
- ii. To look at how these design varied between different regulatory sectors;
- iii. To look at how to explain this variation of legal design between sectors, notably to identify the factors responsible for it; and
- iv. To analyze how the European Union is using these legal provision to influence rules-making globally.]

#### Format and Procedures

You have been invited to participate in a key informant interview because of your unique perspective and expertise on economic sectors interests in international trade. The interview will be [on telephone/face-to-face] and scheduled at a time that would be most convenient for you. The interview is expected to last approximately 30 minutes.

Questions will concern the process behind the development of regulations contained in Free Trade Agreements (FTAs). They will more specifically aim to understand how regulatory cooperation provisions are designed in this new regulatory field and how they influence international negotiations. It is essential to point out that your participation is voluntary and you can decide to end it at all times. If you agree to participate, you may refuse to answer any specific questions without any adverse consequence. Likewise, you can decide to refuse to answer a question or to end your participation, without giving any reasons.

#### Privacy and Confidentiality

The interview will be recorded and transcribed with your consent to facilitate the flow of the discussion and the note-taking. You can always decide to stop the recording. It is furthermore important to point out that neither the records nor the transcriptions will ever be made public. Those documents will only be used as interview notes. Within this context, the transcriptions would not be send to you for approval.



All study materials and data (e.g. recordings, interview transcripts, etc.) will be locked in a secure cabinet in my research office to which only I will have access. Likewise, all electronic files pertaining to this study will be stored on password-protected computers and secured servers with access restricted to me and my two supervisors. Fully anonymized data will also be released to members of my research group (<https://gem-stones.eu/>) on the condition that they respect the same ethics requirements than me. This release will moreover respect the Guidelines on FAIR Data Management in Horizon 2020.

The recordings and transcripts will not have your name or any other identifying information on them. A research code number will be used instead. I will be the only one with an access to the document indicating which code goes with which participant.

All materials and data relating to this study will be used solely for the purpose of this Ph.D. project and they will be destroyed end 2022. I further guarantee that any materials you do not feel comfortable with will be immediately destroyed upon request. No explanations would be asked and the deleted information would never be used. Upon deletion, no copies of such material would remain.

All your input will be kept strictly confidential. Your name will specifically never be associated with any of your views at any phase of my research. Your name will moreover never appear in my Ph.D. thesis or any work related, unless you specifically agree to it.

#### **Risks and Benefits**

The risks of this study are minimal, if non-existent. Your confidentiality will be protected at all times. As noted above, only non-personally identifiable information will be published. Your opinions may be included in my thesis or related papers but never in conjunction with your name or any details that would identify you directly.

No personal benefits will result from this study. Nevertheless, your participation in this research will help to draw a better picture of how e-commerce is being internationally governed. This could have major policy implications by helping to improve the way e-commerce is regulated.

#### **Dissemination of Findings**

As a participant in this research study, you may request a copy of the final report. To benefit from this opportunity, each participant will be asked to show its interest during the interview. The final report would then be sent to the e-mail address used to contact you or another upon request.

#### **Your Rights as a Participant**

You waive no legal rights by participating in this study. You are being provided a copy of this Study Information Sheet to keep for your records. This study has moreover received ethic clearance by the Ethics Committee of Université Laval, approbation number : 2018-375 / 11-03-2019.

#### **Acknowledgement**

Thank you for considering this invitation. I recognize that your time is important but I feel it is important to have your input and I would really appreciate the chance to discuss it with you.

Kevin Kalomeni, Ph. D. Candidate  
LUISS Guido Carli & Université Laval  
GEM-STONES Marie Skłodowska-Curie Doctoral Fellow  
<http://www.gem-stones.eu>  
E-mail: [kevin.kalomeni@gem-stones.eu](mailto:kevin.kalomeni@gem-stones.eu)  
Tel. : +39 329 5863009

**REGULATORY COOPERATION  
IN  
PREFERENTIAL TRADE AGREEMENTS**

**CONSENT FORM**

As part of the above-named research study, you have been asked to take part in a key informant interview. The study information sheet provided with this form describes the purposes of this research and your right as a participant. Again, your participation is voluntary. You can end it at any time without having to provide any explanation. Any information you don't feel comfortable with will moreover be deleted upon request. Your confidentiality will finally be respected at all times. All material related to this study will be fully anonymized as described in the study information sheet.

Please indicate below that you understand that:

- You can withdraw from the study at any time without explanation and without any adverse consequences.
- You have not waived any of your legal right by signing this form
- No direct citations will be used without your prior consent.

Please indicate below if you agree to:

- Be audio-recorded for the purpose of this research

---

Participant's Printed Name

---

Participant's Signature

---

Date

---

Lead Investigator's Printed Name

---

Lead Investigator's Signature

---

Date

N. B.: Each participant should send by e-mail ([kevin.kalomeni@gem-stones.eu](mailto:kevin.kalomeni@gem-stones.eu)) a signed copy of this consent form to the principal investigator before the interview's date. Each interviews will start by verifying that the participant has effectively sent his signed the consent form. In the event a participant fail to do so, his understanding and oral consent to this form would be recorded at the beginning of the interview.