

Expertise and Legitimacy in Models of Regulatory Cooperation

Lessons from the transatlantic experience



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A thesis submitted to Cardiff University in candidature for the degree of

Doctor of Philosophy

May 2022

Abstract

Regulatory cooperation (RC) is the creation of procedural mechanisms in Free Trade Agreements (FTAs) applicable to the preparatory stages of regulation. RC seeks to facilitate trade and thus ultimately aims at the convergence of regulatory standards. RC is essentially an ongoing regulatory dialogue between the executive branches of government. The widening and deepening of RC results in the existence of various policy laboratories across the globe in which countries learn from variation and best practices to work towards regulatory alignment. RC predominantly focuses on non-tariff barriers to trade and thus, essentially, RC is an expansion of the regulatory state in the risk society to the transnational level. In other words, RC is transnational (risk) governance.

As a form of transnational (risk) governance, RC ought to be legitimate. This thesis argues that, as it stands, RC faces a legitimacy deficit that needs to be addressed. To that end, this thesis provides three solutions. Firstly, by applying the democracy-striving approach to RC, the argument is that the law establishing RC ought to provide for parliamentary oversight and strengthen the balanced representation of interested via participatory rights thus improving the input-legitimacy of RC.

Secondly, as the principal focus of this thesis is on scientific expertise enhancing the throughput-legitimacy of RC, this research argues that scientific expertise is a compensatory element that legitimises transnational governance. More precisely, the key argument of this thesis is that when the executive drafts a planned regulatory measure in cooperation with a foreign government, this draft measure ought to rely on *transnational expertise*. The incorporation of scientific expertise in the decision-making process enhances the throughput-legitimacy of RC by increasing the quality of deliberation in the RC process.

Thirdly, this stronger role for expertise requires balancing by better input-legitimacy *on the expertise* used via oversight by parliament and strong participatory rights. In other words, this thesis argues that the democratisation of expertise is required to address the fact that scientific legitimacy alone is insufficient to enhance the throughput-legitimacy of RC. Consequently, the democratisation of expertise addresses the problems of biased expertise by strengthening participatory rights and balances the issue of technocracy by creating oversight mechanisms for parliaments and strengthening participation rights, both on the RC process and the expertise used in the RC process, resulting in a full-circle argument regarding the legitimacy of RC.

Acknowledgements

Firstly, I owe a great deal of gratitude to Stijn Smismans. During the time of this research, my life changed immensely and if it was not for your support throughout, this thesis would not be what it is today. Stijn, thank you for believing in me and for your continuous support during this journey. Furthermore, to Elen Stokes, thank you for your initial insights on my case study at the start of this research project. To Ludivine Petetin and Sara Drake, thank you both immensely for your feedback and thoughts. All of you have contributed greatly to the quality of my work and for that, I owe you all a big thank you.

Secondly, to my family. Dad, none of this would have been possible without your support. Mom, thank you for always being there for me. To my sister and your wonderful children Alina and Lyam, thank you for the moments of peace, away from the research. To my brother and sister-in-law, thank you for all your support. And to all of you, thank you for the support in raising Logan as I finished my thesis and chase my dreams.

Thirdly, to my friends. Kate, Anastasia, Drumeel and Dharu, without you my life would not be the same. You are the people I confide in, the people that make me feel at home. And to my Cardiff friends among whom Pietro, Christos, Kiki, Mariana, without you my journey at Cardiff University would not have been the same. Thank you all for the nights at Buffalo, dates at Cardiff Bay, the wonderful times at Senghennydd, in City Road, sharing in my passion for all things nerdy, Doctor Who, Superman and Wonder-Woman, gaming nights and in general the years filled with marvel. A special thanks to Ruby, my sister across the Atlantic. And to Avi, for being my philosophy sparring partner. You all make my life complete.

And last, but certainly not least, to my son. Logan, you are the light of my life. You make my life increasingly better. Your undefeated happiness and energy brought love into my life in ways that I never imagined possible. You are now, and forever will be, my number one. And so, my dearest Logan, this one is for you.

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List of abbreviations

CETA	Comprehensive Economic and Trade Agreement
EU	European Union
FTA	Free Trade Agreement
GRP	Good Regulatory Practices
IA	Impact assessment
JC	Joint Committee
NTA	New Transatlantic Agenda
OECD	Organisation for Economic Co-operation and Development
RA	Risk assessment
RC	Regulatory Cooperation
RCB	Regulatory Cooperation Body (TTIP)
RCF	Regulatory Cooperation Forum (CETA)
SPS	Sanitary and Phytosanitary Measures
TABD	Transatlantic Business Dialogue
TBT	Technical Barriers to Trade
TCA	EU-UK Trade and Cooperation Agreement
TEP	Transatlantic Economic Partnership
TPP	Trans-Pacific Partnership
TTIP	Transatlantic Trade and Investment Partnership
UK	United Kingdom
US	United States of America
USMCA	United States–Mexico–Canada Agreement
WTO	World Trade Organisation

Chapter 1 Introduction

Regulatory cooperation (RC) is the cooperation between governance institutions on the setting of regulatory standards via an ongoing regulatory dialogue and plays an increasingly important role in contemporary society.¹ In an age characterised by globalisation and transnational problems, the state is transforming, economies are increasingly interdependent and global phenomena such as climate change push states to work together.² The dynamics of globalisation demand cooperation on the setting of regulatory standards between governance institutions resulting in the inevitability of RC – after all, from a free trade perspective, divergence in regulatory standards causes an ‘economic drag’.³ Consequently, there is a continuing expansion (i.e., widening) of RC in Free Trade Agreements (FTAs).

The widening of RC is similarly apparent when considering the actors of RC. The European Union (EU) and the United States of America (US), once the main protagonists in RC, are no longer the only players in the field.⁴ Various FTAs concluded by the EU with a multitude of trading partners contain chapters on RC or cooperation through Good Regulatory Practices (GRP).⁵ Trujillo argues that it is highly likely that the RC trend will continue and that future

¹ See, George A. Bermann, Peter L. Lindseth and Matthias Herdegen, *Transatlantic regulatory cooperation: legal problems and political prospects* (Oxford University Press 2000); Raymond J. Ahearn, 'Transatlantic Regulatory Cooperation: Background and Analysis' (2008) Report for Congress, Congressional Research Service, Washington, DC Alberto Alemanno, 'The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences' (2015) 18 *Journal of International Economic Law* 625.

² There has been an ongoing debate on the decline of the nation state, essentially arguing that the new transgovernmental order is a result of the decline of the nation state, e.g. Anne-Marie Slaughter, 'The Real New World Order' (1997) 76 *Foreign Affairs* 183;

Furthermore, recent FTAs pay little attention to climate change. This is surely a missed opportunity but considering the nature of FTAs and their focus on facilitating trade it is not surprising. Notably, *The Trade and Cooperation Agreement between the European Union and the European Atomic Energy Community, of the one part, and the United Kingdom of Great Britain and Northern Ireland, of the other part of 24 December 2020* (hereinafter TCA), is the first FTA concluded by the EU that considers climate change an ‘essential element’ of the agreement and obligates the EU and the UK to cooperate on matters of climate change, TCA, art. 770, see further chapter 2, section 2.4.3; Clair Gammage, 'General Exceptions and Public Interest Regulation: An Analysis of the EU-UK Trade Cooperation Agreement' (2021) 18 *Manchester Journal of International Economic Law* 101.

³ Jeffery Atik, 'Science and international regulatory convergence' (1997) 17 *Northwestern Journal of International Law & Business* 736, 752.

⁴ E.g., Bermann, Lindseth and Herdegen, *Transatlantic regulatory cooperation: legal problems and political prospects* on the EU and the US specifically. RC chapters are increasingly found in FTAs, for example the ‘new NAFTA’ and other FTAs concluded by the EU with, for example, Singapore, Japan or Vietnam.

⁵ See, for example, the EU-Japan Economic Partnership Agreement – specifically art. 18.12 and 18.13 on RC – at <https://trade.ec.europa.eu/doclib/press/index.cfm?id=1684> (last accessed 1 October 2021); The EU – Vietnam Trade and Investment Agreements – where RC is mostly taking place through GRP – at <https://trade.ec.europa.eu/doclib/press/index.cfm?id=1437> (last accessed 1 October 2021); the EU-Mexico Agreement – where the negotiating papers aim to establish RC through GRP – at https://trade.ec.europa.eu/doclib/docs/2017/may/tradoc_155520.pdf (last accessed 1 October 2021).

trade negotiations will emphasise RC.⁶ Alemanno and Wiener argue that RC can create a ‘transatlantic policy laboratory’ which is a step towards ‘a global policy laboratory’, i.e., an institutional innovation in which regulatory alignment is promoted and countries learn from variation about ‘optimal policy design’.⁷ The global policy laboratory – often seen as an ‘international effort by the rich countries and their companies to control domestic regulation through international trade agreements that override domestic laws’ – is a reoccurring topic in this thesis considering that RC efforts indeed establish RC mechanisms (and accompanying institutional frameworks) that promote regulatory alignment resulting in various policy laboratories across the globe.⁸

The widening of RC is accompanied by a deepening of RC. Whilst initially RC focused on consultation and sharing information, the focus of RC shifted to the regulatory processes.⁹ Accordingly, RC evolved from symbolic political cooperation in annual summits to developing RC mechanisms *in FTAs*. To facilitate trade and ultimately aim for regulatory convergence, RC mechanisms essentially affect the agenda-setting phase of the regulatory process via GRP and RC provisions in legally binding treaties.¹⁰ Importantly, whilst RC is presented as voluntary in the FTAs, FTAs *are* legally binding treaties and the implementation of RC results (at a minimum) in political pressure to engage in RC.¹¹ Moreover, as Mendes argues, the *outcomes* of RC may have legal effects.¹² The FTAs illustrate the willingness of trading partners to engage in RC and moreover guarantee the *ongoing development* of RC – both factors which contribute to political pressure to engage in RC.¹³ Subsequently, RC continues to develop on the basis of the FTA and the shift in focus from political cooperation to regulatory convergence to facilitate trade evolves RC into something conceivably more invasive. Ultimately, RC affects the preparatory (or agenda-setting) stages of the regulatory process, in other words, influences the

⁶ Elizabeth Trujillo, ‘Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power’ (2018) 25 *Indiana Journal of Global Legal Studies* 365, 404.

⁷ Ronan O’Brien, ‘Moving Regulation out of Democratic Reach: Regulatory Cooperation in CETA and its Implications’ (2016) Working Paper Reihe der AK Wien - Materialien zu Wirtschaft und Gesellschaft 158, Kammer für Arbeiter und Angestellte für Wien, Abteilung Wirtschaftswissenschaft und Statistik, 1.

⁸ Jonathan B. Wiener and Alberto Alemanno, ‘The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory’ (2016) 78 *Law & Contemporary Problems*

⁹ See chapter 2, section 2.3.2.

¹⁰ See chapter 2 for a thorough analysis of RC mechanisms in the RC models; and chapter 4 for the common characteristics of RC.

¹¹ On the ‘voluntary’ nature of RC, see chapter 5, section 5.2.4.

¹² Joana Mendes, ‘The External Administrative Layer of EU Law-making: international Decisions in EU Law and the Case of CETA’ (2017) 2 *European Papers* 489, 490.

¹³ See chapter 5, section 5.2.4.

regulatory *discourse*.¹⁴ Consequently, as RC is found in numerous FTAs and affects regulatory processes to facilitate trade, there is a widening and deepening of RC around the globe.¹⁵

1.1 Regulatory cooperation: between transnational risk governance and international trade

The deepening of RC takes place through a broad variety of RC mechanisms, ranging from building trust via good governance principles (i.e., good regulatory practices) to harmonisation or regulatory convergence.¹⁶ In the broadest sense of the word, RC and how it operates conceptualises even full international organisations, such as the EU, as an elaborated institutionalised form of RC. However, this thesis focuses on the more specific tools, mechanisms, procedures of RC (that might be used by international organisations or individual states) *established in FTAs*. Consequently, by focusing on RC models in FTAs, the EU itself is excluded from the definition of RC as the EU is qualitatively different than RC models established in FTAs. Thus, in this thesis RC is understood as:

The creation of procedural mechanisms applicable to the preparatory stages of regulation, aimed at the convergence of standards, with a focus on international free trade agreements.

RC is transnational governance as a transnational ‘process of decision-making and the process by which decisions are implemented (or not implemented)’ since RC creates a transnational process of decision-making in the preparatory stages of regulation.¹⁷ The process of decision-making in RC consists of early notice of planned regulatory measures enabling an ongoing

¹⁴ See, Gabriel Siles-Brügge, *'The Neglected Side to TTIP – Horizontal Regulatory Provisions'* (April 2016) Policy Briefing for Policy@Manchester <<https://documents.manchester.ac.uk/display.aspx?DocID=28672>> accessed 11 May 2022.

¹⁵ The new generation of FTAs often include chapters on RC or cooperation through GRP. More in chapter 2 of this thesis. Also see, Verena Madner, 'A New Generation of Trade Agreements: An Opportunity Not to Be Missed?' in Stefan Griller, Walter Obwexer and Erich Vranes (eds), *Mega-Regional Trade Agreements: CETA, TTIP and TiSA: New Orientations for EU External Economic Relations* (Oxford University Press 2017); Ambassador David L. Aaron, 'The United States and Europe: seeking common ground' in George A. Bermann, Peter L. Lindseth and Matthias Herdegen (eds), *Transatlantic regulatory cooperation: legal problems and political prospects* (Oxford University Press 2000); Bermann, Lindseth and Herdegen, *Transatlantic regulatory cooperation: legal problems and political prospects*; Ahearn, 'Transatlantic Regulatory Cooperation: Background and Analysis' Anne Meuwese, 'Constitutional Aspects of Regulatory Cooperation in TTIP: An EU Perspective' (2015) 78 *Law and Contemporary Problems* 153.

¹⁶ See, OECD, *International Regulatory Co-operation: Addressing Global Challenges*, 2013); R. T. Bull and others, 'New approaches to international regulatory cooperation: The challenge of TTIP, TPP, and mega-regional trade agreements' (2015) 78 *Law and Contemporary Problems* 1.

¹⁷ United Nations Economic and Social Commission for Asia and the Pacific "What is good governance?", Institutional Repository – ESCAP, 2009, Web. 4 May 2022 <<https://hdl.handle.net/20.500.12870/3794>> accessed 11 May 2022.

regulatory dialogue in which decisions can be made to align regulatory measures with a view on facilitating trade.¹⁸

Whilst RC in FTAs can apply to various policy-areas, the predominant focus of RC is *on non-tariff barriers to trade* considering that tariff-barriers are mostly a thing of the past.¹⁹ Non-tariff barriers are the greatest obstacle to trade consisting primarily of Technical Barriers to Trade (TBT) and/or Sanitary and Phytosanitary (SPS) measures aimed at protecting human, animal or plant life or health.²⁰ SPS and TBT measures aim to protect citizens from possible risks. More specifically, sanitary measures focus on protecting human and animal life or health while phytosanitary measures target the protection of plant life or health.²¹ Technical regulations and standards are adopted to protect consumers, public health, product safety and to address environmental concerns.²² Because non-tariff barriers are the biggest regulatory obstacles to trade and FTAs create RC to facilitate trade, the focus of this research is on non-tariff barriers to trade.²³ In the RC models analysed in this thesis and similarly in the World Trade Organisation (WTO), RC mechanisms are predominantly found in the WTO's TBT Agreement and the WTO's SPS Agreement and the TBT and SPS chapters respectively.²⁴ The focus on non-tariff barriers to trade ultimately results in a focus on the regulation of risks.

The regulation of risk, as defined by Hood et al, is 'governmental interference with market or social processes to control potential adverse consequences.'²⁵ Since the 1990s, risk regulation has been an increasingly important subject of academic debate. Beck developed the theory of risk society to describe the modern-day world.²⁶ Harmon and others explain that in modern-day

¹⁸ See chapter 2.

¹⁹ In the CETA, for example, the RC chapter applies to the development of SPS and TBT measures but also on Cross-Border Trade in Services, Trade and Sustainable Development, Trade and Labour and Trade and Environment, *Comprehensive Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part* (OJ L 11, 14.1.2017) art. 21.1.

²⁰ See, OECD, *Looking Beyond Tariffs The Role of Non-Tariff Barriers in World Trade* (OECD Trade Policy Studies, OECD Publishing 2005).

²¹ See the Preamble of the SPS-Agreement and further, Stefan Zleptnig, *Non-economic objectives in WTO law* (Nijhoff international trade law series, v 1, Martinus Nijhoff Publishers 2010), 331.

²² See the Preamble of the TBT Agreement and further *ibid*, 366.

²³ OECD, *International Regulatory Co-operation: Addressing Global Challenges*, 23.

²⁴ See, chapter 2.2 of this thesis; Petros C. Mavroidis, *Regulatory Cooperation: Lessons from the WTO and the World Trade Regime*. (E15 Task Force on Regulatory Systems Coherence – Policy Options Paper E15 Initiative Geneva: International Centre for Trade and Sustainable Development (ICTSD) and World Economic Forum, 2016), 6.

²⁵ Christopher Hood, Robert Baldwin and Henry Rothstein, *The government of risk understanding risk regulation regimes* (Oxford University Press 2001), 3.

²⁶ See, Ulrich Beck, *Risk society: towards a new modernity* (Theory, Culture & Society, Sage Publications 1992); Ulrich Beck, *World at risk* (2nd ed. edn, Cambridge : Polity 2009).

risk society, governments must regulate the acceptable degree of risks.²⁷ Weimer and De Ruijter clarify that nowadays ‘essential political questions often relate to the distribution of economic, environmental and social risks.’²⁸ RC focuses predominantly on risk regulation which is a logical consequence of a globalised world. An expansion of law from the sovereign state to the transnational level has been taking place ever since the existence of the sovereign state, Habermas explains.²⁹ RC is essentially the expansion of risk regulation to the transnational level of governance.³⁰ In other words, since economic interdependence, globalisation and technological progress characterise the world in the twenty-first century, transnational risks increase resulting in governments across the globe engaging in RC to tackle transnational problems via transnational (risk) governance.

As transnational risks increase, the amount of regulation increases along with it – as Hood and others argue, ‘risk and safety are often held to be one of the major drivers of contemporary regulatory growth.’³¹ In other words, the increase in risks results in an increase of regulatory measures. In this there is a relationship between the theory of the risk society and the theory of the regulatory state. In the EU context, in view of the increasing regulatory measures of the EU since the 1970’s, Majone created the theory of the regulatory state.³² Whilst analysing the regulatory state, Majone essentially concludes that ‘the regulatory state is characterised by pluralism, diffusion of power, and extensive delegation of tasks to non-majoritarian institutions like independent agencies or commissions.’³³ This description is reminiscent of the RC models as analysed in this thesis, specifically regarding the delegation of tasks to non-majoritarian institutions, i.e., the institutional framework set up by FTAs supporting the development of

²⁷ Shawn H. E. Harmon, Graeme Laurie and Gill Haddow, ‘Governing risk, engaging publics and engendering trust: New horizons for law and social science?’ (2013) 40 *Science & Public Policy* 25, 19.

²⁸ Maria Weimer and Aniek De Ruijter, ‘Regulating Risks in the European Union: the Co-production of Expert and Executive Power’ in Maria Weimer and Aniek De Ruijter (eds), *Regulating Risks in the European Union: the Co-production of Expert and Executive Power* (Hart Publishing 2017), 3.

²⁹ See Jürgen Habermas, ‘Democracy in Europe: Why the Development of the EU into a Transnational Democracy Is Necessary and How It Is Possible’ (2015) 21 *European Law Journal: Review of European Law in Context* 546; Wouter G. Werner, ‘The politics of expertise: applying paradoxes of scientific expertise to international law’ in Monika Ambrus and others (eds), *The Role of Experts in International and European Decision-Making Processes: Advisors, Decision Makers or Irrelevant Actors?* (Cambridge: Cambridge University Press 2014), 52; also see Mathieu Deflem, *Habermas, modernity and law* (Philosophy & Social Criticism, Sage 1996).

³⁰ Werner, ‘The politics of expertise: applying paradoxes of scientific expertise to international law’, 52.

³¹ Hood, Baldwin and Rothstein, *The government of risk understanding risk regulation regimes*, 4; and quoted in Weimer and De Ruijter, ‘Regulating Risks in the European Union: the Co-production of Expert and Executive Power’, 4.

³² Giandomenico Majone, ‘From the Positive to the Regulatory State: Causes and Consequences of Changes in the Mode of Governance’ (1997) 17 *Journal of Public Policy* 139, 143, 145.

³³ Giandomenico Majone, ‘The rise of the regulatory state in Europe’ (1994) 17 *West European Politics* 77, 149. Non-majoritarian institutions are institutions fulfilling public functions but are not directly accountable to the voters or to their elected representatives, Giandomenico Majone, ‘The regulatory state and its legitimacy problems’ (1999) 22 *West European Politics* 1, 3.

RC.³⁴ Ultimately, the risks in contemporary society are not limited to national borders so countries are engaging in transnational governance to address the regulation of these risks. Essentially, the key argument here is that RC is an expansion of the regulatory state in the risk society to the transnational level, i.e., transnational (risk) governance. However, while the expansion of the risk society and its further reach into aspects of global governance plays a role in the development of RC, RC is primarily framed as an issue of trade. Equally, some issues covered by RC, such as RC on service provisions might struggle to fit into the definition of risk governance, or at least into a narrow conceptualisation of it. The issue with RC, however, is not with RC being *risk* governance but in the *transnational* nature of RC.

RC, as a form of transnational (risk) governance, can be researched from various perspectives. From the 1970s and onwards, research on RC emphasised economic development and global interdependence.³⁵ During that time, global governance was frowned upon by diplomats but by the late 1990s, RC was seen more positively and transgovernmental networks started being considered ‘building blocks’ in a post-Cold War world.³⁶ Whilst RC is increasingly found in current FTAs, it dates to the post-World War II era when the EU and the US set an agenda to foster transgovernmental RC.³⁷ RC ultimately removes regulatory trade barriers, making it intrinsically linked to economic integration and deregulation which is why RC is embedded in trade law and policy.³⁸ It therefore makes sense that RC is formalised in FTAs. It must then also be kept in mind that RC is mainly defined and set out within a framework of facilitating trade. RC could address transnational problems, even problems such as climate change. The potential of RC to address serious problems is considerable however, RC is established through FTAs and thus remains focused on facilitating trade.³⁹ From an economic perspective, RC is surely beneficial to trade as it removes trade barriers. This research focuses on RC from a different – non-economic – perspective: the legitimacy deficit of RC and the role of *scientific expertise* in increasing the *throughput-legitimacy* of RC.

³⁴ See chapter 2.

³⁵ David Bach and Abraham Newman, 'Domestic drivers of transgovernmental regulatory cooperation' (2014) 8 *Regulation and Governance* 395, 2.

³⁶ *ibid.* 2.

³⁷ *ibid.* 2; Also see, Jonathan Macey, R., 'The 'demand' for international regulatory cooperation: a public-choice perspective' in George A. Bermann, Peter L. Lindseth and Matthias Herdegen (eds), *Transatlantic regulatory cooperation: legal problems and political prospects* (Oxford University Press 2000).

³⁸ See, e.g., Atik, 'Science and international regulatory convergence'.

³⁹ Also see chapter 5, section 5.3.

1.2 Regulatory cooperation and legitimacy

RC, as transnational (risk) governance, needs to be (more) legitimate.⁴⁰ The legitimisation of transnational governance is a wider debate than the debate on RC. Essentially, transnational governance faces a legitimacy problem. Esty argues that global governance is inherently illegitimate considering the modern democratic tradition and its connection between the right to exercise power and the expression of the majority, i.e., electoral success.⁴¹ Essentially, transnational governance cannot be legitimised by adhering to the idea of a representative democracy since transnational governance is without *demos*.⁴² An analysis on whether or not transnational governance can be legitimate is beyond the scope of this thesis, but it is important for the purpose of this research that transnational governance faces a legitimacy challenge.

To address the legitimacy challenges of transnational governance, the literature developed various approaches. De Búrca neatly summarised the responses to what she considers ‘the dilemma of the democratic (il)legitimacy of transnational governance’.⁴³ She distils three different approaches to address the legitimacy challenges of transnational governance which she considers the i) denial approach, ii) the wishful-thinking approach and iii) the compensatory approach to which she adds the iv) democracy striving approach.⁴⁴ A brief analysis of these approaches follow below, including the rationale behind the choice for the focus of this research on the compensatory approach combined with the democracy striving approach.

In what De Búrca considers the denial approach, the idea is essentially that democratising transnational governance is not necessary or that states maintain sufficient (direct or indirect) control.⁴⁵ In line with this approach, Rubinfeld for example argues that transnational governance is antidemocratic by design and trying to democratise transnational governance is self-defeating since democracy is only possible in the nation state.⁴⁶ The wishful-thinking

⁴⁰ See above, section 1.1; also see chapter 5 and 6; Gráinne De Búrca, 'Developing Democracy Beyond the State' (2008) 46 *Columbia Journal of Transnational Law* 221, 237.

⁴¹ Daniel C. Esty, 'Good Governance at the Supranational Scale: Globalizing Administrative Law' (2006) 115 *The Yale law journal* 1490, 1515.

⁴² Benedict Kingsbury, Nico Krisch and Richard B. Stewart, 'The Emergence of Global Administrative Law' (2005) 68 *Law and contemporary problems* 15, 49; De Búrca, 'Developing Democracy Beyond the State', 225.

⁴³ De Búrca, 'Developing Democracy Beyond the State', 236.

⁴⁴ *Ibid.*

⁴⁵ See, for example, Giandomenico Majone, *Dilemmas of European Integration: The Ambiguities and Pitfalls of Integration by Stealth* (Oxford University Press, 2005); Andrew Moravcsik, 'The European Constitutional Compromise and the Neofunctionalist Legacy', 12 *Journal of European Public Policy* 349 (2005); Andrew Moravcsik, 'Is there a 'Democratic Deficit' in World Politics? : A Framework for Analysis', 39 *Government & Opposition* 336 (2004); Andrew Moravcsik, 'Reassessing Legitimacy in the European Union', 40 *Journal of Common Market Studies*, 603 (2002).

⁴⁶ Jed Rubinfeld, 'Unilateralism and Constitutionalism', 79 *NYU Law Review*, 1971, 2017-21 (2004).

approach is contrary to the denial approach in that it essentially argues that a global *demos* is possible or that there are ways to develop what De Búrca considers a ‘democratic world political system’.⁴⁷

In line with the argument of De Búrca, this research disagrees with both the denial and the wishful thinking approaches. The legitimacy of transnational governance is important, especially considering the increasing transnational risks faced in a globalised world. Furthermore, RC is becoming increasingly important in FTAs and there is an expectancy that its importance will continue to grow. Transnational governance and RC are of increasing importance in a globalised world and thus it should always strive to be democratically legitimate (see below). However, at the same time, democratising transnational governance similar to the nation state is, due to the very nature of transnational governance, simply impossible – or as De Búrca argues, unrealistic.⁴⁸ Hence, this research is based on the notion that transnational governance, specifically RC, ought to be legitimate and that it is not possible to legitimise RC by developing a democratic political system in RC to legitimise RC similar to nation states. Therefore, compensatory mechanisms can contribute to the legitimacy of RC whilst, at the same time, RC ought to continuously strive to be democratically legitimate.

Consequently, this research focuses on two of these theories and develops a hybrid approach by combining the compensatory approach and the democracy striving approach.⁴⁹ The compensatory approach essentially argues that the legitimacy deficit of transnational governance must be addressed through compensatory elements (‘other justificatory roles’), predominantly focusing on good governance principles.⁵⁰ In the compensatory approach, De Búrca identifies three main categories to legitimise transnational governance that contain various arguments:

- i) the merits of the decision-makers in the sense of the quality of those involved in decision-making;
- ii) the decision-making process itself, which focuses on various arguments, for example, relating to transparency resulting in openness to scrutiny which, in turn, enhances the

⁴⁷ De Búrca, 'Developing Democracy Beyond the State', 239; Richard Falk & Andrew Strauss, *Towards Global Parliament*, Foreign Affairs, 80 (2002), 212; Daniele Archibugi & David Held eds, *Cosmopolitan Democracy: An Agenda for a New World Order* (Polity Press, 1995).

⁴⁸ De Búrca, 'Developing Democracy Beyond the State', 240.

⁴⁹ See Kingsbury, Krisch and Stewart, 'The Emergence of Global Administrative Law', 49 and; De Búrca, 'Developing Democracy Beyond the State', 225.

⁵⁰ Kingsbury, Krisch and Stewart, 'The Emergence of Global Administrative Law', 51.

- accountability of the decision-makers; but also, the quality of deliberation which can compensate for the non-democratic nature of transnational governance, and;
- iii) the output of the process, relating to the ‘quality, efficiency, or general acceptability of the norms’ created through transnational governance.⁵¹

In this research, scientific expertise is understood as part of the compensatory approach. In this view, expertise is a compensatory element that enhances the quality of deliberation which, in turn, enhances the legitimacy of transnational governance and thus, can compensate for the non-democratic nature of RC.

However, RC, as a form of transnational (risk) governance, should also always strive to be democratically legitimate. In response to the compensatory approach, De Búrca developed the democracy striving approach, essentially advocating for democratisation through broader participation rights.⁵² Instead of compensating for the non-democratic nature of transnational governance, De Búrca argues that transnational (risk) governance process must continuously strive to be legitimate.⁵³ Whilst it is beyond the scope of this thesis to conduct a normative analysis of whether transnational governance can be democratic (or not), this thesis argues that compensatory mechanisms contribute to the democratic legitimacy of the RC process but that the RC process should *also* continuously strive to be democratically legitimate. The argument here is thus that compensatory mechanisms such as expertise can contribute to the legitimacy of transnational governance but that the democracy-striving approach is simultaneously of such crucial importance that it cannot be ignored. Broad participation rights are essential to the legitimacy of transnational governance. However, since compensatory elements also hold merit in enhancing the legitimacy of transnational governance, this research advocates a hybrid application of both approaches to the (il)legitimacy of RC.⁵⁴

The need to legitimise RC, while far less analysed, is not unnoticed in the literature. Slaughter argues that a regulatory dialogue ‘with partly unforeseen consequences, must be either authorized ex-ante or monitored ex-post.’⁵⁵ Alemanno argues that RC is the compromise of

⁵¹ De Búrca, 'Developing Democracy Beyond the State', 237.

⁵² See chapter 5, section 5.3.2 and chapter 6; *ibid*, 253. Also see, on the push for democratisation through participation, Sabine Maasen and Peter Weingart, *Democratization of expertise? : exploring novel forms of scientific advice in political decision-making* (Sociology of the sciences : a yearbook, Springer 2009), 3.

⁵³ De Búrca, 'Developing Democracy Beyond the State', 237.

⁵⁴ See chapter 6.

⁵⁵ Anne-Marie Slaughter, 'Agencies on the loose? Holding government networks accountable' in George A. Bermann, Matthias Herdegen and Peter L. Lindseth (eds), *Transatlantic regulatory cooperation: legal problems and political prospects* (Oxford University Press 2000), 534.

national sovereignty and a states' regulatory power for the sake of cooperation at the international level – thus requiring legitimisation.⁵⁶ RC is an ongoing, structured regulatory dialogue essentially creating a 'shared regulatory space', providing access to foreign governments with a focus on facilitating trade thus inherently providing (preferential) access to business *without* accompanied parliamentary oversight mechanisms or participation rights that guarantee a balanced representation of interests.⁵⁷ This results in a legitimacy deficit.⁵⁸ To legitimise RC, this thesis builds on the compensatory approach and combines it with De Búrca's democracy-striving approach.⁵⁹ The first step in legitimising RC is to strengthen input-legitimacy via parliamentary oversight and stronger participatory rights.⁶⁰ However, as the principal focus of this thesis is on scientific expertise, the compensatory approach is taken into account as the throughput-legitimacy of RC can be enhanced by including expertise which enhances the quality of deliberation in RC.⁶¹ Nonetheless, for expertise to fulfil a legitimising role, parliamentary oversight and participatory rights are required on the expertise used, i.e., the democratisation of expertise, resulting in a full-circle argument regarding the legitimacy of RC.⁶²

The legitimacy of RC can be addressed from different perspectives – e.g., democracy, sovereignty, accountability, etc. This thesis focuses on the *throughput-legitimacy* of RC and *the role of expertise* in addressing the legitimacy deficit of RC. The lack of objective criteria to assess the legitimacy of governmental processes results in the need for clarification of legitimacy and the role of expertise in view of the legitimacy of RC.⁶³

⁵⁶ E.g., Alberto Alemanno, 'The Transatlantic Trade and Investment Partnership and the Parliamentary Dimension of Regulatory Cooperation' (2014) Directorate-General for External Policies of The Union, Policy Department, Study, 5.

⁵⁷ Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power', 374; For a more in-depth elaboration on the legitimacy deficit of RC see chapter 5.

⁵⁸ Chapter 5 analyses the legitimacy-deficit of RC in depth.

⁵⁹ See chapter 5, section 5.3.2'; De Búrca, 'Developing Democracy Beyond the State', 253. Also see, on the push for democratisation through participation, Maasen and Weingart, *Democratization of expertise? : exploring novel forms of scientific advice in political decision-making*, 3.

⁶⁰ See chapter 5.

⁶¹ See chapter 6; De Búrca, 'Developing Democracy Beyond the State', 242, also see; Jacqueline Peel, *Science and Risk Regulation in International Law* (Cambridge Studies in International and Comparative Law, Cambridge University Press 2010), 47.

⁶² See chapter 5 and 6. On the democratisation of expertise, see Helga Nowotny, 'Democratising expertise and socially robust knowledge' (2003) 30 *Science and Public Policy* 151; Peel, *Science and Risk Regulation in International Law*; Maasen and Weingart, *Democratization of expertise? : exploring novel forms of scientific advice in political decision-making*.

⁶³ See Jean d'Aspremont, 'Legitimacy of Governments in the Age of Democracy' (2006) 38 *New York University Journal of International Law and Politics* 878, 878. Of course, the FTAs and their democratic legitimacy (or lack thereof) can be (and have been) put up for debate. This thesis will *not* focus on the legitimacy of the FTA itself. To clarify, the legitimacy of trade agreements relates to the authority to ratify international agreements by the

The legitimacy of the RC process is a question on the legitimacy to exercise the competences granted in the FTAs establishing RC.⁶⁴ In other words, the question is if the exercise of power, i.e., engaging in the ongoing regulatory dialogue, is legitimate. The conceptual understanding of legitimacy has developed in the literature resulting in the categorisation of input, output, and throughput legitimacy.⁶⁵ Input- and output-legitimacy have been extensively studied in the literature, to which Schmidt added the idea of throughput-legitimacy.⁶⁶ In short, this thesis qualifies output-legitimacy as focusing on the policy-outcomes *for* the people and input-legitimacy as focuses on participation *by* the people, the responsiveness of governance to this participation and parliamentary oversight.⁶⁷ Schmidt developed throughput-legitimacy to fill in the gaps focusing on what goes on inside the ‘black box’ of governance, i.e., ‘in the space between the political input and the policy output.’⁶⁸ Throughput legitimacy looks at the ‘ways in which policymaking processes work both institutionally and constructively to ensure the efficacy of (...) governance, the accountability of those engaged in making the decisions, the transparency of the information and the inclusiveness and openness to civil society.’⁶⁹ In this thesis, however, parliamentary oversight and openness to civil society in the sense of participation rights in RC (i.e., participation by the people and the responsiveness of governance to this participation) is understood as input-legitimacy.⁷⁰ As Steffek explains:

‘Throughput legitimacy is an innovation that rivals traditional standards of legitimacy focusing either on input (who had a say in a decision?), or output

executive branch, for example in the US this relates to questions regarding the President ratifying executive agreements. In other words, it is not the legitimacy of the FTA or its ratification that is being debated but rather the exercise of the powers granted in the FTA, namely regulators engaging in an ongoing regulatory dialogue with foreign partners. See, Joel R. Paul, ‘Implementing regulatory cooperation through executive agreements and the problem of democratic accountability’ in George A. Bermann, Peter L. Lindseth and Matthias Herdegen (eds), *Transnational regulatory cooperation: legal problems and political prospects* (Oxford University Press 2000)

⁶⁴ The legitimacy of exercise can be distinguished from the legitimacy of origin which refers to the legitimacy of a governance institutions very existence rather than the exercise of its power, see d’Aspremont, ‘Legitimacy of Governments in the Age of Democracy’, 880, 899.

⁶⁵ On input- and output-legitimacy see, Fritz Wilhelm Scharpf, *Governing in Europe : effective and democratic?* (Oxford University Press 1999); On throughput legitimacy see, Vivien A. Schmidt, ‘Democracy and Legitimacy in the European Union Revisited: Input, Output and ‘Throughput’ (2013) 61 *Political Studies* 2.

⁶⁶ Schmidt, ‘Democracy and Legitimacy in the European Union Revisited: Input, Output and ‘Throughput’; Scharpf, *Governing in Europe : effective and democratic?*

⁶⁷ Scharpf, *Governing in Europe : effective and democratic?*, 11; also see Peel, *Science and Risk Regulation in International Law*, 47.

⁶⁸ Schmidt, ‘Democracy and Legitimacy in the European Union Revisited: Input, Output and ‘Throughput’’, 5.

⁶⁹ *ibid*, 7.

⁷⁰ Scharpf, *Governing in Europe : effective and democratic?*, 11; also see Peel, *Science and Risk Regulation in International Law*, 47.

*(who benefits from a decision?). Instead, throughput emphasizes process criteria (how was the decision made?).*⁷¹

Following this, the general definition of legitimacy is, as Schmidt explains, ‘the extent to which input politics, throughput processes and output policies are acceptable to and accepted by the citizenry, such that citizens believe that these are morally authoritative and they therefore voluntarily comply with government acts even when these go against their own interests and desires.’⁷² As Schmidt continues, it is a different matter to determine what citizens accept or find acceptable, and so this thesis critically examines the *throughput-legitimacy* of the RC *process*. The throughput-legitimacy of RC focuses on how decisions are made in RC, or in other words, the RC *process*. It is argued in this thesis that RC is, after all, a policymaking-process that ought to be held up to certain standards enhancing the throughput-legitimacy of the process.

Expertise is part of throughput-legitimacy considering that a scientific basis to regulatory measures creates a need for a justification of decision-making in a rational way thus enhancing the quality of deliberation in RC.⁷³ Enhanced deliberation, as a compensatory element for legitimacy, contributes to the throughput-legitimacy of RC specifically as enhanced deliberation relates to how decisions in RC are made, i.e., the RC *process*. However, scientific legitimacy alone is insufficient in transnational governance.⁷⁴ This thesis brings together an analysis of the concepts of expertise and legitimacy to assess the extent to which reliance on *expertise* can increase the *throughput-legitimacy* of RC.

1.3 Regulatory cooperation and the role of scientific expertise

Before explaining the role of expertise in enhancing the *throughput-legitimacy* of RC, there is an important aspect to consider regarding the role of scientific expertise in RC: a role for expertise in RC can enhance the chances of regulatory convergence.

Science is an indispensable component of risk regulation. Beck observes: ‘Science is one of the causes, the medium of definition and the source of solutions to risks.’⁷⁵ Peel explains that risk regulation requires scientific and technical analyses.⁷⁶ More generally, according to Atik, in today’s (knowledge) society, ‘a regulatory measure lacking a scientific basis will be subject to

⁷¹ Jens Steffek, ‘The limits of proceduralism: Critical remarks on the rise of ‘throughput legitimacy’ (2019) 97 Public Administration (London) 784, 786.

⁷² Schmidt, ‘Democracy and Legitimacy in the European Union Revisited: Input, Output and ‘Throughput’’, 7.

⁷³ See chapter 6.

⁷⁴ Ibid.

⁷⁵ Beck, *Risk society: towards a new modernity*, 155.

⁷⁶ Peel, *Science and Risk Regulation in International Law*, 49.

criticism.⁷⁷ Consequently, Demortain asserts that ‘scientists shape risk regulation more than they would care to admit.’⁷⁸ In the context of RC more particularly, Atik argues that science could serve as a basis for a shared regulatory approach.⁷⁹ For example, in relation to genetically modified organisms, Alemanno argues that cooperating on matters of science can address existing regulatory divergence in the area.⁸⁰ According to Weimer and De Ruijter RC requires ‘cooperation in the field of knowledge production’ which includes to some extent for Wiener and Alemanno, ‘the harmonisation of procedures in this respect.’⁸¹ In short, science is indispensable in risk regulation and could be the basis for a shared regulatory approach – and thus could play an important role in RC.

In the EU-US relationship, for example, there is a long history of RC without materially significant results despite achieving some progress towards reducing regulatory burdens.⁸² The Transatlantic Trade and Investment Partnership (TTIP) was supposed to address EU-US regulatory divergence as the ‘treaty to end trade treaties’ but did not materialise.⁸³ There are several reasons why cooperation between the EU and US is difficult. Murphy argues, for example, that ‘the alignment of bureaucracies across the Atlantic is too dysfunctional for effective interaction.’⁸⁴ From another perspective, Wayne explains that a lack of budget, statutory responsibilities and specific domestic missions makes it difficult for domestic regulatory authorities to engage in transatlantic coordination.⁸⁵ Furthermore, the different

⁷⁷ Atik, ‘Science and international regulatory convergence’, 736. On knowledge society, see for example, Monika Ambrus and others, ‘The role of experts in international and European decision-making processes : setting the scene’ in Monika Ambrus and others (eds), *The Role of Experts in International and European Decision-Making Processes : Advisors, Decision Makers or Irrelevant Actors?* (Cambridge : Cambridge University Press 2014), 5.

⁷⁸ David Demortain, *Scientists and the regulation of risk : standardising control* (Edward Elgar 2011), 1.

⁷⁹ Atik, ‘Science and international regulatory convergence’, 755.

⁸⁰ Alberto Alemanno, ‘How to get out of the transatlantic regulatory deadlock over genetically modified organisms?’ in David Vogel and Johan F.M. Swinnen (eds), *Transatlantic Regulatory Cooperation: The Shifting Roles of the EU, the US and California* (Edward Elgar Publishing 2013)218.

⁸¹ Weimer and De Ruijter, ‘Regulating Risks in the European Union: the Co-production of Expert and Executive Power’, 6; Wiener and Alemanno, ‘The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory’.

⁸² Alemanno, ‘How to get out of the transatlantic regulatory deadlock over genetically modified organisms?’, p. 210. Also see, Ahearn, ‘Transatlantic Regulatory Cooperation: Background and Analysis’; Tamara Takács, ‘Transatlantic regulatory cooperation in trade: objectives, challenges and instruments for economic governance’ in Elaine Fahey and Deirdre Curtin (eds), *A Transatlantic Community of Law: Legal Perspectives on the Relationship Between the EU and US Legal Orders* (Cambridge University Press 2014), 174.

⁸³ Maria Garcia, ‘Building Global Governance One Treaty at a Time? A Comparison of the US and EU Approaches to Preferential Trade Agreements and the Challenge of TTIP’ in Elaine Fahey (ed), *Institutionalisation beyond the Nation State: Transatlantic Relations: Data, Privacy and Trade Law* (Springer Cham 2018) Kenneth Haer, *Cooperating to deregulate* (Corporate Europe Observatory 2015); see further chapter 2 section 2.3.

⁸⁴ Brain M. Murphy, ‘Framing essay : a shift in transatlantic diplomacy’ in Sudeshna Roy, Dana Cooper and Brain M. Murphy (eds), *Transatlantic Relations and Modern Diplomacy: An interdisciplinary examination* (Routledge 2014), 15.

⁸⁵ Anthony E. Wayne, *The U.S. and the EU Today: Trade and Economic Issues in the Trans-Atlantic Relationship* (2002) <<https://2001-2009.state.gov/e/eeb/rls/rm/2002/16079.htm>> last accessed 14 May 2022.

regulatory approaches of the EU and the US seem to be so vast that practical consequences continue to frustrate transatlantic RC.⁸⁶ Meuwese explains:

*'Too much emphasis on 'exporting best practices' ignores the question of the comparability of the constitutional and legal systems of the US and EU at the risk of achieving nothing but the illusion of convergence and raising unrealistic expectations among stakeholders. Concrete shared norms for standard-setting, certainly substantive ones, are a bridge too far for EU-US regulatory cooperation, because of a lack of (discussion on) shared underlying principles.'*⁸⁷

Essentially, the EU and US have vastly different approaches to regulation – including on matters of expertise. Over time, RC efforts started to focus on these regulatory processes. Consequently, the fact that diverging scientific approaches could result in different regulatory responses became increasingly important.⁸⁸ Alemanno argues that ‘without a common basis of scientific understanding and with continued EU deference to consumer preference, the food sector is likely to remain an area of regulatory divergence.’⁸⁹ More broadly, however, when science is at the heart of regulatory divergence, cooperating on scientific expertise can facilitate RC.⁹⁰ If countries work together on the science part – for example by cooperating on risk assessments (RAs) or building a common scientific basis – a clear role for expertise can take RC to the next level.⁹¹

One of the key arguments in this thesis is that the incorporation of scientific expertise in the decision-making process increases the chances of success of RC whilst at the same time, reliance on expertise can enhance the throughput-legitimacy of the RC process. The starting point of this thesis is thus that reliance on scientific expertise, and delegating to independent experts, can enhance the throughput-legitimacy of RC.⁹² Importantly, however, this thesis does not proclaim that science is the answer to all problems. Scientific expertise in policymaking

⁸⁶ Murphy, 'Framing essay: a shift in transatlantic diplomacy', 15, 16. On the institutional mismatch, see, George A. Bermann, 'Regulatory Cooperation between the European Commission and U.S. Administrative Agencies' (1995) 9 *Administrative Law Journal of the American University* 933

⁸⁷ Anne Meuwese, 'EU–US horizontal regulatory cooperation: mutual recognition of impact assessment?', *Transatlantic Regulatory Cooperation: The Shifting Roles of the EU, the US and California* (2011), 264; See above; also see chapter 2, specifically section 2.3.

⁸⁸ J. Black, *The Global Risk Assessment Dialogue* (International Regulatory Co-operation, Case Studies, Vol 2, OECD Publishing), 52, 53; also see, Alemanno, 'How to get out of the transatlantic regulatory deadlock over genetically modified organisms?', 221 and; chapter 2 section 2.3.2.

⁸⁹ Alemanno, 'The Transatlantic Trade and Investment Partnership and the Parliamentary Dimension of Regulatory Cooperation', 34, 35, 36.

⁹⁰ See chapter 3, section 3.3.2.

⁹¹ Also see, Peel, *Science and Risk Regulation in International Law*, 387.

⁹² See chapter 6, section 6.2.

faces many issues, not least the problem of biased or politically manipulated expertise.⁹³ The consequence of the issues faced by scientific expertise in policy-making is that scientific legitimacy alone is insufficient to legitimise transnational governance.⁹⁴

In general, scientific experts are included in decision-making processes to enhance the legitimacy of governance.⁹⁵ Scientific expertise is a vital part of risk regulation and can convince governments and citizens of necessary regulatory measures.⁹⁶ Whilst scientific knowledge is essential in the regulation of risks, as science often forms the basis of these regulations, scientific expertise in policy-making faces issues such as biased or politically manipulated expertise. A key argument in this thesis is that expertise enhances the throughput-legitimacy of RC *because* it places an obligation on decision-makers to make a reasoned and rational decision much earlier than the standard legal requirement in the law-making process (given the implications of RC). Additionally, by requiring decision-makers to make a reasoned and rational decision, expertise balances the influence of business and foreign governments in RC. In such a way, expertise enhances the *quality of deliberation* in RC which enhances the throughput-legitimacy of RC. Importantly, it is acknowledged here that expertise in policymaking is often not neutral and certainly not unproblematic and thus, scientific expertise alone cannot legitimise transnational governance. Consequently, the democratisation of expertise is applied to expertise in RC in this research to address the problems faced when relying on expertise to enhance the throughput-legitimacy of RC. The legitimacy claim of expertise is examined thoroughly in this thesis (Chapter Six).

To assess expertise from this perspective requires further clarification. An important question to consider is: what exactly is meant by scientific expertise in the context of risk regulation and RC? A firm definition of expertise is difficult to find, Fischer writes:

*'In general, it refers to a widely acknowledged source of reliable knowledge, skill, or technique that is accorded status and authority by the peers of the person who holds it and accepted by member of the larger public.'*⁹⁷

⁹³ See chapter 6, section 6.3.

⁹⁴ See chapter 6.

⁹⁵ Ambrus and others, 'The role of experts in international and European decision-making processes: setting the scene', 5.

⁹⁶ Peel, *Science and Risk Regulation in International Law*, 387.

⁹⁷ Frank Fischer, *Democracy and Expertise: Reorienting Policy Inquiry* (Oxford University Press 2009), 17; Weimer and De Ruijter, 'Regulating Risks in the European Union: the Co-production of Expert and Executive Power', 5.

In view of policymaking, Jasanoff developed the term ‘regulatory science.’⁹⁸ Regulatory science is scientific and technical knowledge that serves regulatory decision-making.⁹⁹ In line with Jasanoff’s view on regulatory science, Weimer and De Ruijter focus on the relationship between the EU’s executive power and ‘regulatory science’ and explain that regulatory science is ‘a particular type of expertise, namely regulatory or policy-relevant expertise, which is specialised (often scientific) knowledge that is used for regulatory purposes.’¹⁰⁰ Salter qualified this type of science as ‘mandated science’, i.e., ‘science used for the purposes of making public policy’ and ‘academic studies relied upon by policy makers.’¹⁰¹ In short, regulatory science is science that serves regulation.

The focus of this thesis is on regulatory science in RC. Regulatory science is essentially *the co-production of expertise between experts and regulatory power*. Jasanoff developed the term regulatory science and explained that ‘one of the most telling features of regulatory science is the relatively heavy involvement of government and industry in the process of producing and certifying knowledge.’¹⁰² Armitage and others define the co-production of expertise as: ‘the collaborative process of bringing together a plurality of knowledge sources and types together to address a defined problem and build an integrated or systems-orientated understanding of that problem.’¹⁰³ As Fisher acknowledges, the literature on the co-production of regulatory science is rich.¹⁰⁴

In this thesis, expertise in risk regulation is analysed by focusing on the use of expertise co-produced by the executive which Fisher calls ‘expert executive power.’¹⁰⁵ To clarify what is meant with ‘*the executive*’, the regulatory power in governance is often attributed to this branch

⁹⁸ Sheila Jasanoff, *The Fifth Branch : Science Advisers as Policymakers* (Harvard University Press 1990), 76.

⁹⁹ Ibid.

¹⁰⁰ Weimer and De Ruijter, 'Regulating Risks in the European Union: the Co-production of Expert and Executive Power', 2, 5.

¹⁰¹ Liora Salter, *Mandated science : science and scientists in the making of standards* (Dordrecht ; Boston Mass. : Kluwer Academic Publishers 1988), 186.

¹⁰² Jasanoff, *The Fifth Branch : Science Advisers as Policymakers*, 77. Also see, Sheila Jasanoff, *Science at the bar law, science, and technology in America* (Harvard University Press 1995); Sheila Jasanoff, 'Constitutions of Modernity: Science, Risk and Governable Subjects' in Maria Weimer and Anniek De Ruijter (eds), *Regulating Risks in the European Union: the Co-production of Expert and Executive Power* (Hart Publishing 2017), 210

¹⁰³ Derek Armitage and others, 'Co-management and the co-production of knowledge: Learning to adapt in Canada's Arctic' (2011) 21 *Global environmental change* 995, 996; Camilla Adelle and others, 'Making sense together: The role of scientists in the coproduction of knowledge for policy making' (2020) 47 *Science & Public Policy* 56, 57.

¹⁰⁴ Elizabeth Fisher, 'Expert Executive Power, Administrative Constitutionalism and Co-production: Why They Matter' in Maria Weimer and Anniek De Ruijter (eds), *Regulating Risks in the European Union: the Co-production of Expert and Executive Power* (Hart Publishing 2017), 37; Weimer and De Ruijter, 'Regulating Risks in the European Union: the Co-production of Expert and Executive Power'.

¹⁰⁵ Fisher, 'Expert Executive Power, Administrative Constitutionalism and Co-production: Why They Matter', 38.

of government, i.e., the governance institution overseeing the application and implementation of law that, in view of FTAs, is responsible for external trade relations. Moreover, the executive is the government branch that drafts legislation – even when legislation is subsequently amended and adopted by parliaments. For example, in the EU, the executive power is with the European Commission (hereinafter Commission) – Chalmers argues that ‘expertise is the basis of the European Commission’s purpose and power’¹⁰⁶ – and in the US, the executive power is with the President, the Cabinet and the federal agencies (the latter being the main regulatory power in the US). Essentially regulatory science is co-produced, mandated or relied upon by the executive to support regulatory decision-making. Regulatory science in RC is thus either:

- i) Domestic expertise: co-produced by the *respective* executives and experts, used to support regulatory decision-making and part of the ongoing regulatory dialogue or
- ii) Transnational expertise: co-produced *through RC* resulting in joint co-produced regulatory science, i.e., containing two levels of cooperation, which can consist of aligning domestic expertise.

Importantly, IAs and RAs qualify as expertise in this thesis. Whilst IAs study the impacts of certain decisions, IAs contribute to the quality and information basis of decision-making. RAs, then, are scientific studies done by experts that similarly contribute to the quality and information basis of decision-making. In view of throughput-legitimacy, both the IAs process and the RAs process are based on expertise and can enhance the quality of the decision-making process, i.e., the throughput legitimacy of RC. Consequently, RAs and IAs fall under the definition of expertise in this thesis.

The next question to consider is: what is meant by the term ‘experts’? In line with the understanding of expertise as regulatory science, experts are *those who hold scientific qualifications and act as mediators between science and politics*.¹⁰⁷ In this thesis, in line with the conceptualisation of regulatory science in RC as presented above, experts are:

¹⁰⁶ Adam William Chalmers, 'Getting a Seat at the Table: Capital, Capture and Expert Groups in the European Union' (2014) 37 West European politics 976, 976.

¹⁰⁷ Nico Stehr and Reiner Grundman, *Experts: the knowledge and power of expertise* (Key ideas, Routledge 2011), x; and e.g., Peter Weingart, 'The moment of truth for science' (2002) 3 EMBO reports 703; Peter Weingart, 'Scientific expertise and political accountability: paradoxes of science in politics' (1999) 26 Science and Public Policy 151.

- i) Domestic experts: actors contributing to evidence-based policymaking, i.e., by providing data, reports, information, IAs and RAs that support the regulatory measure which is subsequently discussed in the ongoing regulatory dialogue;
- ii) Transnational experts: actors who are directly involved in the RC process (for example via *joint* RAs or *joint* IAs) which can be domestic experts acting in a transnational setting.

This understanding of experts excludes two types of experts in this thesis. Firstly, this thesis focuses on experts used in the *preparatory stages* of the setting of regulatory standards as this is the stage in which RC takes place. This means that experts involved in dispute settlement mechanisms, for example in the WTO, are not the focus of this thesis. Secondly, experts in the sense of this thesis are experts relied upon *by* the systems of governance (e.g., scientific committees), rather than being an *integral part of* the system (e.g., civil servants, politicians). As the focus is on throughput-legitimacy, the essential argument here is that throughput-legitimacy can only be enhanced by including experts that are not already part of the system.

To further clarify experts that are not part of the system, expertise in the WTO is taken as an example as experts are a widely debated topic in the literature and moreover, expert knowledge is at the very core of the organisation.¹⁰⁸ WTO governance is characterised by expert knowledge.¹⁰⁹ Lawrence argues that experts *define* the WTO as it uses expert knowledge to regularize international trade.¹¹⁰ She concludes that the WTO is a system that is and will always be run by experts in the broadest sense of the word:

(...) scientific experts are additional to a system that is already run by experts. Even without the inclusion of biologists, chemists or civil engineers into the process, WTO-style regulation is regulation on the basis of economic theory and law, by economists and trade lawyers. Economists are experts on the functioning of the international and domestic monetary, business and financial systems. And lawyers – like environmental scientists, doctors and

¹⁰⁸ Many publications have dealt with expertise in the WTO, or expertise in policymaking in general for that matter. For a glimpse of this broad debate see the edited volume of Monica Ambrus; Monika Ambrus and others, *The Role of 'Experts' in International and European Decision-Making Processes: Advisors, Decision Makers or Irrelevant Actors?* (The Role of 'Experts' in International & European Decision-Making Processes, Cambridge University Press 2014); also see, amongst others: Jasanoff, *The Fifth Branch: Science Advisers as Policymakers*; David Wickinoff and others, 'Adjudicating the GM Food Wars: Science, Risk and Democracy in World Trade Law' (2005) 30 *The Yale Journal of International Law*; Atik, 'Science and international regulatory convergence'; Nowotny, 'Democratizing expertise and socially robust knowledge'; Peel, *Science and Risk Regulation in International Law*; Elizabeth Fisher, *Risk regulation and administrative constitutionalism* (Hart 2010).

¹⁰⁹ Jessica Lawrence, 'The structural logic of expert participation in WTO decision-making processes' in Monika Ambrus and others (eds), *The Role of Experts in International and European Decision-Making Processes: Advisors, Decision Makers or Irrelevant Actors?* (Cambridge: Cambridge University Press 2014), 174.

¹¹⁰ *ibid.*, 185, 186.

*geneticists – are also experts in their fields, a privileged group that understands, interprets and enforces a certain set of background norms using language and reasoning that is not immediately comprehensible to outsiders.*¹¹¹

Lawrence's view on expertise in the WTO ultimately leads to the conclusion that the WTO is a system of expert knowledge.¹¹² She states: 'Experts are not something that can be 'added' to 'or subtracted from' the WTO in order to tweak input or output legitimacy. Instead, their [inputs] (...) are the fabric from which the organization is cut.'¹¹³ There is a lot to say for this observation, however, this broad view on experts ultimately leads to the conclusion that governance is 'expert governance' by nature and that RC is cooperation of expert knowledge by its very definition.

Whilst Lawrence's observation is plausible, there is a difference between the experts of which the organisation is shaped and experts that are not an *integral* part of the system. As opposed to being an integral part of the system, experts often work in their respective fields and are asked for their expertise by the governance institution as a form of advice – making them a non-integral part of the system albeit necessary for the functioning of the system. Rather than being an integral part *of* the system, experts are relied upon *by* the system – often through advice. Whilst it could be argued that scientific committees, for example, are an integral part of the system there is a distinction between experts that make up the system (e.g., civil servants, politicians) and experts that are used by the system for advice (e.g., committees consisting of scientists in the relevant field). It is the latter that this thesis focuses on namely experts (and their expertise) advising regulators in the agenda-setting (or preparatory) stages of the regulatory process. Whilst these experts can be part of the governance structure, experts in the sense of this thesis do not *govern* but provide scientific *advice*. Ultimately, the decision is not made by experts in the sense of this thesis – albeit by experts in the broader sense of the word. Consequently, scientific expertise and experts in this thesis relates to advisory experts and their expertise in regulatory science.¹¹⁴

¹¹¹ *ibid*, 174, 177.

¹¹² *ibid*, 174.

¹¹³ *ibid*, 193; Ambrus and others, 'The role of experts in international and European decision-making processes: setting the scene', 11. The specific argument relating to legitimacy will be addressed in chapter 6 of this thesis.

¹¹⁴ E.g., Alexia Herwig, 'Health risks, experts and decision making within the SPS Agreement and the Codex Alimentarius' in Monika Ambrus and others (eds), *The Role of Experts in International and European Decision-Making Processes: Advisors, Decision Makers or Irrelevant Actors?* (Cambridge: Cambridge University Press 2014), 195; Wickinoff and others, 'Adjudicating the GM Food Wars: Science, Risk and Democracy in World Trade Law'; Dale Colyer, 'The Role of Science in Trade Agreements' (2006) 7 *The Estey Centre Journal of International Law and Trade Policy* 84; Theofanis Christoforou, 'Settlement of science-based trade disputes in the WTO: A critical review of the developing case law in the face of scientific uncertainty' (2000) 8 *New York University*

1.4 Importance and novelty of the research

When creating transnational governance through RC, researching its legitimacy is important. As discussed, transnational governance needs to be legitimate.¹¹⁵ Thus, an analysis of different RC models and the throughput-legitimacy (deficit) of RC is of general importance. Furthermore, as expertise is considered a facilitating factor in RC, it is similarly important to research to what extent expertise is used in RC but also to address the throughput-legitimacy claim of expertise. In general, the legitimacy-claim of expertise is challenged and so, with the expectancy that expertise will play an important role in future RC endeavours, it is important to assess if expertise can enhance the throughput-legitimacy of RC considering the issues of biased expertise and technocracy.¹¹⁶

This thesis makes a novel contribution in several ways. Firstly, an analysis on RC mechanisms in various RC models fills a gap in the literature as RC models have not been studied comparatively as done in this thesis. The comparative overview of the RC models forms the basis of the analysis of the common characteristics of RC. Secondly, the role of expertise in RC has not been studied before. By providing an in-depth comparative analysis of the RC mechanisms, the use of expertise in these mechanisms and ultimately analysing the common characteristics of the RC models and the use of expertise in these models, this thesis contributes to the literature. Thirdly, whilst the legitimisation of transnational governance is widely analysed in the literature, there is a gap when it comes to the analysis in relation to RC, a gap which this research fills. An additional contribution comes from combining the compensatory approach and the democracy striving approach and applying it to RC. In such a way, this thesis advocates a hybrid approach by combining the compensatory approach and the democracy striving approach as a way to legitimise RC. Furthermore, considering that expertise alone is not sufficient to legitimise RC, this thesis applies the theory on the democratisation of expertise to expertise in RC – which similarly fills a gap in the literature on the democratisation of expertise.

Nonetheless, whilst RC is widening and deepening across the globe, RC, as it stands, is mostly a matter of future potential. In other words, the subject area is dynamic and the possibility exists that, in a decade or so, RC may not have resulted in widespread practical application. In short,

Environmental Law Journal 622; Jacqueline Peel, 'Risk regulation under the WTO SPS Agreement: Science as an international normative yardstick?' (2004) Jean Monnet Working Paper 02/04, New York School of Law .

¹¹⁵ See above, section 1.2.

¹¹⁶ See chapter 6, section 6.3.

there is a risk of the RC mechanisms being dormant. However, moving towards RC is a logical step from an economic perspective, considering that regulatory divergence is the biggest barrier to trade and RC addresses these barriers. Furthermore, whilst RC is perceived as business and commerce focused as it is embedded in trade law and policies, there is potential in RC to tackle transnational problems such as climate change. In this regard, the EU-UK Trade and Cooperation Agreement (TCA) is the first FTA concluded by the EU that considers climate change an ‘essential element’ of the agreement and obligates the EU and the UK to endeavour ‘global’ cooperation on matters of climate change.¹¹⁷ Globalisation is a reality that continues to develop, accompanied by transnational risks that require addressing. Considering the fact that RC is increasingly included in FTAs and globalisation is a reality that continues to develop, RC holds importance for the future.

Admittedly, nationalism appears to be flourishing in some parts of the world as we witnessed with the vote for Brexit in the UK and the election of ‘make America great again’ President Donald Trump. In this sense, RC is susceptible to political developments and can be curtailed by political barriers. There is currently no telling what will happen to the RC efforts. As the world deals with a pandemic, the EU and the UK deal with Brexit, the war in the Ukraine is ongoing and the US is dealing with political and social turmoil, one can wonder what the practical importance of RC will be.¹¹⁸ However, despite ever-growing nationalism and protectionist policies, FTAs *are* increasingly being used to establish RC. FTAs are still being negotiated and RC *is* creating a new form of transnational governance.

Of course, only time will tell what will happen to RC in the next decade or so. However, based on the trends which have emerged while conducting research for this thesis, RC is and will be important for many years to come. As Hoekman writes, ‘the future international trade agenda is likely to become largely a regulatory agenda.’¹¹⁹ Perhaps the problem lies in underestimating the potential of RC. Whilst RC is developed across the globe, the biggest opposition to RC was voiced by the public, non-governmental organisations, and civil society during the negotiations of the TTIP. The EU-Canada Comprehensive Economic Trade Agreement (CETA), on the other hand, was agreed without much public opposition – aside from the Belgian Walloon region and Italy threatening not to ratify the CETA. RC under the CETA has been taking place

¹¹⁷ TCA, art. 770; see further chapter 2, section 2.3.4; Gammage, 'General Exceptions and Public Interest Regulation: An Analysis of the EU-UK Trade Cooperation Agreement'.

¹¹⁸ On the COVID-19 pandemic see further chapter 6, section 6.3.1.

¹¹⁹ Bernard Hoekman, 'Behind the Border' Regulatory Policies and Trade Agreements' (2018) 22 East Asian Economic Review 243,270.

since 2017.¹²⁰ In the case of the TCA, there were many other issues to be dealt with, and so RC disappears into the background – at least from the perspective of public opposition.¹²¹ Nonetheless, RC is established, is in effect and as there is an inherent danger to RC – at a minimum from a legitimacy perspective – making RC important to address and furthermore to promote awareness of the ongoing regulatory dialogue that is taking place. There is an ongoing regulatory dialogue established across the globe and whilst yes, there is a chance of RC mechanisms remaining dormant, the question is whether such a – potentially invasive – regulatory dialogue should be ignored. Since RC essentially creates a shared regulatory space, the conclusion here is that this requires its own checks and balances and it should be legitimate – whether it is currently a matter of potential or not.¹²²

1.5 Research questions and methodology

The research conducted in this thesis was shaped by an inductive approach and from that, the research formed itself rather naturally. The topic of interest at the start of the research was an interest in comparatively researching the integration of expertise in the EU and the US. At this stage, a substantial amount of data consisting of the literature in this area was researched. By analysing the literature, it became clear that the thesis required a lens at which to look at expertise in the EU and the US and furthermore, required a point of focus. In the analysis of the integration on expertise in the EU and the US, the theory of and attempts at RC quickly stood out.

A case study on the Beef Hormones dispute illustrated that scientific expertise played a big role in frustrating EU-US cooperation efforts and from there, the research started to focus on EU-US RC specifically. The TTIP negotiations at the time provided the lens through which to look at expertise in EU-US RC. Still requiring a point of focus, by collecting and researching the literature on RC and analysing the negotiation papers of the TTIP, worries about the legitimacy of RC quickly appeared, providing further focus to the thesis. Caught up by – at the time – recent events, the TTIP ultimately was not concluded and further research choices had to be made.

¹²⁰ *Comprehensive Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part* (OJ L 11, 14.1.2017) Fahey argues that ‘public opposition to CETA has piggybacked upon TTIP opposition’, Elaine Fahey, ‘CETA and Global Governance Law: What Kind of Model Agreement Is It Really in Law?’ (2017) 2(1) *European Papers* 293, 301.

¹²¹ The TCA, being an agreement on trade *and* cooperation, generally focuses on cooperation between the EU and the UK. More on the TCA in section 2.4.3.

¹²² Trujillo, ‘Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power’, 374. See, chapter 5.2.

Even without the TTIP, EU-US RC remained interesting, but the research was broadened to the transatlantic experience of RC. Thus followed a research choice to include Canada in the understanding of transatlantic as the CETA was, and still is, the most developed example of RC. Furthermore, as the focus of the research is on the legitimacy of RC and using expertise to enhance the legitimacy, the models of RC researched in this thesis were broadened. By looking at RC in FTAs of the key players in the transatlantic relationship, it became possible to detect common characteristics of RC. Subsequently, by analysing the common characteristics of RC, it is possible to analyse the (il)legitimacy of RC and research possible solutions to the (il)legitimacy of RC via expertise. Considering the information set out in the previous sections, the primary question of this thesis is as follows:

Can reliance on scientific expertise, and delegating to independent experts, enhance the throughput-legitimacy of regulatory cooperation?

The thesis encompasses some secondary research questions throughout the thesis as set out below:

- What are the mechanisms of RC? (Chapter 2)
- Are there any attempts at cooperation on the integration of expertise as a way of facilitating RC? (Chapter 3)
- What role does scientific expertise play in RC? (Chapter 3)
- How do the RC mechanisms compare to each other? (Chapter 4)
- How does the use of expertise in RC compare to each other? (Chapter 4)
- What is the effect of RC on throughput-legitimacy? (Chapter 5)
- Is there a throughput-legitimacy deficit in RC? (Chapter 5)
- How can the throughput-legitimacy deficit be addressed? (Chapter 5)
- Can scientific expertise enhance throughput-legitimacy? (Chapter 6)
- Can expertise be used to enhance the throughput-legitimacy of RC considering the legitimacy issues relating to expertise? E.g., problems such as biased expertise and politically manipulated expertise. (Chapter 6)
- What lessons does the transatlantic experience hold for future RC endeavours? (Chapter 7)

The methodology used in this thesis encompasses a combination of the doctrinal legal research methodology as well as the analytical method of comparative research.¹²³ In other words, this research applies a mixed methods methodology by combining the doctrinal legal research methodology to analyse legal concepts and rules in different legal systems in such a way that common parts and differences are detected. The so-called ‘tertium comparationis’, or common point of departure, is that RC, as a form of transnational governance, faces a throughput-legitimacy deficit that can be addressed by including expertise in the process. This thesis thus applies the traditional doctrinal method to compare various models of RC using the text of the FTAs as the main data set.

In other words, the hypothesis of this thesis is that RC, as a form of transnational governance, faces a throughput-legitimacy deficit that can be addressed by including expertise in the process. Under the doctrinal legal research approach, this research conducts a critical, qualitative analysis of the RC models in FTAs to support the hypothesis. Consequently, this research relies on the letter of the law specifically the FTAs that establish the various RC models. By analysing the different FTAs, this thesis gathers, organises and describes the law (i.e., the FTAs) that establish RC. More precisely, this research identifies and describes RC and how the RC models are connected.

The data used in this research are thus the various FTAs. In going about this research, the different FTAs were analysed extensively. Not only by reading through the FTAs, but also by performing various searches related to keywords such as ‘regulatory’, ‘cooperation’, ‘expertise’, ‘science’, ‘scientific’ and variations of these keywords. Furthermore, the data used to support this research aside from the FTAs itself are cases related to RC, the history of RC, for example relating to cooperation in the EU-US relationship, and the literature relating to RC, regulatory science, science and technology, transnational governance, legitimacy of transnational governance and a wide array of literature on the integration of expertise.

Surely, every research project has limitations and shortcomings. It is acknowledged here, and further in the chapters of this thesis, that there is a certain asymmetry of information particularly relating to EU-US RC.¹²⁴ During the TTIP negotiations, the EU frequently published the negotiation texts and draft proposals. From the US side, however, there was no further

¹²³ See Jan B.M. Vranken, ‘Methodology of legal doctrinal research’ in Mark van Hoecke (eds) *Methodologies of legal research. Which kind of method for what kind of discipline*. (Oxford: Hart Publishing 2010), 111-121; Mark Van Hoecke, ‘Methodology of Comparative Legal Research’ (2015) December 2015 Law and Method.

¹²⁴ See chapter 2, section 2.3.3.

information aside from leaked texts by Green Peace Netherlands. Furthermore, whilst the implementation of the CETA provides empirical data and documents on how the CETA is implemented, the same cannot be said about the USMCA. The lack of data from the US is acknowledged here, whilst at the same time the transparency from the EU is appreciated. Furthermore, conducting empirical research by means of interviews was considered during the early stages of the research. Ultimately, as the researched questions formed, it became clear that the research questions of this thesis are suitable to answer through the doctrinal legal method. Whilst the result is a normative study on the legitimacy of RC and the use of expertise to enhance its legitimacy, such an analysis holds value for the practical implementation of RC.

1.6 Case studies: the transatlantic experience in context

The thesis commences by analysing five RC models, namely those which appear in the WTO, in the EU-US RC which culminated in the now defunct TTIP proposals, and three further FTAs: the CETA; the United States Mexico Canada Agreement (USMCA) and the TCA. The WTO is chosen because it provides a foundational framework which forms the basis of all FTAs.

EU-US RC and the three FTAs have been selected for two reasons. First, this thesis focuses on the transatlantic dimension of transnational governance through RC. Transatlantic in this sense refers to RC in the EU-US relationship and the FTAs concluded across the Atlantic, i.e., by the EU (CETA and the TCA) and by the US (the USMCA). By analysing these RC models, examples of RC are taken from the key players in the transatlantic relationship. Second, these models are selected because RC is an important feature in them. To summarise, the justification of the case study selection in this research follows from the focus of this thesis on RC models of the key players in the transatlantic relationship. A brief description of each model is given below.

i) The WTO

It is important to analyse the WTO even though it is not a RC model as such because global trade relationships are embedded in the WTO.¹²⁵ This means that the WTO rules function as a

¹²⁵ See, Mavroidis, *Regulatory Cooperation: Lessons from the WTO and the World Trade Regime.*, 6; OECD, *International Regulatory Co-operation: Addressing Global Challenges*), 31. WTO, *World Trade Report 2012 Trade and public policies: a closer look at non-tariff measures in the 21st century*), 177.

baseline, i.e., FTAs take the WTO rules into account, and RC efforts build on the WTO rules through bilateral (or multilateral) trade agreements. In this sense, RC is layered: it takes the WTO rules as a starting point and adds another layer of RC in FTAs establishing free trade areas, economic partnerships, regulatory dialogues, etc. Consequently, analysing the existing and developing mechanisms of RC starts with the WTO.

ii) EU-US RC, culminating in the (now defunct) TTIP proposals

The choice of including the TTIP requires further explanation in comparison to the choices of the other FTAs. EU-US RC efforts culminated in the TTIP negotiations in 2013. Considering how the RC mechanisms used up until the negotiations for the TTIP were non-binding soft-law instruments, the general idea was that more was required to build a transatlantic marketplace.¹²⁶ However, negotiations for the TTIP were stopped without conclusion at the end of 2016.¹²⁷ As a response to the Trump administration withdrawing from the Paris Agreement and the imposed import tariffs on steel and aluminium as part of President Trump's economic policy, the Council of the EU declared the negotiation directives for the TTIP obsolete and no longer relevant.¹²⁸ Considering the political shift in the US at the time of the election of President Donald Trump in 2016 it became difficult to predict what will take place in the future of EU-US RC.¹²⁹ As it stands, the TTIP is and will remain off the table.

Nonetheless, RC in the TTIP is still worth analysing because, as Latorre and Yonezawa argue, a new Washington Administration may very well wish for a deeper and more comprehensive FTA with the EU.¹³⁰ In November 2020, Joe Biden was elected the 46th President of the United

¹²⁶ See Takács, 'Transatlantic regulatory cooperation in trade: objectives, challenges and instruments for economic governance', 175.

¹²⁷ See Council of the European Union, *Council Decision authorising the opening of negotiations with the United States of America for an agreement on the elimination of tariffs for industrial goods*, no. 6052/19 (9 April 2019) at <http://ec.europa.eu/trade/policy/countries-and-regions/countries/united-states/> (Last accessed 5 May 2018). In this decision, the Council authorised the opening of – new – negotiations for an agreement on the elimination of tariffs for industrial goods, emphasising that the EU seeks deep and comprehensive FTAs with parties to the Paris Agreement and acknowledging the difficulties of negotiations in TTIP to achieve mutually acceptable commitments. The Council therefore concludes that it is 'appropriate to pursue with the United States a more limited agreement covering the elimination of tariffs on industrial products only, and excluding agricultural products.'

¹²⁸ For an analysis on the Trump tariffs, see, Lori Widmer, 'The Business Impact of Trump Tariffs' (2018) 65 *Risk Management* 18; Jacob Schlesinger, Peter Nicholas and Louise Radnofsky, 'Trump to Impose Steep Aluminum and Steel Tariffs; President plans next week to approve 25% duties on steel imports and 10% on aluminum over the objection of allies and some advisers' *Wall Street Journal (Online)* (New York, N.Y. N.A.).

¹²⁹ For an analysis on possible future scenarios of transatlantic relations, see, Sonja Kaufmann and Mathis Lohaus, 'Ever closer or lost at sea? Scenarios for the future of transatlantic relations' (2018) 97 *Futures* 18.

¹³⁰ María C. Latorre and Hidemichi Yonezawa, 'Stopped TTIP? Its potential impact on the world and the role of neglected FDI' (2018) 71 *Economic Modelling* 99, 99. At the start of this research, the TTIP negotiations were not yet stopped. Earlier drafts included more extensive analyses of the TTIP than in the final version of this thesis.

States. President Biden addressed the United Nations in October of 2021 urging unity and global cooperation and specifically addressing that the US had renewed its engagement with the EU, calling the EU a ‘fundamental partner’.¹³¹ This renewal, (and surely President Biden’s attempt to rebuild the alliances of the US) refers to the EU-US joint communication of December 2020: ‘A new EU-US agenda for global change’.¹³² The interconnectedness of the world became painfully clear during the COVID-19 pandemic and the EU-US agenda of 2020 consequently directs its attention to possibilities relating to the pandemic – such as working together to create a pandemic playbook. Furthermore, climate change and biodiversity loss, being the challenges of our times, push the EU and the US to work together. But also, on trade – and thus on RC – the agenda states:

(...) we should facilitate our bilateral trade and deepen our regulatory and standards cooperation. As tariffs go down globally, it is setting and complying with standards and regulations that decides access to markets. While we are still the most influential regulators, both the EU and the US face increasing standard competition from third country actors. Where both sides agree, the world usually follows. This is why we must reactivate proposals for EU-US standards cooperation and re-engage on conformity assessment negotiations. Where possible, the EU and the US should systematically align positions within international standard setting bodies.

The first steps in relation to trade and RC will thus be to renew EU-US cooperation on regulation and standards, starting by re-engaging on conformity assessment negotiations and aligning positions in international bodies. In view of the historical development of EU-US RC, the EU and the US have taken some steps backwards.¹³³ But taking steps backwards does not mean that there will never be any steps forward. If anything, this agenda shows that the EU and the US are working towards re-engaging with RC. The Biden Presidency so far has shown that – whilst there are no explicit talks of negotiating an FTA – cooperation with the EU is considered crucial and further RC efforts can surely be expected in the future.

iii) The CETA

¹³¹ Remarks by President Biden Before the 76th Session of the United Nations General Assembly, <<https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/21/remarks-by-president-biden-before-the-76th-session-of-the-united-nations-general-assembly/>> Accessed 11 October 2021.

¹³² Joint Communication to the European Parliament, The European Council and the Council, A new EU-US agenda for global change, Brussels, <https://ec.europa.eu/info/sites/default/files/joint-communication-eu-us-agenda_en.pdf> Accessed 11 October 2021.

¹³³ See chapter 2, section 2.3.

The CETA is generally regarded as a potential blueprint for future trade deals.¹³⁴ Since the CETA is regarded as a blueprint, this means that in future endeavours, RC can take place along the lines of the CETA. Furthermore, the CETA, an important FTA between the EU and Canada, provides meaningful insight on the transatlantic dimension of RC. As the EU and Canada are both key players in the transatlantic relationship, the CETA is an important example of transatlantic RC.

iv) The USMCA

The USMCA, on the other hand, is a prime example of RC from the other side of the Atlantic – not only in signatories but also in its approach. The USMCA, an FTA between the US, Canada and Mexico, establishes RC between the parties. Considering that the EU-US relationship is an important part of this thesis, it is important to assess RC in the USMCA. Moreover, since the USMCA establishes RC between the US, Canada and Mexico, the common characteristics of the USMCA provide meaningful insights on RC from a non-EU perspective derived from a FTA between at least two of the key players of the transatlantic relationship.

v) The TCA

In the TCA, RC is a key feature – albeit in a unique situation considering that the UK and the EU are moving *away* from harmonisation and falling back on RC whereas the RC models analysed in this thesis are moving *towards* harmonisation of regulatory standards. The TCA, then, is a RC model characterised by a difficult political situation – which is reflected in its approach to RC – and therefore interesting to analyse. Moreover, it is valuable for the purpose of this research to consider a FTA that was conducted in a difficult political reality. After all, this thesis compares RC models to detect common parts and differences and researching a FTA resulting from a political situation such as the Brexit surely adds value to the comparison.

1.7 Chapter structure

Having set out the background, theoretical underpinnings, context and research question in Chapter One, Chapter Two explores the existing and developing mechanisms of RC. As trade relationships are embedded in the WTO, the chapter starts off with addressing RC in the WTO followed by an analysis of the RC models in the respective RC models – including an historical

¹³⁴ E.g., Peter Chase and Jacques Pelkmans, 'This time it's different: Turbo-charging regulatory cooperation in TTIP' (2015) IDEAS Working Paper Series from RePEc, 22; B. Hoekman, 'Fostering Transatlantic Regulatory Cooperation and Gradual Multilateralization' (2015) 18 Journal of International Economic Law 609, 613; Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power', 368.

overview of EU-US RC and proposed RC in the TTIP. The goal of RC is ultimately the reduction of regulatory divergence, primarily regarding non-tariff barriers to trade, to facilitate trade between the partners of the FTA in question. As TBT and SPS measures create non-tariff barriers to trade, the need to cooperate on the setting of regulatory standards is most apparent in these policy areas. Consequently, the analysis in this chapter predominantly focuses on specific RC provisions, RC through GRP and on the TBT and SPS chapters of the respective FTAs.

Chapter Three analyses the role of expertise in the existing and developing RC mechanisms and answers the question: what is the role of scientific expertise in RC? Similar to Chapter Two, the focus of the analysis is on RC provisions, RC through GRP and on the TBT and SPS chapters of the respective FTAs.

Chapter Four establishes the common characteristics of RC and the role of expertise in RC. Through a comparative analysis of the RC models and the role of expertise in these models, this chapter explores the common characteristics of RC to achieve a more comprehensive understanding of RC derived from the details of the FTAs, the individual mechanisms of RC and the use of expertise as set out in the previous chapters. In doing so, the analysis moves away from the details of the individual RC models and establishes the common characteristics of RC and the role of expertise in RC.

Chapter Five analyses the throughput-legitimacy deficit of RC. In this chapter, the three main causes of the legitimacy deficit of RC are assessed. More precisely, the chapter analyses in depth the transforming role of the executive in RC, the preliminary influence of foreign governments and the influence of business and lobbying groups on the setting of regulatory standards through engaging in RC. The analysis of the legitimacy-deficit of RC is followed by two counterarguments to the idea of a legitimacy deficit, namely the argument that RC is voluntary and the argument that, considering that RC takes place in the agenda-setting phase, nothing really changes. Lastly, if RC establishes parliamentary oversight and participatory rights that ensure a balanced representation of interests, RC might not face a legitimacy deficit by having strong input-legitimacy. In view of that, this chapter analyses parliamentary oversight and participation rights in RC.

Chapter Six analyses if expertise can enhance the throughput-legitimacy of RC. Expanding on the argument of Chapter Five (i.e., parliamentary oversight and participatory rights that ensure a balanced representation of interests are required to legitimise RC) this chapter analyses the

role of expertise in enhancing the throughput-legitimacy of RC. In short, this chapter argues that cooperatively set regulatory measures through RC should rely on transnational expertise. In other words, regulatory measures drafted through RC ought to create a common scientific basis as the incorporation of scientific expertise in the decision-making process enhances the throughput-legitimacy of RC by increasing the quality of deliberation in the RC process. Furthermore, this chapter argues that scientific legitimacy is insufficient due to the problems of biased expertise and technocracy and consequently, this chapter applies the democratisation of expertise to RC.

Chapter Seven provides the conclusion to this thesis. This chapter summarises the thesis succinctly, reiterates the key arguments of this research and considers the lessons of the transatlantic experience for future RC endeavours.

Chapter 2 Existing and developing mechanisms of regulatory cooperation

2.1 Introduction

In order to explore whether expertise can enhance the throughput-legitimacy of RC, understanding of the procedural mechanisms of RC is important for two reasons. Firstly, to assess the role of expertise in the RC mechanisms (Chapter 3) it is important to understand the existing and developing mechanisms of RC. Secondly, to assess the throughput-legitimacy of RC and the role of expertise to enhance the throughput-legitimacy of RC, a comprehensive understanding of its mechanisms is essential. Therefore, the first question this thesis answers is: what are the existing and developing mechanisms of RC?

RC mechanisms are found in explicit RC chapters and activities but also through Good Regulatory Practices (GRP) and in the sectoral chapters of the FTAs. This chapter systematically analyses the existing and developing mechanisms of RC, either via RC activities or GRP, or as found in the sectoral chapters, in line with the definition of RC. RC is the creation of procedural mechanisms applicable to the preparatory stages of regulation, aimed at the convergence of standards, with a focus on international FTAs. Regarding the sectoral chapters of the FTAs, the emphasis is on the TBT and SPS chapters considering that non-tariff barriers are the biggest obstacles to trade.¹³⁵ Furthermore, the existing and developing mechanisms of RC in this chapter focus on the case studies selected for this research, namely the WTO (section 2.2), EU-US RC (section 2.3) and RC mechanisms in the three RC models implemented in comprehensive FTAs (section 2.4).

2.2 Regulatory cooperation in the WTO

Trade deals must abide by WTO trade rules since these rules serve as minimum requirements of free trade.¹³⁶ As such, the WTO rules provide a baseline and regulatory coverage in FTAs move beyond WTO rules by including WTO+ issues such as competition and investment.¹³⁷ In light of this, FTAs generally include a reference to WTO rules and build on the rights and obligations under WTO law.¹³⁸ Whilst the interplay between FTAs and the WTO – and more

¹³⁵ See chapter 1, section 1.1.

¹³⁶ Trade deals by WTO members are called Regional Trade Agreements. FTAs fall under this definition and thus, for clarity's sake, this thesis uses the term FTA.

¹³⁷ M. Q. Zang, 'When the Multilateral Meets the Regionals: Regional Trade Agreements at WTO Dispute Settlement' (2018) World Trade Review 1.

¹³⁸ For example, article 1.4 of CETA states: 'The Parties hereby establish a free trade area in conformity with Article XXIV of GATT 1994 and Article V of the GATS.'

generally the relationship between the WTO and other international law – is complex, for the purpose of this thesis it suffices to say that the WTO allows FTAs, monitors them and studies their effect on international trade.¹³⁹

The WTO *promotes* RC through GRP; international standards; equivalence; mutual recognition and works towards harmonisation, most prominently in the SPS and TBT Agreement. The Organisation for Economic Co-operation and Development similarly qualifies the WTO as an inter-governmental organisation that promotes RC.¹⁴⁰ The fact that the WTO *promotes* RC illustrates that at best there are suggestions for engaging in RC. In other words, the WTO creates a baseline which makes cooperation possible, but does not obligate its signatories to engage in RC. What stands out is that promoting RC might not fit the definition of RC – which is further reflected on at the end of this section on the WTO (2.1).

2.2.1 Good Regulatory Practices

RC is dependent on trust amongst regulators since trust is needed for countries to be willing to work together and accept standards or regulatory procedures as equal to their own. Promoting GRP helps to build trust as GRP – in the words of the WTO – ‘helps to provide confidence that SPS/TBT measures and conformity assessment procedures will strike an efficient balance between policy objectives and trade restriction.’¹⁴¹ Through using and disseminating GRP, the TBT Committee and SPS Committee – both committees that develop recommendations and decisions to facilitate the implementation of the TBT and SPS Agreements respectively – deal directly with the impact of regulation on trade and promote RC or even convergence.¹⁴² As such, the WTO promotes the use of GRP to enhance trust between countries and create a level-playing-field for countries to engage in RC.

To promote RC, the WTO focuses predominantly on transparency as a key principle of GRP.¹⁴³ By improving transparency – ‘a necessary condition to achieve (and enforce) trade policy

¹³⁹ As this chapter focuses on RC mechanism in the WTO it is not directly relevant to assess the interplay between the WTO and FTAs. On this interplay see, for example, Joost Pauwelyn 'Interplay between the WTO Treaty and Other International Legal Instruments and Tribunals: Evolution after 20 Years of WTO Jurisprudence' (2016) Forthcoming in: Proceedings of the Québec City Conference on the WTO at 20, held in September 2015 (eds C-E Côté, V Guèvremont, R Ouellet), Presses de l'Université de Laval, 2018

¹⁴⁰ OECD, *International Regulatory Co-operation: Addressing Global Challenges*, 23.

¹⁴¹ WTO, *World Trade Report 2012 Trade and public policies: a closer look at non-tariff measures in the 21st century*, 178, 179 <https://www.wto.org/english/res_e/booksp_e/anrep_e/world_trade_report12_e.pdf> Accessed 15 October 2021.

¹⁴² OECD, *International Regulatory Co-operation: Addressing Global Challenges*, 31; WTO, *World Trade Report 2012 Trade and public policies: a closer look at non-tariff measures in the 21st century*, 177.

¹⁴³ The RC models, discussed below, generally focus on transparency, stakeholder consultations and analytical tools such as impact assessments in their GRP provisions or chapters.

cooperation’ – the WTO seeks to achieve trade policy cooperation and emphasises the need for international cooperation in, for example, climate change and food safety standards.¹⁴⁴ To ensure transparency, the WTO sets up a notification procedure for new trade-related measures and legislation. The TBT and SPS Agreements require early notice of planned regulatory acts that impact trade, which can function as an early signal for possible RC.¹⁴⁵ The idea behind this notification procedure is that it makes room for engaging in RC – after all, there is no cooperation if proposed regulations are kept secret. Transparency in this sense results in notifying the WTO about planned regulatory acts that impact trade. Interestingly, there is not one member in the WTO that complies with the notification obligation which, in view of RC, results in FTAs establishing their own notification procedures.¹⁴⁶ Nonetheless, the notification procedure enables a discussion about planned regulatory acts that impact trade which could in turn establish a regulatory dialogue. In that sense, transparency regarding planned regulatory acts is a prerequisite for RC.¹⁴⁷

2.2.2 *International standards*

Aside from promoting GRP, the TBT and SPS Agreements emphasise international standards to achieve harmonisation.¹⁴⁸ A thorough analysis of international standards in the WTO is beyond the scope of this thesis. For this research, it suffices to argue that harmonisation under the WTO takes place either by partial harmonisation (when measures are based on international standards ex art. 3.1 SPS) or full harmonisation (when measures conform to international standards ex art. 3.2 SPS).¹⁴⁹ Essentially, international standards can result in similar measures across the globe, i.e., harmonisation.

The qualification of international standards as RC mechanism is based on the way international standards are set. Setting standards, standardization or international standards codify ‘state-of-

¹⁴⁴ WTO, *World Trade Report 2012 Trade and public policies: a closer look at non-tariff measures in the 21st century* 173, 175.

¹⁴⁵ OECD/WTO, *Facilitating trade through regulatory cooperation: the case of the WTOs TBT/SPS Agreements and Committees*, (2019), 36 <<https://doi.org/10.1787/ad3c655f-en>> Accessed 15 October 2021.

¹⁴⁶ See, Aileen Kwa and Peter Lunenborg, *Notification and Transparency Issues in the WTO and US*, (November 2018); see further chapter 2 (below), for specific RC mechanisms in the RC models establishing their own notification procedures.

¹⁴⁷ See chapter 4, section 4.2.2.

¹⁴⁸ R. Howse, ‘Regulatory cooperation, regional trade agreements, and world trade law: Conflict or complementarity?’ (2015) 78 *Law and Contemporary Problems* 137, 149; Peel, *Science and Risk Regulation in International Law*, 25.

¹⁴⁹ Also see, Humberto Zuniga Schroder, *Harmonization, Equivalence and Mutual Recognition of Standards in WTO Law* (Global Trade and Customs Journal, Kluwer Law International 2011), 118.

the-art scientific and technical knowledge related to a particular product or policy problem.’¹⁵⁰ International standards are set by ‘hybrid public-private expert bodies’ consisting of stakeholders – including governments – and have ‘(considerable) regulatory force.’¹⁵¹ Peel explains that the regulatory force results from the WTO urging its signatories to use international standards accompanied by the promise of compliance with the TBT and SPS Agreements when using international standards as the basis for national regulatory measures.¹⁵² The cooperative aspect of international standards is in the way these standards are set as they are the result of cooperation between stakeholders (including governments) on matters that directly affect SPS and TBT measures.¹⁵³

Essentially, harmonisation and standard-setting are examples of RC as they aim at converging standards and support regulatory alignment by allowing harmonisation to take place on the technical specifications of products.¹⁵⁴ Considering that international standards are set through a cooperative effort (albeit by public-private expert bodies) they qualify as a RC mechanism in the WTO.

2.2.3 *Equivalence and mutual recognition*

Another WTO mechanism for RC is equivalence which both the SPS and the TBT Agreements use as a tool for cooperation.¹⁵⁵ In essence, equivalence means that WTO signatories accept SPS and TBT measures of other members as equivalent if the exporting member objectively demonstrates to the importing member that its measures achieve the appropriate level of protection.¹⁵⁶ This can relate to specific measures, measures related to certain products or category of products or even on a system-wide basis. Exporting countries should facilitate equivalence by providing access for inspection, testing and ‘other procedures.’¹⁵⁷ WTO signatories must give positive considerations to accept technical regulations as equivalent to

¹⁵⁰ WTO, *World Trade Report 2012 Trade and public policies: a closer look at non-tariff measures in the 21st century*, 179.

¹⁵¹ Peel, *Science and Risk Regulation in International Law*, 26. Also see the SPS Agreement, Introduction, Article 12.3, Annex A paragraph 3(a). Examples of these bodies are the Codex Alimentarius Commission, the International Office for Epizootics, the International Plant Protection Convention, the International Electrochemical Commission, and the International Organization for Standardisation.

¹⁵² *ibid.* 26. See art. 3.2 SPS Agreement and art. 2.5 TBT Agreement. Interestingly, albeit beyond the scope of this thesis, international standards are not agreed upon by consensus and thus standardization faces a legitimacy problem of its own.

¹⁵³ WTO, *World Trade Report 2012 Trade and public policies: a closer look at non-tariff measures in the 21st century*, 179.

¹⁵⁴ OECD, *International Regulatory Co-operation: Addressing Global Challenges*, 39.

¹⁵⁵ Art. 4 of the SPS Agreement and art. 2.7 of the TBT Agreement.

¹⁵⁶ Art. 4 SPS Agreement.

¹⁵⁷ WTO, *World Trade Report 2012 Trade and public policies: a closer look at non-tariff measures in the 21st century*, 180.

their own, ‘provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.’¹⁵⁸ Based on the idea that regulatory goals are achieved by various measures, equivalence results in countries accepting foreign production rules and control systems as equivalent, allowing all products produced and controlled according to these rules to be directly placed in the respective markets.¹⁵⁹ This inevitably demands RC, at a minimum in the sense of an exchange of information.

Considering how art. 6.1 of the TBT-Agreement promotes the acceptance of the results of conformity assessment procedures – if they offer equivalent assurance of conformity as their own – and art. 6.3 of the TBT Agreement encourages mutual recognition of the results of conformity assessment procedures, what exactly is the difference is between equivalence of the results of conformity assessment and mutually recognising conformity assessment procedures? Equivalence and mutual recognition have a lot in common and arguably, as Schroder explains, ‘the only significant difference between them is that in the case of equivalence treatment is unilateral whereas mutual recognition involves a bilateral/multilateral assessment.’¹⁶⁰ A further analysis of the differences between equivalence and mutual recognition is beyond the scope of this thesis but both result in forms of RC.

An important aspect of mutual recognition relates to exporting products. When exporting a product, one of the main difficulties in view of trade is the multiple testing of products, a difficulty that RC aims to reduce.¹⁶¹ By accepting the results of another countries conformity assessment, even with different procedures, ideally a product would need to be tested once and the results would be accepted in all markets across the globe. In article 6.3 of the TBT Agreement, the WTO encourages its members ‘to be willing to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other’s conformity assessment procedures.’ Thus, mutual recognition of conformity assessment procedures can result in a product being tested once and accepted in markets across the globe.

The effects of equivalence and mutual recognition are the removal of trade barriers and allowing, as Schroder explains, ‘products to be accepted in the importing country on the basis

¹⁵⁸ Article 2.7 TBT Agreement.

¹⁵⁹ Frode Veggeland and Christel Elvestad, *Equivalence and Mutual Recognition in Trade Arrangements Relevance for the WTO and the Codex Alimentarius Commission*, 2004), 8.

¹⁶⁰ Zuniga Schroder, *Harmonization, Equivalence and Mutual Recognition of Standards in WTO Law*, 98.

¹⁶¹ This was also mentioned when TTIP was announced, relating to car safety regulation specifically. See, European Commission, *TTIP: The Regulatory Part* (September 2013) <http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151605.pdf> Accessed 16 August 2019.

that foreign standards and conformity assessment procedures fulfil its relevant regulatory objectives' whilst achieving the desired level of protection in both countries.¹⁶² However, conformity assessment procedures take place at the level of implementation and does not result in harmonised regulatory acts. Whilst equivalence and mutual recognition are arguably a form of RC, they are very minimal in the sense of RC in this thesis. After all, equivalence and mutual recognition do not regulate much as such; it simply sets a principle of recognition of each other's rules. From the latter perspective, it is indeed RC, but minimal at best.

2.2.4 *Working towards harmonisation: regulatory cooperation in the WTO*

Arguably, the endgame of RC is harmonisation. Whilst the WTO has yet to come close to achieving such an ideal, the TBT and SPS Agreements work towards the harmonisation of TBT and SPS measures.¹⁶³ Harmonisation in case of SPS measures results from the previously addressed international standards that provide compliance with the SPS Agreement.¹⁶⁴ The SPS Committee monitors and coordinates the process of international harmonisation.¹⁶⁵ In the TBT Agreement there are similar provisions dealing with harmonisation, focusing on signatories playing a full part 'in the preparation by international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations' with a view on harmonising technical regulations, conformity assessment procedures and standards 'on as wide a basis as possible'.¹⁶⁶ Harmonisation therefore plays the biggest role in international standards and since the process of setting these standards is a cooperative effort it qualifies (in principle) as RC.

To conclude, RC in the WTO takes place by promoting GRP, setting international standards, equivalence, mutual recognition and working towards harmonisation – most notably in the SPS and TBT Agreement. These agreements encourage RC, bilateral equivalence and mutual recognition agreements and are, according to the WTO, beneficial to exporters because cooperation lowers costs made in relation to monitoring policy changes in export markets.¹⁶⁷ The RC mechanisms in the WTO are non-binding in the sense that it is 'encouraged', signatories should 'give positive consideration' or are simply 'promoted' by the WTO. This results in WTO signatories entering in negotiations on FTAs rather than RC being an obligation from the WTO

¹⁶² Zuniga Schroder, *Harmonization, Equivalence and Mutual Recognition of Standards in WTO Law*, 98.

¹⁶³ See art. 3 SPS Agreement / art. 2.6, 2.7, 5.5 and Annex 3. G TBT Agreement.

¹⁶⁴ Art. 3.1 and art. 3.2 SPS Agreement.

¹⁶⁵ Art. 3.5 SPS Agreement.

¹⁶⁶ Art. 2.6, 5.5, annex 3.G TBT Agreement.

¹⁶⁷ WTO, *World Trade Report 2012 Trade and public policies: a closer look at non-tariff measures in the 21st century*, 179.

itself. Considering international standards, however, compliance with these standards guarantee compliance with the TBT and SPS Agreements, providing them with regulatory force.

An important question is: do the RC mechanisms of the WTO fit the definition of RC in this thesis? The WTO does create procedural mechanisms applicable to the preparatory stages of regulation, aimed at the convergence of standards. This is most notably the case in the notification procedure and the setting of international standards. It is, however, minimal in the sense that there are no obligations of RC under the WTO. The WTO creates common ground upon which RC is built through FTAs. RC thus takes the WTO rules as a starting point and adds another layer of (transatlantic) RC through FTAs.

2.3 EU-US regulatory cooperation

Arguably the most significant economic relationship in the world, the EU and the US have been seeking common ground by various means. It is generally accepted that a cooperative relationship between the EU and the US is vital to them and the rest of the world.¹⁶⁸ In 2000, hidden technical barriers were the most significant barriers to EU-US trade.¹⁶⁹ These barriers are predominantly of regulatory nature making RC the last step towards building a transatlantic marketplace.¹⁷⁰ EU-US RC is characterised by attempts to establish an ongoing regulatory dialogue, ultimately resulting in the TTIP negotiations – aiming to be the ‘treaty to end trade treaties’ and realise the potential of EU-US RC.¹⁷¹ Alas, the TTIP negotiations eventually failed, but RC remains important in the EU-US relationship and ever since the Cold War, the EU and US have been attempting to enhance RC.¹⁷² In this section, EU-US RC is analysed, culminating in the TTIP negotiations.

Although diplomatic relations between the EU and the US existed since the very foundation of the EU, EU-US cooperation was formalised by the Transatlantic Declaration of 1990.¹⁷³ The

¹⁶⁸ See, Bermann, Lindseth and Herdegen, *Transatlantic regulatory cooperation: legal problems and political prospects*, foreword. Aaron, 'The United States and Europe: seeking common ground', 28.

¹⁶⁹ The Right Honourable Lord Brittan of Spennithorne QC, 'Transatlantic economic partnership: breaking down the hidden barriers' in George A. Bermann, Peter L. Lindseth and Matthias Herdegen (eds), *Transnational regulatory cooperation: legal problems and political prospects* (Oxford University Press 2000), 17.

¹⁷⁰ Aaron, 'The United States and Europe: seeking common ground', 25.

¹⁷¹ E.g. Haar, *Cooperating to deregulate*; Chase and Pelkmans, 'This time it's different: Turbo-charging regulatory cooperation in TTIP'; Wiener and Alemanno, 'The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory', 130; Garcia, 'Building Global Governance One Treaty at a Time? A Comparison of the US and EU Approaches to Preferential Trade Agreements and the Challenge of TTIP', 235.

¹⁷² On the importance of RC, see chapter 1, section 1.5.

¹⁷³ The foundation of the EU in this sense relates to the foundation of the European Coal and Steel Community in 1953. See, Rebecca Steffenson, *Managing EU-US relations: actors, institutions and the new transatlantic agenda*

central principle in EU-US RC is one of consultation and sharing information on matters of mutual interest to align their respective positions.¹⁷⁴ The desire for an ongoing dialogue thus existed since, as the EU and US dedicated themselves to informing and consulting each other on important matters of common interest, with a view to bringing their positions as close as possible – which Meuwese argues is an implicit reference to RC.¹⁷⁵ At the time considered a ‘ground-breaking move to create a structured dialogue’, the Declaration sets up an institutional framework for consultation.¹⁷⁶ For example through the EU-US summits, organised to apply top-down pressure to engage in RC.¹⁷⁷ Although having little success in sorting out trade conflicts involving protective regulatory policies, the EU-US summits take place regularly ever since the Declaration.¹⁷⁸ Steffenson explains that the summits are the biggest achievement of the Declaration and where the big decisions are made on the highest political level – although in terms of RC symbolic at best since its role as an effective policy producer is inadequate.¹⁷⁹ EU-US RC started out as a highly political effort and whilst the Declaration is so broad that it could not successfully establish EU-US RC, it remains its foundation.¹⁸⁰

2.3.1 *The New Transatlantic Agenda: from top-down to bottom-up*

The New Transatlantic Agenda (NTA) of 1995 is ‘the cornerstone’ of EU-US RC.¹⁸¹ The NTA is accompanied by a Joint EU-US Action Plan which develops the objectives stated in the NTA in more detail.¹⁸² And, whilst a Sub-Cabinet Group – consisting of sub-cabinet officials – was

(Manchester: Manchester University Press 2005), 25; see The Transatlantic Declaration On EC-US relations 1990 <http://www.europarl.europa.eu/cmsdata/124320/trans_declaration_90_en.pdf> accessed 30 September 2021.

¹⁷⁴ See, Davor Jancic, 'The European Parliament and EU-US relations: revamping institutional cooperation?' in Elaine Fahey and Deirdre Curtin (eds), *A Transatlantic Community of Law: Legal Perspectives on the Relationship between the EU and US Legal Orders* (Cambridge University Press 2014), 48.

¹⁷⁵ Meuwese, 'EU-US horizontal regulatory cooperation: mutual recognition of impact assessment?', 253. Bermann, 'Regulatory Cooperation between the European Commission and U.S. Administrative Agencies', 955.

¹⁷⁶ Steffenson, *Managing EU-US relations: actors, institutions and the new transatlantic agenda*, 35. This framework consists of bi-annual consultations between the President of the European Council, the President of the Commission and the President of the US (i.e. the EU-US summit); between the European Community Foreign Ministers, the Commission, and the US Secretary of State; between the Commission and the US Government at Cabinet level; ad hoc consultations between the Presidency Foreign Minister or the Troika and the US Secretary of State and; briefings by the Presidency to US Representatives on European Political Cooperation meetings at the Ministerial level.

¹⁷⁷ Murphy, 'Framing essay: a shift in transatlantic diplomacy', 14.

¹⁷⁸ The EU and US have found themselves in need of arbitration before the WTO increasingly since the Declaration. See, *ibid*, 15.

¹⁷⁹ Steffenson, *Managing EU-US relations: actors, institutions and the new transatlantic agenda*, 65.

¹⁸⁰ Bermann, 'Regulatory Cooperation between the European Commission and U.S. Administrative Agencies', 958.

¹⁸¹ Steffenson, *Managing EU-US relations: actors, institutions and the new transatlantic agenda*, 25 35; The New Transatlantic Agenda 1995 <http://eeas.europa.eu/archives/docs/us/docs/new_transatlantic_agenda_en.pdf> accessed 5 October 2021.

¹⁸² Joint EU – US Action Plan NTA 1995, <http://eeas.europa.eu/archives/docs/us/docs/joint_eu_us_action_plan_95_en.pdf> accessed 5 October 2021.

the first to explicitly encourage RC between regulatory officials across the Atlantic, the NTA provides explicit high-level political support for RC.¹⁸³ By creating, for the first time in EU-US relations, transgovernmental institutions – for example the NTA Task Force and the Senior Level Group – the NTA creates mechanisms to help, drive, coordinate, organise, monitor and implement the agenda for the EU-US summits.¹⁸⁴ The NTA actually provides mechanisms and creates institutions to fulfil the goals of RC as set out on the highest political level via the summits and in doing so, indeed becomes the cornerstone of EU-US RC.

Additionally, to build bridges across the Atlantic, the NTA set up various people-to-people dialogues – often considered the main achievement of the NTA.¹⁸⁵ These permanent dialogues are the Transatlantic Business Dialogue (TABD), the Transatlantic Consumer Dialogue, the Transatlantic Environmental Dialogue and the Transatlantic Labour Dialogue.¹⁸⁶ Fahey explains that the permanent dialogues is where most rulemaking has been achieved.¹⁸⁷ Bignami and Charnovitz explain that the dialogues provide the opportunity for interest groups to take their issues to governments and push for bilateral negotiations.¹⁸⁸ These dialogues are surely an interesting form of proceduralisation beyond the standard diplomatic dialogue. The dialogues built bridges between the EU and the US considering that the dialogues allow participation of interest groups in a transatlantic setting. However, this transnational institutionalisation through permanent dialogues is not without any issues due to the privileged position of the TABD.

¹⁸³ See text of the NTA; Bermann, 'Regulatory Cooperation between the European Commission and U.S. Administrative Agencies', 960. Meuwese, 'EU-US horizontal regulatory cooperation: mutual recognition of impact assessment?', 253.

¹⁸⁴ Steffenson, *Managing EU-US relations: actors, institutions and the new transatlantic agenda*, 41.

¹⁸⁵ *ibid*, 38.

¹⁸⁶ Francesca Bignami and Steve Charnovitz, 'Transnational Civil Society Dialogues' in Mark A. Pollack and Gregory Shaffer (eds), *Transatlantic Governance in the Global Economy* (Rowman & Littlefield 2001), 274. Elaine Fahey, 'Towards a Transatlantic Community of Law?' in Elaine Fahey and Deirdre Curtin (eds), *A Transatlantic Community of Law: Legal Perspectives on the Relationship between the EU and US Legal Orders* (Cambridge University Press 2014), 136. In addition to these dialogues, several sectoral dialogues have emerged in specific policy areas, i.e., the Transatlantic Economic Council; the EU-US Financial Markets Regulatory Dialogue; the EU-US Development Dialogue; the EU-US Education Policy Forum; The EU-US Energy Council; the EU-US Task Force on Biotechnology Research; the EU-US Insurance Regulatory Dialogue and unofficial non-government sponsored dialogues such as the Transatlantic Policy Network, the Transatlantic Dialogue on Sustainable Development; The Transatlantic Dialogue of Aviation and Climate Change, and the Transatlantic Donors Dialogue. Jancic, 'The European Parliament and EU-US relations: revamping institutional cooperation?', 53, 54. Also see Bignami and Charnovitz, 'Transnational Civil Society Dialogues'. This section will discuss the TABD and the Transatlantic Consumer Dialogue seeing how these are the most influential dialogues.

¹⁸⁷ Fahey, 'Towards a Transatlantic Community of Law?', 136.

¹⁸⁸ Bignami and Charnovitz, 'Transnational Civil Society Dialogues', 256.

The TABD is a formal business dialogue attempting to secure US business support and boost the impact of EU businesses in transatlantic negotiations.¹⁸⁹ By conducting a bottom-up approach to RC, the TABD became a shared meeting ground for officials from both sides of the Atlantic and has made many achievements, amongst which the EU-US Mutual Recognition Agreement (MRA).¹⁹⁰ Officially an advisory body, Zoller argues that evidence suggests otherwise and implies that the TABD has greater influence than merely advisory, considering how its recommendations are often directly adopted into policies.¹⁹¹ As Cowles explains, the TABD exerts influence by setting the agenda through its recommendations and promotes debates between US agencies and their European counterparts through annual conferences, dinners and forums.¹⁹² In 2013, the TABD merged with the European-American Business Council to establish the Transatlantic Business Council, making the TABD the executive of the Transatlantic Business Council and continuing to exert its influence on various transatlantic RC platforms.¹⁹³ This dialogue illustrates a shift in approach from top-down RC to bottom-up RC. Furthermore, it shows the focus and predominant influence of business and commerce on RC – a fact that is still seen in recent FTAs and is surely a cause for concern.¹⁹⁴

Where the TABD was established due to lobbying from the American side (i.e., the US Department of Commerce) the Transatlantic Consumer Dialogue was actively promoted by the European Commission (hereinafter Commission).¹⁹⁵ Bignami and Charnovitz explain that, under the perception that the business sector was influencing trade talks to the detriment of consumers, consumer organisations lobbied for a dialogue with governmental recognition, providing direct access to policymakers, similarly to the TABD.¹⁹⁶ This resulted in the creation of the Transatlantic Consumer Dialogue of which its members are the leading organisations representing consumer interests on both sides of the Atlantic.¹⁹⁷ Whilst the Environmental, Labour and Consumer dialogues were established to counterbalance the influence of the TABD,

¹⁸⁹ Steffenson, *Managing EU-US relations: actors, institutions and the new transatlantic agenda*, 72. Maria Green Cowles, 'The Transatlantic Business Dialogue: Transforming the New Transatlantic Dialogue' in Mark A. Pollack and Gregory C. Shaffer (eds), *Transatlantic governance in the global economy* (Lanham, Md. : Rowman & Littlefield 2001), 213.

¹⁹⁰ The MRA will be discussed further on in this section. Green Cowles, 'The Transatlantic Business Dialogue: Transforming the New Transatlantic Dialogue', 213, 215.

¹⁹¹ Heather Zoller, 'Dialogue As Global Issue Management: Legitimizing Corporate Influence in the Transatlantic Business Dialogue' (2004) 18 *Management Communication Quarterly* 204, 231.

¹⁹² Green Cowles, 'The Transatlantic Business Dialogue: Transforming the New Transatlantic Dialogue', 231, 232.

¹⁹³ Jancic, 'The European Parliament and EU-US relations: revamping institutional cooperation?', 55.

¹⁹⁴ The legitimacy implications of the influence of the TABD will be further discussed in section 5.2.5.

¹⁹⁵ Bignami and Charnovitz, 'Transnational Civil Society Dialogues', 258.

¹⁹⁶ *ibid*, 258.

¹⁹⁷ Members list available at <<http://tacd.org/about-tacd/member-list/>> accessed 5 October 2021.

in reality counterbalancing the impact of the TABD remains difficult due to its privileged position.¹⁹⁸ Even though both the US and EU have made the promise to take recommendations from the Transatlantic Consumer Dialogue into account, practical evidence remains very hard to find.¹⁹⁹ In practice, Bignami and Charnovitz argue, the commitment to consumers playing a formal role in international policymaking is difficult to realise and consumers continuously struggle to establish policy changes in the transatlantic relationship.²⁰⁰

Importantly, EU-US RC pays attention parliamentary cooperation in the preparatory stages of regulation rather than executive cooperation as seen in recent FTAs – where parliament (merely) gets a say at the signing of the FTA and subsequently after the adoption of the draft proposal.²⁰¹ In an attempt to legitimise the dialogues, the Transatlantic Legislators Dialogue liaises with the permanent dialogues.²⁰² After the established practice of biannual interparliamentary meetings, the formal response to the commitment to enhance parliamentary – framed in the NTA – was setting up the Transatlantic Legislators Dialogue in 1999.²⁰³ Transatlantic parliamentary cooperation has evolved and grown over the years and is likely to grow even further in future RC endeavours.²⁰⁴

To summarise, RC under the NTA takes place on the intergovernmental, transgovernmental and transnational levels, with three distinct actors and types of decisions.²⁰⁵ Steffenson argues that the structural institutionalisation of the transatlantic dialogue is the most significant change brought about by the NTA.²⁰⁶ Through the institutionalisation, the NTA attempts to create an ongoing regulatory dialogue. Nonetheless, non-binding, soft law RC mechanisms are at the heart of EU-US RC under the NTA. Whilst progress was made, RC has so far been insufficient

¹⁹⁸ Corporate Europe Observatory, a CEO issue briefing, *'TABD in Troubled Water'* (October 2001), 6 <<http://archive.corporateeurope.org/tabd/troubled.pdf>> accessed 18 May 2022.

¹⁹⁹ *ibid*, p. 6; Bignami and Charnovitz, 'Transnational Civil Society Dialogues', 268. Also see Transatlantic Economic Partnership statement, section 15; Action Plan, art. 3.8.

²⁰⁰ Bignami and Charnovitz, 'Transnational Civil Society Dialogues', 279.

²⁰¹ More on this below in section 2.4; also see chapter 5, section 5.3.

²⁰² Jancic, 'The European Parliament and EU-US relations: revamping institutional cooperation?', 54, 55.

²⁰³ *ibid*, 51.

²⁰⁴ *ibid*, 51; see chapter 5, section 5.3.1 and chapter 6, section 6.4.1.

²⁰⁵ On the intergovernmental level, the actors are chiefs of government and other high-level officials negotiating on behalf of the EU and the US such as the US President and the President of the European Commission, who engage in history making more than anything. The transgovernmental level relates to the previously mentioned NTA Task Force and other actors such as transatlantic working groups or the transatlantic legislators dialogue, who engage in policy setting and policy shaping. And lastly, on the transnational level, the permanent dialogues such as the TABD, generally private actors coordinating efforts to advance their respective goals, who engage in policy shaping. See, Mark A. Pollack and Gregory C. Shaffer, 'Transatlantic Governance in Historical and Theoretical Perspective' in Mark A. Pollack and Gregory C. Shaffer (eds), *Transatlantic governance in the global economy* (Lanham, Md. : Rowman & Littlefield 2001), 5; Steffenson, *Managing EU-US relations : actors, institutions and the new transatlantic agenda*, 18, 19.

²⁰⁶ Steffenson, *Managing EU-US relations : actors, institutions and the new transatlantic agenda*, 41.

in preventing disputes and tackling trade barriers resulting from diverging regulatory standards.²⁰⁷ The NTA is still an achievement in EU-US RC due to its institutionalisation, albeit predominantly through non-binding, soft law RC mechanisms.

2.3.2 *En route to the Transatlantic Trade and Investment Partnership*

Considering how the RC mechanisms used up until the negotiations for the TTIP were non-binding soft-law instruments, the general idea was that more was required to build a transatlantic marketplace.²⁰⁸

A consistent feature of EU-US RC is the attempt to build a structured ongoing regulatory dialogue. In 1997, a Joint Statement on Regulatory Cooperation called for the creation of a ‘new transatlantic marketplace’ by use of RC in the early stages of drafting regulations and ‘greater reliance on each other’s technical resources and expertise, and harmonization of regulatory requirements or mutual recognition.’²⁰⁹ The EU and US continuously search for ways to move away from the non-binding, soft law mechanisms towards something more substantial – which ultimately should have happened with the TTIP. But before the negotiations of the TTIP commenced, other attempts were made to establish a structured ongoing regulatory dialogue.

A milestone in EU-US RC is the MRA of 1998, one of the most well-known international regulatory agreements and an excellent example of cooperation between the EU and the US.²¹⁰ The MRA aims to ‘produce savings for US companies of a billion dollars a year in six sectors (...).’²¹¹ As acknowledged by the WTO, mutual recognition creates conditions that accelerate free trade by relying on the other parties’ conformity assessments.²¹² EU-US MRAs are, however, not to be mistaken for a mutual acceptance of standards. MRAs apply to conformity assessments and are limited to the sectors discussed in the MRA.²¹³ In short, an MRA assures that (in a certain sector) procedural frameworks for inspections of manufacturers are considered equal. MRAs do not regulate as such but set a principle of recognition of respective rules. The

²⁰⁷ See, for example, Takács, ‘Transatlantic regulatory cooperation in trade: objectives, challenges and instruments for economic governance’.

²⁰⁸ See *ibid.*, 175.

²⁰⁹ See EP Resolution on Transatlantic trade and economic relations, <<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A51997IP0403>> accessed 6 October 2021.

²¹⁰ Agreement on mutual recognition between the European Community and the United States of America, at: <[http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:21999A0204\(01\)&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:21999A0204(01)&from=EN)> accessed 6 October 2021.

²¹¹ Aaron, ‘The United States and Europe: seeking common ground’, 28.

²¹² See above, section 2.2.3.

²¹³ Takács, ‘Transatlantic regulatory cooperation in trade: objectives, challenges and instruments for economic governance’, 173.

MRA is thus – albeit minimal – a form of EU-US RC that is surely beneficial to the EU-US trade relationship.²¹⁴

To further the EU-US regulatory dialogue, the EU and the US committed to the Transatlantic Economic Partnership (TEP) in 1998.²¹⁵ Enhanced RC is one of the cornerstones of the TEP.²¹⁶ The TEP and its accompanying Action Plan commit to strengthening RC in two ways: firstly, by mutual recognition of regulatory procedures and certifications and secondly, by actively cooperating in matters of common interest.²¹⁷ However, falling short in outlining practical steps, the Joint Statement on Regulatory Cooperation and the TEP itself were so limited that, Murphy argues, even the very tradition of transatlantic economic cooperation were arguably at risk.²¹⁸ Once again, achieving the desired ongoing regulatory dialogue failed.

In light of the TEP – and yet another attempt to create an ongoing dialogue – the EU and US adopted the Joint Statement on Early Warning and Problem Prevention Principles and Mechanisms.²¹⁹ Essentially, the Joint Statement on Early Warnings asks regulators of the US Federal Government and the services of the Commission to – voluntarily – consult one another and exchange information to achieve the objectives aimed at improving cooperation between them ‘and to promote transparency to the public in establishing and amending regulations.’²²⁰ The consultations and exchanges are meant to occur throughout the development process of regulations and should begin ‘as early as possible in that process’.²²¹ Whilst this could have been a step in the right direction in view of establishing an ongoing regulatory dialogue, Murphy explains that this informal and non-obligatory exchange of information as intended by the Early Warnings system failed as regulators were hesitant to partake in the experiment driven by their

²¹⁴ Also see, chapter 2, section 2.2.3 of this thesis.

²¹⁵ Transatlantic Economic Partnership at:

http://eeas.europa.eu/archives/docs/us/docs/trans_econ_partner_11_98_en.pdf accessed 6 October 2021; Aaron, 'The United States and Europe: seeking common ground', 28.

²¹⁶ See the text of TEP; also see, Meuwese, 'EU-US horizontal regulatory cooperation: mutual recognition of impact assessment?', 254.

²¹⁷ Wulf-Henning Roth, 'Building the 'Transatlantic Economic Partnership': are new general institutions needed?' in George A. Bermann, Peter L. Lindseth and Matthias Herdegen (eds), *Transatlantic regulatory cooperation: legal problems and political prospects* (Oxford University Press 2000), 603.

²¹⁸ Murphy, 'Framing essay: a shift in transatlantic diplomacy', 15; Ellen L. Frost, 'The Transatlantic Economic Partnership' (1998) Policy Brief 98-6 Peterson Institute For International Economics

²¹⁹ Joint U.S.-EU Statement on Early Warning and Problem Prevention Principles and Mechanisms, Bonn June 1999, http://trade.ec.europa.eu/doclib/docs/2003/october/tradoc_111711.pdf accessed 6 October 2021.

²²⁰ Joint Statement on Early Warnings, II.4, III 7.

²²¹ Ibid, IV 10.

own political agendas.²²² Moving away from soft-law, non-binding RC to establish a structured ongoing regulatory dialogue surely has been a reoccurring goal in EU-US RC.

In the early 2000's, transatlantic RC seemed to stagnate which, according to Alemanno, can be attributed to the limits of non-legally binding RC.²²³ This is when RC started focusing on the regulatory processes of the EU and US respectively, in line with the Early Warning Statement of 1999. In 2002, Guidelines on Regulatory Cooperation and Transparency were drafted and adopted by the EU and US, based on the Action Plan of the TEP.²²⁴ Where the Joint Statement on Regulatory Cooperation of 1997 failed in outlining practical steps, the Guidelines provided in a new direction through the intent of (early) public consultations on draft regulatory measures.²²⁵ The Guidelines focus on government-to-government consultation, data and information exchange and the early warning system for anticipated regulatory action, facilitating, as Ahearn calls it, 'a more effective dialogue' across the Atlantic.²²⁶ Despite not explicitly mentioned, Meuwese argues that these Guidelines push towards cooperation through impact assessments (IAs).²²⁷ The ongoing dialogue 'as early as possible' in the regulatory process is at the very heart of RC as seen today.²²⁸ Importantly, RC in the Guidelines were considered a non-legally binding process, illustrated by two cases brought forth by the French government before the of European Court of Justice.²²⁹ The stagnation of RC efforts in the early 2000's thus evolved in a focus on the regulatory processes, ultimately leading to the TTIP negotiations in 2013. And thus, through various attempts, RC evolved from a high-level political effort to focusing on the preparatory stages of the regulatory process.

In 2004, the EU-US summit continued working on cooperation with the Roadmap for EU-US Regulatory Cooperation and Transparency, focusing on 'prospective regulations and reducing regulatory barriers.'²³⁰ This Roadmap established a few new dialogues: a horizontal dialogue

²²² Murphy, 'Framing essay : a shift in transatlantic diplomacy', 14.

²²³ Alemanno, 'How to get out of the transatlantic regulatory deadlock over genetically modified organisms?', 211.

²²⁴ See the Guidelines at <<https://obamawhitehouse.archives.gov/sites/default/files/omb/oir/irc/2002-guidelines-on-reg-coop-and-transparency.pdf>> accessed 6 October 2021.

²²⁵ Murphy, 'Framing essay : a shift in transatlantic diplomacy', 15.

²²⁶ Ahearn, 'Transatlantic Regulatory Cooperation: Background and Analysis', 17.

²²⁷ Meuwese, 'EU-US horizontal regulatory cooperation: mutual recognition of impact assessment?', 254.

²²⁸ See below, section 2.4.

²²⁹ *Case C-233/02, France v. Commission*, [2004] ECR I-2759, Also see, Meuwese, 'EU-US horizontal regulatory cooperation: mutual recognition of impact assessment?', 255. In these cases, the Guidelines were – according to the ECJ – non-binding and within competence of the Commission. Applying this to RC, which is presented as voluntary in both CETA and TTIP, the ECJ will consider – rather formalistically – RC as a non-binding even when established in an internationally binding agreement. More on the non-binding nature of RC in chapter 5, section 5.2.4.

²³⁰ Ahearn, 'Transatlantic Regulatory Cooperation: Background and Analysis', 17.

between the Commission and the US Office of Management and Budget to gain understanding of each other's regulatory practices and encourage compatible regulations; the establishment of the High Level Regulatory Cooperation Forum and; several 'regulatory dialogues' between US agencies and the relevant Directorate General in the Commission.²³¹ The High-Level Regulatory Cooperation Forum, established in 2005, is a new dialogue paving the way towards a more systematic cooperative approach. Consisting of senior US and Commission officials, academics, business executives and other officials, the High-Level Regulatory Cooperation Forum aimed to develop a joint regulatory work-plan based on mutual best practices and establishing GRP.²³² In general, the Roadmap of 2004 progressed EU-US RC through regulatory dialogues yet more steps were required.

During the EU-US summit of 2007, the EU and US acknowledged that initiatives to establish and enhance RC continuously failed and thus the Framework for Advancing Transatlantic Economic Integration and the Transatlantic Economic Council (TEC) were created. The TEC, in the words of the Framework, is 'a political body entrusted with overseeing and accelerating government-to-government cooperation with the purpose of advancing economic integration.'²³³ Designed to deal with shortcomings of the previous attempts at RC – i.e., 'lack of high level political leadership and not enough involvement of legislators and other stakeholders in the regulatory process' – the TEC focuses on the diverging EU and US regulatory processes and approaches, a task that Ahearn claims is less challenging than attempting to change existing regulations or resolving regulatory disputes.²³⁴ Acknowledging that the regulatory processes and applications have an impact on trade, the TEC aims to 'find ways to reduce barriers to transatlantic economic integration posed by new regulations and or prevent them from happening' through 'efforts to reform, harmonize or converge regulatory processes, both through the development of comparable methodologies to assess risk and do

²³¹ See the Joint Report on the Roadmap for US-EU Regulatory Cooperation, at <https://obamawhitehouse.archives.gov/sites/default/files/omb/oira/irc/joint_report_on_the_roadmap_for_us-eu_regulatory_cooperation_april_2007.pdf> accessed 6 September 2020; For progress/results, see <https://ustr.gov/archive/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/2005_Roadmap_for_EU-US_Regulatory_Cooperation_Transparency.html> accessed 6 September 2020.

²³² Ahearn, 'Transatlantic Regulatory Cooperation: Background and Analysis', 15; on RC through GRP, see below, section 2.3.3 and chapter 4, section 4.2.2.

²³³ European Union and the United States, *Framework for Advancing Transatlantic Economic Integration Between the European Union and the United States of America* (April 2007) <http://eeas.europa.eu/archives/docs/us/docs/framework_trans_economic_integration07_en.pdf> accessed 6 September 2020; Ahearn, 'Transatlantic Regulatory Cooperation: Background and Analysis', 20; Alemanno, 'How to get out of the transatlantic regulatory deadlock over genetically modified organisms?', 212.

²³⁴ Ahearn, 'Transatlantic Regulatory Cooperation: Background and Analysis', 21. Whether this is indeed an easier task is beyond the scope of this thesis to address.

cost-benefit analysis and intensified interactions among regulators.²³⁵ The TEC aims for ‘intensified sector-by-sector-cooperation’ by promoting the 2002 Guidelines and the sectoral dialogues of the Roadmap for Regulatory Cooperation.²³⁶ Thus in response to previous failures, the focus of the TEC is on harmonising the EU and US regulatory *processes* – in line with the trend of the early 2000s by focusing on the regulatory processes instead of its outcomes.

In line with the focus on regulatory processes and approaches of the TEC, the High-Level Regulatory Cooperation Forum reported to the TEC in 2008 and stresses – whilst it does not mean to convey that regulatory measures with severe trade impacts cannot have any benefits – the importance of ‘timely announcement of planned legislative and regulatory initiatives’, transparency in IAs, methodologies and procedures and putting forward the impacts on international trade and investment in the already existing forums for RC, including ‘exchange of preliminary results and technical studies.’²³⁷ In 2011, the High-Level Regulatory Cooperation Forum – at the request of the TEC – released a statement on ‘Common Understanding on Regulatory Principles and Best Practices’, reiterating their shared commitments to regulatory principles such as evidence-based policymaking, transparency and the participation of citizens and stakeholders.²³⁸ The regulatory principles in this statement convey a shared understanding and make way for new cooperative efforts – but remain non-binding.²³⁹

An extra step was taken in EU-US RC before the commencement of the TTIP negotiations in 2013, namely the establishment of a triangular dialogue between the US, EU and Canada calling for cooperation on risk assessments (RAs). After years of (political and regulatory) RC and a newly found attention for IAs, the fact that different scientific approaches to RAs leads to different responses from governments was emphasised.²⁴⁰ And thus the Transatlantic Risk Dialogue, connected to the TEC and steered by the High-Level Regulatory Cooperation Forum,

²³⁵ *ibid.*, 21, 22, 23.

²³⁶ *ibid.*, 22.

²³⁷ Office of Management and Budget and the Secretariat-General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment, Final Report and Conclusions* (13 May 2008), 10, 15 <https://georgewbush-whitehouse.archives.gov/omb/inforeg/reports/sg-omb_final.pdf> accessed 12 October 2021.

²³⁸ United States - European Commission High-Level Regulatory Cooperation Forum, *Common Understanding on Regulatory Principles and Best Practices* (2011)

<http://trade.ec.europa.eu/doclib/docs/2011/july/tradoc_148030.pdf> accessed 2 June 2018.

²³⁹ *Ibid.* Also see, Takács, 'Transatlantic regulatory cooperation in trade: objectives, challenges and instruments for economic governance', 172.

²⁴⁰ Black, *The Global Risk Assessment Dialogue*, 52/3. Also see, Alemanno, 'How to get out of the transatlantic regulatory deadlock over genetically modified organisms?', 221.

was established in 2008 – and subsequently broadened to a Global Risk Assessment dialogue.²⁴¹ Rather than regulatory or political cooperation, this dialogue calls for scientific cooperation on risk assessment itself and establishes as the key objectives ‘to improve mutual understanding of risk assessment across jurisdictions and to promote consistency on specific methodological and substantive issues relating to risk assessment.’²⁴² With the intention to ‘reduce divergences in approaches to risk between countries, improve the governance of risks, and to build trust by facilitating communication between scientists, political risk managers and the public at large’, the Risk Assessment Dialogue sets up ‘international and collaborative working between members of the scientific community, both within government agencies and in research institutions and on an issue by issue basis.’²⁴³ This Dialogue did not amount to much as (see section 3.1.6) but it does illustrate a growing interest in the role of expertise in RC and the idea that cooperating on matters of expertise can facilitate RC.

EU-US RC has developed gradually over time, culminating in the TTIP negotiations starting in July 2013. The EU-US High Level Working Group on Jobs and Growth, set up at the EU-US summit of 2011, analysed the possibility of a trade deal to strengthen the transatlantic economic partnership ‘with the aim of moving progressively toward a more integrated transatlantic marketplace’ and concluded that the EU and US should ‘launch negotiations on a comprehensive trade and investment agreement.’²⁴⁴ Thus, the well-known and rather controversial TTIP negotiations started in July 2013.

2.3.3 *Proposed regulatory cooperation in the TTIP*

The TTIP negotiations faced immense criticism and ultimately failed. Whilst many economic scholars agree the TTIP would have economic benefits for consumers, a wide range of criticism comes from NGO’s, academics, civil society, and social movements from both the EU and US.²⁴⁵ By 2016, the TTIP negotiations stopped – not necessarily because of the criticism but as a response to the Trump administration withdrawing from the Paris Agreement and the imposed import tariffs on steel and aluminium as part of President Trump’s economic policy – and the Council of the EU declared the negotiation directives for TTIP obsolete and no longer

²⁴¹ Black, *The Global Risk Assessment Dialogue*, 53.

²⁴² *ibid*, 52, 53.

²⁴³ *ibid*, 52, 53.

²⁴⁴ Final Report High Level Working Group on Jobs and Growth, February 11, 2013, <http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf> last accessed 2 May 2018.

²⁴⁵ See, Latorre and Yonezawa, ‘Stopped TTIP? Its potential impact on the world and the role of neglected FDI’; Haar, *Cooperating to deregulate*; Ferdi De Ville and Gabriel Siles-Brügge, *TTIP: The Truth about the Transatlantic Trade and Investment Partnership* (Polity Press 2016); Ferdi De Ville and Gabriel Siles-Brügge, ‘Why TTIP is a game-changer and its critics have a point’ (2017) 24 *Journal of European Public Policy* 1491.

relevant.²⁴⁶ As explained in the introduction of this research, however, the end of the negotiations do not render the TTIP documents irrelevant.²⁴⁷ Therefore, whilst TTIP will not come to fruition, it is still worth analysing proposed RC in TTIP.

It is important to acknowledge that the TTIP analysis in this research is predominantly based on the European proposals on the TTIP while the TTIP would, of course, be the result of negotiations with the US. Consequently, there is a certain information asymmetry in this as US positions remain rather confidential except for when Greenpeace leaked restricted documents.²⁴⁸ What follows is an analysis of the tools proposed in the TTIP based on the textual proposals on RC released – in the name of transparency – by the EU. The most recent EU proposals for the TTIP chapter on RC – and the texts that will be used for this analysis – are dated 10 February 2015, 4 May 2015 and 21 March 2016.²⁴⁹ The only time the US position was offered to the public was when Greenpeace leaked restricted documents in May 2016 – documents that will contribute to this analysis.²⁵⁰

The TTIP would have consisted of horizontal and sectoral chapters: the horizontal chapters consisting of chapters on GRP, RC, TBT and SPS measures and the sectoral chapters consisting of chapters on industries such as chemicals, cosmetics, engineering products, information and communication technologies, medical devices, pesticides, pharmaceuticals, textiles, and vehicles.²⁵¹ The horizontal chapters would thus include the RC mechanisms but the sectoral chapters also included provisions on RC.²⁵² This section focuses on the horizontal chapters of the TTIP. Regarding the applicability of the horizontal chapters, the general idea was that when the EU and US determined common interest in certain regulatory issues and there was or was likely to be a significant impact on trade or investment, the RC chapter would apply to any

²⁴⁶ For an analysis, see, Widmer, 'The Business Impact of Trump Tariffs'; Schlesinger, Nicholas and Radnofsky, 'Trump to Impose Steep Aluminium and Steel Tariffs; President plans next week to approve 25% duties on steel imports and 10% on aluminium over the objection of allies and some advisers'. European Union, *Council Decision authorising the opening of negotiations with the United States of America for an agreement on the elimination of tariffs for industrial goods, no. 6052/19*.

²⁴⁷ See chapter 1, section 1.5.

²⁴⁸ See, Alberto Alemanno, 'What the TTIP Leaks Mean for the On-going Negotiations and Future Agreement?' (2016) 7 *European Journal of Risk Regulation* 237; Greenpeace Netherlands, 'Leaked, consolidated TTIP chapter: Initial Provisions for Chapter [] [EU: Regulatory Cooperation] [US: Regulatory Coherence, Transparency, and other Good Regulatory Practices]' (May 2016) accessed May 2018.

²⁴⁹ See the Commission website specifically dedicated to TTIP <<http://ec.europa.eu/trade/policy/in-focus/ttip/>> accessed May 2018; The negotiation proposals have been published and updated online rather frequently, <<http://trade.ec.europa.eu/doclib/press/index.cfm?id=1230#regulatory-cooperation>> accessed 16 August 2019

²⁵⁰ Netherlands, 'Leaked, consolidated TTIP chapter: Initial Provisions for Chapter [] [EU: Regulatory Cooperation] [US: Regulatory Coherence, Transparency, and other Good Regulatory Practices]'.

²⁵¹ European Commission, 'TTIP and Regulation: An Overview' (10 February 2015) <https://trade.ec.europa.eu/doclib/docs/2015/february/tradoc_153121.pdf> accessed 20 April 2020.

²⁵² See below, section 2.3.4.

regulatory measure falling within this broad description.²⁵³ This applies to all the horizontal chapters, resulting in broad applicability of TTIP across policy areas.

Called ‘an innovative approach to international RC’, the EU’s RC proposals for the TTIP set out the scope, objectives, principles, and a model for enhanced cooperation across the Atlantic.²⁵⁴ The TTIP’s RC chapter included objectives and principles of RC and is supported by an institutional framework. The ratio behind the TTIP’s RC chapter was, as Alemanno explains, that ‘convergence upon procedures might induce to convergence upon regulatory outcomes’²⁵⁵ Jančić explains that RC in the TTIP focused on 1) increasing transparency of regulatory intentions and 2) encouraging ex ante policy analysis between EU and US regulatory authorities.²⁵⁶ The general idea behind the objectives and principles of RC in the TTIP and its supporting institutional framework was that the EU and US ought to be more transparent about planned regulatory actions. Essentially, the TTIP enabled an ongoing regulatory dialogue in which ex ante policy analysis would take place thus enabling deeper RC between the EU and the US.

Ultimately, the goal – in the words of the Commission – was moving towards ‘a more integrated transatlantic market where goods produced and services originating in one party in accordance with its regulatory requirements could be marketed in the other without adaptations or requirements.’²⁵⁷ In light of this goal, the TTIP’s RC was envisioned as a ‘living agreement’ consisting of an ongoing regulatory dialogue and exchanges between regulatory authorities.²⁵⁸

²⁵³ European Commission, *TTIP - EU proposal for Chapter: Regulatory Cooperation* (21 March 2016) <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf> accessed 14 May 2022, art. x3. The logical conclusion is that ‘purely domestic rules’ will not fall under the scope of either of the FTAs, Alemanno, ‘The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences’, 629.

²⁵⁴ Alemanno, ‘The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences’, 626; European Commission, *TTIP - EU proposal for Chapter: Regulatory Cooperation* (21 March 2016) <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf> accessed 14 May 2022.

²⁵⁵ Alemanno, ‘The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences’, 630.

²⁵⁶ Davor Jančić, ‘Democratic Legitimacy of Enhanced Regulatory Cooperation in TTIP’ in Luca Pantaleo, Wybe Douma and Tamara Takács (eds), *Tiptoeing to TTIP: What Kind Of Agreement for What Kind of Partnership?* (Centre for the Law of EU External Relations (CLEER) 2016), 20.

²⁵⁷ European Commission, *EU - US Transatlantic Trade and Investment Partnership: Trade Cross-cutting disciplines and Institutional provisions, Initial EU position Paper* (20 June 2013), 3, <http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151622.pdf> accessed 16 August 2019; Marise Cremona, ‘Negotiating the Transatlantic Trade and Investment Partnership (TTIP)’ (2015) 52 *Common Market Law Review* 351, 352.

²⁵⁸ Alemanno, ‘The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences’, 631; Wiener and Alemanno, ‘The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory’, 133; Cremona,

A living agreement indicates that the TTIP would have created an ongoing regulatory dialogue that develops over time and as such created the more integrated market the Commission envisioned. In other words, TTIP would set up procedural mechanism in the preparatory stages of regulation – i.e., the ongoing regulatory dialogue – to converge standards. TTIP’s regulatory dialogue would have been ongoing and as such, the agreement ‘lives’ in the sense that it continued to develop over time through the ongoing regulatory dialogue with the purpose of achieving a more integrated transatlantic market.²⁵⁹

Notably, RC through GRP is a common feature of RC models, acknowledged by the High-Level Regulatory Cooperation Forum as a way of enhancing EU-US RC, and thus also in the TTIP proposals.²⁶⁰ TTIP’s GRP – designed to promote good governance in the EU and US alike – related to ‘transparent planning, stakeholder consultation, impact assessments and retrospective evaluations of regulatory acts.’²⁶¹ Where GRP were first part of the RC chapter, the textual proposals of a later date establish a separate GRP chapter.²⁶² This implies that, whilst GRP are important to RC, they are important on their own and thus require a separate chapter – in line with the view on GRP in the WTO since GRP are of great importance in the setting of regulatory standards.²⁶³ An important question is why FTAs include GRP to enhance RC when governments across the globe generally abide by good governance principles? Essentially, GRP are included in RC models for the same reasons as in the WTO, i.e., to build trust and create a level-playing-field to engage in further RC.²⁶⁴ As in the TTIP, GRP in the RC models generally focus on transparency, stakeholder consultation and analytical tools such as IAs.²⁶⁵ RC through GRP is sort of a RC *light*: there is no cooperation as such but shared good governance principles

²⁵⁹ ‘Negotiating the Transatlantic Trade and Investment Partnership (TTIP)’, 352; Commission, *TTIP - EU proposal for Chapter: Regulatory Cooperation*, art. x2.

²⁵⁹ For more on living agreements, see chapter 4, section 4.2.1.

²⁶⁰ RC through GRP will be addressed throughout this chapter and in chapter 4.

²⁶¹ European Commission, *TTIP - EU proposal for Chapter: Good Regulatory Practices* (21 March 2016), art. 3. Also see, Christian Pitschas, ‘Transatlantic Trade and Investment Partnership (TTIP): The Devil in Disguise or a Golden Opportunity to Build a Transatlantic Marketplace?’ (2016) 5 *British Journal of American Legal Studies* 315, 331.

²⁶² Good Regulatory Practices was part of the Regulatory Cooperation chapter as section II in European Commission, *Initial Provisions for Chapter [] Regulatory Cooperation* (10 February 2015) <http://trade.ec.europa.eu/doclib/docs/2015/february/tradoc_153120.pdf> accessed 20 April 2020.

and European Commission, *TTIP - Initial Provisions for Chapter [] Regulatory Cooperation* (4 May 2015) <http://trade.ec.europa.eu/doclib/docs/2015/april/tradoc_153403.pdf> accessed 20 April 2020.

Now these chapters are separated into: Commission, *TTIP - EU proposal for Chapter: Regulatory Cooperation* <http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf> accessed 20 April 2020.

and Commission, *TTIP - EU proposal for Chapter: Good Regulatory Practices* <http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154380.pdf> accessed 20 April 2020.

²⁶³ See section 2.2.1.

²⁶⁴ See above, section 2.2.1.

²⁶⁵ See below, section 2.3.3 and section 2.4.

that regulatory measures should comply with which makes parties more likely to engage in RC. Additionally, insofar as GRP relate to transparency, there is another reason to include GRP in FTAs. Transparency, i.e., early notice of planned regulatory acts, enable the ongoing regulatory dialogue and thus functions as a prerequisite for RC.²⁶⁶ Moreover, as is argued in this research, transparency functions not only as a prerequisite for RC but also as a prerequisite for the throughput-legitimacy of RC.²⁶⁷ After all, notifying the other party of the FTA of planned regulatory measures allows a regulatory dialogue to take place on these planned measures and ultimately allows for participation and parliamentary oversight on the RC process.

Furthermore, as GRP in the TTIP focused on publishing major regulatory acts and their accompanying IAs ‘as early as possible’ there is also an obligation to consult stakeholders when preparing a regulatory measure.²⁶⁸ By including provisions, such as the TTIP GRP’s, requiring that parties ‘offer a reasonable opportunity for *any* natural or legal person, *on a non-discriminatory* basis, to provide input’, RC through GRP enables access to regulatory processes.²⁶⁹ Where transparency enables the regulatory dialogue (see above), stakeholder participation essentially guarantees that the EU and US (including, for example, respective civil society organisations and lobbying groups) would be allowed to provide input that ought to be considered on planned regulatory measures – thus guaranteeing access to their respective regulatory processes. TTIP’s GRP thus aimed to enhance transparency (in the sense of openness about planned regulatory measures) and enable input on planned regulatory measures between the EU and US to facilitate cooperation – which in view of the failing notification procedure under the WTO would be a good step towards increasing transparency on planned regulatory acts.²⁷⁰

On IAs specifically, the GRP chapter provides some guidelines – with a distinction made on major regulatory acts and non-major regulatory acts, which were to be defined by the EU and the US respectively.²⁷¹ Considering major regulatory acts undergoing an IA, the intent was to create an obligation to provide, as early as possible, information on the planning and timing

²⁶⁶ See above, section 2.2.1.

²⁶⁷ See chapter 3, section 3.4.1; chapter 4, section 4.2.2, and chapter 6.

²⁶⁸ European Commission, 'TTIP - EU proposal for Chapter: Good Regulatory Practices' 21 March 2016) <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154380.pdf> accessed 20 April 2020, art. 5, 6 and 7. Chapter 5 of this thesis elaborates more on stakeholder involvement to discuss the legitimacy (problems) of RC.

²⁶⁹ Emphasis added. European Commission, 'TTIP - EU proposal for Chapter: Good Regulatory Practices' 21 March 2016) <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154380.pdf> accessed 20 April 2020, art. 6; see chapter 5, section 5.3.2.

²⁷⁰ See section 2.2.1.

²⁷¹ European Commission, 'TTIP - EU proposal for Chapter: Good Regulatory Practices' 21 March 2016) <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154380.pdf> accessed 20 April 2020, art. 5.1.

until the adoption of the act and stakeholder consultations, potential for significant impact on trade, investment and on small and medium sized enterprises.²⁷² Thus, in case of major regulatory acts accompanied by an IA, there would be an exchange of information in the ongoing regulatory dialogue. In any case, both parties affirm the ‘intention to carry out, in accordance with its respective rules and procedures, a regulatory IA for planned regulatory acts’ and publish the findings ‘no later than the proposed or final regulatory act.’²⁷³ These regulatory IAs ought to assess the need to regulate, address the nature and significance of the problem, examine alternatives – including an option not to regulate at all – as well as assess the impacts of alternatives.²⁷⁴ Furthermore, in the regulatory IA, the regulatory authority has to assess the relation to ‘relevant internationally agreed regulatory documents’, its impact on international trade and investment but also take account of the regulatory approaches of each other ‘when the other Party has adopted or is planning to adopt regulatory acts on the same matter.’²⁷⁵ With regard to the content of the IAs, the EU and US ‘shall promote the exchange of information on available relevant evidence and data, on their practices in assessing impacts on international trade or investment, as well as on the methodology and economic assumptions applied in regulatory policy analysis.’²⁷⁶ Thus, planned regulatory acts would have to be accompanied by a regulatory IA and an exchange of information should be promoted, specifically on evidence, data and the methodology and economic assumptions used in the IA.

Moreover, TTIP’s GRP chapter adds the possibility of ex post evaluations.²⁷⁷ Jancic calls this the ‘principle of mutual awareness’, which is a good way to summarise RC in the TTIP.²⁷⁸ Essentially, the idea is that mutual awareness reduces disputes as TTIP’s RC and GRP proposals result in an ongoing regulatory dialogue including a discussion on IAs and the methodologies and assumptions used in these assessments.²⁷⁹ RC in the TTIP would thus consist of an ongoing regulatory dialogue in which early notice of planned regulatory acts enables an exchange of

²⁷² European Commission, 'TTIP - EU proposal for Chapter: Good Regulatory Practices' 21 March 2016) <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154380.pdf> accessed 20 April 2020, art. 5.

²⁷³ Ibid, art. 8.

²⁷⁴ Ibid, art. 8.2

²⁷⁵ Ibid, art. 8.4.

²⁷⁶ Ibid, art. 8.6

²⁷⁷ Ibid, art. 9. Also see, Jančić, 'Democratic Legitimacy of Enhanced Regulatory Cooperation in TTIP', 21.

²⁷⁸ Jančić, 'Democratic Legitimacy of Enhanced Regulatory Cooperation in TTIP', 21.

²⁷⁹ As Jancic further argues, this is reminiscent of the Better Regulation Agenda of the EU, *ibid*, 21. The parallels between the TTIP and the EU’s Better Regulation Agenda are interesting but beyond the scope of this thesis to address further.

information (including on IAs) to ‘aim at achieving common or compatible regulatory measures.’²⁸⁰

2.3.4 Proposed regulatory cooperation in the sectoral chapters of the TTIP

The proposals for the sectoral chapters of the TTIP include provisions on RC, most prominently in the chapters on TBT and SPS measures respectively.

The TTIP’s TBT chapter aimed at achieving RC. The TBT chapter obligated (*shall*) the EU and US to strengthen their cooperation on TBT measures through the RC chapter – which is peculiar considering that RC is presented as voluntary.²⁸¹ Furthermore, the TTIP chapter on TBT measures stated that the EU and US would cooperate ‘as far as possible’ to ensure compatibility of TBT regulations.²⁸² In light of that, the TBT chapter decided that parties must endeavour to ensure that products that are subject to technical regulations can be marketed in EU and US on the basis of a single authorization, approval or certificate of conformity, indicating cooperation on conformity assessment procedures.²⁸³ The main objective of the TBT chapter was to promote convergence in regulatory approaches through reducing or eliminating conflicting technical requirements and ‘redundant and burdensome’ conformity assessment requirements.²⁸⁴ The TBT chapter also aimed to allow, in principle, comments in writing in proposed technical regulations or conformity assessment procedures – which then ought to be discussed – resulting in an exchange of information.²⁸⁵ With the TBT chapter of the TTIP, the EU and the US intended to exchange information on the relevant data used in the preparation of the technical regulation and discuss, on request, possibilities of harmonised or compatible technical regulations.²⁸⁶

The TTIPs TBT chapter incorporated the WTO’s TBT Agreement and was essentially a WTO+ chapter. The EU and US thus decided to cooperate towards global harmonisation relating to TBT measures in the framework of international agreements or organisations (e.g., in the WTO).²⁸⁷ Moreover, to promote convergence and reduce or eliminate conflicting technical requirements, a notification procedure is necessary. To this end, the TBT chapter of the TTIP

²⁸⁰ More on IAs in RC in chapter 4. Commission, *TTIP - EU proposal for Chapter: Regulatory Cooperation* <http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf> accessed 20 April 2020, art. x4.

²⁸¹ See section 5.2.4.

²⁸² European Commission, *TTIP – EU proposal for Technical Barriers to Trade in TTIP*, 7 January 2015 <https://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153025.pdf> accessed 22 October 2020, art. 4.

²⁸³ *Ibid.*, art. 4(4).

²⁸⁴ *Ibid.*, art. 1.

²⁸⁵ *Ibid.*, art. 5(1).

²⁸⁶ *Ibid.*, art. 4(2).

²⁸⁷ *Ibid.*, art. 2, art. 4(3).

aimed to enhance (through a transparency provision), the WTO notification procedure regarding technical regulations and conformity assessment procedures.²⁸⁸ The TBT chapter states: ‘the parties agree to notify (...)’, thus enforcing the notification procedure under the WTO.²⁸⁹ This notification procedure enhances the notification procedure of the WTO.²⁹⁰

The SPS chapter of the TTIP was similarly a WTO+ chapter – albeit more modest than the TBT chapter. To facilitate trade whilst preserving the right to protect human animal or plant life and health and respecting regulatory systems, risk assessment, risk management and policy development processes, the SPS chapter was to improve communication and cooperation, consistency, predictability, and transparency of SPS measures.²⁹¹ The SPS chapter also aimed to provide a framework for dialogue and cooperation in view of the protection of welfare of animals and to reach a common understanding regarding animal welfare standards.²⁹² In general, the SPS chapter aimed to obligate the EU and the US to establish SPS procedures with the objective to minimise negative trade effects.²⁹³ To this end – i.e., to facilitate trade – the SPS chapter relied on making information available as the EU and US would ‘endeavour to exchange information’.²⁹⁴ Essentially, the SPS chapter focuses on facilitating trade and exchanging information in non-obligatory terms.

2.3.5 *The institutional framework of the TTIP*

Considering its goals, the TTIP was to create an institutional framework.²⁹⁵ In other words, the objectives, and principles of the TTIP were supported by an institutional framework that would have been created by the FTA. To support the principles and objectives of RC under the TTIP, a Joint Committee (JC) – TTIP’s overarching body – and various committees would have been created. Relating to RC specifically, the TTIP created the Transatlantic Regulators’ Forum (the Forum).

²⁸⁸ Ibid, art. 5.

²⁸⁹ European Commission, TTIP – *EU proposal for Technical Barriers to Trade in TTIP*, 7 January 2015 <https://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153025.pdf> accessed 22 October 2020, art. 5.

²⁹⁰ Ibid, art. 5(1).

²⁹¹ European Commission, TTIP – *EU proposal for Sanitary and Phytosanitary Measures in TTIP*, 7 January 2015 <https://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153026.pdf> accessed 22 October 2020, art. 2.

²⁹² Ibid, art. 2(7).

²⁹³ Ibid, art. 7(1).

²⁹⁴ Ibid, art. 7, art. 14.

²⁹⁵ Alemanno, 'The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences', 629.

TTIP's JC would consist of representatives of the EU and the US, co-chaired by the US Trade Representative and the EU's Trade Commissioner.²⁹⁶ The JC was envisioned to be the overarching body, supervising, and facilitating the implementation and application of the agreement. The JC was given specific duties as to 'guide and facilitate the implementation and application of RC', consider ways to further enhance RC and 'have a dedicated session on RC at its meeting, at least once a year'.²⁹⁷ The JC would review the overall process of RC every three years, suggest improvement where needed and present the results of this review results at the EU-US summit.²⁹⁸

The JC may also makes recommendations on RC, including to the Forum.²⁹⁹ This Forum replaces the previously established RC Body (RCB), 'implying a more casual and informal institution', as Garcia argued.³⁰⁰ The RCB was faced with criticism in that 'it will circumvent parliaments, governments or stakeholders' roles in the regulatory process'.³⁰¹ Whilst it has been argued by Garcia and Fahey that the role of Forum and the RCB do not differ as much as presented by the Commission, the textual proposals imply a downgrade of the significance of the RCB.³⁰² Seeking to evolve the RCB 'into a mere institutional mechanism', as Fahey puts it, the TTIP's institutional framework emphasised on supporting the ongoing regulatory dialogue through 'learning processes and exchanges', however, in a strictly formalistic approach, institutionalisation in TTIP became significantly weaker by 2016.³⁰³

The difference between the RCB and the Forum was that the tasks of the Forum were rather limited compared to the RCB. The Forum would discuss general trends in RC; consider RC activities covered by TTIP; prepare a joint overview of RC and; organise public sessions

²⁹⁶ European Commission, *EU Proposal for Institutional, General and Final Provisions* (14 July 2016) <https://trade.ec.europa.eu/doclib/docs/2016/july/tradoc_154802.pdf> accessed 22 October 2020, art. x1.1 and art. x.1.3.

²⁹⁷ *ibid.*, art. x1.4 and art. x.1.5.b.

²⁹⁸ *ibid.*, art. x1.4.

²⁹⁹ *ibid.*, art. x1.6. d., art. x2 establishes the Transatlantic Regulators' Forum.

³⁰⁰ Garcia, 'Building Global Governance One Treaty at a Time? A Comparison of the US and EU Approaches to Preferential Trade Agreements and the Challenge of TTIP', 232.

³⁰¹ European Commission, *Factsheet on Regulatory cooperation* (January 2015) <https://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153002.1%20RegCo.pdf> accessed 22 October 2020, 2.

³⁰² Garcia, 'Building Global Governance One Treaty at a Time? A Comparison of the US and EU Approaches to Preferential Trade Agreements and the Challenge of TTIP', 232; also see, Elaine Fahey, 'Introduction: Institutionalisation beyond the Nation State: New Paradigms? Transatlantic Relations: Data, Privacy and Trade Law' in Elaine Fahey (ed), *Institutionalisation beyond the Nation State: Transatlantic Relations: Data, Privacy and Trade Law* (Springer Law 2018), 12.

³⁰³ Fahey, 'Introduction: Institutionalisation beyond the Nation State: New Paradigms? Transatlantic Relations: Data, Privacy and Trade Law', 12.

involving EU and US stakeholders.³⁰⁴ Whilst it was unclear who would participate in the RCB, the Forum would be composed of senior officials.³⁰⁵ The RCB had a much broader task list as it would have monitored and facilitated the implementation of RC in the TTIP and reported its findings through various tasks such as; preparing an Annual RC Programme; considering new initiatives for RC; preparing joint initiatives; ensuring transparency, with the power to create sectoral working groups.³⁰⁶ This affirms that from a textual point of view, the Forum is significantly weaker than the RCB. However, the JC now has powers the RCB used to have, which changes practically nothing in the bigger picture of RC in the TTIP.

Generally, TTIP built on past experiences in RC and attempted to improve – or ‘turbo-charge’ – previous EU-US RC efforts.³⁰⁷ EU-US RC is characterised by efforts to create an ongoing, structured dialogue between the respective regulators. So far, due to changes in the political landscape, the envisioned structured dialogue has not been established – and with current political developments most likely will not be for years to come. However, EU-US RC mechanisms have changed over the years. Starting out with dialogues and summits, RC has shifted towards cooperating on regulatory procedures.³⁰⁸ This shift is accompanied by a shift in invasiveness of RC mechanisms. Dialogues and/or summits are political gestures to cooperate but engaging in cooperation prior to the adoption of a draft regulatory measure is potentially far more invasive. By doing so, governments are inviting foreign governments into regulatory procedures when drafting proposals. It is logical that – whilst many economic scholars agree the TTIP will have economic benefits for consumers – TTIP negotiations were faced with immense criticism from NGO’s, academics, civil society, and social movements from both the EU and US.³⁰⁹

³⁰⁴ European Commission, *EU Proposal for Institutional, General and Final Provisions* <https://trade.ec.europa.eu/doclib/docs/2016/july/tradoc_154802.pdf> accessed 22 October 2020, art. X.2.2.

³⁰⁵ Senior officials responsible for cross-cutting issues of regulatory policy and good regulatory practices, senior officials responsible for international trade, and senior regulators for the areas they are responsible for, *ibid.*, art. X.2.1.

³⁰⁶ European Commission, *TTIP - Initial Provisions for Chapter [] Regulatory Cooperation, 4 May 2015* <http://trade.ec.europa.eu/doclib/docs/2015/april/tradoc_153403.pdf> (4 May 2015) accessed 22 October 2020, art. 14; also see European Commission, *TTIP and Regulation: An Overview, 10 February 2015* <https://trade.ec.europa.eu/doclib/docs/2015/february/tradoc_153121.pdf> (10 February 2015), accessed 22 October 2020.

³⁰⁷ E.g., Chase and Pelkmans, 'This time it's different: Turbo-charging regulatory cooperation in TTIP'.

³⁰⁸ See chapter 2, section 2.3.2.

³⁰⁹ E.g., Latorre and Yonezawa, 'Stopped TTIP? Its potential impact on the world and the role of neglected FDI'; Haar, *Cooperating to deregulate*; De Ville and Siles-Brügge, *TTIP: The Truth about the Transatlantic Trade and Investment Partnership*; De Ville and Siles-Brügge, 'Why TTIP is a game-changer and its critics have a point'.

Essentially, RC in the TTIP was envisioned as an ongoing regulatory dialogue between the EU and US in areas where the EU and US determined common interest and where there was (an expected) impact on trade. By agreeing to inform each other ‘at the earliest possible stage’ when there would be or likely would be an impact on trade, in practice the EU would ‘provide cooperation opportunities before the Commission adopts a formal position’ and the ‘US regulatory agencies shall provide cooperation opportunities before the launch of the (advanced) notice of proposed rulemaking or in a timely manner before adopting or consulting on a guidance document.’³¹⁰ As a footnote in the EU proposal stated that ‘such cooperation opportunities do not imply any commitment to share draft texts before they have been made public under the respective regulatory or administrative procedures’, the question remains when exactly this should take place?³¹¹ For now, reassurances found in TTIP are that RC is intended to improve – ‘and not reduce’ – the level of protection in policy areas such as human health, that RC does not oblige a particular outcome and that TTIP will not ‘affect the ability of each Party to adopt, maintain and apply measures without delay, in accordance with deadlines under its respective regulatory or administrative procedures, to achieve its public policy objectives (...) in accordance with its regulatory framework and principles.’³¹² Furthermore, the Commission has made the promise that TTIP ‘will not change the principles and the procedures set out in the EU treaties defining how our regulations should be made.’³¹³ Assurances were thus made by including the right to regulate in the proposed FTA, but establishing an ongoing regulatory dialogue such as envisioned in the TTIP nonetheless brings forward many questions.

An important question in relation to the TTIP, but also to RC in a broader perspective, is what the TTIP would have changed? And as Meuwese rightfully asked, ‘should the regulatory coherence chapter in TTIP be adopted, who will exercise what degree of influence over substantive regulatory outcomes?’³¹⁴ Moreover, as Meuwese further argues, why did the EU and US bother with a chapter on RC, consisting of joint principles and procedures to achieve RC, if there is no effect on rulemaking? Meuwese continues that the TTIP ‘would not bother with an entire chapter on regulatory coherence, which consists of joint principles and procedures for cooperation, if the provisions were not expected to have effects on rulemaking

³¹⁰ Commission, *TTIP - EU proposal for Chapter: Regulatory Cooperation* <http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf> accessed 20 April 2020, art. x4.

³¹¹ *ibid.* art. x.4 footnote. More on this in chapter 5.

³¹² *ibid.*, art. x1.

³¹³ European Commission, *TTIP and Regulation: An Overview, 10 February 2015* <https://trade.ec.europa.eu/doclib/docs/2015/february/tradoc_153121.pdf> (10 February 2015), accessed 22 October 2020, 7.

³¹⁴ Meuwese, ‘Constitutional Aspects of Regulatory Cooperation in TTIP: An EU Perspective’, 157.

or lawmaking, on both sides of the Atlantic.³¹⁵ And Meuwese is correct in questioning and addressing this. Should the RC chapter in the TTIP result in say, the Commission giving the US the possibility to comment on draft proposals before being adopted by the College of Commissioners, and thus prolonging the democratic debate in Parliament or Council, the level of democratic accountability in the EU might reach a new low.³¹⁶ An ongoing regulatory dialogue through RC as envisioned in the TTIP brings about many questions that need to be addressed – which explains why there was so much public opposition to the TTIP during its negotiations.

Nonetheless, the process of RC could also be viewed, as Cremona puts it ‘as a collaborative effort, aimed at a greater mutual understanding of different regulatory approaches.’³¹⁷ According to Alemanno, TTIP ‘is set to create the conditions for prompting a new awareness in the minds of the respective regulators: that of the extraterritorial impact of their existing and proposed regulations.’³¹⁸ This rings true, as the purpose of TTIP is to raise mutual awareness of planned regulatory action and the data supporting this action (e.g. IAs). The TTIP aims to enhance mutual awareness by setting up an ongoing regulatory dialogue regarding regulatory actions and through this, cooperation can be achieved and at the very least, disputes can be prevented. It is, however, important to recognise that creating such an ongoing dialogue result in a procedural mechanism considered during the preparatory stages of regulations. Whilst the TTIP does not obligate RC as such, the result of an FTA such as TTIP is that – at the least – there is some political pressure to engage in the dialogue before deciding on regulatory action. Whilst this is not a bad thing inherently, and extraterritorial awareness is important considering the global challenges faced today, democratic checks and balances on this dialogue are hard to find but are crucial. The other RC models face the same issues briefly touched on here.³¹⁹

2.4 Regulatory cooperation models in recent Free Trade Agreements

The CETA is generally regarded as a possible blueprint for future trade deals.³²⁰ The analyses in this thesis illustrate that CETA is the most far-reaching of the RC models. And since the CETA is regarded as a blueprint, this means that in future endeavours, RC might become more

³¹⁵ *ibid*, 155, 156.

³¹⁶ See chapter 5.

³¹⁷ Cremona, 'Negotiating the Transatlantic Trade and Investment Partnership (TTIP)', 353.

³¹⁸ Alemanno, 'The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences', 631.

³¹⁹ See chapter 5.

³²⁰ E.g., Chase and Pelkmans, 'This time it's different: Turbo-charging regulatory cooperation in TTIP', 22; Hoekman, 'Fostering Transatlantic Regulatory Cooperation and Gradual Multilateralization', 613; Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power', 368.

important and far-reaching. The USMCA, on the other hand, is a prime example of RC from the other side of the Atlantic – not only in signatories but also in its approach. The TCA, then, is a RC model characterised by a difficult political situation – which is reflected in its approach to RC. To assess the common characteristics of RC in chapter 4, this section analyses these RC models starting with the CETA.³²¹

2.4.1 *Regulatory cooperation in CETA*

Building on an existing agreement between the EU and Canada, the CETA's RC is to provide 'a platform to facilitate cooperation between regulatory authorities, with the objective of achieving better quality of regulation and more efficient use of administrative resources.'³²² RC in the CETA is said to be voluntary and regulators in the EU and Canada maintain the power to adopt legislation as they see fit.³²³ It is important, however, to realise that outcomes of RC in the CETA – whether by decisions taken in its context or by the processes RC adheres to – may have substantive legal effects in both the EU and Canada, as Mendes explains.³²⁴ To facilitate trade, investment and contribute to improving competitiveness, RC in the CETA encourages regulators to exchange experiences, information and to identify areas where they could cooperate.³²⁵

The CETA is, as in its very name, a comprehensive trade agreement containing thirty chapters and numerous annexes. The RC chapter is the twenty-first chapter of the Agreement, following its more classic chapters on goods, services, intellectual property, investment, and other issues that affect trade. As in the TTIP, RC in the CETA takes places two folded: on the one hand, an institutional framework is put in place to implement RC in the CETA and on the other hand, RC is achieved through objectives and mechanisms. Proposed RC in the TTIP takes place along the same lines as in the CETA. In contrast to the TTIP negotiations, however, the adoption of the CETA went by relatively unnoticed aside from the Belgian Walloon region and Italy

³²¹ See chapter 4.

³²² The Framework on Regulatory Co-operation and Transparency between the Government of Canada and the European Commission, done at Brussels on 21 December 2004. *Joint Interpretative Instrument on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union and its Member States (OJ L 11, 14.1.2017)*, 3; CETA, art. 21.2.5.

³²³ With regulators it is meant the responsible regulatory departments and agencies, consulted and coordinated by the Canadian Technical Barriers and Regulations Divisions of the Department of Foreign Affairs, Trade and Development and the EU's International Affairs Unit of the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs respectively, ex art. 21.9 CETA. More on the voluntary nature of RC in 5.2.2.

³²⁴ Mendes, 'The External Administrative Layer of EU Law-making: international Decisions in EU Law and the Case of CETA', 490.

³²⁵ In accordance with the TBT Agreement, SPS Agreement and both GATT 1994 and the GATS, CETA commits, when doing so, to ensuring high levels of protection for human, animal and plant life or health and the environment ex CETA, art. 21.2.

threatening not to ratify the CETA.³²⁶ To assess RC under the CETA, firstly the objectives and activities (i.e., mechanisms of RC) are analysed, secondly RC in the sectoral chapters of the CETA are examined and lastly, an analysis of the institutional framework as set up by the CETA follows.

2.4.1.1 Objectives and activities of regulatory cooperation in the CETA

The objectives of RC in art. 21.3 CETA give the impression that the EU and Canada dedicate themselves to, by means of RC, finding best practices and learning from each other to ideally achieve some sort of harmonisation in their regulations or work towards uniform regulatory standards. Canada and the EU intent to share their resources and knowledge to address regulatory issues, build a common base of information used by regulatory departments for matters of risk identification, assessment and management.³²⁷ By obtaining each other's expertise and perspectives – including the use of best practices – avoiding unnecessary regulatory difference, identifying alternative instruments, improving planning, development, implementation, compliance and promoting transparency and predictability in developing and establishing regulations, the EU and Canada are working to 'deepen mutual understanding of regulatory governance.'³²⁸

To facilitate trade, investment and contribute to improving competitiveness, RC in the CETA aims at reducing unnecessary differences in regulation and generally pursues compatibility in regulatory approaches.³²⁹ Even though provisions in the CETA address the protection of for example, the environment, RC is ultimately aimed towards the facilitation of trade, investment and converging regulatory policies.³³⁰ The 'promotion of convergence' is explicitly mentioned in article 21.3 in relation to contributing to the improvement of competitiveness and efficiency of industry, however the entire article dealing with the objectives of RC suggests that the CETA aims at converging regulatory standards.³³¹ Through mechanisms such as equivalence of regulations, mutual recognition, and the use of international standards the CETA moves towards the harmonisation of regulatory standards.³³² And whilst the CETA does not obligate regulatory

³²⁶ It is argued that 'public opposition to CETA has piggybacked upon TTIP opposition', Fahey, 'CETA and Global Governance Law: What Kind of Model Agreement Is It Really in Law?' , 301.

³²⁷ CETA, art. 21.3 (a).

³²⁸ CETA, art. 21.3 (b).

³²⁹ CETA, art. 21.3 (c) and (d.iii).

³³⁰ See, Nils Meyer-Ohlendorf, Christiane Gerstetter and Inga Bach, *Regulatory Cooperation under CETA: Implications for Environmental Policies*, 2016)

³³¹ See, for example, CETA, art. 21.4(f)(i) and 21.4(g).

³³² CETA, articles 21.2.4, 21.3d, 21.4g and 21.4r; also see, O'Brien, 'Moving Regulation out of Democratic Reach: Regulatory Cooperation in CETA and its Implications', 5.

authorities to cooperate or to apply the outcome of cooperation efforts, RC in the CETA is not as voluntary as may seem at first hand as it dictates parties to either cooperate or explain resulting in political pressure to engage in RC or, at a minimum, explain why either party decides not to explain.³³³

The CETA provides a long non-exhaustive list of activities that RC *may* include.³³⁴ To establish an ongoing regulatory dialogue, the EU and Canada engage in continuing bilateral discussions on regulatory governance, including on – but not limited to – regulatory reforms and its effect; lessons learned; exploring alternatives approaches to regulation and; exchanging experiences with regulatory tools and instruments, including regulatory IAs, RA and compliance and enforcement strategies.³³⁵ Providing endless activities to achieve RC, the CETA goes beyond cooperation and towards convergence of regulatory standards and procedures: the EU and Canada will inform and consult each other throughout the regulatory process – preferably as early as possible – to consider measures of the other party with the aim to avoid the adoption of conflicting regulations and thus ultimately to work towards convergence to facilitate trade and investment.

Interestingly, as opposed to the TTIP, the CETA does not have a separate GRP chapter but includes GRP on, for example, IAs and stakeholder consultations in the RC chapter. On IAs specifically there is an exchange of information but CETA also provides the possibility to conduct joint IA as well as joint RA ‘if practicable and mutually beneficial’.³³⁶ Transparency in the CETA has its own chapter (Chapter 27 of the CETA), but similarly enables an ongoing regulatory dialogue by stating in art. 27.1 that ‘laws, regulations, procedures and administrative rulings of general application respecting any matter covered by this Agreement are promptly published or made available in such a manner as to enable interested persons and the other Party to

³³³ See section 5.2.4; CETA, art. 21.2.6 reads: The Parties may undertake RC activities on a voluntary basis. For greater certainty, a Party is not required to enter into any particular RC activity, and may refuse to cooperate or may withdraw from cooperation. However, if a Party refuses to initiate RC or withdraws from cooperation, it should be prepared to explain the reasons for its decision to the other Party. Also see, *Joint Interpretative Instrument on the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union and its Member States (OJ L 11, 14.1.2017)*, 3; Regulatory cooperation in CETA: Exporting the NAFTA model or something more? By Stuart Trew and Max Plank. Presented at CETA Implementation Workshop, May 18, 2018, at <<https://ciipda.ca/wp-content/uploads/2019/01/Trew.pdf>> accessed 16 August 2019.

³³⁴ CETA, art. 21.4.

³³⁵ CETA, art. 21.4 (a). Other activities of RC include, amongst others; sharing non-public information; sharing – proposed – regulations to allow sufficient time for interested parties to provide comments; exchange information regarding contemplated regulatory actions, measures or amendments at the earliest stage possible; assessing opportunities to minimise regulatory divergence; examining possibilities on using the same methodologies and data and; conduction cooperative research agendas to possibly establish a common scientific basis.

³³⁶ CETA, art. 21.4(f)(ii).

become acquainted with them'. Thus, whilst GRP are not in a separate chapter, they are included in the CETA and similarly enable RC as seen in the TTIP.³³⁷

2.4.1.2 Regulatory cooperation in the sectoral chapters of the CETA

The sectoral chapters of the CETA contain several other references to RC. In the TBT chapter specifically, the CETA establishes an obligation – ‘Parties shall’ – to strengthen RC as set out in the chapter on RC, particularly by promoting Mutual Recognition Agreements.³³⁸ So whilst RC is presented as voluntary, the TBT chapter then establishes an obligation to strengthen such RC – similar to the intentions of the TBT chapter of the TTIP.³³⁹ This means that under the TBT chapter, strengthening cooperation is obligatory – though unclear how this should be done exactly. On TBT measures, another way to achieve compatibility is by requesting a recognition of equivalence when there is a compatible objective and product scope.³⁴⁰ This way of achieving compatibility presumes the use of RC or, in other words, that the EU and Canada keep each other up to date about planned technical regulations.³⁴¹ Interestingly so, the RC activities are non-obligatory by nature but the sectoral chapter on TBT measures assumes RC activities mentioned in the RC chapter will indeed take place.

The SPS Chapter further implements the SPS Agreement.³⁴² The WTO’s notification procedure is enhanced – and made obligatory in certain pressing situations.³⁴³ In other – non-pressing – situations, the exchange of information is ‘endeavoured’ if not done under the WTO notification procedure. These chapters clearly build on the WTO Agreement. Furthermore, RC is specifically mentioned in case of car safety regulations. RC on car safety regulation is limited to ‘endeavouring’ to maintain an open and ongoing dialogue; meeting annually; sharing information; encouraging and promoting greater international harmonisation; share and discuss research; conduct joint analyses and develop additional provisions for cooperation.³⁴⁴

³³⁷ See above, section 2.3.3.

³³⁸ ‘This may include promoting and encouraging cooperation between the Parties’ respective public or private organisations responsible for metrology, standardisation, testing, certification and accreditation, market surveillance or monitoring and enforcement activities; and, in particular, encouraging their accreditation and conformity assessment bodies to participate in cooperation arrangements that promote the acceptance of conformity assessment results’ ex CETA, art 4.3.

³³⁹ See section 2.3.4; also see chapter 5 section 5.2.4.

³⁴⁰ CETA, art 4.4.2.

³⁴¹ CETA, art. 21.4 (d) indeed mentions this as a possible RC activity ‘sharing proposed technical or sanitary and phytosanitary regulations that may have an impact on trade with the other Party at the earliest stage possible so that comments and proposals for amendments may be taken into account.’

³⁴² CETA, art. 5.2.

³⁴³ CETA, art. 5.10

³⁴⁴ CETA Annex 4-A, art. 3. Interestingly, this mutual interest to cooperate with the US in this field is expressed, stating: ‘if the European Union and the United States conclude an agreement or an arrangement on the

Essentially, the SPS chapter of the CETA is a WTO+ chapter most notably by enhancing the WTO's notification procedure.

2.4.1.3 *The institutional framework of the CETA*

Similar to the TTIP, the CETA creates an institutional framework to supervise and facilitate the implementation and application of the agreement, attempting to create a 'living agreement'.³⁴⁵ Decision-making in CETA is reserved to the JC, having 'the power to make decisions in respect of all matters when this Agreement so provides', by mutual consent, with the purpose of attaining the objectives of the CETA.³⁴⁶ The JC's decisions are binding on the Parties alongside an obligation to implement decisions made by the JC – assuring legal effect in both legal systems.³⁴⁷ Furthermore, the JC has been given general oversight powers as it shall 'supervise the work of all specialised committees and other bodies established under this Agreement.'³⁴⁸

Aside from the JC, the CETA sets up specialised committees, required to report to the JC, as established in their distinctive articles, and able to develop recommendations to submit them to the JC for decision.³⁴⁹ The tasks and remit of these committees are defined in their relevant chapters and protocols.³⁵⁰ Specialised committees must inform the JC of their meetings and report the results and conclusions from these meetings.³⁵¹ Despite their existence, Parties can

harmonisation of their respective technical regulations related to motor vehicles, the Parties shall cooperate with a view to determining whether they should conclude a similar agreement or arrangement, ex art. 6 Annex 4 -A CETA.

³⁴⁵ Art. 26.1.4.a. CETA; see above section 2.3.3; also see, Alemanno, 'The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences', 631; Wiener and Alemanno, 'The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory', 133; Cremona, 'Negotiating the Transatlantic Trade and Investment Partnership (TTIP)', 352.

³⁴⁶ CETA, art. 26.3.

³⁴⁷ CETA, art. 26.3.2; the JC also has several discretionary powers ex art. 26.3.2, 26.1.5. CETA.

³⁴⁸ CETA, art. 26.1.4. A first glance on how the JC works was given at its inaugural meeting on the 26th of September, 2018, when it formally adopted its first three recommendations, co-chaired by the Canadian Minister for International Trade Diversification, James Carr, and the European Commissioner for Trade, Cecilia Malmström. See the meeting report <<https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/committees-comites.aspx?lang=eng>> accessed on 15 August 2019. Interestingly, the recommendations are said to be adopted by the JC but the rules of procedure are adopted by the co-chairs, i.e., the Canadian Minister for International Trade Diversification and the EU Trade Commissioner. The recommendations are plausibly an outcome of the JC. Instead, the rules of procedures are adopted by the co-chairs; as they have not been delegated this power explicitly in the CETA agreement, maybe it is implicit that an international agreement like CETA can be further administratively implemented by the respective ministers authorised to sign the agreement. This would be odd, but beyond the scope of this paper to assess further.

³⁴⁹ CETA, art. 26.2.

³⁵⁰ CETA, art. 26.2.3.

³⁵¹ CETA, art. 26.3.6.

still bring any matter directly to the JC.³⁵² The specialised committees in the CETA can propose draft decisions to the JC or, when provided by the CETA, take decisions.³⁵³

One of the CETA's specialised committees is the RC Forum (RCF), set up to facilitate and promote RC.³⁵⁴ The RCF reports 'as appropriate' to the JC on the implementation of the RC chapter.³⁵⁵ The functions of the RCF are to: a) provide a forum to discuss regulatory policy issues; b) assist individual regulators to identify potential partners for cooperation activities; c) review regulatory initiatives, whether in progress or anticipated, that may provide potential for cooperation; d) encourage the development of bilateral cooperation activities in accordance with the RC activities and review the progress, achievements and best practices of RC initiatives in specific sectors.³⁵⁶ Furthermore, in accordance with these functions of the Forum, article 21.7 makes way for further RC: to enable monitoring of upcoming regulatory projects and to identify opportunities for RC, the EU and Canada will periodically exchange information of ongoing or planned regulatory projects in their areas of responsibility.³⁵⁷

The impact of the RCF is extremely hard to predict however, it has been argued by Meyer-Ohlendorf et al that – due to the technical nature of RC – the discussions in the RCF may 'de-facto predetermine the JC's decision-making and shape the regulatory agendas of the Parties.'³⁵⁸ This remains to be seen, but it could also go in another direction. The CETA sets up the RCF to provide information to the JC and to provide a (literal) forum to discuss RC activities and possibilities to cooperate. Whilst the JC expectedly benefits from the information given by the RCF, the JC is the overarching and thus most powerful body of the CETA. This means that the JC is the highest level of the institutionalisation as created by the CETA and it seems doubtful that such a body would let its decisions be dictated by a specialised committee – although surely a part of the JC's information will come from the RCF. Nonetheless, it is hard

³⁵² CETA, art. 26.3.6.

³⁵³ CETA, art. 26.2.4.

³⁵⁴ CETA, art. 21.6 and 26.2.h. CETA. The RCF is co-chaired by a senior representative of the Government of Canada at the level of a Deputy Minister and a senior representative of the European Commission at the level of a Director General and further comprised of officials of the EU and Canada respectively. Other parties may – by mutual consent – be invited to participate in the RCF meetings ex CETA, art. 21.6.3. The RCF meets annually and will adopt a term of reference, procedure and work-plan at the first meeting after CETA enters into force, CETA, art. 21.6.4 a & b.

³⁵⁵ CETA, art. 21.6.4.c.

³⁵⁶ CETA, art. 21.6.2.

³⁵⁷ CETA, art. 21.7.1. CETA. On non-food product safety specifically, the EU and Canada will attempt to cooperate and voluntarily share information, particularly relating to, amongst others, scientific, technical, and regulatory matters, to help improve non-food product safety and risk assessment methods and product testing, CETA, art. 21.7.3.

³⁵⁸ Meyer-Ohlendorf, Gerstetter and Bach, *Regulatory Cooperation under CETA: Implications for Environmental Policies*, 5.

to predict how this will work out in future RC endeavours but overall, it is safe to say that the RCF will influence the decisions made in the JC.

Since the CETA is (provisionally) in effect, Canada and the EU are working to identify issues of mutual interest and in line with article 21.8 CETA on stakeholder involvement and called for stakeholder to share their views prior to the inaugural meeting of the RCF.³⁵⁹ RC in practice in the CETA is analysed extensively in chapter 3, section 3.4.1.5. Generally, RC under CETA's RCF is taking place in several areas, varying from the exchange of information to increasing regulatory harmonisation and mutual recognition.³⁶⁰ Most notably, the transparency of the RCF's work is refreshing as the RCF has dedicated itself to post online agendas, work plans and reports, in response to the great level of public interest shown in the RCF, to promote transparency and facilitate consultations with stakeholders.³⁶¹ RC in the CETA is an exchange of information in the sense of a discussion taking place on how to increase cooperation or harmonisation of regulatory standards with a view on facilitating trade.

2.4.2 Regulatory cooperation in the USMCA

The second RC model analysed in this thesis is the USMCA. The USMCA defines RC as 'an effort between two or more Parties to prevent, reduce, or eliminate unnecessary regulatory differences to facilitate trade and promote economic growth, while maintaining or enhancing standards of public health and safety and environmental protection.'³⁶² RC in the USMCA thus mainly focuses on deregulating for the sake of international trade by preventing, reducing, or eliminating unnecessary regulatory differences. The USMCA recognizes that GRP can facilitate trade 'while contributing to each Party's ability to achieve its public policy objectives.'³⁶³ The GRP chapter is obligatory – whilst the RC provision in the GRP chapter obligates parties to *encourage* RC – and applies to all regulations meaning: 'a measure of general application adopted, issued, or maintained by a regulatory authority with which compliance is mandatory', with the exception of very few regulations.³⁶⁴ The authorities

³⁵⁹ The Commission posted a call for proposals for RC activities at <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1781> accessed 31 October 2019. Also, the Work Plan shows that from February to April 2018 Canada sought comments from stakeholders, received 40 responses and has committed to make them public.

³⁶⁰ See chapter 3, section 3.4.1.5.

³⁶¹ Report of the first meeting of the RCF https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/2018-12-14_rcf_report-rapport_fcr.aspx?lang=eng accessed 15 August 2019.

³⁶² USMCA, art. 21.8.

³⁶³ USMCA, art. 28.2. This article makes a passing mention of health, safety and environmental goals.

³⁶⁴ See Annex 28-A USMCA. The exceptions are mostly regarding taxation, financial services regulations, or military functions.

obligated by the GRP chapter are administrative authorities or agencies at the central level of government, not including legislatures or courts and explicitly excluding the Governor in Council of Canada and the President of the US.³⁶⁵ RC in the USMCA thus takes place through GRP with the aim of facilitating trade through eliminating regulatory differences.

2.4.2.1 Objectives and activities of regulatory cooperation in the USMCA

The focus in USMCA's RC is on GRP supporting 'the development of compatible regulatory approaches' and reducing or eliminating 'unnecessarily burdensome, duplicative or divergent regulatory requirements' considering how GRP are fundamental to effective RC.³⁶⁶ The GRP chapter – focused on deregulation – sets out obligations ('shall') with respect to GRP, including practices relating to the planning, design, issuance, implementation, and review of the Parties' respective regulations.³⁶⁷ Aside from the GRP provisions on, for example, information quality, early planning, and the transparent development of regulation, the GRP chapter includes a provision on RC specifically.³⁶⁸ The provision on RC in the GRP chapter is article 28.17. According to this provision, parties are obligated – to facilitate trade and investment and to achieve regulatory objectives – to *encourage* regulatory authorities to engage in RC activities whilst simultaneously encouraging input from the public to identify areas for RC.³⁶⁹ The idea is that GRP are fundamental to RC in the sense that its application supports developing compatible regulatory approaches.

The RC mechanisms in the USMCA, art. 28.17 in the GRP chapter, are presented in a non-exhaustive list. This means that using other RC mechanisms is theoretically possible as the USMCA states that the mechanisms 'may include, as appropriate to the particular circumstances.'³⁷⁰ The mechanisms used for RC are, amongst others, early stage exchange of technical or scientific information or data to reduce duplicative research; exploring common approaches to the evaluation and mitigation of risk including potentially posed by the use of emerging technologies; regulating by specifying performance requirements rather than design characteristics; collaborating in international fora; exchanging information; co-funding of research; facilitating the use of international standards; considering relevant scientific or technical guidance documents developed through international collaborative initiatives;

³⁶⁵ USMCA, annex 28-A.

³⁶⁶ USMCA, art. 28.2.

³⁶⁷ Ibid.

³⁶⁸ USMCA, art. 28.5, art. 28.6, art. 28.9.

³⁶⁹ USMCA, art. 28.17.

³⁷⁰ USMCA, art. 28.17(3).

common approaches to the display of product or consumer information and; periodically exchanging information, as appropriate, concerning any planned or ongoing post-implementation review or evaluation of regulations in effect affecting trade or investment.³⁷¹ There is no mention of a joint IAs or RAs but a provision on regulatory IAs as GRP recognising IAs as a tool to assist regulatory authorities addressing the need for and potential impact of regulations when preparing regulatory measures.³⁷² There is thus a broad variety of RC mechanisms specifically mentioned by the USMCA that ought to contribute to minimising unnecessary regulatory differences and to facilitate trade or investment – whilst also recognising the RC mechanisms of the WTO. This means that RC is open-ended in the sense that it could, in theory, include any kind of cooperation mechanisms if the USMCA's GRP are kept in mind.

The USMCA focuses on enforcing RC through requirements to consider the effect on trade³⁷³, annually releasing a list of planned regulatory acts³⁷⁴, allowing written comments by interested parties³⁷⁵ and retrospective review³⁷⁶. In a way, this notice and review process in RC mirrors the US administrative process.³⁷⁷ Taking the aforementioned in conjunction with retrospective review and suggestions for improvement as established by the USMCA, not only are regulations influenced prior to the adoption of a draft, regulatory standards are also being assessed retroactively, giving room for foreign countries and multinationals to influence regulatory standards both before the adoption of a draft and in retrospect.³⁷⁸ Retrospective review leads to modification or repeal of the regulation initiated by, for example, a suggestion for improvement. A suggestion for improvement can be made – by any interested person – for the issuance, modification or repeal of a regulation based on the regulation becoming ineffective at protecting health, welfare or safety or having become more burdensome than necessary – for example with respect to its impact on trade – or due to changed circumstances, incorrect or outdated information. This all-American way of regulating and developing the regulatory processes by maximising the influence of lobbying groups has consequences for the throughput-legitimacy

³⁷¹ USMCA, art. 28.17.3.

³⁷² USMCA, art. 28.11. On IAs, see chapter 4.

³⁷³ USMCA, art. 28.6.c.

³⁷⁴ USMCA, art. 28.6.

³⁷⁵ USMCA, art. 28.9.

³⁷⁶ USMCA, art. 28.13.

³⁷⁷ On the notice and comment procedure in the US federal regulatory process see, David L. Weimer, 'The Puzzle of Private Rulemaking: Expertise, Flexibility, and Blame Avoidance in U.S. Regulation' (2006) 66 *Public Administration Review* 569, 569. More in this in chapter 4 of this thesis and; chapter 3 section 3.4.2.

³⁷⁸ USMCA, art. 28.13 and 28.14.

of RC as it is unclear how participation rights are balanced in the USMCA.³⁷⁹ Subsequently, engaging with the US in RC leads to automatically including multinationals in the process, leading to the opportunity for their lobbyists to influence regulatory standards prior to the adoption of a draft and through retrospective review, after the adoption.

2.4.2.2 Regulatory cooperation in the sectoral chapters of the USMCA

There are also references to cooperation in the sectoral chapters of the USMCA. In the TBT chapter of the USMCA, international standards, guides and recommendations are recognised as important in view of supporting greater regulatory alignment, GRP and reducing unnecessary barriers to trade.³⁸⁰ The US, Canada and Mexico are obligated to cooperate ‘in appropriate circumstances’ to ensure that technical regulations and conformity assessment procedures that are based on these international standards, guidelines and recommendations do not create unnecessary obstacles to trade.³⁸¹ Furthermore, there is an information exchange – on request – when either of the parties deviates from an international standard.³⁸² This information exchange takes place in the sense of asking why the other party has deviated from the international standard as a basis for a technical regulation and the explanation addressing why the standards was considered ineffective for the pursued objective – including an identification of the scientific or technical evidence on which this was based.

The TBT chapter generally includes WTO+ provisions. For example, on conformity assessment, the USMCA creates additions to article 6.4 of the TBT Agreement – in essence to facilitate the use of conformity assessment bodies located in territories of the USMCA parties.³⁸³ It also creates possibilities of interested persons of the parties to participate in the development of technical regulations, standards and conformity assessment procedures on terms that are no less favourable than to nationals – resulting in influence of foreign countries when developing technical regulations.³⁸⁴ Furthermore, the USMCA enhances the notification procedure of articles 2.9 and 5.6 of the TBT Agreement by establishing an obligation to publish the proposed technical regulation or conformity assessment procedure and allow for writing comments by interested persons.³⁸⁵ Essentially, the TBT chapter of the USMCA includes

³⁷⁹ This is not to say that business and lobbyists have no influence in the European regulatory processes.

³⁸⁰ USMCA, art. 11.4(1).

³⁸¹ USMCA, art. 11.4(4).

³⁸² USMCA, art. 11.5(6).

³⁸³ USMCA, art. 11.6.

³⁸⁴ USMCA, art. 11.7. More on this in chapter 5, section 5.3.2.

³⁸⁵ Ibid. The USMCA states that ‘A Party satisfies this obligation by, for example, providing interested persons a reasonable opportunity to provide comments on the measure it proposes to develop and by taking those comments into account in the development of the measure.’

WTO+ issues to allow for greater cooperation. Moreover, the TBT chapter of the USMCA considers a regulatory dialogue and cooperation as a mechanism to eliminate unnecessary technical barriers to trade.³⁸⁶ This dialogue consists of exchanging information on regulatory approaches and practices; promoting the use of GRP to improve efficiency and effectiveness; providing technical advice and assistance or; provide technical assistance and cooperation.³⁸⁷ The TBT Committee of the USMCA then encourages cooperation and the exchange of information between the US, Canada and Mexico and non-governmental bodies in their territories.³⁸⁸ With a great focus on conformity assessment procedures, the TBT chapter of the USMCA aims to enhance the RC mechanisms that are used by the WTO in the TBT Agreement – whilst emphasising the possibility to engage in a regulatory dialogue.

On SPS measures, the objectives of the SPS chapter of the USMCA are, in relation to RC, to strengthen cooperation (particularly between the competent authorities of the parties) and enhance compatibility of SPS measures.³⁸⁹ Similar to the TBT chapter, the SPS chapter of the USMCA affirms and builds on the WTO rules. To enhance compatibility of SPS measures and to reduce unnecessary obstacles to trade, the parties of the USMCA are encouraged to consider SPS measures of the other parties and must have the objective to make its SPS measures equivalent or even identical to that of the other parties – however only to the extent that it does not reduce the appropriate level of protection.³⁹⁰ Furthermore, transparency is used to enhance understanding of each other's SPS measures, i.e., through the ongoing exchange of information, notifications, and opportunities to comment on proposed SPS measures and their underlying risk assessments.³⁹¹ Essentially this results in an ongoing regulatory dialogue about planned SPS measures – which also extends to considering a positive determination of equivalence of SPS measures.³⁹² The USMCA's SPS chapter is ultimately a WTO+ chapter (similar to the TBT chapter of the USMCA) as the RC mechanisms used reflect the WTO mechanisms, i.e., equivalence, international standards, and furthermore results in an ongoing regulatory dialogue about SPS measures with the aim to facilitate trade and reduce unnecessary obstacles to trade.

The SPS chapter further decides that the parties of the USMCA must 'explore opportunities for further cooperation, collaboration, and information exchange' on SPS measures that are of

³⁸⁶ USMCA, art. 11.9.

³⁸⁷ USMCA, art. 11.9 (2).

³⁸⁸ USMCA, art. 11.11.

³⁸⁹ USMCA, art. 9.3.

³⁹⁰ USMCA, art. 9.7.

³⁹¹ USMCA, art. 9.13.

³⁹² USMCA, art. 9.9.

mutual interest and to facilitate the implementation of the chapter.³⁹³ The SPS chapter of the USMCA further decides that the parties *shall* cooperate and, when mutually decided, *may* work on SPS matters for example by developing common principles, guidelines and approaches to eliminate unnecessary obstacles to trade.³⁹⁴ Furthermore, the parties can decide to share information on approaches to risk management in order to enhance compatibility of risk management approaches and also aim to establish a common scientific foundation.³⁹⁵ RC in the SPS chapter focuses on an ongoing dialogue which also extends to the scientific foundations of the SPS measures, and in that respect creates the possibility to cooperate on scientific data collection and to undertake science-based joint RA.³⁹⁶

Furthermore, the sectoral annexes of the USMCA similarly establish cooperation opportunities specifically relating to chemicals safety. On chemicals, the USMCA acknowledges the importance of developing measures in a way that does not create unnecessary economic barriers.³⁹⁷ The USMCA further decides that parties will endeavour to align RA methodologies and risk management measures in relation to chemicals and to consider measures from the other parties as informative to its decision-making.³⁹⁸ Cooperation and alignment on chemicals also takes place by endeavouring to exchange data and information on methodologies for assessing chemical substances and, upon request, data or assessments on particular chemical substances.³⁹⁹ Essentially, RC mechanisms in the USMCA's sectoral annexes are in line with RC in the SPS chapter as it establishes possibilities to engage in an ongoing regulatory dialogue including on RAs methodologies.

2.4.2.3 *The institutional framework of the USMCA*

Institutionally the USMCA sets up an oversight body – the USMCA Free Trade Commission – and an institution focused on RC, namely the Committee on GRP – similar to the institutional frameworks of the other RC models.⁴⁰⁰ Both responsible for the implementation and operation of the USMCA, the Free Trade Commission is the overarching body of the USMCA that supervises the work of other committees (such as the SPS Committee of the USMCA that serves as a forum to enhance cooperation relating to SPS matters); considers proposals to amend the

³⁹³ USMCA, art. 9.16.

³⁹⁴ USMCA, art. 9.16(2).

³⁹⁵ USMCA, art. 9.16(3). See chapter 3, section 3.4.2.

³⁹⁶ USMCA, art. 9.16(5). See chapter 3, section 3.4.2.

³⁹⁷ USMCA, Annex 12-A, art. 12.A.4(1) and art. 12.A.4(2). This whilst recognising that the principal objective of regulating chemicals is the protection of human health and the environment.

³⁹⁸ USMCA, Annex 12-A, art. 12.A.4(4) and art. 12.A.4(5). See chapter 3, section 3.4.2.

³⁹⁹ USMCA, Annex 12-A, art. 12.A.5. See chapter 3, section 3.4.2.

⁴⁰⁰ USMCA, art. 30.30; art. 28.18.

USCMA and considers ways to further enhance trade and investment. The Free Trade Commission takes decisions by consensus.⁴⁰¹ The GPR Committee – composed of government representatives – monitors implementation and operation of the GRP chapter.⁴⁰² Through the GRP Committee, communication and collaboration is supposed to be enhanced, including encouraging regulatory compatibility and RC to facilitate trade. The GRP Committee can invite interested persons to contribute to its work.⁴⁰³ It also has a role in updating the parties on their regulatory practices and processes; the exchange of information considering approaches to RC; considering suggestions from stakeholders and identifying future work for the GPR Committee as well as providing assistance. The Committee annually reports to the Commission. This institutional framework is very similar to the ones attempted in the TTIP and established by the CETA.⁴⁰⁴

2.4.3 Regulatory cooperation in the TCA

The third RC model is the TCA considering that RC is a key feature in this FTA. Essentially, the TCA aims to establish a broad relationship between the EU and the UK and characterises this relationship by ‘close and peaceful relations based on cooperation’, respectful of the autonomy and sovereignty of both parties.⁴⁰⁵ Cooperation is at the heart of the TCA but cooperation in the TCA is by its very nature different from RC in the other FTAs analysed in this thesis considering that Brexit is a process that aims at more divergence. RC then intends to make sure that the EU and the UK have some common ground and common standards – predominantly through international standards (see below) – to fall back on. Thus, by its very nature, RC in the TCA is the opposite of other RC efforts.

2.4.3.1 Objectives and activities of regulatory cooperation in the TCA

As cooperation is at the heart of the TCA, there is an abundance of references to cooperation throughout the Agreement and its annexes. After all, the agreement is one on trade and cooperation. The question is if cooperation in the TCA qualifies as RC as defined in this thesis. Certain types of cooperation can be excluded, for example judicial cooperation in criminal matters; police and judicial cooperation; cooperation on Operational Information; cooperation

⁴⁰¹ USMCA, art. 9.17(2)(d); art. 30.3.

⁴⁰² USMCA, art. 28.18.

⁴⁰³ USMCA, art. 28.18(6).

⁴⁰⁴ See chapter 4 of this thesis for a further comparison.

⁴⁰⁵ TCA, art. 1.

with the European Police Office (i.e., EUROPOL) and the European Union Agency for Criminal Justice Cooperation (i.e., Eurojust).⁴⁰⁶

As an example, cooperation with Eurojust and a UK ‘authority with responsibilities relating to the investigation and prosecution of criminal offences’ (i.e., the police) relates to serious crimes within the competence of Eurojust.⁴⁰⁷ The TCA in conjunction with the Eurojust Regulation decides that Eurojust supports and strengthens coordination and cooperation between national investigating and prosecuting authorities in relation to serious crime – the UK in this sense being a third country in accordance with article 54 of the Eurojust Regulation.⁴⁰⁸ What this all means – broadly speaking – is that in case of cross-border crimes the UK police will receive information and support from Eurojust.

Whilst this is not RC in the sense of creating procedural mechanisms in the preparatory stages of the setting of regulatory standards, this type of cooperation is essential in a post-Brexit world. Another example is found in relation to tax issues, where there is administrative cooperation between the Member States and the UK to enable mutual assistance in ensuring compliance with Value Added Tax legislation.⁴⁰⁹ These types of cooperation efforts, generally presented as an exchange of information by the competent authorities in respective policy areas, are very understandable in a post-Brexit world where the EU and UK authorities must continue to work together. However, cooperation in this sense does not qualify as RC as they do not create procedural mechanisms in the preparatory stages of the setting of regulatory standards and do not work towards setting standards cooperatively – but aim to assure that UK and EU authorities can work together in a world where the UK is not part of the EU.

Prominent in the TCA is the cooperation on the setting of international standards or, more broadly, cooperation in international organisations. On chemical regulations, for example, the EU and UK cooperate in international organisations ‘with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines’ to the extent that ‘where feasible’ the EU and UK present joint initiatives, proposals

⁴⁰⁶ TCA, art. 522; art. 546; art. 563; art. 564; art. 580.

⁴⁰⁷ TCA, art. 581(b). Serious crimes are defined in the annex of Regulation (EU) 2018/1727 of The European Parliament and of the Council of 14 November 2018 on the European Union Agency for Criminal Justice Cooperation (Eurojust), and replacing and repealing Council Decision 2002/187/JHA (i.e., the Eurojust Regulation).

⁴⁰⁸ TCA, art. 583 and the Eurojust Regulation, art. 2, art. 54.

⁴⁰⁹ TCA, Protocol on Administrative Cooperation and Combating Fraud in the field of value added tax and on mutual assistance for the recovery of claims relating to taxes and duties, art. 2.

and approaches.⁴¹⁰ Furthermore, regarding the setting of standards on TBT measures, the TCA decides that the EU and UK cooperate with standardising bodies in international standardisation activities but also foster bilateral cooperation with the other Parties' standardising bodies – which includes an exchange of information between these bodies.⁴¹¹ Similarly, on SPS measures, an objective is to enhance cooperation in international organisations to develop international standards, guidelines, and recommendations.⁴¹² Comparable provisions can be found on, for example, on cyber security and energy regulation.⁴¹³ Interesting is that these types of cooperation efforts can result in joint initiatives, proposals and approaches in international institutions. This type of cooperation shows that the EU and UK are dedicated to working together in international organisations despite the UK no longer being a member of the EU.

Under Part Two of the TCA, relating to Trade, Transport, Fisheries and other arrangements, Title X is on GRP and RC. The chapter starts out with general principles, definitions, and the scope of the chapter. The GRP and RC chapter applies to regulatory measures – whether proposed or issued – covered by the trade chapters in the TCA and the chapter on other provisions.⁴¹⁴ Furthermore, specific provisions in the trade chapters prevail over the GRP and RC chapter if necessary, for the application of these provision.⁴¹⁵ Interestingly, the provision on RC activities also applies to 'other measures of general application' covered by the trade chapters in the TCA when relevant to the RC activities.⁴¹⁶ This arguably means that guidelines, policy documents or recommendations fall under the RC provisions – whilst GRP are not applicable here. The GRP and RC title do not apply to the EU Member States.⁴¹⁷

The GRP and RC chapter in the TCA commences by formulating a safeguard in art. 340. It clearly states that both the UK and the EU freely determine their approaches to GRP and RC under the Agreement consistent with their respective legal framework, practice, procedures, and fundamental principles underlying its regulatory system.⁴¹⁸ GRP and RC under the TCA

⁴¹⁰ TCA, Annex 13, Chemicals, art. 7(3).

⁴¹¹ TCA, art. 92.

⁴¹² TCA, art. 69.

⁴¹³ TCA, art. 704(2). On cyber issues, in case of mutual interests, there is also cooperation by sharing best practices and through cooperative practical actions aimed at promoting and protecting an open, free, stable, peaceful and secure cyberspace based on the application of existing international law norms; TCA, art. 323 on energy regulation.

⁴¹⁴ TCA, art. 342. The other provisions in Heading Six of the TCA mostly relate to definitions, the establishment of a free trade area and the relation to the WTO agreement.

⁴¹⁵ TCA, art. 342(4).

⁴¹⁶ TCA, art. 342(2).

⁴¹⁷ TCA, art. 342(3).

⁴¹⁸ TCA, art. 340(1). A footnote here mentions the precautionary principle as a fundamental principle of the EU. This illustrates the importance of the precautionary principle for the EU.

does not require the parties to deviate from procedures for preparing and adopting regulatory measures; or to take actions that undermine or impede the timely adoption of regulatory measures and; does not obligate any particular regulatory outcome.⁴¹⁹ Furthermore, it is stated that nothing under the RC chapter affects the right to define or regulate its own levels of protection in various policy areas.⁴²⁰ This provision ends by the statement that ‘regulatory measures shall not constitute a disguised barrier to trade’, which is a well-known requirement under the WTO.⁴²¹ These provisions are safeguards – i.e., provisions that assure both the EU and the UK that RC will not lead to obligatory outcomes or procedures. Considering the political developments leading up to the TCA and the difficulties faced in reaching an agreement, these safeguards were to be expected in an EU-UK FTA.

To summarise, GRP in the TCA relate to 1) publicly available description of processes and mechanisms that prepare, evaluate, and review regulatory measures, including rules relating to public comments; 2) early information on planned regulatory measures; 3) ensuring public consultations; 4) carrying out IAs; 5) retrospective evaluation and 6) publishing of a regulatory register.⁴²² The TCA dictates that the EU and UK *must endeavour* to exchange information on these GRP, including in the Trade Specialised Committee on RC.⁴²³ The TCA further decides on internal coordination for the parties, i.e., that both parties must have internal coordination or review processes or mechanisms when preparing regulatory measures.⁴²⁴ These internal mechanisms must strive to foster GRP; identify and avoid unnecessary duplicative and inconsistent requirements of regulatory measures; ensure compliance with international trade and investment obligations; and promote the consideration of the impact of the regulations on small and medium-sized enterprises.⁴²⁵ Thus, aside from endeavouring to exchange information on GRP, the TCA leaves the implementation of GRP in the hands of the parties. What the GRP provisions mainly do is codify the norms that the regulatory process should adhere to – similar to GRP in the other RC models.⁴²⁶ This brings back the question asked before: why do FTAs include GRP when governments across the globe generally abide by good governance principles?⁴²⁷ And, as in the other RC models, the goal of GRP in FTAs is to enable and enhance

⁴¹⁹ TCA, art. 340(2)(c).

⁴²⁰ TCA, art. 340(3).

⁴²¹ TCA, art. 340(4). See, for example, article XX GATT.

⁴²² TCA, art. 344; art. 345; art. 346; art. 347; art. 348; art. 349.

⁴²³ TCA, art. 350. See below, section 2.4.3.3 on the institutional framework of the TCA.

⁴²⁴ TCA, art. 343.

⁴²⁵ TCA, art. 343.

⁴²⁶ See further chapter 4, section 4.2.2.

⁴²⁷ See above, section 2.3.3.

RC, i.e., early notice on planned regulatory measures and public consultation enhances mutual awareness of respective regulatory systems and ultimately enable a regulatory dialogue.

In the GRP and RC chapter of the TCA there is one provision on RC, specifically art. 351. This provision dictates that RC is voluntary, ‘without prejudice to the autonomy of their own decision-making and their respective legal orders.’⁴²⁸ Furthermore, the provision states that the EU and the UK can withdraw or refuse to engage in RC if the reasons are explained, i.e., to cooperate or explain.⁴²⁹ RC mechanisms in the TCA are dependent on political will for their existence. The TCA does not define specific RC activities or mechanisms but RC activities can be proposed by either party via the contact points as provided in the agreement.⁴³⁰ Proposals ought to be reviewed within a ‘reasonable period’ and parties must inform the proposing party if the RC activity is seen as suitable.⁴³¹ To identify activities for RC, the EU and UK must consider the list referred to in the provision on early information on planned regulatory measures, i.e., a list of planned major regulatory measures that are expected to be proposed or adopted within a year.⁴³² Furthermore, RC activities can be identified through proposals by ‘persons of a Party’ when substantiated and accompanied by relevant information.⁴³³ If the EU and UK decide to engage in a RC activity, the regulatory authorities must endeavour ‘where appropriate’, to inform each other on the preparation or revision of a regulatory measure, guideline, policy document or recommendation relevant to the RC activity; provide information and discuss regulatory measures relevant to the activity; and consider – ‘to the extent feasible’ – regulatory approaches of the other party on similar or related matters.⁴³⁴ Essentially, the TCA assures that, through GRP provisions, the EU and the UK remain up to date on their respective regulatory framework and that the EU and the UK can engage in RC if desired.

2.4.3.2 Regulatory cooperation in the sectoral chapters of the TCA

On TBT regulations specifically, the EU and UK obligate themselves to cooperate on technical regulations, standards, and conformity assessment procedures when in mutual interest and without prejudice to the autonomy of decision-making processes and legal orders.⁴³⁵ Whilst cooperation on technical regulations in the TCA mostly aim for convergence based on the use

⁴²⁸ TCA, art. 351(1).

⁴²⁹ Ibid, The ‘cooperate or explain’ principle will be further discussed in chapter 5 of this thesis.

⁴³⁰ TCA, art. 351(2). The contact points are to be appointed after the agreement enters into force, TCA, art. 353.

⁴³¹ Ibid.

⁴³² Ibid, TCA, art. 351(3)(a) and art. 345.

⁴³³ TCA, art. 351(2), 351(3)(b).

⁴³⁴ TCA, art. 351; art. 342(2).

⁴³⁵ TCA, art. 98(1).

of international standards, the EU and UK will pursue to identify, develop and promote cooperation activities that may consist of exchanging information, experiences and data, including regarding international agreements; interaction and cooperation of regulatory authorities and; establishing trade facilitating initiatives or participating in them.⁴³⁶ This provision specifically appoints the Commission to act on behalf of the EU regarding TBT measures.⁴³⁷ Where the TCA frequently refers to the competent authorities, i.e. relevant agencies, Member States' institutions, or the relevant DG's, on TBT measures it is decided that specifically the Commission is responsible regarding TBT measures. Surely TBT measures are extremely important in trade post-Brexit and the access to the Single Market which explains the appointment of the Commission specifically.

Furthermore, on TBT measures there is a provision that states that in case of developing a major technical regulation that may have a significant effect on trade, parties must ensure procedures on public consultation – with the results made public and interested persons being treated no less no less favourable than its own nationals – ‘except where urgent problems of safety, health, environment or national security arise or threaten to arise.’⁴³⁸ A transparency provision in the TBT chapter further decides that – except in case of urgent problems – the EU and UK allow each other to provide written comments on proposed technical regulations and conformity assessment procedures after a notification to the WTO – which allows for a dialogue on proposed technical regulations to take place.⁴³⁹ Notably absent is a general provision relating to the mutual recognition of conformity assessment procedures. Essentially, the TBT chapter establishes RC to the extent of exchanging information and thus enhancing mutual awareness.

Regarding SPS measures, the SPS chapter of the TCA has to objective to cooperate in international organisation.⁴⁴⁰ Further cooperation takes place through a transparency and exchange of information provision.⁴⁴¹ When there is change to SPS measures and approval procedures, for example, the parties will promptly communicate this change.⁴⁴² Notifications with undue delay must take place in case of emergency situations.⁴⁴³ Emergency measures, however, can be taken without prior notification – but notification will follow as soon as

⁴³⁶ TCA, art. 91(3); art. 98(2).

⁴³⁷ TCA, art. 98(3).

⁴³⁸ TCA, art. 91(8).

⁴³⁹ TCA, art. 94.

⁴⁴⁰ TCA, art. 69(f).

⁴⁴¹ TCA, art. 77.

⁴⁴² TCA, art. 77(1)(a).

⁴⁴³ TCA, art. 80. These situations are: a significant change to pest or disease status; emergence of a new animal disease; significant food safety issues etc.

possible and no later than 24 hours after the decision.⁴⁴⁴ The SPS chapter contains further cooperation provisions on animal welfare, antimicrobial resistance, and sustainable food systems.⁴⁴⁵ On animal welfare specifically, cooperation takes place through international fora but also through an exchange of information, expertise, and experiences.⁴⁴⁶ On antimicrobial resistance, the TCA foresees in cooperating through a dialogue that allows collaboration to follow up existing and future guidelines, standards, recommendations and actions; the exchange of information on good farming practices ⁴⁴⁷ Essentially the SPS chapter of the TCA aims to enhance mutual understanding of SPS measures and the regulatory framework of both parties.

There are furthermore several explicit references to RC made in annexes of the sectoral chapters of the TCA, for example on motor vehicle regulation, medicinal products, and chemicals:

On motor vehicles the TCA dictates that regulatory convergence takes place based on relevant international standards – much like with TBT measures in general.⁴⁴⁸ The EU and the UK are, according to this annex, not allowed to introduce or maintain technical regulations, markings or conformity assessment procedures that diverge from United Nations Regulations or a Global Technical Regulation, unless there are substantive reasons that direct to ineffectiveness or inappropriateness of the regulation in question – for the fulfilment of legitimate objectives.⁴⁴⁹ When diverging regulations are adopted, the EU and the UK will inform each other of such changes and these regulations must be reviewed regularly – ‘preferably not exceeding five years’ – with the purpose of increasing convergence with relevant international regulations.⁴⁵⁰ To further facilitate trade in motor vehicles, their parts and equipment, the EU and UK will endeavour to cooperate and exchange information.⁴⁵¹ Areas of cooperation mentioned are: developing and establishing technical regulations or standards; exchanging ‘to the extent possible’ research, information and results when developing new vehicle safety regulations or standards; exchanging information on the identification of safety-related or emission-related defects and non-compliance with technical regulations; promoting greater international harmonisation in multilateral fora.⁴⁵²

On medicinal products, in an annex to the TBT chapter of the TCA, a provision titled RC states that the EU and UK will endeavour to consult each other when introducing significant changes to technical regulations or inspection procedures, including the recognition of documents. Cooperation on medicinal products is endeavoured equally, ‘with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines including, where feasible,

⁴⁴⁴ TCA, art. 81.

⁴⁴⁵ TCA, art. 70.

⁴⁴⁶ TCA, art. 84.

⁴⁴⁷ TCA, art. 85(5).

⁴⁴⁸ TCA, Annex 11, art. 3(b).

⁴⁴⁹ TCA, Annex 11, art. 5(1).

⁴⁵⁰ TCA, Annex 11, art. 5(2)(4).

⁴⁵¹ TCA, Annex 11, art. 8.

⁴⁵² TCA, Annex 11, art. 8(2).

through the presentation of joint initiatives, proposals and approaches in the relevant international organisations and bodies.⁴⁵³

And, in relation to chemicals, the objectives in an annex to the TCA are to provide for cooperation between the responsible authorities of the EU and the UK, respectively, whilst acknowledging that the commitments in the annex do not prevent parties from setting their own priorities or their own level of protection.⁴⁵⁴ In view of RC, the chemicals annex decides that the EU and the UK will cooperate to facilitate trade and acknowledge that voluntary cooperation on chemicals regulation can facilitate trade.⁴⁵⁵ This is RC that will then take place through an exchange of information with a focus on scientific guidelines and data.⁴⁵⁶

The exchange of information plays a pivotal role in cooperation under the TCA. On competition policy, for example, there are provisions on cooperation to enhance effective enforcement of the competition law of the EU and UK, respectively.⁴⁵⁷ This cooperation takes place between the European Commission or the competent authorities of the Member States and the UK's competition authorities. The competent authorities endeavour to cooperate and coordinate regarding developments in competition policy and enforcement activities by exchanging information.⁴⁵⁸ Essentially, this means exchanging information about developments in competition law, i.e., if something changes in the policies, the EU and UK can inform each other about these upcoming changes. These types of provisions are found throughout the TCA, in relation to an exchange of information by competent authorities on, for example, digital trade (which is obligatory); energy regulation; organic products; market surveillance and non-food product safety; cyber security; aviation safety; and so on.⁴⁵⁹ The exchange of information takes place on the development of regulations and so the TCA frequently dictates that the EU and the UK keep each other up to date about regulatory developments and policy changes. It makes sense that this is decided in the TCA since the UK leaving the EU does not change the fact that the UK and the EU are strongly connected in areas of trade. An exchange of information is therefore of the utmost importance in the continuing EU-UK relationship.

⁴⁵³ TCA, Annex 12, art. 10. The international organisations referred to are the World Health Organization, the Organization for Economic Cooperation and Development, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, and the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products ex TAC, Annex 11, art. 4.

⁴⁵⁴ TCA, Annex 13, Chemicals, art. 3(1)(c).

⁴⁵⁵ TCA, Annex 13, Chemicals, art. 7.

⁴⁵⁶ TCA, Annex 13, Chemicals, art. 7, art. 8; see further chapter 3 section 3.4.3 of this thesis.

⁴⁵⁷ TCA, art. 361.

⁴⁵⁸ TCA, art. 361. The EU and UK can also enter into a separate agreement to include sharing and using confidential information.

⁴⁵⁹ TCA, art. 211; art. 318; Annex 14, art. 6; art. 96; art. 704; art. 434.

The customs and trade facilitation chapter deserves some attention since leaving the Single Market is not an easy feat and thus cooperation is inevitable in this area.⁴⁶⁰ In the words of the TCA, an objective of this chapter is to reinforce cooperation in the area of customs and trade facilitation ‘and to support or maintain, where relevant, appropriate levels of compatibility of their customs legislation and practices with a view to ensuring that relevant legislation and procedures (...) fulfil the objectives of promoting trade facilitation while ensuring effective customs controls and effective enforcement of customs legislation and trade related laws and regulations, the proper protection of security and safety of citizens and the respect of prohibitions and restrictions and financial interests of the Parties.’⁴⁶¹ To this end, the EU and the UK will develop cooperation by exchanging information on customs legislations, the implementation of customs legislations and procedures.⁴⁶² They will furthermore *consider* to develop joint initiatives relating to import, export and other customs procedures.⁴⁶³ In international organisations, the EU and UK decided to strengthen cooperation, exchange information or having discussions to possibly establish a common position in these international organisations.⁴⁶⁴ Moreover, the EU and UK will strengthen their cooperation on risk management techniques, including sharing best practices and, ‘where appropriate’, risk information and control results.⁴⁶⁵ Essentially, the customs and trade facilitation chapters aims to support or maintain levels of compatibility to promote trade facilitation.

2.4.3.3 *The institutional framework of the TCA*

Institutionally, the TCA sets up the Partnership Council to oversee reaching the objectives of the Agreement and to supervise and facilitate the implementation and application of the Agreement and any supplementing agreement.⁴⁶⁶ The Partnership Council is thus the overseeing body of the TCA – similar to the JC as seen in the TTIP negotiation papers and the CETA’s institutional framework. On trade matters, the TCA sets up the Trade Partnership Committee and various Specialised Trade Committees.⁴⁶⁷ There are three levels of institutions under the TCA when focusing on trade and RC specifically.⁴⁶⁸ The Partnership Council

⁴⁶⁰ TCA, art. 101.

⁴⁶¹ TCA, art. 101(a).

⁴⁶² TCA, art. 103(2).

⁴⁶³ TCA, art. 103(2)(c).

⁴⁶⁴ TCA, art. 103(2)(d).

⁴⁶⁵ TCA, art. 103(2)(f).

⁴⁶⁶ TCA, art. 7. For clarity, the Partnership Council consists of representatives of the EU and the UK, in different configurations depending on the matters that are being discussed and is co-chaired by a member of the Commission and a minister of the government of the UK.

⁴⁶⁷ TCA, art. 8.

⁴⁶⁸ Other areas of the TCA are beyond the scope of this thesis.

oversees the Agreement as the leading institution. Next comes the Trade Partnership Committee that deals with most of the trade matters covered by the TCA, including RC. Together, the Partnership Council and the Trade Partnership Committee supervise the work of the Trade Specialised Committees, the third level of the institutional framework.

These three levels also could result in three levels of binding decision-making under the TCA.⁴⁶⁹ The Partnership Council can adopt decisions; the Trade Partnership Committee can adopt decisions as provided in the Agreement or if delegated to it by the Partnership Council and the Trade Specialised Committees can adopt decisions if provided by the Agreement. The general idea of the institutional framework is that the Partnership Council oversees the Agreement; the Trade Partnership Committee assists the Partnership Council, reports to it and carries out tasks assigned by the Partnership Council and the Specialised Committees functions as a forum to exchange information, discuss best practices and share implementation experiences and more generally, function as a preparatory institution in the sense that it conducts preparatory technical work to support the partnership Council and the Trade Partnership Committee.

The Specialised Trade Committees relate to the various sectoral chapters of the TCA. For example, the Trade Specialised Committee on TBT measures in which views are exchanged on the cooperation activities as mentioned in the TBT chapter and its annex and the Trade Specialised Committee on SPS measures in which views information, and experiences regarding cooperation activities are exchanged on the protection of animal welfare and the fight against antimicrobial resistance specifically.⁴⁷⁰ On RC, the Trade Specialised Committee on RC addresses matters covered by the GRP and RC chapter of the Agreement.⁴⁷¹ The Trade Specialised Committee on RC has three functions namely i) enhancing and promoting GRP and RC between the Parties; ii) exchanging views with respect to the cooperation activities proposed or carried out under art. 351 (i.e., RC) and; iii) encouraging RC and coordination in international fora, including, when appropriate, periodic bilateral exchanges of information on relevant ongoing or planned activities.⁴⁷² Interestingly, the TCA and the Trade Specialised Committee

⁴⁶⁹ See TCA, art. 10.

⁴⁷⁰ TCA, art. 100; art. 87(e).

⁴⁷¹ TCA, art. 8(i).

⁴⁷² TCA, art. 352.

on RC pay attention to participatory rights in its institutional framework by stating that parties may invite interested persons to participate in its meetings.⁴⁷³

Cooperation is a term that is being used very broadly in the TCA. As with TTIP and the other FTAs, the question is what the GRP and RC chapter will change and why the EU and UK bothered with including the RC in the first place. RC under the TCA creates mechanisms in the preparatory stages of regulations, predominantly through an information exchange, i.e., the EU and the UK will keep each other up to date about developments in the regulatory policies and changes in regulations. Of course, the TCA is a special FTA in the sense that it illustrates a disassembling of a Union whilst trying to preserve some common standards. Various practical issues are reflected in the TCA, for example in the Customs and Trade chapters. The practical issues are, of course, related to trade and the UK leaving the Single Market. The TCA mentions cooperation extensively, mainly through an exchange of information, but when it comes to the setting of standards and the regulatory process, it is frequently reaffirmed that both the EU and the UK decide their own standards. Essentially, the TCA is a reflection of the political reality regarding (new) relationship between the EU and the UK.

2.5 Concluding remarks

This chapter illustrates that RC is layered in the sense that the WTO forms a basis and WTO members build on this basis by engaging in further RC through FTAs. FTAs therefore generally refer to the WTO and build on the rights and obligations under WTO law – in other words by including WTO+ issues. RC in the WTO is predominantly found in the TBT and SPS Agreement – since these are the policy areas in which non-tariff barriers are generally created. Notwithstanding, RC under the WTO is minimal in the sense that it promotes RC which is not more than suggesting parties should engage in RC for the benefit of trade. RC is promoted through GRP, international standards; equivalence; mutual recognition and working towards harmonisation. Harmonisation predominantly takes place through the setting of international standards – standards that have regulatory force throughout the globe. RC under the WTO, however, is minimal and can best be considered as something that is promoted by the WTO as it will facilitate trade and thus the WTO creates the basis upon which further RC can be built.

EU-US RC ultimately resulted in the TTIP negotiations as attempts to establish an ongoing regulatory dialogue continuously fail. Essentially, TTIP attempted to create an ongoing regulatory dialogue that focused on early information on planned regulatory measures (i.e.,

⁴⁷³ TCA, art. 352; also see articles, 11, 12, 13 and 14; for further analysis see chapter 5, section 5.3.2.

transparency about planned regulatory measures) enabling a dialogue which allowed an ex-ante policy analysis to take place. The basis for this ongoing regulatory dialogue would have been in the TTIP but would 'live on' over time. In other words, the TTIP was considered a 'living agreement' in the sense that the TTIP would set up RC and its accompanied institutional structure which thereafter could have functioned on its own. Broadly applicable – in case of common interest and / or a significant impact on trade or investment – RC would have set up an ongoing regulatory dialogue between the EU and the US, more specifically a dialogue between relevant Directorate Generals of the Commission and their American counterparts, i.e., the US agencies. RC would thus be an effort of the executive branch in the EU and the US respectively and there were no signs in the TTIP indicating involvement of the European Parliament or the US Congress. Moreover, the institutional framework supporting the objectives and principles of the TTIP creates a new transnational governance structure that supports the ongoing regulatory dialogue. The TTIP was faced with a lot of criticism but was, in view of the historical development of EU-US RC, a logical step – albeit a problematic one.

The ongoing regulatory dialogue as imagined by the TTIP is implemented in the RC models researched in this thesis. The CETA is broadly taking place along the same lines as the TTIP, albeit with a broad variety of RC activities. The CETA's RC activities result in an exchange of information, i.e., an ongoing regulatory dialogue assessing cooperation possibilities. The RC mechanisms as established by the USMCA are similar. The TCA, whilst being inherently different from the other RC models, similarly focuses on an exchange of information with the aim to enhance mutual awareness of respective regulatory measures. Essentially, the RC mechanisms are similar in all the RC models and the focus is predominantly on the (early) exchange of information.⁴⁷⁴ Consequently, the throughput-legitimacy deficit of RC is also similar in all the RC models as they create an ongoing regulatory dialogue without explicit oversight by parliament nor participation rights that include a balanced representation of interests.⁴⁷⁵ A role for expertise in the ongoing regulatory dialogue can possibly enhance the legitimacy of RC and to that end, the next chapter assesses the role of expertise in the ongoing regulatory dialogue.

⁴⁷⁴ See chapter 4 for a further analysis on the common characteristics of RC.

⁴⁷⁵ See chapter 5 for the analysis on the throughput-legitimacy deficit of RC.

Chapter 3 The role of expertise in regulatory cooperation

3.1 Introduction

RC creates a structured, ongoing regulatory dialogue aimed at facilitating trade and preventing trade disputes through the creation of RC mechanisms in the *preparatory stages* of regulation. Considering that RC is increasingly a key element of FTAs, a widening of RC is taking place across the globe. Furthermore, there is a deepening of RC by moving from a top-down approach through high-level political efforts such as annual summits and declarations to a bottom-up approach focusing more on regulating the regulatory process itself.⁴⁷⁶ This widening and deepening of RC efforts indicates that the idea of a global policy laboratory is implemented via FTAs – whilst RC simultaneously remains a matter of potential.⁴⁷⁷ Chapter 2 analysed the RC mechanisms in recent FTAs (or envisioned in case of the TTIP), this chapter focuses on the role of expertise in these mechanisms.

This chapter answers the question if there is a role for expertise in the RC models analysed in this thesis. There are two main reasons to provide a role to expertise in the RC process, namely i) increasing the chances of convergences and ii) attributing expert-based legitimacy to the RC process.⁴⁷⁸ Providing a role to expertise in RC can increase the chance of convergence and with this in mind, EU-US RC indeed started to focus on a (stronger) role for expertise.⁴⁷⁹ The increased chance of convergence can result from, for example, establishing a common scientific basis for regulatory standards, conducting joint IAs or joint RAs contributing to a common basis of information on which regulatory measures can be based.⁴⁸⁰ Moreover, scientific experts and expertise can enhance the legitimacy of transnational risk governance and a scientific basis to regulatory measures is crucial not at the least in view of legitimacy.⁴⁸¹ Both these factors create the expectation that expertise will play a role in the RC models analysed in this thesis. A role for expertise can provide expert-based legitimacy to a transnational system of governance, which can address the legitimacy deficit of RC.⁴⁸² This chapter assesses the RC mechanisms through this lens exactly, to analyse the role of expertise in RC.

⁴⁷⁶ See chapter 2, section 2.3.2.

⁴⁷⁷ See chapter 1, section 1.1.

⁴⁷⁸ See chapter 1, section 1.3.

⁴⁷⁹ See chapter 1, section 1.3; chapter 2, section 2.3.2.

⁴⁸⁰ See chapter 1, section 1.3; Atik, 'Science and international regulatory convergence'; On knowledge society, see for example, Ambrus and others, 'The role of experts in international and European decision-making processes : setting the scene', 5.

⁴⁸¹ See chapter 6, section 6.2; Atik, 'Science and international regulatory convergence'; also see, Ambrus and others, 'The role of experts in international and European decision-making processes : setting the scene', 5.

⁴⁸² See chapter 6, section 6.2.

As ‘expertise’ is used as an overarching term in governance, the type of expertise this thesis focuses on is applied in this chapter.⁴⁸³ As set out more extensively in the introduction, expertise in the sense of this thesis is what Jasanoff refers to as regulatory science.⁴⁸⁴ Regulatory science is science that is *mandated* by regulators thus produced under specific legal requirements and *serves* regulation, in other words ‘policy-relevant’ expertise used to support public-policy.⁴⁸⁵ In RC, expertise is thus:

- i) Domestic expertise: co-produced by the *respective* executives and experts, used to support regulatory decision-making and part of the ongoing regulatory dialogue or
- ii) Transnational expertise: co-produced *through RC* resulting in joint co-produced regulatory science, i.e., containing two levels of cooperation, which can consist of aligning domestic expertise.

Subsequently, experts in RC are:

- i) Domestic experts: actors contributing to evidence-based policymaking, i.e., by providing data, reports, information, IAs and RAs that support the regulatory measure which is subsequently discussed in the ongoing regulatory dialogue;
- ii) Transnational experts: actors who are directly involved in the RC process (for example via *joint* RAs or *joint* IAs) which can be domestic experts acting in a transnational setting.

This chapter analyses the role of expertise in RC or, in other words, the role of regulatory science in the RC models.

3.2 Expertise in the WTO

The WTO is *the* governance institution which – due to its intrinsic link with expertise – sparked the most debate about expertise in the literature.⁴⁸⁶ In general, the WTO provides a framework for FTAs, trade negotiations, dispute settlement and RC. RC in the WTO predominantly evolves around working towards harmonisation, mainly through relying on international standards but also by using GRP to build trust and promote RC. RC in the WTO is minimal

⁴⁸³ See chapter 1, section 1.3.

⁴⁸⁴ Jasanoff developed this term in Jasanoff, *The Fifth Branch : Science Advisers as Policymakers* .

⁴⁸⁵ Ibid. See, Salter, *Mandated science : science and scientists in the making of standards*; Weimer and De Ruijter, ‘Regulating Risks in the European Union: the Co-production of Expert and Executive Power’, .

⁴⁸⁶ See chapter 1, section 1.3.

since the WTO mainly functions as a starting point for RC – or in more general terms a framework for further trade liberalisation.

Expertise, however, is of great importance in the WTO to the extent that Peel argues that science has been given an unjustifiably privileged position in the management of SPS risks.⁴⁸⁷ Wickinoff and others similarly argue that scientific expertise in the WTO has been given too much of a pivotal role in dispute settlement.⁴⁸⁸ Essentially, the criticism often relates to scientific expertise being given too much importance in comparison to domestic principles, cultural and political factors.⁴⁸⁹ In light of that, if expertise is to enhance the legitimacy of RC, considering the critique voiced towards the WTO is important.⁴⁹⁰ As RC establishes transnational cooperation through FTAs, a role for expertise in RC can expect to face similar criticisms as the WTO. Contrarily, the WTO might function as an example for the role of expertise in RC. An elaboration on the role of expertise in the WTO is thus necessary for the broader purpose of this thesis.

Experts are relied on heavily for the functioning of the WTO specifically in two areas: conformity with scientific norms in SPS measures and through relying on international standards.⁴⁹¹ Aside from experts that are integral part of the WTO, the WTO relies heavily on scientific experts for advice for example in case of WTO committees consulting experts when making recommendations.⁴⁹² For RC this means that the baseline created for cooperation by the WTO – through promoting and encouraging cooperation and working towards harmonisation – inevitably affects RC and the use of WTO expertise. When countries adhere to WTO rules, WTO expertise is automatically – albeit implicitly – implemented by its members. This is not a strong example of cooperating on expertise as such, however, the WTO does have an influence on the regulatory standards of its members. The two areas in which expertise has the strongest influence on the setting of regulatory standards by its members are i) conformity with scientific norms in SPS measures and ii) through relying on international standards.

⁴⁸⁷ Peel, 'Risk regulation under the WTO SPS Agreement: Science as an international normative yardstick?'; also see chapter 6, section 6.3.

⁴⁸⁸ Wickinoff and others, 'Adjudicating the GM Food Wars: Science, Risk and Democracy in World Trade Law'; also see chapter 6, section 6.3.

⁴⁸⁹ See chapter 6, section 6.2.2.

⁴⁹⁰ See chapter 6, section 6.3.

⁴⁹¹ See, for example, Herwig, 'Health risks, experts and decision making within the SPS Agreement and the Codex Alimentarius', 194.

⁴⁹² See chapter 1, section 1.3; also see Lawrence, 'The structural logic of expert participation in WTO decision-making processes', 176.

3.2.1 *The SPS Agreement*

The WTO's SPS Agreement merits closer consideration since science mediates tensions between national policies by functioning as a benchmark. It is important, however, to remember that the SPS Agreement lays down requirements for the administrative process of standard setting and not just the scientific part of standards setting, even though it puts considerable weight on SPS measures being based on scientific expertise.⁴⁹³ In short, the requirement for the administrative process is that regulations that fall under the WTO's SPS Agreement must be non-discriminatory, based on science and the least trade restrictive.⁴⁹⁴ Based on science means a required conformity with scientific norms resulting in science mediating conflicts between national policy and the demands of international trade.⁴⁹⁵ This conformity with scientific norms generally results in measures based on international standards or maintained with sufficient scientific evidence.⁴⁹⁶ Sufficient scientific evidence then indicates a measure that is based on RA.⁴⁹⁷ Here, experts have a crucial role as they are essential in determining if a regulation has sufficient scientific evidence.⁴⁹⁸ Through demanding a scientific justification or a RA, science becomes a mediator – or a benchmark – against which national measures are tested in disputes amongst national regulatory standards. Expert knowledge thus supposedly functions as a 'neutral' or 'scientific' check on what could be deemed illegitimate or legitimate rulemaking by its members.⁴⁹⁹ Noteworthy is that this idea of expertise as a neutral check has been challenged by, for example, Peel and Walker.⁵⁰⁰ After all, regulatory science is mandated by regulators and produced under specific legal requirements resulting in science that is by its very nature dependent on politics and thus often perceived as biased.⁵⁰¹

Generally, the idea behind the principle of scientific conformity is that if there is a scientific justification resulting from RA, in principle, the measures will be immune from free-trade challenge.⁵⁰² In practice this is not necessarily the case, as many cases are brought before the WTO's dispute settlement mechanism where sufficient scientific evidence is the essence of the

⁴⁹³ Fisher, *Risk regulation and administrative constitutionalism*, 182.

⁴⁹⁴ SPS Agreement, art 2, TBT Agreement, art 2; Also see, Colyer, 'The Role of Science in Trade Agreements'.

⁴⁹⁵ Atik, 'Science and international regulatory convergence', 736, 740.

⁴⁹⁶ Unless the state of evidence is insufficient, SPS Agreement art 3, 5.7, 2.2 and 5.1.

⁴⁹⁷ SPS Agreement, art 5.1. In the TBT Agreement art. 2.2 states: 'necessity is evaluated in terms of scientific and technical evidence.'

⁴⁹⁸ E.g., Herwig, 'Health risks, experts and decision making within the SPS Agreement and the Codex Alimentarius', 194.

⁴⁹⁹ Lawrence, 'The structural logic of expert participation in WTO decision-making processes', 179, 180.

⁵⁰⁰ Vern Walker, 'The Myth of Science as a "Neutral Arbiter" for Triggering Precautions' (2003) 26 BC Int'l & Comp L Rev 197, Peel, *Science and Risk Regulation in International Law*, 383.

⁵⁰¹ See chapter 6, section 6.3.1.

⁵⁰² Atik, 'Science and international regulatory convergence', 740.

dispute.⁵⁰³ Questions such as what exactly is sufficient scientific evidence? Was a proper RA undertaken? And what reports establish this scientific evidence? become matters of dispute before the WTO's Appellate Body. The SPS Committee clarified many of these questions over the years thus Scott argues that the SPS Committee plays a 'quasi-legislative role' in the WTO.⁵⁰⁴ In other words, the Appellate Body and SPS Committee both define the required sufficient scientific evidence and, in doing so, play a quasi-legislative role, affecting countries abiding by WTO rules as these scientific norms becoming the standard that prevents WTO disputes.⁵⁰⁵ The decisions of the Appellate Body and the SPS Committee thus set a precedent. When decided what, for example, sufficient evidence is, this becomes a standard to which regulations should adhere to prevent WTO disputes. If a regulation is in line with the interpretation of the Appellate Body, should a dispute arise, the WTO signatory in question can appeal with direct reference to that interpretation:

*'A regulatory measure upheld by a WTO (...) dispute panel may likely be immune from further challenge, and might well be adopted by other nations with a high degree of confidence. Thus, over time there may be a cumulative growth of permitted trade restrictions. Once blessed as supported by scientific justification, a trade restriction may be replicated and become thereby an effective standard for a larger territory.'*⁵⁰⁶

This could lead to what Atik describes as a 'common law of scientific considerations' or at the very least establish a 'precedential pattern'.⁵⁰⁷ RC between WTO signatories is naturally influenced through this precedential pattern. FTAs generally build on the WTO framework and when cooperating on the setting of standards parties to the agreement will reference to the WTO and, if desired, build upon the WTO obligations. Through this precedential pattern, the expertise becomes part of the WTO baseline to which its signatories adhere. A common law of scientific considerations is perhaps too far-fetched considering how disputes continue to exist and disputes such as the Hormone case are ongoing despite dispute settlement before the Appellate Body.⁵⁰⁸ A precedential pattern, however, cannot be denied. The rulings in the WTO affect the setting of standards and the scientific evidence required by the WTO as compliance with the

⁵⁰³ SPS Agreement, art 2.2.

⁵⁰⁴ Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* (Oxford Commentaries on International Law, Oxford University Press 2007), 45; also referenced in, Peel, *Science and Risk Regulation in International Law*, 173.

⁵⁰⁵ See, Herwig, 'Health risks, experts and decision making within the SPS Agreement and the Codex Alimentarius', 194, 195.

⁵⁰⁶ Atik, 'Science and international regulatory convergence', 755.

⁵⁰⁷ Ibid.

⁵⁰⁸ On the Hormones case see, for example, Renée Johnson, 'The U.S.-EU Beef Hormone Dispute' (2015) Congressional Research Service Reports on Foreign Policy and Regional Affairs 34.

WTO, in principle, prevents free-trade challenges. In RC specifically, whilst this is not a cooperation on expertise as such, it does – as seems to be the case with the WTO in general – build a base upon which RC is built. From the examples of RC seen so far, countries indeed build on the baseline provided by the WTO which means that, in the case of SPS measures specifically, scientific expertise is expected to play a significant role in RC.⁵⁰⁹

3.2.2 *International standards*

Another way in which expertise is integrated into RC under the WTO is through relying on international standards.⁵¹⁰ As discussed in chapter 2, the WTO does not set its own standards but relies heavily on the international standards set by hybrid public-private bodies.⁵¹¹ Through international standards, according to Herwig, expert knowledge is ‘built into the political determination of risk acceptability and its appropriate mitigation.’⁵¹² As these standards are used in FTAs another effect on RC is that international standards become the appropriate standard to use. In RC efforts – as analysed in the following sections – international standards are indeed used to cooperate on regulatory measures. Consequently, the common law of scientific determinations that Atik describes is perhaps most noticeable with the use of international standards.⁵¹³ International standards provide a common basis and as analysed in chapter 2, RC efforts use these standards – moreover the CETA aims for the EU and Canada to set international standards cooperatively.⁵¹⁴

Nonetheless, WTO RC is minimal in the sense that it merely promotes cooperation and aims to provide common ground. It enables further cooperation and makes way for FTAs to engage in deeper RC. At the very least, this provides WTO signatories with the opportunity to provide a role to expertise in RC, specifically in SPS measures. Scientific evidence plays an important role in determining whether a national measure is considered legitimate or illegitimate under the WTO framework. Cooperating on matters of expertise can facilitate RC because the countries engaging in cooperative efforts can take into account the precedential pattern set by the WTO institutions regarding matters of scientific expertise, i.e., measures supported by scientific justification in the WTO framework. Taking this scientific justification into account

⁵⁰⁹ See chapter 2, section 2.2.

⁵¹⁰ Peel, *Science and Risk Regulation in International Law*, 50; SPS Agreement art 2.2, 3.1, 3.2.

⁵¹¹ See chapter 2, section 2.2.2.

⁵¹² Herwig, 'Health risks, experts and decision making within the SPS Agreement and the Codex Alimentarius', 211.

⁵¹³ Atik, 'Science and international regulatory convergence', 755.

⁵¹⁴ The CETA states that the EU and Canada aim to cooperate on the development, adoption, implementation and maintenance of international standards, guides and recommendations, CETA, art 21.4 (h).

essentially guarantees compliance with the WTO and thus can be used as a baseline in RC efforts. It therefore seems logical to further engage in cooperation on expertise in RC. Whilst explicit cooperation on expertise is minimal in the WTO – similarly to RC in the WTO – it creates common ground upon which can be built. RC efforts build on the WTO level and so the question remains if the same can be said for the role of expertise.⁵¹⁵

3.3 Expertise in EU-US regulatory cooperation

EU-US RC has developed over the years from high-level political cooperation to attempts at creating an ongoing regulatory dialogue, ultimately resulting in the TTIP negotiations. Even before these negotiations, there was a push towards cooperating on IAs most notably through the EU-US Guidelines on RC in 2002. Steps to create an ongoing regulatory dialogue have been taken over the years. Subsequently, the attention shifted from political cooperation to cooperation on methodologies, creating regulatory dialogues between agencies and a general focus on processes and approaches rather than resolving regulatory disputes or changing existing regulatory standards. What was the rationale behind this shift in approach? Black and Alemanno argue that on both sides of the Atlantic, there was a realisation that the differences in scientific approaches to RA leads to different responses.⁵¹⁶ Not only can this threaten scientifically sound risk governance, but the diverging approaches result in diverging regulatory responses and can eventually lead to disputes such as the Hormone case.⁵¹⁷ Cooperating on transnational expertise via joint RAs, joint IAs, or on domestic expertise by involving experts or exchanging data at an early stage of the regulatory process originates from the idea that prevention is better than the cure. It therefore seems logical to turn to expertise to achieve deeper RC. The question is thus if cooperation on expertise it is taking place in EU-US RC and if so, to what extent.

3.3.1 Expertise in the early beginnings of EU-US cooperation

Whilst there are no explicit references to the involvement of expertise in intergovernmental policymaking in either the official texts or academic reflections, a role for expertise is found implicitly when exploring the nature of transatlantic policymaking. The Transatlantic Declaration 1990 mentions strengthening cooperation on science. From this date onwards, the call for cooperation on scientific expertise has grown. In the NTA there is an explicit call for

⁵¹⁵ See chapter 2.

⁵¹⁶ Julia Black, *The Global Risk Assessment Dialogue* (International Regulatory Co-operation, Case Studies, Vol 2, OECD Publishing 2013), 52/3. Also see, Alemanno, 'How to get out of the transatlantic regulatory deadlock over genetically modified organisms?', 221.

⁵¹⁷ Ibid.

cooperation amongst regulatory agencies to address technical and non-tariff barriers resulting from divergent regulatory processes:

We will strengthen regulatory cooperation, in particular by encouraging regulatory agencies to give a high priority to cooperation with their respective transatlantic counterparts, so as to address technical and non-tariff barriers to trade resulting from divergent regulatory processes.

In this, there is an implicit call for cooperation on scientific expertise – by domestic experts discussing domestic expertise. After all, when regulatory agencies cooperate to address technical and non-tariff barriers to trade because of diverging regulatory processes, it is the processes themselves and the (domestic) expertise used in these processes that are being put up for discussion. Whilst this could result in cooperation on domestic expertise via domestic experts, there are no practical steps accompanying the call for cooperation, resulting in an attention for expertise but no specific cooperative efforts. Furthermore, the EU-US Science and Technology agreement, whilst not directly relating to scientific expertise in policymaking but scientific expertise in research facilities, may very well affect policymaking. After all, if EU and US research facilities conduct cooperative research, this might influence how both assess risks and thus regulate these risks.

On the distinctive levels of cooperation in the NTA, there are more examples of possible cooperation on scientific expertise.⁵¹⁸ On the transgovernmental level, the transatlantic working groups and Transatlantic Legislators Dialogue are a form of using expertise to influence transatlantic policymaking. For example, the cross-committee delegation of the European Parliament consisted of ‘experts in fields such as intellectual property, telecommunications, aviation and energy efficiency.’⁵¹⁹ The Transatlantic Policy Network’s working groups necessarily involve expertise due to its academic nature and topics of discussion, covering science in their discussion. On the transnational level, i.e., the dialogues, expertise cannot be excluded. The Consumer Dialogue, for example, came to a principal disagreement in the case of beef hormones.⁵²⁰ Where the WTO Appellate Body judged the EU to have insufficient

⁵¹⁸ For the different levels of the NTA see, chapter 2, section 2.3.1.

⁵¹⁹ Jancic, 'The European Parliament and EU-US relations: revamping institutional cooperation?', 55.

⁵²⁰ For more on the beef hormones dispute see chapter 6, section 6.2.2; also see, for example, Christophe Charlier and Michel Rainelli, 'Hormones, Risk Management, Precaution and Protectionism: An Analysis of the Dispute on Hormone-Treated Beef between the European Union and the United States' (2002) 14 *European Journal of Law and Economics* 83; Christian Joerges, 'Law, Science and the Management of Risks to Health at the National, European and International Level - Stories on Baby Dummies, Mad Cows and Hormones in Beef' (2001) 7 *Columbia Journal of European Law* 1; Jacqueline Peel, 'Of apples and oranges (and hormones in beef): science and the standard review in WTO disputes under the SPS Agreement' (2012) 61 *ICLQ* 427.

scientific evidence to warrant the ban on hormones, the Consumer Dialogue reflected on the different attitudes between US and EU governments relating to the risk of growth-hormones and where EU consumer organisations supported the ban, US consumer organisations opposed the ban on growth-hormones.⁵²¹ In general, for consumer organisations to support or oppose certain legislation, (domestic) scientific experts must be consulted. The type of expertise in these EU-US RC working groups and dialogues are specifically domestic experts and domestic expertise involved in the dialogues who then influence the transatlantic agenda. Thus, despite not being explicitly mentioned, expertise inevitably plays a role in RC set up by the NTA predominantly through the influence of the bilateral dialogues.

Moving forward, the Joint Statement on Regulatory Cooperation asks for greater reliance on each other's technical resources and expertise and the Transatlantic Economic Partnership explicitly states a guarantee that regulatory policies will be predictable and scientific.⁵²² Both examples illustrate at a minimum a growing attention for science in regulatory policy in general and strengthening cooperation on scientific expertise across the Atlantic. In the following years, this attention kept growing resulting in a push towards cooperating on RAs, i.e., transnational expertise.

3.3.2 *A push towards cooperation on risk assessments and expertise*

In EU-US cooperation, the most work to be done is cooperation on health and safety standards. Health and safety standards are the biggest cause of divergence in the transatlantic relationship and frequently a cause of conflict. It is also in these areas that the TTIP negotiations raised a large amount of concern amongst consumers due to worries over fear of lowered levels of regulatory protection or problems with democratic accountability.⁵²³ As Alemanno analyses, the regulatory divergence between EU and the US health and safety standards is ascribed to different interpretations of the SPS Agreement.⁵²⁴ As seen in the WTO section of this chapter, science is the principle determining lawfulness when regulating on the protection of human, animal or plant life or health.⁵²⁵ As the EU and the US struggle to cooperate on these matters,

⁵²¹ Bignami and Charnovitz, 'Transnational Civil Society Dialogues', 266.

⁵²² For more on the Joint Statement on Regulatory Cooperation and the Transatlantic Economic Partnership see, chapter 2, section 2.3.2.

⁵²³ E.g., Latorre and Yonezawa, 'Stopped TTIP? Its potential impact on the world and the role of neglected FDI'; Haar, *Cooperating to deregulate*; De Ville and Siles-Brügge, *TTIP: The Truth about the Transatlantic Trade and Investment Partnership*; De Ville and Siles-Brügge, 'Why TTIP is a game-changer and its critics have a point'; notably, concerns relating to democratic accountability related predominantly to the Investor State Dispute Settlement Procedure which is beyond the scope of this thesis but interesting nonetheless.

⁵²⁴ Alemanno, 'The Transatlantic Trade and Investment Partnership and the Parliamentary Dimension of Regulatory Cooperation', 35.

⁵²⁵ SPS Agreement, art 2.2; also see *ibid*, 35.

it is science that is ever so often at the heart of EU-US regulatory divergence and any attempts at cooperating on scientific expertise have so far failed. Whilst on one level, science presupposes universality, Alemanno explains that in the setting of regulatory standards the *perception of risk* often drives regulatory decisions which can result in ‘scientifically unsubstantiated’ regulations.⁵²⁶ This seems true as, for example in the case of beef hormones, where the EU upheld its ban despite the fact that the WTO Panel ruled that there was insufficient scientific evidence to justify a ban on hormone fed beef.⁵²⁷ Public perception of risk and consumer preference in the EU played a crucial role in the EU upholding the ban on hormone fed beef, illustrating that requiring sufficient scientific evidence does not necessarily address regulatory divergence in certain areas due to societal preferences and the (cultural) perception of risk.⁵²⁸

With a view on these divergences in health and safety policies, the TTIP was supposed to include a SPS+ chapter, building on the principles of the SPS Agreement.⁵²⁹ Particularly on SPS measures, Alemanno rightfully concludes that ‘without a common basis of scientific understanding and with continued EU deference to consumer preference, the food sector is likely to remain an area of regulatory divergence.’⁵³⁰ When science is at the heart of regulatory divergence, cooperating on the integration of scientific expertise is *the* way to facilitate RC.⁵³¹ This has not gone by unnoticed by scholars such as Alemanno and Murphy. In the years before the TTIP, the focus of RC shifted to cooperating on RA and an understanding of frameworks, principles, and the integration of expertise:

*‘The immediate goal (...) should not be a harmonization of standards, but mutual understanding of the respective frameworks. Achieving this less ambitious objective of mutual understanding might in itself be a Herculean task, yet – if successful – this regulatory cooperation exercise may identify the real points of regulatory convergence/divergence, thus leading to the establishment of some common transatlantic principles on risk assessment.’*⁵³²

Furthermore, they add:

⁵²⁶ *ibid*, 35, 36

⁵²⁷ See, Johnson, 'The U.S.-EU Beef Hormone Dispute'.

⁵²⁸ Alemanno, 'The Transatlantic Trade and Investment Partnership and the Parliamentary Dimension of Regulatory Cooperation', 35,36.

⁵²⁹ *Ibid*, 4. And indeed, the proposals on TTIP’s SPS chapter seem to illustrate the desire to do so.

⁵³⁰ Alemanno, 'The Transatlantic Trade and Investment Partnership and the Parliamentary Dimension of Regulatory Cooperation', 34, 35, 36.

⁵³¹ See chapter 1, section 1.3.

⁵³² Alemanno, 'How to get out of the transatlantic regulatory deadlock over genetically modified organisms?', , 221.

*'Since regulatory policies are aimed at shielding public wellbeing from harmful products or practices, scientific convergence on risk assessment and risk management on a transatlantic basis would go a long way in short-circuiting commercial friction.'*⁵³³

As the literature presented these conclusions, the focus of RC efforts also aimed towards cooperating on domestic *and* transnational expertise. RC on expertise was first pursued by the High-Level RC Forum and several regulatory dialogues established between US agencies and relevant Directorate Generals in the Commission. The RC Forum moved towards sharing results and technical studies and thus arguably towards cooperation on IAs, committing to evidence-based policymaking as a regulatory principle.⁵³⁴ Further steps were supposed to be taken with the TTIP, even to propose more science-based decisions into measures outside of the SPS and TBT Agreement.⁵³⁵ However, with the TTIP failing to be concluded and ratified, further cooperation on expertise implemented into an FTA was put to halt. Only time will tell if an EU-US agreement such as the TTIP will be negotiated once more. Nevertheless, this chapter considers whether the negotiation papers on the TTIP indeed illustrate further cooperation on expertise (section 3.3.4). Before that, however, the Global Risk Assessment Dialogue deserves some attention (see below).

3.3.3 The Global Risk Assessment Dialogue

There is another example of the EU and the US cooperating on expertise: The Global Risk Assessment Dialogue – perhaps the most prominent example of explicit cooperation on expertise as a way of facilitating RC. This Dialogue, initially named the Transatlantic Risk Dialogue, took place between the EU, US and Canada and was broadened to a Global Risk Assessment Dialogue in 2008. So far, this multilateral Dialogue has taken place in the form of two conferences on RA, both hosted by the Commission.⁵³⁶ The objectives of the Dialogue are: improving mutual understanding of RA to reduce divergences in approaches to risk, improving governance of risks and building trust through enabling communications between scientists, risk managers in the political spectrum and the public.⁵³⁷ The Dialogue, set up as a dialogue in

⁵³³ Murphy, 'Framing essay : a shift in transatlantic diplomacy', 17/8. Also see, Frances G. Burwell, *Risk and Reward: U.S.-EU Regulatory Cooperation on Food Safety and the Environment*, 2002), 27.

⁵³⁴ See, Meuwese, 'EU–US horizontal regulatory cooperation: mutual recognition of impact assessment?', .

⁵³⁵ On evidence-based decision-making in the TTIP, see A. Herwig, 'TTIP regulatory cooperation: Changes in transnational risk regulation from WTO Law and WTO-consistency' (2016) 7 *European Journal of Risk Regulation* 262, 265.

⁵³⁶ See, Black, *The Global Risk Assessment Dialogue* and; Global Risk Assessment Dialogue, 'Summary report of the 2nd international risk assessment conference: a global risk assessment dialogue' 26-28 January 2011) <https://ec.europa.eu/health/sites/health/files/dialogue_collaboration/docs/ev_20110126_mi_en.pdf> accessed 20 April 2020.

⁵³⁷ Black, *The Global Risk Assessment Dialogue*, 53.

line with the dialogues taking place in RC in general, lacked essential high-level political support and was mainly set-up through bottom up interest and commitment.⁵³⁸ Whilst this Dialogue is potentially beneficial in view of RC by developing mutual understanding it is next to impossible to cooperate on regulatory standards without high level political support.⁵³⁹ It is a positive sign that there are civil servants within the Commission and US agencies who are keen to participate in such a dialogue, however this does not produce ‘institutional underpinning’ thus no basis for the Dialogue to continue to take place.⁵⁴⁰ Black explains that the ‘institutional momentum has dwindled’ and the Dialogue is been put on hold for the foreseeable future without any tangible progress.⁵⁴¹

The aim of the Risk Assessment Dialogue is developing common approaches through a dialogue, more specifically through scientific experts in government agencies and by enabling research institutions to work together – with a focus on developing common approaches regarding issues central to RA.⁵⁴² This type of expertise thus clearly relates to developing transnational expertise by a cooperation of domestic experts. Rather than exchanging information on domestic expertise gathered separately, transnational expertise can result in deeper RC as the expertise on which a regulation is based is conducted cooperatively thus creating a common scientific basis to a regulatory measure. The Risk Assessment Dialogue aimed to create possibilities for the EU and the US to establish a common scientific basis transnational expertise.

The 2011 conference, organised by the Commission’s Directorate General for Health and Consumers was attended by RA experts including scientists and representatives from the EU institutions and international RA bodies.⁵⁴³ During the conferences, discussions took place on RA terminology, characterisation and description of uncertainty, exposure assessment and the approaches to weigh scientific evidence in RA and for RA of mixtures of chemicals.⁵⁴⁴ Whilst the Directorate General for Health and Consumers concluded that the objectives of the dialogue

⁵³⁸ Black, *The Global Risk Assessment Dialogue*, 64.

⁵³⁹ Ibid.

⁵⁴⁰ Ibid.

⁵⁴¹ Ibid, 65.

⁵⁴² Ibid, 53. The conference report for the Transatlantic Risk Assessment Conference in 2008 was available at <http://ec.europa.eu/health/risk_assessment/events/ev_20081113_en.htm>but is currently (13 February 2020) no longer available.

⁵⁴³ See Dialogue, 'Summary report of the 2nd international risk assessment conference: a global risk assessment dialogue', 1.

⁵⁴⁴ Ibid, 2.

should be pursued further, the Dialogue has been put on hold since the last conference in 2011 and no joint outputs followed from the conferences on any of the discussion topics.⁵⁴⁵

3.3.4 *En route to and expertise in the TTIP*

Whilst the Joint Statement on RC in 1997 called for greater reliance on domestic expertise, not much has been achieved. The biggest development so far has been the Risk Assessment Dialogue (discussed above) which, upon closer look, is not more than a conference in the very sense of the word meaning an exchange of ideas by experts which did not result in joint outputs. The Risk Assessment Dialogue had the potential to launch further cooperation on matters of expertise in RC by creating possibilities for transnational expertise via collaborations between research institutions in the EU and the US and between domestic experts in government agencies. Whilst the existence of the Risk Assessment Dialogue is a recognition of the importance of a role for expertise in EU-US RC it does not provide much more than that.

Possibly, more could have been achieved with the TTIP. The proposal for the RC chapter of the TTIP states that the EU and US ‘will promote cooperation at the stage preceding the regulatory process, including on research, where appropriate’ which ‘may include the exchange of any information relevant for this purpose.’⁵⁴⁶ This means that the TTIP aimed to promote transnational expertise (i.e., the negotiation papers states cooperation on research) and an exchange of information on domestic expertise. Furthermore, as seen in chapter 2, the negotiation papers on GRP in the TTIP foresee in an exchange of information on available evidence, data, methodology and economic assumptions applied in the regulatory policy analysis considering the content of IAs.⁵⁴⁷ Thus in case of IAs, an exchange of information on domestic expertise would be promoted under the TTIP. Both the GRP chapter and the RC chapter of the TTIP thus aimed towards providing a role for expertise either through promoting transnational expertise or an exchange of information on domestic expertise.

In the negotiation papers of the TTIP, its sectoral chapters make reference to enhance RC through the exchange of information, data, or scientific opinions. The TBT chapter negotiation papers states that if a party expresses an interest in developing a technical regulation that resembles a (prepared) technical regulation of the other party, the party can request to provide

⁵⁴⁵ Black, *The Global Risk Assessment Dialogue*, 57. Dialogue, 'Summary report of the 2nd international risk assessment conference: a global risk assessment dialogue', 3.

⁵⁴⁶ European Commission, 'TTIP - EU proposal for Chapter: Regulatory Cooperation' (21 March 2016), art. x5(4) <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf> accessed 30 June 2020.

⁵⁴⁷ Commission, *TTIP - EU proposal for Chapter: Good Regulatory Practices*, art. 8.6

the data which the technical regulation is or will be based on – replying to this request is an obligation but confidential information may be withheld after a clarification on the scope of the request.⁵⁴⁸ To this end the EU and the US aimed to exchange domestic expertise which would allow for a discussion on possibilities of harmonised or compatible technical regulations.⁵⁴⁹ In case of SPS measures, the negotiation papers from the EU similarly promote the exchange of information on domestic expertise.⁵⁵⁰ The sectoral chapters of the TTIP thus predominantly focused on providing a role for expertise in the sense of exchanging information about domestic expertise.

Achieving an ongoing regulatory dialogue characterised the TTIP but there is no explicit mentioning of cooperation on expertise in the sense of developing transnational expertise via transnational experts, not even in the SPS chapter of the TTIP. In other words, there is an exchange of information but no mention of joint RAs or joint IAs (i.e., transnational expertise by transnational experts). The TTIP focused predominantly on exchanging information on domestic expertise aside from a general provision in the RC chapter that states the EU and US would promote cooperation on research. Alemanno doubts whether the TTIP's SPS chapter would have been more successful than the SPS Agreement itself considering how there is no 'common basis of scientific understanding', nor any work done to build such a common basis.⁵⁵¹ If the TTIP came to fruition it would have expectedly resulted in an exchange of information establishing an ongoing dialogue, possibly including a dialogue on domestic expertise.

3.4 Expertise in regulatory cooperation models

As opposed to the TTIP, the FTAs that establish the other three RC models researched in this thesis are signed and are (provisionally) in force. This section elaborates on the role of expertise in existing tools and approaches in RC in the CETA, the USMCA and the TCA respectively to answer the question: what is the role of expertise in current RC efforts?

⁵⁴⁸ European Commission, *TTIP – EU proposal for Technical Barriers to Trade in TTIP*, 7 January 2015 <https://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153025.pdf> accessed 22 October 2020, art. 4(2).

⁵⁴⁹ *Ibid.*, art. 4(2).

⁵⁵⁰ Commission, 'TTIP - EU proposal for Chapter: Good Regulatory Practices' accessed , art 8.6; European Commission, 'Textual Proposal Sanitary and Phytosanitary Measures (SPS)' 7 January 2015 <https://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153026.pdf> accessed 20 April 2020, art 14.2(c).

⁵⁵¹ Alemanno, 'The Transatlantic Trade and Investment Partnership and the Parliamentary Dimension of Regulatory Cooperation', 36.

3.4.1 Expertise in the CETA

This section analyses the role of expertise in the CETA's RC chapter and its sectoral chapters. Since the CETA is provisionally in force (as of September 2017), the following section examines if the activities that provide a role to expertise in CETA's RC are put to practice in EU-Canada RC (section 3.4.2).

3.4.1.1 Expertise in the CETA's RC chapter

There are two explicit references in the objectives of RC that assign a role to both domestic expertise and domestic experts.⁵⁵² Firstly, to contribute to the protection of human life, health or safety, plant life or health and the environment, the EU and Canada have the objective to contribute cooperatively to the base of information used by regulatory departments to identify, assess and manage risks.⁵⁵³ Secondly, Canada and the EU set out to build trust, deepen mutual understanding of regulatory governance *and obtain the benefit of each other's expertise* with the aim to avoid – amongst others – unnecessary regulatory differences.⁵⁵⁴ These objectives of RC explicitly provide a role to domestic experts (by obtaining the benefit of each other's expertise) and domestic expertise via an exchange of information (by contributing to the base of information). However, what is exactly meant with obtaining the benefit of each other's expertise? Furthermore, is the base of information used by regulatory departments a cooperative effort of the EU and Canada or, more generally, what base of information is the CETA referring to? Whilst a role for expertise is explicitly mentioned in the CETA's RC chapter, specific legal rules, procedural requirements, or more generally any kind of details relating to the involvement of expertise in the RC process are absent in the FTA.

Answers to the questions posed above can possibly be found in the RC activities of the CETA; after all, these activities contribute to achieving the objectives. As the objectives of RC under the CETA do provide a role to expertise – which acknowledges that expertise can address regulatory divergence and prevent disputes – the question is what RC activities involve expertise to either obtain the benefit of each other's expertise or to contribute to the base of information used by regulatory departments. The non-exhaustive list of RC activities set out in the CETA contain several textual references on expertise ranging from implicit to explicit mentioning of expertise and primarily aim at some form of exchanging information on domestic

⁵⁵² For a detailed examination of the CETA's RC chapter see, chapter 2, section 2.4.1.

⁵⁵³ CETA, art. 21.3 (a) (ii).

⁵⁵⁴ CETA, art 21.3.

expertise.⁵⁵⁵ Obtaining the benefit of each other's expertise arguably refers to the ongoing regulatory dialogue and the possibilities to involve expertise in said dialogue – but as it the case in the CETA in general, detailed procedural requirements are notably absent.⁵⁵⁶

The RC activities in the CETA create an ongoing regulatory dialogue and domestic expertise can be part of this dialogue. In general, the RC activities aim to establish an ongoing regulatory dialogue 'as early as possible' through consultation and the exchange of information – which the CETA calls bilateral dialogues on regulatory governance.⁵⁵⁷ In the ongoing regulatory dialogue, exchanging information on domestic expertise can take place as the RC activities mention exchanging information about experiences with regulatory tools such as RAs.⁵⁵⁸ Furthermore, regarding contemplated regulatory actions the EU and CETA exchange information to understand the rationale behind certain regulatory choices, comparing methods and assumptions and examining the possibilities for convergence.⁵⁵⁹ Understanding the rationale behind a regulatory decision is understanding the domestic expertise involved in taking such a decision. Thus, on contemplated regulatory action, there is an exchange of information on domestic expertise (used to support regulatory decision).⁵⁶⁰ In other words, the ongoing regulatory dialogue in the CETA creates the possibility to discuss domestic regulatory science supporting contemplated regulatory action of each of the parties.⁵⁶¹ This is the essence of RC the EU and Canada discuss regulatory measures and its supporting domestic regulatory science in the bilateral dialogue prior to adopting a proposal.⁵⁶²

The CETA moves beyond exchanging information on regulatory science by creating the possibility to conduct joint regulatory science, i.e., transnational expertise. One of the RC activities creates the possibility to conduct a joint RA and regulatory IA to examine the possibilities to minimise unnecessary divergences in regulations.⁵⁶³ Joint RAs and joint IAs are

⁵⁵⁵ See chapter 2, section 2.4.1.

⁵⁵⁶ Ibid.

⁵⁵⁷ CETA, art. 21.4 (b)(c)(d)(e); see chapter 2, section 2.4.1.

⁵⁵⁸ CETA, art. 21.4 (a).

⁵⁵⁹ CETA, art. 21.4 (f)(i).

⁵⁶⁰ Noteworthy are the considerations that decide that the EU and Canada aim to cooperate on the development, adoption, implementation and maintenance of international standards, guides and recommendations, CETA, art 21.4 (h). In the field of animal welfare, the exchange of expertise is specifically mentioned as a RC activity, CETA, art 21.4 (s). Furthermore, regarding post-implementation reviews, a summary of the results can be made available including a comparison of methods and assumptions used in these reviews, expectedly resulting in an exchange of information on these methods and assumptions, CETA, art 21.4 (o) (p) and (q).

⁵⁶¹ On regulatory science, see chapter 1, section 1.3.

⁵⁶² See chapter 5.

⁵⁶³ CETA, art 21.4 (g) (i); also see chapter 2, section 2.4.1.

transnational expertise, or in other words, joint regulatory science.⁵⁶⁴ The CETA creates possibilities for the EU and Canada to collect the same data, compare data collection practices and periodically compare data collection practices, analytical assumptions and methodologies.⁵⁶⁵ Moreover, the EU and Canada examine the possibilities to use the same or similar assumptions and methodologies (i.e., domestic expertise) with the aim to reduce differences in identifying issues and to promote similarity of results.⁵⁶⁶ Additionally, the CETA creates the possibility to conduct cooperative research agendas to, amongst others, reduce duplicative research, gather the best data and establish, when appropriate, a common scientific basis.⁵⁶⁷ This results in a stronger role for expertise than merely exchanging information on domestic expertise as the EU and Canada aim to establish a common scientific basis via transnational expertise. Whilst it is unknown what ‘when appropriate’ means, conducting cooperative research agendas implies that domestic experts cooperate under the CETA – whilst the CETA does not clarify how cooperative research takes place or if there is any funding for cooperative research. Arguably, the CETA achieves what the TTIP set out to achieve by attempting to create a common scientific basis and thus provide a stronger role for expertise in RC activities.

Overall, the CETA’s RC activities illustrate that the EU and Canada involve expertise to facilitate RC and considers expertise a potential facilitator of RC both through possible transnational expertise and an exchange of information on domestic expertise. Words such as *may*, *if* or *when appropriate*, *examining opportunities* or *appropriateness* or *promoting*, however, lead to the conclusion that none of the activities are obligatory and so the ongoing regulatory dialogue can result in discussions on domestic expertise or possibilities for transnational expertise, but this is not guaranteed.⁵⁶⁸ The role of expertise in RC thus depends on the practical implementation of the RC activities.⁵⁶⁹ The overall picture that emerges is that the EU and Canada consider expertise capable of being a facilitating factor in such cooperation either via transnational expertise (i.e., joint RAs or joint IAs) but more broadly through an exchange of information on domestic expertise in the ongoing regulatory dialogue. To reach a

⁵⁶⁴ See chapter 1, section 1.4.

⁵⁶⁵ CETA, art. 21.4 (i) (j) (l).

⁵⁶⁶ CETA, art 21.4 (k).

⁵⁶⁷ CETA, art 21.4. (n)

⁵⁶⁸ For more on the voluntary nature of RC see chapter 5, section 5.2.4.

⁵⁶⁹ See sub-section 3.4.1.6.

definitive conclusion on expertise in the CETA, further analysis is required on the sectoral chapters of the CETA and subsequently on the CETA in practice (section 3.4.1.5).

3.4.1.2 CETA's TBT chapter

The TBT chapter focuses predominantly on cooperation relating to the setting of standards. The EU and Canada agree to strengthen cooperation on TBT measures and cooperation activities may include promoting and encouraging cooperation between public or private organisation responsible for metrology, standardisation, testing, certification and accreditation, market surveillance or monitoring and enforcement activities.⁵⁷⁰ In other words, this could lead to private or public organisations (domestic experts) located in the EU to cooperate with their equivalent in Canada or vice versa. Furthermore, Canada and the EU promote and encourage promoting the acceptance of conformity assessment results, or, in other words, promote cooperation towards the mutual acceptance of conformity assessments results.⁵⁷¹

Another dimension of cooperation on standardisation is added by promoting closer cooperation between standard-setting bodies specifically.⁵⁷² As standardisation bodies develop standards through their expertise, this type of cooperation results in a role for domestic experts in private and public organisations in EU-Canada RC.⁵⁷³ Cooperation between standardisation bodies can result in an exchange of information about respective activities but the CETA also has a view on facilitating 'the harmonisation of standards based on mutual interest and reciprocity, according to modalities to be agreed by the standardisation bodies.'⁵⁷⁴ This can result in a cooperative setting of standards which thus results in transnational expertise via cooperation between domestic experts (i.e., standardisation bodies) or an exchange of information on domestic expertise. Whilst this is not cooperation between the two executives as such (i.e., the relevant Canadian Ministries or agencies and the – Directorate Generals of the – European Commission), the TBT chapter promotes cooperation on the setting of standards through domestic experts involved in public or private organisations, possibly resulting in transnational expertise.

Regarding the cooperation on TBT measures by the executives (i.e., the relevant Canadian Ministries or agencies and the – Directorate Generals of the – European Commission) – 'to the

⁵⁷⁰ CETA, art 4.3.

⁵⁷¹ Ibid.

⁵⁷² CETA, art 4.6.2.

⁵⁷³ NB this is notably different from cooperation on the setting of international standards as this relates to domestic standardisation bodies that will then cooperate with each other.

⁵⁷⁴ CETA, art 4.6.2.

extent possible' – the goal is to ensure that these regulations are compatible.⁵⁷⁵ To ensure compatibility, if the EU is interested in developing a technical regulation similar in scope to an existing or developing regulation in Canada, the EU can request relevant information, studies and data used in the preparatory stages whether the regulation is adopted or being developed (or vice versa).⁵⁷⁶ When there is a request for relevant information there is an obligation to provide the information – although it is unclear what happens if the information is not provided.⁵⁷⁷ Through this mechanism, the role of expertise in TBT measures is the exchange of information on domestic expertise – similar to the role of expertise in CETA's RC chapter.

3.4.1.3 CETA's SPS chapter

On SPS measures in general, there is an expectancy for science to play a stronger role in RC because science mediates tensions between national SPS policies.⁵⁷⁸ In the SPS Chapter of the CETA, Canada and the EU establish to endeavour to, on request, exchange information on a risk analysis or scientific opinion that has been produced and is relevant to SPS measures – except if notified to the WTO to avoid duplication.⁵⁷⁹ This results in an exchange of information on domestic expertise. Notably, it is specifically stated that this exchange of information could take place (*endeavoured to on request*) on the risk analysis or scientific opinion used when preparing SPS measures. This exchange of information on scientific information is to be supported by the CETA's Joint Management Committee for SPS measures, where an exchange of information relating to respective regulatory systems – including scientific basis for planned or existing measures – should take place.⁵⁸⁰ From this, the conclusion can be drawn that expertise – more specifically the scientific basis of regulatory standards – is put to discussion regarding SPS measures. Whilst there is explicit attention for scientific expertise, the role for expertise in the SPS chapter is limited to an exchange of information. Joint regulatory science is possible via the RC chapter (i.e., the RC activities) but not explicitly via the SPS Chapter of the CETA.

3.4.1.4 Other sectoral chapters

The references in the other sectoral chapters of the CETA that provide a role to expertise are in line with the CETA's RC chapter. The Trade and Sustainable Development Chapter, the Trade

⁵⁷⁵ CETA, art 4.4.1.

⁵⁷⁶ Ibid.

⁵⁷⁷ Ibid. NB it can be considered necessary to clarify and agree on the scope of the request and confidential information can be withheld.

⁵⁷⁸ See chapter 3, section 3.2.

⁵⁷⁹ CETA, art 5.11.2 (e), 5.11.3.

⁵⁸⁰ CETA, art 5.14 (f).

and Labour Chapter and the Trade and Environment Chapter all provide varying roles to expertise in cooperation ranging from joint IAs in Trade and Sustainable Development to exchanging information and ‘any other form of cooperation deemed appropriate’ in Trade and Labour.⁵⁸¹ This is in line with the role of expertise in the RC chapter of the CETA (as seen above) in that the ongoing regulatory dialogue can include matters of expertise and in some cases (although unclear what these cases exactly are) transnational expertise (i.e., joint RAs or joint IAs) is possible. For example, on Trade and Environment, specifically regarding trade in fisheries and aquaculture products, the CETA states that cooperation should take place with non-contracting parties with the aim of achieving good governance, which includes advocating for science-based decisions and compliance with those decisions in said organisations.⁵⁸² On environmental issues specifically, cooperation takes place through an exchange of information that may include exchanges on expertise (‘technical exchanges, exchanges of information and best practices, research projects, studies, reports, conferences and workshops’).⁵⁸³ Generally, expertise in these sectoral chapters either relate predominantly to an exchange of information on domestic expertise.

The conclusion here is that in the CETA’s RC there is a role for expertise, varying from an exchange of information on domestic expertise to possibilities for transnational expertise. The focus of the CETA’s RC is on establishing an ongoing regulatory dialogue that enables a discussion on contemplated or existing regulatory measures that affect trade including on the science supporting the regulatory measures (i.e., domestic expertise). What stands out in the role for expertise in CETA’s RC – and RC in general – is the absence of procedural rules and/or legal requirements.⁵⁸⁴ This leads to important questions such as, who is conducting the joint RA’s or joint IAs? The CETA does not provide any further answers to this question or a general framework in which this takes place. Thus, the RC activities and the role for expertise depends severely on what takes place in practice. The next sub-section assesses what takes place in practice since the CETA came into force (provisionally) in September 2017.

3.4.1.5 The CETA in practice

Meetings of the CETA’s institutions have been taking place through three mechanisms, the RC Forum, the bilateral dialogues and lastly, the sectoral committees. Essentially, the RC Forum,

⁵⁸¹ CETA, art 22.3; CETA, art 23.7.1.

⁵⁸² CETA, art 24.11.

⁵⁸³ CETA, art 24.12.

⁵⁸⁴ See chapter 2, section 2.4.1.

the bilateral dialogues and the sectoral committees engage in an exchange of information. The bilateral dialogues and arguably all other exchanges of information under the CETA expand on the work of international institutions confirming the idea that the WTO provides common ground that is expanded on through RC.⁵⁸⁵ CETA's RC results in Canada and the EU informing each other on their respective processes and having an informative dialogue as intended in the CETA's RC chapter. In some cases (see below), there is a push for cooperation of domestic experts however, in most cases domestic expertise is part of the information exchange. This takes place through respective parties conducting research (or RAs) which are then being discussed in the several institutions of the CETA. In line with the objectives and activities of RC as set out in the CETA, the essence of cooperation is in the exchange of information through an ongoing dialogue which sometimes includes discussing possibilities for transnational expertise.⁵⁸⁶

Importantly, and fundamental from a transparency point of view, the CETA's RC Forum and the sectoral Committees publish the results of their meetings online. The analysis in this section is based on the data available until February 2022.⁵⁸⁷ These documents clarify if there are any practical attempts at cooperating on expertise whether by conducting joint regulatory science or through an exchange of information on domestic expertise. These documents are important to assess if expertise is used to cooperate, but also fundamental from a transparency point of view. After all, the focus of this thesis is the throughput-legitimacy deficit of RC and addressing this deficit by providing a role to expertise in the RC process.⁵⁸⁸ In this view, transparency is a prerequisite for throughput-legitimacy because without transparency, the entire RC process would take place behind closed doors.⁵⁸⁹ The fact that all the documents are available online is thus a fundamentally important aspect of the legitimacy of CETA's RC.

3.4.1.5.1 The RC Forum

The RC Forum had its first meeting in December 2018, followed by meetings in February 2020 and February 2021.⁵⁹⁰ In line with the CETA's RC objectives and activities as analysed in this

⁵⁸⁵ See chapter 2, section 2.2; See, for example, EU-Canada, 'Joint Report Meeting of the Bilateral Dialogue on Motor Vehicle Regulations' 5 October 2018) <https://trade.ec.europa.eu/doclib/docs/2019/january/tradoc_157626.pdf> accessed 20 April 2020.

⁵⁸⁶ See chapter 2, section 2.4.1.

⁵⁸⁷ Available via <<https://trade.ec.europa.eu/doclib/press/index.cfm?id=1811>> accessed 20 February 2022.

⁵⁸⁸ See chapter 1.

⁵⁸⁹ See chapter 6.

⁵⁹⁰ Available via <<https://trade.ec.europa.eu/doclib/press/index.cfm?id=1811>> accessed 20 February 2022.

thesis so far, the focus of the RC is indeed on the exchange of information.⁵⁹¹ More precisely, expertise is used by the EU and Canada in accordance with their respective regulatory frameworks and at most there is an information exchange about domestic expertise in the RC Forum – but no signs of transnational science. RC takes place through an exchange of information. In the analysed data, there is no sign of IAs conducted cooperatively nor the co-use of expertise. When expertise is discussed in the RC Forum it revolves around an exchange of data, information (for example on the state-of-play) and an exchange of expert reports conducted in their respective legal orders. Other discussion may involve the impact of regulations on the respective legal orders, for example:

When discussing the deployment of connected devices, the RC Forum concluded to a lack of understanding on applicable regulations by the EU and Canada, respectively. Consequently, the EU and Canada ‘agreed that a more thorough analysis could be conducted with respect to identifying the impact of possible differences in regulation, certification, or labelling approaches’ and decided that ‘teams on both sides will engage in this regard in the next months.’⁵⁹²

What this illustrates is that the EU and Canada are aiming to develop a greater understanding of their respective regulatory framework and in doing so, find cooperation opportunities. The areas on which the RC Forum focused in its inaugural meeting in 2018 were Cybersecurity and the Internet of Things, Animal Welfare, Cosmetic-like Drug Products, Pharmaceutical Inspections and Consumer Product Safety.⁵⁹³ By its second meeting in 2020, ‘drawn from stakeholder input and based on feedback from EU and Canadian regulators’, other topics were added to the agenda of the RC Forum, for example Paediatric Medicines.⁵⁹⁴ The third meeting in 2021 provides an update on the work done so far but does not add any new topics considering the effect of the COVID19 pandemic on the progress of EU-Canada RC.⁵⁹⁵ Through the ongoing regulatory dialogue, regulators from the EU (i.e., officials from various Directorate Generals of the Commission) and Canada (i.e., regulators from the federal Canadian

⁵⁹¹ Regulatory Cooperation Forum, 'Report of the 1st meeting of the CETA Regulatory Cooperation Forum' (2018) <https://trade.ec.europa.eu/doclib/docs/2019/february/tradoc_157679.pdf> accessed 20 April 2020).

⁵⁹² *ibid.*, 2.

⁵⁹³ *Ibid.*

⁵⁹⁴ Regulatory Cooperation Forum, 'Joint Report of the 2nd meeting of the CETA Regulatory Cooperation Forum', 3-4 February 2020, <<https://circabc.europa.eu/ui/group/09242a36-a438-40fd-a7af-fe32e36cbd0e/library/972e6f0e-5f4b-4be6-aed0-657a04720ba7/details>> accessed 9 February 2022.

⁵⁹⁵ Regulatory Cooperation Forum, 'Joint Report of the 3rd meeting of the CETA Regulatory Cooperation Forum', 9-10 February 2021 <<https://circabc.europa.eu/ui/group/09242a36-a438-40fd-a7af-fe32e36cbd0e/library/3a12dcc0-78bf-4007-beec-fd5084520819/details>> accessed 9 February 2022.

government such as Global Affairs Canada) create a policy laboratory in which they discuss possibilities to facilitate trade between them.

What stands out in the analysis of this data – and fundamental to assessing the throughput-legitimacy deficit of RC – is that the focus of the ongoing regulatory dialogue is indeed on facilitating trade. For example, on Cosmetic-like Drug Products, a pilot to exempt sunscreen products from re-testing and quarantine resulted in an exemption for EU sunscreen products and anti-dandruff shampoos that has been implemented through regulation.⁵⁹⁶ This confirms that the policy laboratory created through RC does result in new (or amended) regulations that facilitate trade between the EU and Canada. Whilst, for example, RC on Consumer Product Safety enables a dialogue on the safety of products in their respective markets, the predominant focus of RC is on facilitating trade and indeed, RC affects regulatory frameworks and the political discourse in the preparatory stages of regulatory policymaking.⁵⁹⁷ Whilst this is not a surprise, it is concerning from a throughput-legitimacy point of view because a focus on trade results in participation by business interests.⁵⁹⁸

3.4.1.5.2 *The CETA's bilateral dialogues*

The CETA's bilateral dialogues are taking place annually since 2018 and are attended by the relevant Directorate Generals from the European Commission and relevant federal government agencies from Canada.⁵⁹⁹ The CETA's bilateral dialogues take place on various policy areas, specifically on Biotech Market Access Issues, Motor Vehicle Regulations, Forest Products, Raw Materials, Enhanced Cooperation on Science, Technology, Research and Innovation and on Electric Commerce.⁶⁰⁰ These dialogues, in line with RC as set out in the CETA, result in an exchange of information – which sometimes includes an exchange of information on domestic expertise.

The bilateral dialogues in the CETA illustrate a varying focus when exchanging information. Biotech Market Access issues is a contested policymaking area as the bilateral dialogue on Agricultural Biotech Market Access Issues existed prior to the CETA following a WTO dispute

⁵⁹⁶ Regulatory Cooperation Forum, 'Joint Report of the 3rd meeting of the CETA Regulatory Cooperation Forum', 9-10 February 2021 <<https://circabc.europa.eu/ui/group/09242a36-a438-40fd-a7af-fe32e36cbd0e/library/3a12dcc0-78bf-4007-beec-fd5084520819/details>> accessed 9 February 2022.

⁵⁹⁷ See chapter 1.

⁵⁹⁸ See chapter 5, section 5.2.3.

⁵⁹⁹ The reports of the meetings are available at <https://circabc.europa.eu/ui/group/09242a36-a438-40fd-a7af-fe32e36cbd0e/library/892edc0e-c670-433a-9fae-26fd5e8e53f3?p=1&n=10&sort=modified_DESC> accessed 9 February 2022.

⁶⁰⁰ CETA, art. 25.1.

resulting in a Mutually Agreed Solution between Canada and the EU that established the dialogue.⁶⁰¹ Further analysis of this dispute is beyond the scope of this thesis. What this illustrates, however, is that the focus of the information exchange is dependent on whether the policy area is contested or not. In general, the bilateral dialogues are dialogues in which the EU and Canada can express concerns and request further information about their respective regulatory frameworks. On Biotech Market Access issues expressing concerns regarding certain regulatory standards or even explaining respective regulatory procedures is dominant, for example:

*'Canada stressed the importance of timely approvals of biotechnology events in the EU and the importance for the EU to ensure that proposals for GM events are processed as fast as possible within the procedures laid down in EU approval legislation. (...) The Commission explained the procedural steps set out in the EU legislation, following the adoption by the EFSA GMO Panel of a favourable Scientific Opinion. The first step, after the publication of the EFSA overall opinion, is to launch a public consultation on the EFSA opinion for a period of one month. In case scientific comments are received during this period, EFSA is consulted to assess if they contain new information that could lead the GMO Panel to reconsider its opinion. Subsequently, a draft authorisation decision is prepared and presented for a vote in the Standing Committee on Plants, Animals, Food and Feed (section GMO). In case this vote does not result in a qualified majority, the draft decision is submitted to the Appeal Committee for a vote. In case no opinion is delivered by the Appeal Committee, it is for the Commission to decide on the draft authorisation.'*⁶⁰²

Through this information exchange such as this, a deeper understanding of respective regulatory processes is achieved. Deblock argues that Canadian regulators will likely have difficulty understand the EU regulatory process – which indeed seems to be the case – and thus expects that a transatlantic regulatory dialogue ‘will be a source of misunderstanding and disillusionment for both Canadians and Europeans.’⁶⁰³ The transatlantic dialogue, however, is a positive development in view of cooperating as understanding respective regulatory procedures facilitates cooperation. However, it does illustrate that in this contested policy area, the information exchange is limited to gaining a mutual understanding – or in this case enhance the understanding of the EU regulatory process.

⁶⁰¹ European Communities – Measures Affecting the Approval and Marketing of Biotech Products WT/DS292 <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm> accessed 9 February 2022.

⁶⁰² EU-Canada, 'Joint Report 11th Meeting of the Bilateral Dialogue on Biotech Market Access Issues' 4 March 2019 <https://trade.ec.europa.eu/doclib/docs/2019/september/tradoc_158341.pdf> accessed 20 April 2020, 2.

⁶⁰³ Christian Deblock, 'Canada and International Regulatory Cooperation: A Comparison of USMCA, CETA and CPTPP' in Gilbert Gagné and Michèle Rioux (eds), *NAFTA 20: From the first NAFTA to the United States-Mexico-Canada Agreement* (Springer Nature 2021), 193.

On the contrary, in a less controversial policy area, the EU and Canada decided to deepen cooperation. Rather than focusing on how the regulatory process works, on forest products, the EU and Canada shared information about forthcoming studies, tools & standards, and implementation guidance.⁶⁰⁴ On raw materials, the EU and Canada plan to share results of research and innovation projects.⁶⁰⁵ Moreover, the EU and Canada decided to increase collaboration between relevant scientific partners on research and development relating to raw materials.⁶⁰⁶ On raw materials there is thus work being done beyond sharing or exchanging information through increasing collaboration on research and development between scientific partners, including sharing information about funding opportunities. There is a possibility for cooperative research on raw materials and thus for a possible common scientific basis for future regulatory standards relating to raw materials, i.e., transnational expertise. Whilst further research is required to assess the different focus of the exchange of information in contested and less contested policy areas, the analysis of the data so far illustrates that the exchange of information and the use of expertise to build a common scientific basis varies in focus depending on the policy area.

In general, the CETA's bilateral dialogue illustrate that cooperation is taking place by exchanging information – in line with the CETA's RC chapter – and that the level of cooperation (rather unsurprisingly) varies from policy area to policy area.⁶⁰⁷

3.4.1.5.3 Sectoral committees of the CETA

Other information exchanges have taken place in the sectoral committees of the CETA.

Under the TBT Chapter of the CETA there is an exchange of information. The encouragement of cooperation between standardisation bodies is assigned to the *Trade in Goods Committee*.⁶⁰⁸ The dialogue in this Committee discusses development of the dialogue in the *Specialised Committees* (see below). Regarding expertise, this ongoing dialogue results in discussions on the assessment of risk or hazard (on request) and an information exchange (where there is mutual interest) on standards, technical regulations or conformity assessment procedures

⁶⁰⁴ EU-Canada, 'Joint Report Meeting of Bilateral Dialogue on Forest Products' 24 May 2019) <https://trade.ec.europa.eu/doclib/docs/2019/july/tradoc_158172.pdf> accessed 20 April 2020.

⁶⁰⁵ EU-Canada, 'Joint Report Meeting of Bilateral Dialogue on Raw Materials' 16 November 2018) <https://trade.ec.europa.eu/doclib/docs/2018/december/tradoc_157567.pdf> accessed 20 April 2020.

⁶⁰⁶ EU-Canada, 'Joint Report 2nd Meeting of Bilateral Dialogue on Raw Materials' 6 March 2019) <https://trade.ec.europa.eu/doclib/docs/2019/april/tradoc_157819.pdf> accessed 20 April 2020.

⁶⁰⁷ See chapter 4.

⁶⁰⁸ CETA, art 4.7 (d).

including those of third parties or international bodies.⁶⁰⁹ There are no signs of explicit cooperation but rather a discussion of respective regulatory frameworks and how this affects trade between Canada and the EU.

As in the bilateral dialogues (see above), cooperation varies in the different policy-areas in which RC takes place – through the CETA’s *Specialised Committees*. On Wines and Spirits for example, the EU expressed the need for involvement at an early stage when Canada consults with its Provinces on reforms of measures regulating wines and spirits resulting – which resulted in Canada ‘ensuring an enhanced participation of provincial representatives.’⁶¹⁰ This illustrates that whilst RC in the CETA is an effort of the executive (i.e., the Commission and the Canadian federal government), RC can affect the Canadian Provinces. Other dialogues, for example on pharmaceuticals, relate to possible risks relating to products traded between the EU and Canada – on pharmaceuticals an administrative arrangement was set up consisting of a two-way alert program through Rapid Alert Notifications in case of, for example, life-threatening product recalls – accompanied by its health RA.⁶¹¹ The ongoing dialogue on Agriculture, an important trade area for both the EU and Canada, is predominantly a dialogue over regulatory standards and requirements that affect trade between the parties and how to address this.⁶¹² Moreover, the EU and Canada are discussing FTAs with other countries and its ratification processes with a view to keep each other up to date about what is going in their respective legal orders.⁶¹³ More precisely, the EU and Canada discuss the impact of the USMCA and the EU has asked – specifically on dairy ingredients – that a solution under the USMCA also applies to the EU.⁶¹⁴ This illustrates that RC under the CETA can also include a dialogue on the effects

⁶⁰⁹ CETA Trade in Goods Committee, 'Meeting of the Trade in Goods Committee' 29 November 2018) <https://trade.ec.europa.eu/doclib/docs/2019/april/tradoc_157818.pdf> accessed 20 April 2020; CETA, art 4.7 (c) (e). Mutual recognition of conformity assessment bodies is, whilst a minimal form of RC, not the integration of expertise as analysed by this chapter. Conformity assessment procedures take place at the implementation stage and does not qualify as regulating as such. Therefore, this will not be dealt with when analysing the integration of expertise in RC.

⁶¹⁰ *ibid.*; CETA Wines and Spirits Committee, 'Meeting of the Wines and Spirit Committee' 24 September 2019) <https://trade.ec.europa.eu/doclib/docs/2019/december/tradoc_158508.09.19.pdf> accessed 20 April 2020

⁶¹¹ Administrative Arrangement under Article 15.3(b) of the Protocol on the Mutual Recognition of the Compliance and Enforcement Programme regarding Good Manufacturing Practices for Pharmaceutical Products, art. 5 <https://trade.ec.europa.eu/doclib/docs/2019/july/tradoc_157977.pdf> accessed 20 April 2020.

⁶¹² CETA Report of the Meeting of the Committee on Agriculture, 23 September 2019, <<https://circabc.europa.eu/ui/group/09242a36-a438-40fd-a7af-fe32e36cbd0e/library/048e7f05-5a6a-4e0f-8860-41585fb93e0c/details>> accessed 20 April 2020.

⁶¹³ See, for example, CETA Wines and Spirits Committee, 'Meeting of the Wines and Spirit Committee' 24 September 2019) <https://trade.ec.europa.eu/doclib/docs/2019/december/tradoc_158508.09.19.pdf> accessed 20 April 2020.

⁶¹⁴ CETA Report of the Meeting of the Committee on Agriculture, 23 September 2019, <<https://circabc.europa.eu/ui/group/09242a36-a438-40fd-a7af-fe32e36cbd0e/library/048e7f05-5a6a-4e0f-8860-41585fb93e0c/details>> accessed 20 April 2020.

of other FTAs that include RC – a sign of a global policy laboratory.⁶¹⁵ Essentially, the sectoral dialogues in the Trade Committees result in an ongoing regulatory dialogue between Canada and the EU regarding the state-of-play of different trade areas and aim to facilitate trade – and depending on the trade area in question there is a varying degree from simply exchanging information to establishing cooperation – whilst no explicit cooperation is established (yet).

The *SPS Committee* similarly focuses on the exchange of information, as seen with the other committees and RC in general in the CETA. On food safety measures, there is an information exchange including on one specific measures from Member States: ‘Canada registered its concerns regarding the scientific basis for, and trade restrictive nature of, France's ban on cherry imports from countries which permit the use of dimethoate.’⁶¹⁶ Interestingly, this specific dialogue refers to expertise of a Member State rather than the EU itself, but this does not happen often. It does illustrate, however, that discussions on domestic expertise of a Member State is possible in the CETA’s RC resulting in a possible effect of RC on Canada’s provinces (see above) and the EU’s Member States. So far, however, the ongoing dialogue is an exchange of information with the possibility to discuss domestic expertise. Possibilities to cooperate on expertise matters do exist as, for example, on antimicrobial resistance the EU and Canada wish to enhance cooperation and ‘it was agreed at expert level to consider possible areas of bilateral interest for future cooperation and the way forward.’⁶¹⁷ Whilst in SPS measures, cooperation on expertise seems expected, at best the EU and Canada are considering possible areas to conduct joint regulatory science.

Overall, the CETA in practice illustrates that RC is a work in progress. As set out in the FTA, RC is an exchange of information and the CETA established an ongoing regulatory dialogue. Discussions on joint regulatory science is present in the ongoing dialogue – however not (yet) implemented. Interestingly, the RC dialogue also refers to regulatory science by EU Member States. Moreover, other RC models are discussed in the EU-Canada ongoing regulatory dialogue, such as the USMCA. The global policy laboratory is therefore increasingly apparent in the RC models as RC affects the regulatory framework of Canada and the EU but also has an indirect effect on EU Member States, Canadian provinces, and the other RC models.⁶¹⁸

⁶¹⁵ See chapter 4.

⁶¹⁶ CETA SPS Committee, 'Second Joint Management Committee' 25-27 February 2019) at 5.4 <https://trade.ec.europa.eu/doclib/docs/2019/march/tradoc_157809.pdf> accessed 20 April 2020.

⁶¹⁷ *ibid* at 6.

⁶¹⁸ See chapter 4, section 4.2.

3.4.2 Expertise in the USMCA

As seen in chapter 2, the USMCA generally affirms the right to regulate, however, limits this right by stating that regulating must be done in accordance with the rights and obligations provided by the agreement.⁶¹⁹ Consequently, the GRP chapter of the USMCA is obligatory – as opposed to voluntary as seen in other efforts. The RC provision in the GRP chapter of the USMCA states parties are obligated to *encourage* RC – whilst the GRP that are stipulated in its chapter are obligatory.⁶²⁰ The USMCA takes another approach as opposed to the other RC models by using obligatory GRP to facilitate trade and aim for deregulation.⁶²¹

3.4.2.1 Expertise through Good Regulatory Practices

Whilst the USMCA emphasises the need of scientific expertise as a basis for regulatory standards, it creates requirements for respective regulatory procedures rather than establishing cooperative efforts on expertise explicitly. Aimed at the liberation of trade, science-based policymaking is considered a crucial regulatory practice and the importance of basing regulations on the best available scientific evidence and expertise – i.e. the ‘sound science’ principle – is very much in line with North American traditions.⁶²² Expertise in the USMCA is reminiscent of the role of expertise in the US regulatory system since sound science is embedded in USMCA’s GRP explicitly demanding that regulatory standards ought to be based on reliable and high-quality information and that regulatory authorities should adopt publicly available mechanisms to encourage them to seek the best, reasonably available (scientific) information.⁶²³ In case this information is systematically collected through surveys when developing a regulation ‘sound statistical methodologies’ have to be used ‘before drawing generalized conclusions concerning the impact of regulation.’⁶²⁴ RC in the USMCA thus integrates expertise by implementing GRP that are considered fundamental to cooperation resulting in a focus on converging regulatory practices.⁶²⁵

However, the focus of the GRP chapter is on public input rather than expertise. The GRP chapter focuses on the inclusion of expertise in the preparatory or implementation stages of the

⁶¹⁹ USCMA, preamble. Also see chapter 2, section 2.4.2.

⁶²⁰ See further chapter 2, section 2.4.2.

⁶²¹ See chapter 4.

⁶²² The ‘sound science paradigm’, is generally a North American approach on regulations, see Peel, *Science and Risk Regulation in International Law*, 113. This is not to say, however, that the EU, for example, does not adhere to this principle. See, Veerle Heyvaert, *Transnational Environmental Regulation and Governance: Purpose, Strategies and Principles* (Cambridge University Press 2018), 244; see further chapter 4.

⁶²³ USMCA, art 28.5.1; See chapter 4 at ...; On the role of expertise in US administrative law see, for example, Richard B. Stewart, ‘The reformation of American administrative law’ (1975) 88 Harvard law review 1669.

⁶²⁴ USMCA, art 28.5

⁶²⁵ See chapter 2, section 2.4.2; USMCA, art 28.2.1

regulatory process but emphasises that expert advice *may* be obtained but should not substitute comments from the public.⁶²⁶ Expertise thus complements the notice and comment procedure under the USMCA, putting expertise in a secondary position as opposed to public input. Accordingly, the USMCA makes it explicitly possible for any interested person, regardless of domicile, to provide written comments on the work of the expert groups or bodies – i.e., expertise – used in the preparation or implementation of regulations.⁶²⁷ Why is this included in the USMCA? Expert advice is generally sought by regulatory authorities in the preparation of regulatory standards – presumably through administrative law provisions in their domestic legal systems – which seemingly makes including it in an FTA redundant. Moreover, the USMCA already states that regulatory standards ought to be based on high-quality information, assuming the inclusion of expertise in the regulatory process. The need for including this is better explained by the importance of the notice and comment procedure rather than the inclusion of expertise. The most obvious conclusion is, as Labonté and others conclude, that the article on expert advisory groups makes way for industry (i.e., lobbying groups) to be involved in policy development rather than constituting a cooperation on expertise.⁶²⁸ Furthermore, since the USMCA is an FTA between the US, Mexico and Canada, the USMCA incorporates the regulatory practices of the US and so Deblock concludes that this ‘convergence of regulatory practices (...) is expected to go in one direction: that of the dominant market, in other word the United States.’⁶²⁹ He continues that RC is arguably to develop in favour of the US.⁶³⁰ The USMCA thus incorporates US regulatory practices that are obligatory to the parties of the USMCA.

The USMCA’s public input procedure is realised through the transparent development of regulations – and public input can also relate to the expertise supporting regulatory measures, i.e., regulatory science.⁶³¹ The USMCA demands an explanation of the data used in preparation of the regulation and that other information, such as the scientific analysis that the regulation relies on (including the RA) must be made publicly available.⁶³² And in the final publication of a regulatory measure, parties are obligated to elaborate on the relationship between the

⁶²⁶ USMCA, art 28.10 and 29.9.3

⁶²⁷ USMCA, art 28.10(4).

⁶²⁸ Ronald Labonté and others, 'USMCA (NAFTA 2.0): tightening the constraints on the right to regulate for public health' (2019) 15 *Globalization And Health*, 7.

⁶²⁹ Deblock, 'Canada and International Regulatory Cooperation: A Comparison of USMCA, CETA and CPTPP', 193.

⁶³⁰ *ibid.*, 193.

⁶³¹ USMCA, art 28.9; for participatory rights in the USMCA, see chapter 5, section 5.3.2.

⁶³² *Ibid.*

regulation and the key evidence and data used.⁶³³ These considerations illustrate the importance of expertise when preparing regulatory standards and provide the opportunity for public input on matters of expertise, regardless of their impact on trade.⁶³⁴ Suggestions for improvement can be given as well ‘for the issuance, modification, or repeal of a regulation’ based on, amongst others, failing to take into account changed circumstances such as relevant scientific developments.⁶³⁵ These suggestions for improvement can trigger a retrospective review leading to parties determining whether modification or repeal of the regulations is needed.⁶³⁶ The USMCA thus creates a variety of possibilities for any interested person, regardless of domicile, to submit written comments relating to the expertise used in the setting of a regulatory standard claiming, for example, that the expertise used is wrong or outdated.⁶³⁷ Overall, the USMCA demands transparency on domestic expertise resulting in possibilities for public input on expertise which the regulatory authority must evaluate before finalising the regulation.⁶³⁸

3.4.2.2 Expertise in the encouragement of regulatory compatibility and cooperation

On encouraging RC, the USMCA acknowledges the importance of regulatory dialogues to promote regulatory compatibility and cooperation and in light of that encourages regulatory authorities to engage in such a dialogue and RC activities with their counterparts. Recognising the mechanisms from the WTO Agreement, the USMCA provides specific RC mechanisms that can be used ‘as appropriate’ to promote regulatory compatibility and cooperation. The mechanisms that relate to expertise specifically are:

- the early exchange of early stage formal or informal exchange of technical or scientific information or data, including coordinating research agendas to reduce duplicative research;
- exploring possible common approaches to the evaluation and mitigation of risks or hazards, including those potentially posed by the use of emerging technologies
- co-funding of research in support of regulations and implementation tools of joint interest;
- facilitating the greater use of relevant international standards, guides, and recommendations as the basis for regulations, testing, and approval procedures;
- when developing or implementing regulations, considering relevant scientific or technical guidance documents developed through international collaborative initiatives.⁶³⁹

⁶³³ USMCA, art. 28.12.1 (e).

⁶³⁴ USMCA, art. 28.9.1, 3 and 4. Namely, art. 28.9.3 decides that any interested person ‘regardless of domicile’, has an opportunity to submit written comments on the items mentioned in 28.9.1 (which includes expertise). When there is an expected significant impact on trade, art. 28.9.4 stipulates specific timings that must be adhered to (no less than 60 days or a longer period if appropriate). In other cases (i.e., when there is no expected significant impact on trade), the opportunity to submit written comments cannot be less favourable than is provided to citizens of the respective parties.

⁶³⁵ USMCA, art. 28.14.

⁶³⁶ USMCA, art. 28.13 and 28.14.

⁶³⁷ USMCA, art. 28.9.3.

⁶³⁸ USMCA, art. 28.9.8.

⁶³⁹ USMCA, art. 28.17.3.

In so many words, the USMCA aims to create an ongoing dialogue through the (early) exchange of early-stage formal or informal exchange of technical or scientific information or data. Coordinating and co-funding research also plays a role and through a dialogue it is possible that duplicative research is reduced. Furthermore, cooperation on expertise through international initiatives can take place regarding the use of international standards and guidance developed through international collaborative initiatives. Cooperation on expertise thus most likely takes place or strengthened through (already existing) international cooperation. The USMCA does aim to establish an ongoing dialogue but does not put much weight on this as it is simply encouraged – as appropriate to the particular circumstances.⁶⁴⁰ As of April 2022, there is no further data available on how these considerations are implemented. Essentially, the RC mechanisms of the USMCA that relate to expertise are predominantly focused on an exchange of information on domestic expertise although exploring common approaches to the evaluation of risks and the co-funding of research could also result in transnational expertise.

3.4.2.3 Expertise in the sectoral chapters of the USMCA

In the sectoral chapters of the USMCA, specifically on TBT and SPS measures, there are efforts to establish a role for expertise.

On TBT measures it is stated that these should adhere to international standards and parties are obligated to cooperate on ensuring that technical regulations are based on international standards, guidelines, recommendations and do not create unnecessary obstacles to trade.⁶⁴¹ In other words: TBT measures ought to be the least trade restrictive as they should not create unnecessary obstacles to trade. Facilitating trade is therefore at the heart of the USMCA's TBT chapter – and frankly at the heart of the USMCA (and more broadly FTAs) in general. If international standards are not considered, the reason for doing so is provided including an identification of the scientific or technical evidence on which the decision was based.⁶⁴² Thus, when diverting from international standards, scientific evidence (i.e., domestic expertise) is possibly a topic of discussion.

The USMCAs TBT chapter focuses on international standards. As argued by Labonté and others, the focus on international standards could lead to the negative outcome of governments choosing to regulate in accordance with international standards that conceivably provide a

⁶⁴⁰ USMCA, art. 28.17.3.

⁶⁴¹ USMCA, art. 11.4; Labonté and others, 'USMCA (NAFTA 2.0): tightening the constraints on the right to regulate for public health', 5.

⁶⁴² USMCA, art. 11.4.5.3.

lower threshold of safety rather than opting for more protective ones.⁶⁴³ After all, considerations such as these provide no incentive to choose higher protection than provided by international standards – which is an issue with international standards in general. Even so, via these considerations, expertise is used in TBT measures to facilitate cooperation through adhering to international standards. After all, if all parties to the USMCA adhere to international standards, the outcome of regulations is similar and based on the same expertise by standardisation bodies (albeit with a possible lower protective threshold) and if not, a discussion on underlying scientific evidence (i.e., domestic expertise) can take place. Cooperation on expertise in the USMCA’s TBT chapter is minimal. The expertise used is the expertise of the standardisation bodies as a common standard which provides added regulatory force to international standards. This does not go much further than cooperation on the WTO level.

In the SPS chapter of USMCA the objectives relating to expertise are advancing science-based decision-making, encouraging the development and adoption of science-based international standards, guidelines, and recommendations, and promote their implementation.⁶⁴⁴ In conjunction with the objective to enhance compatibility of SPS measures, science-based decision-making – novel requirements in comparison to the WTO’s SPS Agreement – suggests that science could play a role in enhancing said compatibility.⁶⁴⁵ Advancing science-based decision-making in the USMCA’s SPS chapter takes place through the provision on science and risk analysis which recognises the importance of basing SPS measures on scientific principles.⁶⁴⁶ As with TBT measures, the USMCA states that SPS measures must be based on international standards, guidelines or recommendations.⁶⁴⁷ SPS measures must be based on RA when deviating from international standards.⁶⁴⁸ The USMCA does not prevent a party to adopt or maintain an SPS measures provisionally in case of insufficient evidence, however, it does set some rules in place regarding these provisional measures.⁶⁴⁹ Whilst these rules are

⁶⁴³ This is a generally reported issue with international standards. Labonté and others, 'USMCA (NAFTA 2.0): tightening the constraints on the right to regulate for public health', 5.

⁶⁴⁴ USMCA, art. 9.3.1 (h).

⁶⁴⁵ USMCA, art. 9.3.1 (g) (h).

⁶⁴⁶ USMCA, art. 9.6.

⁶⁴⁷ USMCA, art. 9.6.3.

⁶⁴⁸ USMCA, art. 9.6.3. See below.

⁶⁴⁹ USMCA, art. 9.6.5 and 9.6.6. Whilst provisional measures are allowed in case of insufficient scientific evidence, the required information must be obtained and used in a new risk assessment leading to revising the provisional measure 'within a reasonable period of time'. Although unclear how long this exactly is, it is decided that SPS measures are only applied to the extent necessary to protect human, animal, or plant life or health, must be based on relevant scientific principles and are not maintained if there is no longer a scientific basis. Unless there is an emergency, measures can be taken precautionarily and even in case of an emergency, the scientific basis of the measure has to be reviewed within six months – or reviewed of an emergency, the scientific basis of the

reminiscent of insufficient evidence in art. 5.7 of the WTO's SPS Agreement and a comparison between the USMCA's and the WTO's SPS Agreement is interesting, it is beyond the scope of this chapter to establish such a comparison. Cooperation on matters of expertise does not take place explicitly when advancing science-based decision-making. There are, however, ways for Mexico, Canada, and the US to cooperate on measures of expertise when considering the objective to enhance compatibility of SPS measures.

Enhancing compatibility of SPS measures in the name of facilitating trade results in an obligation for the parties of the USMCA to regulate with the objective to make measures equivalent or identical.⁶⁵⁰ Enhancing compatibility is realised through RC and the SPS chapter creates the opportunity for the US, Mexico, and Canada to cooperate on expertise. The USMCA states that in case of mutual interest 'and with the objective of establishing a common scientific foundation' for risk management approaches, the USMCA encourages: sharing best practices on approaches to risk analysis; cooperating on joint scientific data collection; undertaking science-based joint RAs; providing access to completed RAs and the data used in these assessments or; cooperating on aligning data requirements for RAs.⁶⁵¹ In short, this creates the possibility for transnational expertise. Enhancing compatibility requires the realisation of an ongoing regulatory dialogue. Supported by the transparency provision in the SPS chapter, the USMCAs SPS chapter indeed aims to create an ongoing dialogue, including a dialogue on domestic expertise.⁶⁵² In case of SPS measures, the USMCA thus creates the possibility for transnational expertise (for example in case of joint scientific data collection and joint RAs) and an exchange of information on domestic expertise (for example by sharing best practices on risk analysis approaches or providing access to completed RAs).

Furthermore, scientific evidence is discussed, on request, in case of non-conformity with international standards.⁶⁵³ The USMCA creates a dialogue through the WTO's notification system; through making proposed SPS measures public; or by providing information to each other on request.⁶⁵⁴ In some cases, notification to the competent authorities is obligatory. For example, when there are new scientific findings that affect regulatory responses regarding food

measure has to be reviewed within six months – or reviewed periodically if nothing has changed. Importantly, undertaking a review does not justify stopping the import of goods.

⁶⁵⁰ USMCA, art. 9.7.

⁶⁵¹ USMCA, art. 9.16.5.

⁶⁵² USMCA, art. 9.13.

⁶⁵³ USMCA, art. 9.13.7 and 8.

⁶⁵⁴ USCMA, art. 9.13.

safety, pests, or diseases.⁶⁵⁵ Taken together, regarding SPS measures there is clear attempt at creating an ongoing dialogue regarding domestic expertise but also at transnational expertise through undertaking joint RAs and in view of the objective to establish a common scientific foundation.

3.4.2.4 *Expertise in the sectoral annexes of the USMCA*

The sectoral annexes of the USMCA creates other cooperation opportunities.⁶⁵⁶ For example on the regulation of chemical substances, the sectoral annex states that the parties of the USMCA recognise cooperation on the scientific criteria used for the reliability of the data supporting the regulatory decisions as a potential area of cooperation.⁶⁵⁷ This does not necessarily create cooperation on expertise as such but does acknowledge that cooperation on scientific criteria is a way to advance RC on the regulation of chemical substances. Furthermore, the sectoral annex on chemicals decides that parties must *endeavour* to exchange information regarding methodologies assessing chemical substances; share available data or assessments on particular chemical substances upon request, for example full data studies or data summaries (whilst preventing disclosure of confidential information); exchange, *as appropriate*, information about the information given to the public regarding the safety of chemical substances and; exchange, *as appropriate*, the scientific data and technical information on new and emerging issues relating to the management of chemical substances.⁶⁵⁸ Whilst there is no sign of joint RAs in this sectoral chapter as in the SPS chapter, domestic expertise is part of the information exchange.

In general, whilst there is quite some attention for scientific approaches to regulations and science is heavily integrated into regulatory decision-making in the USMCA, there are not many attempts distinguishable at transnational expertise. In the notice and comment procedure there are possibilities to cooperate on expertise through providing comments on the expertise used in the preparation of regulatory measures.⁶⁵⁹ More implicitly than explicitly so, the USMCA supposes that when parties adhere to the principle of sound science and GRP in general – keeping in mind the objective to coordinate research agendas to reduce duplicative research – RC follows naturally. The SPS chapter of the USMCA, however, creates the explicit possibility to conduct joint RAs (transnational expertise) to facilitate regulatory compatibility

⁶⁵⁵ USMCA, art. 9.13.12(b).

⁶⁵⁶ See chapter 2, section 2.4.2.2.

⁶⁵⁷ USMCA, Annex 12-A, art. 12.A.4(6)(f).

⁶⁵⁸ USMCA, Annex 12-A, Article 12.A.5.

⁶⁵⁹ USMCA, art. 28.12.1 (e). See above.

and cooperation. The sectoral chapters (such as the TBT chapter) further illustrate that the USMCA prefers the use of international standards over ‘arbitrary efforts to protect local producers’ as Gantz explains.⁶⁶⁰ The SPS chapter of the USMCA creates most prominent opportunities for experts to cooperate in the preparatory stages of the regulatory process.

Moreover, whilst there is a role for expertise in RC under the USMCA – most prominently in SPS measures – practical examples are yet to be found. It is highly likely that this will take place in the future as the Canada-United States Regulatory Cooperation Council has undertaken joint RAs.⁶⁶¹ This illustrates that conducting joint RAs can happen in the framework of the USMCA. Like in the CETA, further procedural rules on how joint regulatory science is conducted are notably absent. And as opposed to RC under the CETA, the USMCA limits transnational expertise to SPS measures.

3.4.3 *Expertise in the TCA*

The TCA differs from the other RC models as it starts from a place of divergence but aims to maintain some common standards.⁶⁶² Joint regulatory science is therefore not likely in the TCA. Moreover, since RC activities in the TCA are dependent on the political will to create them (i.e., there is no basic framework) it is impossible to address the role of expertise in RC mechanisms.⁶⁶³ Moreover, the GRP chapter of the TCA makes no reference to expertise, science, (scientific) data whatsoever. As an agreement on trade and cooperation, however, there are references that relate to cooperation on expertise and data used – predominantly relating to an exchange of information – in the sectoral chapters of the TCA

Whilst the GRP chapter and the RC provision do not contain any reference to expertise, there are several references to expertise in the TCA relating to an exchange of information. For example, on counterterrorism, cooperation on preventing and combatting acts of terrorisms also includes a regulatory dialogue on best practices and expertise on countering terrorism.⁶⁶⁴ On personal data protection, the TCA states that parties cooperate ‘while respecting their respective laws and regulations’, implying that there is no RC in the sense of the setting of standards

⁶⁶⁰ David A. Gantz, 'The USMCA: Updating NAFTA by Drawing on the Trans-Pacific Partnership' (2020) Baker Institute Report no 022120 Rice University's Baker Institute for Public Policy , 8.

⁶⁶¹ See, the work of the Canada – United States Regulatory Cooperation Council at <https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/canada-united-states-regulatory-cooperation-council.html> accessed 28 October 2021.

⁶⁶² See chapter 2, section 2.4.3.

⁶⁶³ Ibid.

⁶⁶⁴ TCA, art. 768(3)(b).

cooperatively, but nonetheless there could be a dialogue and exchanges of expertise.⁶⁶⁵ These provisions reference expertise and by doing so establish the possibility for an exchange of information on domestic expertise.

On TBT measures, the TCA similarly focuses on an exchange of information. The TBT chapter of the TCA mentions the exchange of information and data related to technical regulations, standards, and conformity assessment procedures in the provision on cooperation on technical regulations – when in mutual interest.⁶⁶⁶ Furthermore, on market surveillance and non-food product safety and compliance, cooperation and an exchange of information can take place regarding RA methods and scientific, technical and regulatory matters to improve non-food product safety and compliance.⁶⁶⁷ The TBT chapter thus again foresees in an exchange of information which could include matters of domestic expertise – but on market surveillance and non-food product safety and compliance there is a possibility to cooperate on (i.e., the parties must cooperate but this may include) RA methods and scientific matters. Since there is no mention of joint RAs but the TCA mentions RA methods, this seems to be an exchange of information on RA methods and/or scientific matters.

The SPS chapter of the TCA aims to enhance mutual awareness through transparency and understanding on the application of SPS measures, predominantly through an exchange of information.⁶⁶⁸ As is standard practice with SPS measures and thus also in the TCA, SPS measures require scientific and technical justification.⁶⁶⁹ The SPS chapter creates an exchange of information on new available scientific evidence that affects (or may affect) trade, with a view on minimising negative trade effects.⁶⁷⁰ More generally, the SPS chapter of the TCA foresees in an exchange of information ‘on matters related to the development and application of SPS measures.’⁶⁷¹ Such an exchange of information could include information regarding expertise, especially in relation to the development of SPS measures, but there is no explicit mention of expertise here. In case of emergency measures, the TCA foresees in technical consultations in which any information provided ought to be considered to avoid unnecessary disruptions to trade.⁶⁷² These technical consultations could include expertise as the TCA states,

⁶⁶⁵ TCA, art. 769(3).

⁶⁶⁶ TCA, art. 98(2)(a).

⁶⁶⁷ TCA, art. 96(3).

⁶⁶⁸ See chapter 2, section 2.4.3.2.

⁶⁶⁹ TCA, art. 73(2)

⁶⁷⁰ TCA, art. 77(1)(c).

⁶⁷¹ Ibid.

⁶⁷² TCA, art. 81(2).

‘any information provided’, but again does not explicitly refer to expertise. On animal welfare specifically, the UK and the EU shall exchange information, expertise, experiences and shall strengthen cooperation on research relating to animal breeding and the treatment of animals on farms, during transport and at slaughter particularly.⁶⁷³ This could include cooperation of experts in case of cooperation on research. Thus, aside from the specific provision on animal welfare and an exchange of information in case of new available scientific evidence, the SPS chapter generally aims to enhance mutual understanding of respective SPS measures through an exchange of information without an explicit exchange on expertise.

Specifically relating to chemicals regulations, the TCA creates the possibility for cooperation on scientific expertise in international institutions that can lead to joint initiatives and in case of new and emerging issues relating to hazards or risks posed by chemicals, the EU and the UK can enter in consultations to create a common pool of knowledge and to promote a common understanding of the science relating to the hazards or risks. Annex 13 to the TCA states that the EU and the UK will participate and actively contribute to the development of scientific or technical guidelines with respect to the assessment of hazard and risk of chemicals in the relevant international organisation regarding chemicals regulations.⁶⁷⁴ The EU and UK must implement the guidelines issues by these international organisation, unless considered ineffective or inappropriate in view of the legitimate objective.⁶⁷⁵ On (voluntary) cooperation regarding chemicals regulation, the EU and UK decided to cooperate *where appropriate* with the aim to strengthen, develop and promote the adoption and implementation of internationally agreed scientific guidelines.⁶⁷⁶ This can, if feasible, take place through presenting joint initiatives, proposals and approaches in international organisations.⁶⁷⁷ Moreover, when it is considered beneficial by both the EU and the UK, cooperation must take place on the dissemination of data regarding chemicals safety.⁶⁷⁸ This means that information on chemicals safety must be made available to the public and that, upon request, non-confidential information is provided to the parties of the TCA.⁶⁷⁹ Furthermore, in relation to new and emerging issues related to the hazards or risks of chemicals to human health and the environment, there is a possibility to create a common pool of knowledge and (if feasible and to the extent possible)

⁶⁷³ TCA, art. 84(3).

⁶⁷⁴ TCA, Annex 13, art. 4, art. 5.

⁶⁷⁵ TCA, Annex 13, art. 5(2).

⁶⁷⁶ TCA, Annex 13, art. 7(2).

⁶⁷⁷ TCA, Annex 13, art. 7(3).

⁶⁷⁸ TCA, Annex 13, art. 7(4).

⁶⁷⁹ Ibid.

promote a common understanding of the science relating through consultations on scientific information and data.⁶⁸⁰ In case of chemicals there is thus a possibility for domestic experts to cooperate to prepare presenting joint initiatives in international organisations.

The thematic cooperation chapter of the TCA was not mentioned in the RC chapter as it does not establish RC as such. Interestingly, however, the provision on health security states that the European Centre for Disease Prevention and Control and the relevant body in the UK ‘responsible for surveillance, epidemic intelligence and scientific advice on infectious diseases’ must cooperate on technical and scientific matters of mutual interest and may conclude a memorandum of understanding.⁶⁸¹ Regarding cross-border threats to health there is an information duty in the TCA but cooperation on scientific expertise in this regard is, in view of the COVID-19 pandemic, indeed a necessity.⁶⁸² Cooperation by domestic experts takes place here through the relevant bodies in the EU and the UK when dealing with cross border threats to health.

The role of expertise in the TCA is thus very much in line with RC in the TCA. The TCA reflects the dissembling of a Union whilst trying to preserve some common standards and a regulatory dialogue to the extent necessary for the co-existence of the EU and the UK. Expertise can be part of this dialogue, but as the EU and the UK move away from each other, joint regulatory science is not expected and indeed not taking place under the TCA.

3.5 Concluding remarks

At the start of this chapter, it was clarified that the aim of this chapter is assessing the role of expertise in the RC models. Furthermore, the expectation was that a role for expertise in RC is the logical next step considering the widening and deepening of RC across the globe. The role of expertise in RC, however, is predominantly limited to an exchange of information on domestic expertise in the ongoing regulatory dialogue. The most far-reaching of the RC models is the CETA. The CETA creates the possibility to conduct joint RAs or joint IAs, attributing a significant role to joint regulatory science, however empirical data shows that this has not taken place so far. Whilst a significant role for expertise is expected in SPS measures, the analysis in this chapter illustrates that this is not necessarily the case.

⁶⁸⁰ TCA, Annex 13, art. 5(4).

⁶⁸¹ TCA, art. 702(7).

⁶⁸² TCA, art. 702. The cooperation on health security provision states that the EU and UK must inform each other of a serious cross-border threat to health.

This chapter commenced by addressing expertise in the WTO considering that trade relationships are embedded in the framework of the WTO as a framework for further trade liberalisation. Moreover, the use of expertise (and science) in the WTO is a widely debated topic and thus deserves analysis – be it to consider the criticism voiced towards the WTO or to use the WTO as an example for providing a role to expertise in transnational governance through RC. As seen, the WTO is characterised by expert knowledge and has consequently faced criticism for giving scientific expertise a critical role in its decision-making and dispute settlement processes. It is predominantly regarding SPS measures where expertise could play a big role. As SPS measures must be non-discriminatory, based on science and the least trade restrictive, it's the based-on science element that makes room for RC to focus on cooperating on the science part.

The EU-US relationship, then, is characterised by attempts to establish an ongoing regulatory dialogue and from the early 2000's onwards started to focus on matters of expertise. Whilst the aim to cooperate on science existed from the Transatlantic Declaration of 1990, to really provide a meaningful role to expertise in the preparatory stages of regulation more steps needed to be taken. As RC evolved from high-level top-down RC efforts, the use of expertise similarly evolved. In the NTA, the transatlantic dialogues focused on the influence of expertise in the sense of involving actors (experts) in these dialogues that then influence the transatlantic agenda. The work done by the High-Level RC Forum started focusing on expertise involved in the preparatory stages of regulation in view of evidence-based policy making, namely by sharing results and technical studies. The Global Risk Assessment Dialogue seemed promising in providing ways to enhance cooperation through exchanging information and enhance cooperation between actors, but alas did not amount to much. The TTIP then was supposed to include a SPS-Plus chapter. Upon further reflection, the TTIP did aim to promote cooperation on expertise through actors involved by cooperating on research in the preparatory stages of the regulatory process but predominantly relating to evidence-based policymaking, i.e., through an exchange of information.

To assess the role of expertise in the other models of RC, this chapter analysed the role of expertise in RC efforts in the CETA, the USMCA and the TCA respectively. Further comparison will follow in Chapter Four of this thesis. For now, it suffices to say on the CETA that at its core there is an exchange of information on domestic expertise that supports regulatory measures. The CETA goes further and implements cooperation between actors involved in the regulatory process and an exchange of information on expertise in view of

evidence-based policymaking. The section on the CETA in practice conforms that CETA is being implemented along these lines. The USMCA then focuses on scientific evidence and expertise in its GRP chapter. Several RC mechanisms relate to expertise resulting in expertise being part of the ongoing dialogue, i.e., through an information exchange. In the SPS chapter, the role of expertise is enhanced in the SPS chapter by creating the possibility to establish a common scientific foundation (for risk management approaches) and conducting joint risk assessments, i.e., cooperation by experts in the preparatory stages of the regulatory process. The TCA remains different to the other models by not referring to expertise explicitly in either the GRP chapter or the RC provision. However, some sectoral chapters of the TCA do establish a dialogue on expertise – with the most far-reaching example being the annex on chemicals regulation. Essentially, the examples on the role of expertise in RC take place along the same lines. The next chapter will further compare the RC mechanisms and the role of expertise.

Chapter 4 The common characteristics of regulatory cooperation and the role of expertise

4.1 Introduction

Transatlantic RC shifted from a focus on the rules itself to the procedures for making the rules, thus focusing on regulatory procedures to facilitate trade.⁶⁸³ In other words, by providing mutual access to regulatory processes, RC creates possibilities to influence the preparatory stages of regulatory decision-making. Primarily through soft-law, non-binding instruments, RC creates a structured dialogue between participating parties predominantly consisting of an exchange of information – including an exchange of information on regulatory science. Essentially, by creating joint procedures and institutional mechanisms, governance is a gateway to deeper cooperation.⁶⁸⁴

The widening and deepening of RC results in policy laboratories across the globe – not a global policy laboratory as such but rather bilateral or multilateral policy laboratories that possibly affect each other.⁶⁸⁵ The extraterritorial effect of the RC models can be seen for example in the implementation of the CETA where there are signs that RC in the CETA influences other RC models, i.e., the USMCA.⁶⁸⁶ As RC models are increasingly key-elements in FTAs across the globe, the idea of a policy laboratory is implemented through soft-law, non-binding mechanisms.

This chapter analyses the common characteristics of the RC mechanisms and the role of expertise in these mechanisms. The purpose is to achieve a more comprehensive understanding of RC derived from the details of the FTAs, the individual mechanisms of RC and the use of expertise as set out in the previous chapters. In doing so, the analysis moves away from the details of the individual RC models and establishes the common characteristics of RC and the role of expertise in RC.

4.2 Policy laboratories: the common characteristics of the RC models

There are three aspects in the FTAs that support the development of RC, or in other words, structures that enable the ongoing regulatory dialogue: the institutional framework set up by the FTAs, GRP chapters (or provisions) and RC activities accompanied by RC objectives.

⁶⁸³ Meuwese, 'Constitutional Aspects of Regulatory Cooperation in TTIP: An EU Perspective' , 153.

⁶⁸⁴ *ibid.*, 154.

⁶⁸⁵ See chapter 1.

⁶⁸⁶ See chapter 3, section 3.4.1.5.3.

4.2.1 *Institutional framework*

The RC models create an institutional framework to aid in developing RC. The CETA, USMCA and the TCA set up similar institutional frameworks to achieve the goals of the respective FTAs – and the TTIP aimed to set up an institutional framework along the same lines – which Trujillo calls the institutionalisation of RC through FTAs.⁶⁸⁷ The oversight bodies of the FTAs, i.e., the Joint Committees of the CETA and as planned in the TTIP, the Free Trade Commission of the USMCA and the Partnership Council of the TCA, are the institutions with decision-making powers overseeing the implementation of the FTAs and the work of the specialised committees. The specialised committees, amongst which RC committees or fora and bilateral dialogues, make recommendations to the oversight body and discuss planned regulatory measures or regulatory reforms in various policy-areas. Essentially, the institutionalisation supports the ongoing regulatory dialogue in policy-areas that affect trade. This institutionalisation of RC is a common feature of the RC models analysed in this thesis.

The institutional framework supports the creation of living agreements. The TTIP and the CETA specifically have been called ‘living agreements’ as these FTAs establish an ongoing dialogue and allow their respective Joint Committees to make decisions to ‘supervise and facilitate the implementation and application of this Agreement and further its general aims.’⁶⁸⁸ Whilst this is specifically stated about the TTIP and the CETA, it applies to all the RC models analysed in this thesis since the institutional framework of the RC models are strikingly similar.⁶⁸⁹ Whilst (predominantly textual) differences can be found – reflecting different traditions of the parties but also relationships between countries – the overarching idea of RC and its institutionalisation is the same. RC in CETA is frequently called a blueprint for future RC.⁶⁹⁰ The analysis of the RC models in this thesis confirms this idea, at least from an institutional point of view, as RC and its institutionalisation is taking place along the lines of the CETA – and the CETA was indeed the first of the RC models.⁶⁹¹ By creating institutions that enable an ongoing dialogue, the agreement ‘lives’ since the institutions allow the regulatory dialogue to constantly develop.

⁶⁸⁷ Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power', 366.

⁶⁸⁸ CETA, art. 26.1.1

⁶⁸⁹ Garcia, 'Building Global Governance One Treaty at a Time? A Comparison of the US and EU Approaches to Preferential Trade Agreements and the Challenge of TTIP', 235.

⁶⁹⁰ Chase and Pelkmans, 'This time it's different: Turbo-charging regulatory cooperation in TTIP', 22; Hoekman, 'Fostering Transatlantic Regulatory Cooperation and Gradual Multilateralization', 613; Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power', 368.

⁶⁹¹ More on the CETA as the blueprint for future RC below, section 4.2.3.

Living agreements focused on learning under supervision of an institutional framework can strengthen the application of GRP and consequently turn these FTAs into a ‘transatlantic policy laboratory.’⁶⁹² Trujillo explains that RC can be seen as an important step towards global governance.⁶⁹³ Wiener and Alemanno argue that a global policy laboratory such as the TTIP encourages regulators to consider extraterritorial impacts, encourage aligning regulatory outcomes whilst learning from regulatory variation.⁶⁹⁴ The idea of a global policy laboratory is based on the laboratory federalism theory by Oates, in which a central government learns from policy variation in its member states to choose the best policy.⁶⁹⁵ The RC models implement the idea of a policy laboratory by creating ongoing regulatory dialogues created and overseen by the institutional framework, enabling regulators to discuss extraterritorial impacts of planned regulatory measures and encourage aligning regulatory outcomes – to what extent the existing RC models result in a *global* policy laboratory remains to be seen. The institutional framework of the RC models supports the development of policy laboratories, or, in other words, the institutional framework guarantees the continuing existence of an ongoing regulatory dialogue.

There is, however, a complete absence of democratic features in the institutional framework as set up by the respective RC models. More precisely, democratic features such as parliamentary involvement are notably absent in the FTAs. The overarching bodies of the RC models have decision-making powers, but it is unclear what the democratic checks and balances are? When the decisions are made, who exercises democratic control on the decisions? The oversight bodies supervise the work of the specialised committees in the RC models and have the power to make decisions to attain the objectives of the Agreements, including on RC, but who exercises control on the oversight bodies? The expectancy is that national structures will exercise control over what happens in the RC institutional framework.⁶⁹⁶ When international governance structures are created, however, these institutional structures should include

⁶⁹² Alemanno, 'The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences', 631; Wiener and Alemanno, 'The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory', 132; Cremona, 'Negotiating the Transatlantic Trade and Investment Partnership (TTIP)', 352.

⁶⁹³ Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power', 410.

⁶⁹⁴ Wiener and Alemanno, 'The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory'

⁶⁹⁵ See, Wallace E. Oates, 'An Essay on Fiscal Federalism' (1999) 37 *Journal of Economic Literature* 1120; Wiener and Alemanno, 'The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory', 132.

⁶⁹⁶ See chapter 5, section 5.2.5.

democratic checks and balances – at a minimum an obligatory notification procedure to the respective parliaments.⁶⁹⁷

In RC, a policy laboratory is implemented through soft-law, non-binding mechanisms resulting in various policy laboratories across the globe. These policy laboratories, consisting of an ongoing regulatory dialogue, can potentially influence other regulatory dialogues, as seen in the CETA where the EU asked the outcomes of the USMCA dialogue be equally applied to the EU.⁶⁹⁸ Whilst the mechanisms are non-binding, the institutionalisation of RC is a fact. And in the CETA, for example, the JC's decisions are binding on the Parties alongside an obligation to implement decisions made by the JC – assuring legal effect in both legal systems.⁶⁹⁹ The outcomes of RC can have a legal effect in the participating nations as RC ultimately result in regulatory measures that are (potentially) drafted in cooperation with the other party.⁷⁰⁰ Since the outcomes of the ongoing regulatory dialogue can have legal (regulatory) effects, transatlantic policy laboratories require legitimisation.⁷⁰¹ Learning from each other is surely positive, however, the focus of RC on trade and the absence of democratic features in the institutionalisation of RC and beyond contributes to the throughput-legitimacy deficit of RC.⁷⁰²

4.2.2 *Good Regulatory Practices*

A common characteristic of RC is RC through GRP, considering that GRP create common ground that facilitates cooperation – subsequently facilitating trade – whilst simultaneously enabling RC through transparency and participation provisions.

A key element of GRP in the RC models are transparency and notification requirements. More precisely, early notice, requesting information and clarification are common GRP in the RC models. Transparency is a prerequisite for cooperation.⁷⁰³ This point of view is shared by the WTO and RC clearly builds on the WTO.⁷⁰⁴ For example, since the WTO attempts to establish a notification procedure but WTO signatories generally do not comply with the notification procedure, countries engage in bilateral – or multilateral – efforts to establish such an obligation.⁷⁰⁵ By creating early information mechanisms regarding regulatory developments,

⁶⁹⁷ See chapter 5 and chapter 6.

⁶⁹⁸ See chapter 3, section 3.4.1.5.3.

⁶⁹⁹ CETA, art. 26.3.2; the JC also has several discretionary powers ex art. 26.3.2, 26.1.5. CETA.

⁷⁰⁰ See, for example, chapter 2, section 2.4.1.

⁷⁰¹ See chapter 1, section 1.2.

⁷⁰² See chapter 5, section 5.2.

⁷⁰³ See chapter 3, section 3.4.1.5; also see chapter 6, section 6.1.

⁷⁰⁴ See chapter 2.

⁷⁰⁵ See chapter 2, section 2.2.1.

RC models establish their own notification procedure and more generally RC increases the transparency of the development of regulatory measures between parties. Transparency provisions are thus a key element in the RC models. Transparency in GRP chapters or provisions relate to transparency in the sense of either notifying new regulatory measures – to each other or to the WTO – or publishing (planned) regulatory measures. Essentially this creates mutual awareness of (planned) regulatory measures systems. Transparency is a prerequisite of RC since there is no cooperation without transparency – and simultaneously a prerequisite for the throughput-legitimacy of RC.⁷⁰⁶ In other words, an ongoing regulatory dialogue is impossible if the parties are unaware of each other's (planned) regulatory measures.

The transparency provisions are often accompanied by participation provisions. Participation is important in global risk governance and can contribute to its legitimacy.⁷⁰⁷ The participation provisions in RC establish stakeholder participation – and calls for stakeholder input are realised in practice.⁷⁰⁸ Stakeholder participation can contribute to the legitimacy of RC as it provides ways of input for the public.⁷⁰⁹ However, RC focuses on facilitating trade and a consequence of allowing sufficient time for interested parties to provide comments on planned regulatory measures is granting access to the regulatory process by business i.e., lobbying groups.⁷¹⁰ Furthermore, participation provisions in RC focus on allowing input by natural and legal persons, regardless of domicile, resulting in ways for the other party (i.e., a foreign government) to provide input on planned regulatory measures.⁷¹¹ Participation and input by the public is generally established in domestic laws and procedures and so the focus of RC is on providing the other party to the FTAs and lobbying groups possibilities to influence the regulatory process. Additionally, participation rights are often phrased in non-obligatory terms and the RC models do not provide ways in which the interests of the public will be balanced against the influence of business.⁷¹² As chapter 5 elaborates on participation rights in RC more in-depth, for now it suffices to say that whilst GRP seemingly contribute to the legitimacy of RC, and transparency is a key element of RC, the focus is on increasing awareness, enabling a regulatory dialogue and allowing participation between the RC parties ultimately with the aim to facilitate trade.

⁷⁰⁶ See chapter 2, section 2.2.1; chapter 3, section 3.4.1.5, also see chapter 6, section 6.1.

⁷⁰⁷ See chapter 1, section 1.2; chapter 5, section 5.3.2 and chapter 6, section 6.4.2.

⁷⁰⁸ See for example, chapter 3 section 3.4.1.5.

⁷⁰⁹ See chapter 5, section 5.3.

⁷¹⁰ See chapter 5, section 5.2.3.

⁷¹¹ See chapter 5, section 5.2.2.

⁷¹² See chapter 5, section 5.3.2.

Good governance principles such as transparency, accountability and stakeholder participation are important in global risk governance. Nonetheless, the regulatory processes and more generally the administrative systems of the RC parties are different and these differences are reflected in RC most notably in participation rights. For example, on stakeholder participation, CETA states that the Parties of the Agreement ‘may consult, as appropriate’ and the TCA essentially states that each Party must ensure publication of the draft and allow reasonable opportunities for interested persons to provide comments and that these comments must be considered.⁷¹³ Whereas CETA does create a possibility but leaves this to the parties to decide and the TCA essentially acknowledges its importance but also leaves it up to the parties, the USMCA establishes a specific procedure to consider the comments (e.g., the time period for consideration) in the FTA itself. In this respect, the USMCA is reminiscent of the American notice and review process.⁷¹⁴ Whilst good governance principles are important to all the RC models, the textual differences in the FTAs reflect the differences in the various systems, most notably regarding the US based notice and comment procedure reflected in the USMCA.⁷¹⁵

Another element included with the aim to facilitate cooperation is the reliance on international standards. Relying on international standards in RC means referring to international standards as a basis for regulatory measures and cooperating in international fora. By relying on international standards, common ground in the sense of similar regulatory measures, can be achieved. After all, international standards ultimately aim towards harmonisation.⁷¹⁶

Furthermore, common ground is built by requiring regulatory measures to be based on IAs and RAs. Whilst cooperation on IAs or RAs – in the sense of transnational expertise – is limited, both IAs and RAs are included in the GRP chapters and provisions as an obligation for parties, i.e., that regulatory measures ought to be based on IAs and RAs. Essentially, the GRP are good governance principles that build trust between countries and from that trust, cooperation can follow as RC is dependent on trust between regulators.⁷¹⁷

4.2.3 Regulatory cooperation: an ongoing regulatory dialogue

The essence of RC is in establishing an ongoing regulatory dialogue. Bilateral mutual recognition and equivalence are encouraged in RC, but the essence of RC is establishing an

⁷¹³ CETA, art. 21.8; TCA, art. 346.

⁷¹⁴ Namely in USMCA, art. 28.9.

⁷¹⁵ See chapter 2, section 2.4.2; and chapter 5, section 5.3.2.

⁷¹⁶ See chapter 2, section 2.2.2.

⁷¹⁷ Also see chapter 2, section 2.2.1.

ongoing regulatory dialogue. Both the TTIP and the CETA attempt to create a structured regulatory dialogue to engage in RC, including early notice of planned regulatory acts – essentially a bilateral notification procedure. The USCMA also establishes an ongoing regulatory dialogue, albeit that the USMCA uses more obligatory terms (i.e., shall) in comparison to the other RC models. The TCA focuses on an exchange of information, ultimately resulting in a regulatory dialogue – but only if the political will to do so exists. Fundamentally, the RC models focus on an exchange of information that results in an ongoing regulatory dialogue. After all, when information is exchanged regularly and concerns developments in regulations – including planned regulatory acts or changes to regulatory policy – this exchange of information results in an ongoing regulatory dialogue. The overarching aim of the RC mechanisms is to work towards (cooperatively) setting common standards or, at a minimum, improve mutual understanding and awareness of respective regulatory frameworks through the exchange of information – with a view on facilitating trade.

Worth mentioning is that all RC models include sovereignty safeguards. CETA, for example, states that RC is ‘without limiting the ability of each Party to carry out its regulatory, legislative and policy activities.’⁷¹⁸ The TCA emphasises more the right to regulate and the freedom of the UK in setting its own regulatory standards. This is unsurprising considering the difficulties to come to the Agreement and the political situation surrounding the Brexit. The TTIP negotiation documents emphasised similarly that TTIP will not ‘affect the ability of each Party to adopt, maintain and apply measures without delay, in accordance with deadlines under its respective regulatory or administrative procedures, to achieve its public policy objectives (...) in accordance with its regulatory framework and principles.’⁷¹⁹ The USMCA states that nothing in the GRP and RC chapter prevents a party from pursuing policy objectives at the level it considers appropriate and that parties are free to choose the methods of implementing the obligations in the chapter ‘within the framework of its own legal system and institutions’ and are lastly free to adopt supplementing GRP.⁷²⁰ Thus, with some variations that often depend on the political situation at the time of the FTA and the relationship between countries, safeguards generally make their way into the RC provisions.

⁷¹⁸ CETA, art. 21.2(4)

⁷¹⁹ European Commission, ‘TTIP - EU proposal for Chapter: Regulatory Cooperation’ (21 March 2016), art. x1 <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf> accessed 30 June 2020.

⁷²⁰ USMCA, art. 28.2(3).

Overall, the trend discovered through the analysis of the RC models is that RC is shaped broadly along the same lines – whilst simultaneously reflecting the political will of the participating parties and their (trade) relationship. The exchange of information is key and, in that exchange, focus points, topics, and to what extent cooperation takes place varies from policy-area to policy-area reflecting the relationship between parties. RC and its structured ongoing regulatory dialogue are dependent on political will to succeed but in the TCA, for example, RC is completely dependent on the political will to create RC mechanisms in the first place. This is illustrative of the fact that RC is, and always will be, dependent on political will. However, as the CETA is considered a blueprint of RC, the implementation of the CETA in practice illustrates that RC is indeed taking place.⁷²¹ Moreover, the RC models work towards creating an ongoing regulatory dialogue that, whilst dependent on political will, at a minimum creates some political pressure to engage in RC. Whilst RC is presented as voluntary, it is not as voluntary as it seems.⁷²² After all, RC is created in legally binding trade agreements and the institutional frameworks is set up to support and further develop RC. Voluntary RC in FTAs is the preferred method to generate more political will and whilst Murphy argues that this lacks ‘teeth to generate any substantive improvements’, the potential of RC is undeniable.⁷²³ Whilst RC remains voluntary from a textual point of view, its mechanisms, their consideration during the preparatory stages of regulation, the existence of the institutional framework and the fact that RC is created in legally binding agreements result in at least some political pressure to engage in RC before deciding on regulatory action.

RC can contribute to regulators considering extraterritorial impacts and – by learning from variation – align regulatory outcomes through the exchange of information thus resulting in a policy laboratory. Laboratory federalism is essentially trial and error in policymaking: by observing different policies amongst states and its outcomes, a state can then choose the best policy and dismiss the worst ones.⁷²⁴ RC is, however, focused on trade. Whilst RC results in a policy laboratory, the focus is on trade and consequently, the influence of business is inherent to RC.⁷²⁵ Whilst the RC models contribute to learning from variation, the focus is engaging in an ongoing regulatory dialogue with the purpose to align regulatory outcomes to facilitating trade.

⁷²¹ See chapter 3, section 3.4.1.5.

⁷²² See chapter 5, section 5.2.4.

⁷²³ Murphy, 'Framing essay : a shift in transatlantic diplomacy', 15.

⁷²⁴ See, Oates, 'An Essay on Fiscal Federalism'.

⁷²⁵ See chapter 5, section 5.2.3.

4.2.4 *Expertise*

The RC models aim at developing a common approach in the preparatory stages of regulation to facilitate trade – a stage in which expertise is essential.⁷²⁶ In other words, to develop a common approach to regulatory standards, cooperation on expertise is crucial since expertise has a critical role at this stage. Moreover, the WTO relies heavily on scientific experts and requires that SPS measures specifically are based on a scientific justification resulting from RA.⁷²⁷ Since RC builds on the WTO, the expectancy is that bilateral RC efforts focus on expertise, even if only on SPS measures. So far, however, RC results in an ongoing regulatory dialogue in which transnational expertise has a minimal role. Cooperating on matter of expertise address regulatory divergence, especially when science is at the heart of regulatory divergence.⁷²⁸ In other words, the deepening of RC ultimately requires transnational expertise since building a common scientific basis is crucial to develop regulatory standards cooperatively. In the RC models, however, the role of expertise is in its infancy.

The role of expertise in the RC models is that domestic expertise is part of the exchange of information. In the EU-US relationship, attempts to cooperate on expertise ultimately resulted in the Global Risk Assessment Dialogue. Whilst this Dialogue did not achieve practical results, it illustrates that a role for expertise is a goal in the EU-US relationship – but is perhaps still a step too far. The TTIP also did not include specific provisions on transnational expertise but expectedly, expertise could have been part of the information exchange. The USMCA and the CETA similarly establish an exchange of information on domestic expertise. As the implementation of the CETA illustrates, RC results in an exchange of information on domestic expertise, i.e., a discussion on the regulatory science supporting regulatory decisions. And whilst the RC mechanisms of the TCA are dependent on the political will to create them, the TCA does refer to expertise – for example by creating a common pool of knowledge and promoting a common understanding of the science on the issues at hand regarding chemicals safety.⁷²⁹ The fact that expertise is explicitly mentioned in certain sectoral chapters of the TCA makes it plausible that expertise is considered a possible facilitator of cooperative efforts. This conclusion applies to the RC models in general as expertise is considered in the RC models to enhance cooperation – and thus facilitate trade. Consequently, domestic expertise is part of the

⁷²⁶ Wiener and Alemanno also acknowledge that RC emphasizes developing a common approach to the preparation of regulation: Wiener and Alemanno, 'The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory', 117.

⁷²⁷ See chapter 3, section 3.2.1.

⁷²⁸ See chapter 1, section 1.3.

⁷²⁹ See chapter 3, section 3.4.3.

information exchange – in the sense of discussing regulatory science that support regulatory decisions. The RC models essentially establish an ongoing regulatory dialogue in which an information exchange takes place, including an information exchange on domestic expertise.

Possibilities to conduct transnational expertise are very limited in the RC models. The analyses of the RC models in this thesis illustrate that in the CETA there is a possibility for transnational expertise and in the USMCA there is a similar possibility, albeit restricted to SPS measures.⁷³⁰ In general there is a push for joint IAs and joint RAs (i.e., transnational expertise), however, the role of expertise in the RC models is predominantly limited an exchange of information of domestic expertise.⁷³¹ The CETA is the only RC model explicitly creates possibilities for transnational expertise by creating the possibility to conduct joint-RAs, joint-IAs, or establishing a common scientific basis. The USMCA creates the possibility to conduct joint RAs in the SPS chapter. Prior to the USMCA, the US and Canada have a history of conducting joint RAs making it plausible that this will continue in the future.⁷³² The implementation of RC in the CETA illustrates that RC and discussions on domestic expertise – or possibilities to conduct transnational expertise – vary from policy area to policy area.⁷³³ The reality of RC under the CETA is in line with Peel’s argument that science cannot function as a universal arbiter (and legitimator) but a case-by-case solution is required.⁷³⁴ The RC models confirm this idea and in RC, the exchange of information varies from policy area to policy area including to what extent information on expertise is exchanged and possibilities to conduct joint regulatory science are utilised.

So far, the use of transnational expertise is minimal in RC. It is, however, considered in the RC models and so can arguably play an important role – either now or in the future.⁷³⁵ In view of RC, Weimer and De Ruijter acknowledge that ‘the general trend towards more centralised and institutionalised production of policy-relevant knowledge was augmented by the trend towards [RC] (...) and hence the transnationalisation of expertise.’⁷³⁶ Considering the limited

⁷³⁰ See chapter 3, sections 3.4.1 and 3.4.2.

⁷³¹ See chapter 3.

⁷³² See, for example, the Canada and USA Joint Risk Assessment on Norovirus in Bivalve Molluscan Shellfish, at <https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/canada-usa-joint-risk-assessment-norovirus-bivalve-molluscan-shellfish.html> (last accessed 31 august 2021).

⁷³³ See chapter 3, section 3.4.1.5.

⁷³⁴ Peel, *Science and Risk Regulation in International Law*, 383.

⁷³⁵ See chapter 3, section 3.4.2.4, specifically the consideration that the Canada-United States Regulatory Cooperation Council has undertaken joint RAs and so it is not out of the question that future endeavours include joint regulatory science.

⁷³⁶ Weimer and De Ruijter, 'Regulating Risks in the European Union: the Co-production of Expert and Executive Power', 6.

possibilities to conduct joint RAs in the RC models as analysed in this thesis, a transnationalisation of expertise – in the sense of transnational expertise as defined in this research – is yet to occur. Whilst the idea that RC requires cooperation on expertise is certainly valid (see above), the analyses of the RC models in this thesis illustrate, in general, domestic expertise is part of the information exchange in RC. Explicit transnational expertise is more the exception than the rule, namely in the CETA and the USMCA’s SPS chapter. As the CETA is considered a blueprint for RC, the role of expertise in RC is possibly further developed in the future. Whilst expertise can address regulatory divergence, expertise can also contribute to the throughput-legitimacy of global governance and so strengthening the role of expertise in RC is important.⁷³⁷

4.3 Concluding remarks

A transatlantic or even global policy laboratory sounds appealing considering increasing transnational risks faced. A global policy laboratory can address transnational risks, even major global risks such as climate change. However, RC is aimed at facilitating trade rather than addressing transnational problems. When RC addresses transnational problems, the focus is on facilitating trade between the RC parties. To the extent that current RC efforts establish bilateral – or multilateral policy laboratory – considering that the RC models do not establish a *global* laboratory – the focus is still on facilitating trade rather than aimed at addressing transnational risks.

Moreover, national structures put in place to guarantee democracy and the protection of democratic principles cannot be ignored. A transnational or global policy laboratory inevitably faces immense criticism by national governments and interest groups alike on principle issues of democracy. As Pitschas argues regarding the TTIP it ‘is a golden opportunity to build a transatlantic marketplace, but this opportunity comes with a hefty price tag. Only the future will tell whether that price is worth paying.’⁷³⁸ RC is indeed a matter of potential but what is clear, is that RC faces a throughput-legitimacy deficit as it provides access to foreign governments in the preparatory stages of the regulatory process whilst simultaneously focusing on facilitating trade and thus creating possibilities for business to influence regulatory measures.⁷³⁹ And whilst RC does not change legislative frameworks and national democratic structures retain their

⁷³⁷ See chapter 6.

⁷³⁸ Pitschas, ‘Transatlantic Trade and Investment Partnership (TTIP): The Devil in Disguise or a Golden Opportunity to Build a Transatlantic Marketplace?’, 340.

⁷³⁹ See chapter 1, section 1.2; and chapter 5.

power, the legitimacy problem of RC is essentially one of political pressure or in other words, as Siles-Brügge argues, ‘shaping the discursive context in which regulation is crafted by privileging certain voices (business) and considerations (reducing the impact of regulation on international trade).’⁷⁴⁰

⁷⁴⁰ Siles-Brügge and Gabriel, *Policy Briefing: The Neglected Side to TTIP – Horizontal Regulatory Provisions* (April 2016), 9.

Chapter 5 The Legitimacy Deficit of Regulatory Cooperation

5.1 Introduction

The democratic legitimacy of the RC process is problematic. As Chase and Pelkmans explain, engaging in RC through living agreements enables future RC to develop in unpredictable ways.⁷⁴¹ Since RC continues to develop through living agreements and is increasingly important in transnational governance, its legitimacy problems need addressing. After all, cooperating in regulatory processes prior to national democratic processes with the aim to facilitate trade is a step that should not be taken lightly.⁷⁴² Whilst RC focuses on learning through a continuous dialogue, increasing efficiency and effectiveness of regulators across the Atlantic, the democratic decision-making processes of the participating parties is potentially limited by engaging in RC.⁷⁴³ As Mendes explains, claiming that the RC processes will not affect domestic regulatory processes is unrealistic.⁷⁴⁴ Without democratic checks and balances, the RC process is hardly legitimate and as it stands, RC faces a throughput-legitimacy deficit. This chapter analyses *the throughput-legitimacy deficit* of RC.

The key argument of this chapter is that RC faces a legitimacy deficit due to i) the transformation of the role of the executive in the setting of regulatory standards whilst ii) opening the RC process to the influence of foreign governments and iii) focusing on facilitating trade thus providing a privileged position to business influence in the RC process with iv) a lack of parliamentary oversight and weak participatory rights in the FTAs establishing RC.

This chapter starts by examining the legitimacy problems of RC (section 5.2) and its three key elements: the transforming role of the executive in RC (section 5.2.1), the preliminary influence of foreign governments (section 5.2.2) and the influence of business and lobbying groups on the setting of regulatory standards through engaging in RC (section 5.2.3). The chapter then moves on to discuss two prominent counterarguments which refute the notion that there is a legitimacy deficit in the RC process, namely that the voluntary nature of RC (section 5.2.5) and the fact that RC occurs in the agenda-setting phases of the regulatory process results in RC

⁷⁴¹ See, Chase and Pelkmans, 'This time it's different: Turbo-charging regulatory cooperation in TTIP', 25.

⁷⁴² See, Pitschas, 'Transatlantic Trade and Investment Partnership (TTIP): The Devil in Disguise or a Golden Opportunity to Build a Transatlantic Marketplace?', 340.

⁷⁴³ See Chase and Pelkmans, 'This time it's different: Turbo-charging regulatory cooperation in TTIP', 11; Meuwese, 'Constitutional Aspects of Regulatory Cooperation in TTIP: An EU Perspective', 157. Also see, Cremona, 'Negotiating the Transatlantic Trade and Investment Partnership (TTIP)', 353; Also see Madner, 'A New Generation of Trade Agreements: An Opportunity Not to Be Missed?'

⁷⁴⁴ Joana Mendes, 'Regulatory cooperation under TTIP: Rulemaking and the ambiguity of participation' in Luca Pantaleo, Wybe Douma and Tamara Takács (eds), *Tiptoeing to TTIP: What kind of agreement for what kind of partnership?* (Centre for the Law of EU External Relations (CLEER) 2016), 29.

being within the powers of the executive and parliament retains its usual oversight (section 5.2.6).

This chapter will consider in more detail the role for parliament and strong participatory rights in enhancing the legitimacy of the RC process. It will assess the legitimacy deficit in view of the role of parliament and participatory rights provided by the FTAs (section 5.3). The key argument of this chapter is that there is clear evidence that the RC process faces a legitimacy deficit that should be addressed (section 5.4). Chapter 6 then investigates potential solutions to address the legitimacy deficit identified in this chapter.

5.2 Legitimacy problems of regulatory cooperation

RC creates a shared regulatory space in the transnational arena resulting in a transformation of the role of the executive whilst allowing the influence of foreign governments, all with a focus on business and commerce. The term ‘shared regulatory space’ is developed by Trujillo and as she argues, the shared space allows the merging of domestic regulatory goals with trade liberalisation by the executive branch.⁷⁴⁵ The creation of such a shared regulatory space certainly follows from the analysis of the RC models in this thesis as RC, via cooperation efforts between governments, influences the agenda-setting stages of regulatory decision-making, or in other words, shapes the regulatory discourse.⁷⁴⁶ Regulators across nations work together through RC processes established in FTAs with the aim to facilitate trade through the reduction of regulatory burdens.

The creation of a shared regulatory space has at least two very important consequences that affect the legitimacy of the RC process. Firstly, RC results in the executive branch to participate in the regulatory process in ways it has not done before (section 5.2.1).⁷⁴⁷ Secondly, RC and the creation of a shared regulatory space by its very definition allows foreign governments access to domestic regulatory processes (section 5.2.2). Another consequence of using internationally binding FTAs to establish RC is that RC is embedded in trade law and thus predominantly focused on facilitating trade by attempting to reduce regulatory barriers to trade, resulting in a business focused system of influence (5.2.3). On the other hand, it could also be argued that RC could at least provide some regulatory level playing field, as a protection against

⁷⁴⁵ Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power', 374.

⁷⁴⁶ See chapter 4, section 4.3.

⁷⁴⁷ Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power', 367.

more crude removal of trade barriers in FTAs. While this is theoretically at least an option, the question is whether this is the case in practice and whether the institutional framework is helpful in that direction. Considering that all this is taking place without the FTAs establishing explicit oversight by parliament and that participatory rights are weak at best (section 5.3); the shared regulatory space created by the RC process results in a legitimacy deficit.

This section (5.2) elaborates on the legitimacy problems of RC. The essence of the legitimacy problems of RC is that the executive branch engages in an ongoing regulatory dialogue with a foreign country to facilitate trade through the reduction of regulatory burdens *without* added parliamentary oversight and weak participatory rights. RC changes the role of the executive in the sense that – aside from its role as trade negotiator – it now engages in a regulatory dialogue during the preparatory stages of regulation i.e., at the drafting stages. The fact that the executive is setting the agenda is not the issue. Traditionally, it *is* the job of the executive to set the agenda. It is, however, an issue when the executive engages in this regulatory dialogue with foreign governments without any oversight by parliament and with weak participatory rights guaranteed in the FTAs that establish RC. There are thus three elements to the legitimacy problem of RC that will be discussed in this section specifically: the transformed role of the executive (section 5.2.1); the influence of foreign government (section 5.2.2) and the focus on business and commerce which further the interests of business and commerce (section 5.2.3). These elements may not be detrimental to legitimacy on their own, however, taken together with the lack of parliamentary oversight and weak participatory rights (section 5.3), the overall legitimacy of the RC process and its ongoing regulatory dialogue is at stake.

5.2.1 The transforming role of the executive

RC transforms the role of the executive from negotiating FTAs to actively participating in an ongoing regulatory dialogue seeking to set regulatory standards in cooperation with foreign governments. Through FTAs, trading partners engage in RC. Together, the trading partners (i.e., the executive branch of the respective parties) set the agenda for new regulatory measures, i.e., shaping the regulatory discourse by engaging with foreign governments. This results in the executive participating in the regulatory process in a way it has not done before, as Clausen and Trujillo argue.⁷⁴⁸ By managing RC and its ongoing regulatory dialogue the executive takes on, as Claussen puts it, ‘managerial responsibilities’ and, as Trujillo explains, becomes a

⁷⁴⁸ Kathleen Claussen, 'Trading Spaces: The Changing Role of the Executive in U.S. Trade Lawmaking' (2017) 24 *Indiana Journal of Global Legal Studies* 345, 359; Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power', 367.

'regulatory partner'.⁷⁴⁹ Indeed, the executive branch is front and centre of RC. In the EU-US relationship for instance, the ongoing regulatory dialogue takes place between the relevant DGs of the Commission and US agencies. Whilst this allows for important dialogues to take place, regulatory and trade interests are merged and through RC, the executive decides when and how areas are regulated by participating in an ongoing regulatory dialogue with foreign governments.⁷⁵⁰ As RC transforms the role of the executive through participating in an ongoing regulatory dialogue *with foreign counterparts*, the essence of the problem is that the strengthening of regulatory authority of the executive branch is without an accompanied oversight mechanism for parliament and weak participation rights (section 5.3).

5.2.2 Preliminary influence of foreign governments

The influence of foreign governments is perhaps the biggest source of opposition to FTAs such as the CETA and the TTIP. At the time of the TTIP negotiations, public opposition to the TTIP was voiced loudly and centred around concerns for consumer safety. The public voiced its concerns about RC in the TTIP as they feared engaging in RC with the US would result in lower levels of protection in the EU, for example by allowing chlorine-washed chicken or hormone-fed beef to enter the European market. Whilst the Commission tried to reassure the public that levels of protection would not drop by engaging in RC with the US, the essence of criticism towards the TTIP relates to co-decision-making with foreign governments.

The issue with the influence of foreign governments on the setting of regulatory standards is not unnoticed in academia either. Whilst RC is predominantly about the exchange of information – at best with suggestions for joint RAs or joint IAs in the CETA for example – there is a possibility for RC to result in co-decision-making, as Meuwese explains.⁷⁵¹ Co-decision-making could take place most prominently in the ongoing regulatory dialogue – either *explicitly* through joint decisions or *implicitly* by exerting influence over decisions regarding draft legislation. Thus ultimately, RC can result in co-decision-making and blur the nature of the exercised authority.⁷⁵² When foreign governments have the possibility of influencing the executive in the agenda-setting phase, draft proposals are tainted by this influence. Questions such as who is making the actual decisions are problematic and negatively affect the legitimacy

⁷⁴⁹ Claussen, 'Trading Spaces: The Changing Role of the Executive in U.S. Trade Lawmaking', 359; Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power', 366.

⁷⁵⁰ See, Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power', 412.

⁷⁵¹ Meuwese, 'EU-US horizontal regulatory cooperation: mutual recognition of impact assessment?', 261.

⁷⁵² See, *ibid*; David Vogel, 'Can it be done? Suggestions for better regulatory cooperation between the US and Europe' (2007) *Transatlantic Thinkers* No 7, Bertelsmann Stiftung, Gütersloh

of the RC process. In the end, the principle of regulatory sovereignty is compromised by allowing foreign governments to participate in regulatory decision-making – or as Alemanno puts it: ‘any efforts at international regulatory cooperation may compromise the principle of regulatory sovereignty.’⁷⁵³ Moreover, RC under the CETA is ‘open to participation by other international trading partners’ which, as Trew argues, shows an openness towards US regulators and companies to engage in RC under the CETA.⁷⁵⁴ Consequently, not only do these FTAs establish an ongoing regulatory dialogue between the participating parties, other (third) countries can participate in RC; which adds another level to the already existing legitimacy issues when allowing foreign countries to influence the setting of regulatory standards. Whilst scholars reach various conclusions, it seems that most agree on the fact that allowing foreign government participation in the drafting process of setting regulatory standards raises questions about the legitimacy of such processes.

An issue with legitimacy occurs as a consequence of the reoccurring RC mechanism to consult each other as appropriate and as early as possible in the regulatory process.⁷⁵⁵ For example, the CETA decides that the EU and Canada will consult each other ‘as appropriate’, exchange information throughout the regulatory process and consider the others regulatory measures or initiatives ‘as early as possible’ in that process with a view on enhancing convergence and compatibility between regulatory measures.⁷⁵⁶ Since it is unclear what is meant with ‘as appropriate’, this could be interpreted in various ways. Considering that risks are in fact largely transnational, it could be deemed appropriate to consider *any* planned regulatory measure in RC. Additionally, it could be appropriate when concerning trade in one way or the other. This could mean that regulating any product covered by the CETA and the other RC models – which, considering the broad applications of the FTAs on matters of trade, are many of them – call for the parties of the respective FTAs to any planned regulatory measure before proposing them to their respective bodies responsible for approving draft regulatory measures. De facto, for example in the CETA, this would lead to the responsible Directorate General of the Commission to discuss a regulatory measure with Directorate General Growth which then has to negotiate with, for example, the Canadian Technical Barriers and Regulations Divisions of

⁷⁵³ Alemanno, ‘The Transatlantic Trade and Investment Partnership and the Parliamentary Dimension of Regulatory Cooperation’, 5.

⁷⁵⁴ CETA, art. 21.2.3; Stuart Trew, *International regulatory cooperation and the public good: How “good regulatory practices” in trade agreements erode protections for the environment, public health, workers and consumers*, April 2019), 25.

⁷⁵⁵ See, for example, art. 21.4(b) CETA. See further chapter 2, sections 2.3.3; 2.4.1; 2.4.2; 2.4.3.

⁷⁵⁶ CETA, art. 21.4 (b); art. 21.5.

the Department of Foreign Affairs on most matters considering risk regulation before the draft proposal is formally adopted and thus sent to the European Parliament and Council.⁷⁵⁷

Similar provisions are found in the negotiation documents of the TTIP. The TTIP would have required the parties to inform each other ‘at the earliest possible stage’ when there is or likely to be an impact on trade. This means, in practice, that the EU will ‘provide cooperation opportunities before the Commission adopts a formal position’ and the ‘US regulatory agencies shall provide cooperation opportunities before the launch of the (advanced) notice of proposed rulemaking or in a timely manner before adopting or consulting on a guidance document.’⁷⁵⁸ Whilst the Commission states that RC does not imply a commitment to sharing draft texts before these draft texts are made public, the question remains when exactly RC should take place?⁷⁵⁹ And, as Meuwese rightfully asks: ‘Will de facto regulatory authority migrate to a transatlantic forum of executive governance?’⁷⁶⁰ To publish draft legislation before adoption by the College of Commissioners is problematic and this is – as Chase and Pelkmans explain – also an issue for the Commission:

*When it comes to legislative proposals, publication of a draft for comment prior to adoption of a proposal by the College of Commissioners is a sensitive issue for the Commission, as it is seen as undermining one of the central powers of the Commission under the EU treaties – the right to initiate legislation. The Commission is concerned that the member states in the Council and Members of the European Parliament would be among the most active participants in the public consultations about the drafts, which would essentially eliminate its right to initiate legislation. It therefore balks at making such a radical constitutional change in the context of a trade negotiation.*⁷⁶¹

This concern of the Commission is peculiar considering that in one of the TTIP proposals for RC, the Commission explains that the cooperation efforts will take place before the Commission adopts a formal position – i.e., before a draft is adopted by the College of Commissioners – and that the US similarly engage in RC before launching the notice of proposed rulemaking.⁷⁶² If the Commission is indeed worried that its right to initiative is tempered by the European Parliament being amongst the most active participants in the public

⁷⁵⁷ Also see, O'Brien, 'Moving Regulation out of Democratic Reach: Regulatory Cooperation in CETA and its Implications', 6.

⁷⁵⁸ European Commission, *TTIP - EU proposal for Chapter: Regulatory Cooperation* (21 March 2016) <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf> accessed 14 May 2022, art. x4.

⁷⁵⁹ *ibid.* art. x.4 footnote.

⁷⁶⁰ Meuwese, 'Constitutional Aspects of Regulatory Cooperation in TTIP: An EU Perspective' . 164.

⁷⁶¹ Chase and Pelkmans, 'This time it's different: Turbo-charging regulatory cooperation in TTIP', 14.

⁷⁶² European Commission, *TTIP - EU proposal for Chapter: Regulatory Cooperation* (21 March 2016) <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf> accessed 14 May 2022, art. x4.

consultations about the draft, why is it not worried about foreign governments doing the same? RC can result in the Commission consulting with foreign governments on a draft proposal before the draft is adopted by the College of Commissioners and thus before Council and Parliament even get word of it.⁷⁶³ In general, RC taking place outside regular decision-making processes is problematic.⁷⁶⁴ Whilst the RC activities are essentially procedural and presented as voluntary, they could be far reaching. By agreeing to inform each other as early as possible in the regulatory process, other governments are given access to information before a democratic debate takes place.

Contrastingly, the process of RC is sometimes viewed more positively. As stated in the introduction, RC can result in a regulatory level playing field, as a protection against more crude removal of trade barriers in FTAs. While this is theoretically at least an option, the question is whether this is the case in practice and whether the institutional framework is helpful in that direction. Furthermore, as Cremona argues, RC can be seen ‘as a collaborative effort, aimed at a greater mutual understanding of different regulatory approaches.’⁷⁶⁵ Alemanno argues with regard to the TTIP that it ‘is set to create the conditions for prompting a new awareness in the minds of the respective regulators: that of the extraterritorial impact of their existing and proposed regulations.’⁷⁶⁶ Additionally, allowing foreign government participation is not inherently negative when tackling transnational risks. As Slaughter astutely observes, ‘foreign ideas should not be emulated solely because they are foreign, but neither should they be rejected solely because they are not homegrown.’⁷⁶⁷ However, as Meuwese explains, foreign authorities are not accountable to the domestic constituencies of the party they are cooperating with.⁷⁶⁸ And, regulators need to trust their foreign peers not to arrive at the dialogue table with the exclusive aim of representing their domestic stakeholders and voters.⁷⁶⁹ Essentially, by participating in an ongoing dialogue with foreign governments on regulatory measures, the executive plays a new role in setting regulatory standards without added oversight by

⁷⁶³ For a possible solution to this specific problem see below, section 5.3.1.

⁷⁶⁴ See, for example, Meuwese, 'Constitutional Aspects of Regulatory Cooperation in TTIP: An EU Perspective', 163.

⁷⁶⁵ Cremona, 'Negotiating the Transatlantic Trade and Investment Partnership (TTIP)', 353.

⁷⁶⁶ Alemanno, 'The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences', 631.

⁷⁶⁷ Slaughter, 'Agencies on the loose? Holding government networks accountable', 535.

⁷⁶⁸ Meuwese, 'EU-US horizontal regulatory cooperation: mutual recognition of impact assessment?', 262.

⁷⁶⁹ *ibid*, 262.

parliaments and insufficient participatory rights.⁷⁷⁰ This problem becomes more acute when considering the influence of business and lobbying groups.

5.2.3 *Biased influence of business and lobbying groups*

RC is – disappointingly – industry and commerce focused. Whilst there is great potential in RC to tackle, for example, climate change, RC is embedded in trade and consequently there is a strong bias towards trade and investment facilitation rather than protecting citizens or the environment.⁷⁷¹ That the industry and its lobbying groups have an influence on regulatory processes is a well-known fact. And the fact that economic actors have a preferential or even ‘privileged’ position in RC – is, as Fahey explains, a common objection to FTAs such as CETA and the TTIP.⁷⁷² In matters of RC, the influence of business is twofold. On the one hand, business and commerce *explicitly* exert influence on RC as RC provides access to the early stages of regulatory processes and, on the other hand, *implicitly*, by exerting influence over national policymakers that trickle down to RC between governments.⁷⁷³ Whilst RC does not necessarily alter domestic processes, Meyer-Ohlendorf, Gerstetter and Bach explain that the bias towards trade facilitation ‘can lead to a discursive shift where trade and investment facilitation through deregulation becomes the focus of the discussion’, conceivably at the expense of other considerations.⁷⁷⁴ The focus of RC on business and commerce in view of the aim to facilitate trade adds another dimension of worries regarding the throughput-legitimacy of RC.

There are several examples in the FTAs that illustrate the focus on business. The RC models calls for sufficient time to be permitted for, ‘interested parties’ to provide comments in writing. This opens up the RC models’ regulatory processes to the influence of lobbying groups and other countries.⁷⁷⁵ Moreover, as seen in chapter 2 and illustrated by the approach to RC in the USMCA, the focus of the US is on creating a notice and review process that somewhat mirrors

⁷⁷⁰ See below, section 5.3.

⁷⁷¹ See Meyer-Ohlendorf, Gerstetter and Bach, *Regulatory Cooperation under CETA: Implications for Environmental Policies*, 5.

⁷⁷² Fahey, ‘CETA and Global Governance Law: What Kind of Model Agreement Is It Really in Law?’ , 302.

⁷⁷³ See *ibid*, 301; The explicit influence enhanced by the Investor State Dispute Settlement provisions. Whilst interesting, Investor State Dispute Settlement provisions are beyond the scope of this thesis. For further reading see, Laurens Ankersmit, ‘The Compatibility of Investment Arbitration in Trade Agreements with the Judicial System’ (2016) 13 *Journal for European Environmental & Planning Law* 46; Gisèle Uwera, ‘Investor-State Dispute Settlement in Future Investment-Related Agreements: Is the Autonomy of the Legal Order an Obstacle?’ (2016) 15 *The Law & Practice of International Courts and Tribunals* 102.

⁷⁷⁴ Meyer-Ohlendorf, Gerstetter and Bach, *Regulatory Cooperation under CETA: Implications for Environmental Policies*, 5.

⁷⁷⁵ See, for example, CETA, art. 21.4.e; further discussed in section 5.3.2.

the US administrative process.⁷⁷⁶ The risk of including a US based process in RC is creating possibilities for multinationals to abuse such a process.⁷⁷⁷ This can potentially result in multinationals and their lobbyists to influence regulatory processes – an aspect of TTIP that received immense criticism throughout the EU.⁷⁷⁸

RC can negatively influence the regulatory process by allowing multinationals a seat at the table when discussing draft proposals.⁷⁷⁹ In fact, this situation is severely worsened in the USMCA since RC is applicable to dispute settlement – in contrast to the CETA where RC is excluded from the scope of dispute settlement.⁷⁸⁰ This can result in multinationals claiming loss of profits due to the US, Mexico and Canada not cooperating on regulatory standards as agreed upon in the USMCA.⁷⁸¹ Factually, this would most likely lead to American big business to influence regulatory standards in Canada and Mexico to converge on US standards and facilitate trade in that way – and to litigate if it does not. And as the USMCA countries must publish online the descriptions of the processes and mechanisms employed by its regulatory authorities to prepare, evaluate or review regulations, a situation occurs where interested persons – read: lobbyists – can track and trace the regulatory process from start to finish.⁷⁸² Thus, business and lobbyists have the possibility to exert influence from drafting of the proposal to the adoption of a draft regulation that will be sent to elected bodies. This can result in ideas that protect the public interest but negatively affect trade not making it out of the drafting phase.⁷⁸³

Taking the aforementioned in conjunction with the retrospective review or ex post evaluations and suggestions for improvement, not only are regulations influenced prior to the adoption of a draft, regulatory standards are also assessed retroactively, giving room for foreign countries and

⁷⁷⁶ See chapter 2, section 2.4.2.

⁷⁷⁷ See, Trew, *International regulatory cooperation and the public good: How "good regulatory practices" in trade agreements erode protections for the environment, public health, workers and consumers*, 33.

⁷⁷⁸ See, for example, Latorre and Yonezawa, 'Stopped TTIP? Its potential impact on the world and the role of neglected FDI'; Haar, *Cooperating to deregulate*; De Ville and Siles-Brügge, *TTIP: The Truth about the Transatlantic Trade and Investment Partnership*; De Ville and Siles-Brügge, 'Why TTIP is a game-changer and its critics have a point'.

⁷⁷⁹ The Corporate Europe Observatory contains several articles discussing this problem. See, for example <<https://corporateeurope.org/en/2017/02/regulatory-cooperation>> accessed 18 May 2022; see specifically a paper on The Corporate Europe Observatory, '*Regulatory cooperation: big business' wishes come true in TTIP and CETA*' <https://corporateeurope.org/sites/default/files/attachments/ceo_regulatory_cooperation_06.1.pdf> accessed 18 May 2022.

⁷⁸⁰ USMCA, art. 28.20; CETA, art 8.18.

⁷⁸¹ USMCA, art. 28.20.

⁷⁸² USMCA, art. 28.15; also see, European Commission, 'TTIP - EU proposal for Chapter: Good Regulatory Practices' 21 March 2016), art 9, <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154380.pdf> accessed 20 April 2020; Labonté and others, 'USMCA (NAFTA 2.0): tightening the constraints on the right to regulate for public health' and

⁷⁸³ USMCA, art. 28.15.

multinationals to influence regulatory standards both before the adoption of a draft *and* in retrospect.⁷⁸⁴ Retrospective review leads to modification or repeal of the regulation initiated by, for example, a suggestion for improvement. A suggestion for improvement can be made – by any interested person – for the issuance, modification or repeal of a regulation on the grounds that the regulation has become ineffective at protecting health, welfare or safety or; has become more burdensome than necessary – for example with respect to its impact on trade – or; due to changed circumstances, incorrect or outdated information. This all-American way of regulating and developing the regulatory processes by maximising the influence of lobbying groups has consequences for legitimacy. Subsequently, engaging with the US in RC leads to the automatic inclusion of multinationals in the process, giving their lobbyists the opportunity to influence regulatory standards both *ex ante* and *ex post*, namely prior to the adoption of a draft and through retrospective review after the adoption.

Putting aside the TTIP proposals for one moment, the influence of business is already problematic in EU-US cooperation. In the EU-US New Transatlantic Agenda (NTA), RC developed from top-down to bottom-up RC and established the transatlantic dialogues.⁷⁸⁵ The most influential dialogue in the NTA is the Transatlantic Business Dialogue (TABD), as Zoller argues that evidence implies that its recommendations are often directly adopted into policies.⁷⁸⁶ At the same time, the TABD is the dialogue that raises the most questions about the democratic credentials of transatlantic policymaking. Fahey argues that the TABD is ‘perceived to have given certain economic actors privileged access to policy-makers at the expense of other sectors of transatlantic society.’⁷⁸⁷ The TABD and its influence are controversial due to its undemocratic nature and privileged position in intergovernmental policymaking.⁷⁸⁸ The TABD similarly illustrates the focus of RC on business and commerce. Thus, the environmental, labour and consumer dialogues were created as a response to the concern that the business sector was influencing trade talks to the detriment of consumers. However, in reality the powerful position

⁷⁸⁴ USMCA, 28.13; 28.14. For an interesting analysis on the USMCA see, Gantz, 'The USMCA: Updating NAFTA by Drawing on the Trans-Pacific Partnership'.

⁷⁸⁵ See chapter 2, section 2.3.1.

⁷⁸⁶ Heather Zoller, 'Dialogue As Global Issue Management: Legitimizing Corporate Influence in the Transatlantic Business Dialogue' (2004) 18 *Management Communication Quarterly* 204, 231.

⁷⁸⁷ Fahey, 'Towards a Transatlantic Community of Law?', 136. Also see, for example, Bignami and Charnovitz, 'Transnational Civil Society Dialogues'; Corporate Europe Observatory, a CEO issue briefing, '*TABD in Troubled Water*' (October 2001) <<http://archive.corporateeurope.org/tabd/troubled.pdf>> accessed 18 May 2022; Zoller, 'Dialogue As Global Issue Management: Legitimizing Corporate Influence in the Transatlantic Business Dialogue'.

⁷⁸⁸ See, for example, Corporate Europe Observatory, a CEO issue briefing, '*TABD in Troubled Water*' (October 2001) <<http://archive.corporateeurope.org/tabd/troubled.pdf>> accessed 18 May 2022.; Fahey, 'Towards a Transatlantic Community of Law?', 136.

of the TABD and its impact are not counterbalanced by the other dialogues.⁷⁸⁹ Both the US and EU have made the promise to take recommendations from the other dialogues into account, scholars have found little practical evidence.⁷⁹⁰ Bignami and Charnovitz argue that in practice, the commitment to consumers playing a formal role in international policymaking has not been realised and consumers are continuously unable to establish policy change in the transatlantic relationship.⁷⁹¹ Thus, even without the fruition of the TTIP, existing EU-US cooperative efforts are predominantly business focused.

Essentially, in summary, by participating in an ongoing dialogue with foreign governments on regulatory measures – before a draft proposal is agreed on – the executive plays a new role in setting regulatory standards whilst simultaneously allowing foreign governments and business to influence the setting of these regulatory standards. Traditionally, the executive negotiates trade agreements. Through RC, a cooperative effort of executives with a focus on facilitating trade and consequently an inherent influence of business interests is embedded in the RC process, but parliamentary oversight mechanisms and participation rights that guarantee a balanced representation of interests are notably absent in the RC models.⁷⁹² With this new way of working, procedural, and judicial control, participation of civil society and citizens, transparency, legitimacy, and democratic accountability become extremely important – although, as Trujillo argues, this is disappointingly not acknowledged enough in recent FTAs.⁷⁹³ The RC models analysed in this thesis negatively affect the throughput-legitimacy of the RC process as cooperative efforts between executive branches of government take place with a focus on facilitating trade without accompanied parliamentary oversight or strong participatory rights.⁷⁹⁴

Yet, it is acknowledged that there are some counterarguments that require attention. It is possible to argue that RC consists of nothing more than a ‘talking shop’ where regulators share ideas and information, but that RC does not lead to concrete results.⁷⁹⁵ This is particularly so if

⁷⁸⁹ Corporate Europe Observatory, a CEO issue briefing, *TABD in Troubled Water* (October 2001), 6 <<http://archive.corporateeurope.org/tabd/troubled.pdf>> accessed 18 May 2022; see chapter 2, section 2.3.1.

⁷⁹⁰ *ibid.*, 6; Bignami and Charnovitz, 'Transnational Civil Society Dialogues', 268. Also see Transatlantic Economic Partnership statement, section 15; Action Plan, art. 3.8.

⁷⁹¹ Bignami and Charnovitz, 'Transnational Civil Society Dialogues', 279.

⁷⁹² See below, section 5.3.

⁷⁹³ See Mendes, 'The External Administrative Layer of EU Law-making: international Decisions in EU Law and the Case of CETA'; Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power', 405; Hoekman, 'Fostering Transatlantic Regulatory Cooperation and Gradual Multilateralization'.

⁷⁹⁴ See below, section 5.3; also see chapter 6.

⁷⁹⁵ See, Slaughter, 'Agencies on the loose? Holding government networks accountable', 526.

RC is viewed as a voluntary effort. RC could be seen as no more than a voluntary forum for sharing ideas and information, a function which is within the powers of the executive. A further counterargument is that legitimacy is *not* negatively affected as RC takes place in the agenda-setting phase, which again is within the powers of the executive and where existing oversight mechanisms are sufficient. In essence, there is a claim that the executive has the power to engage in a regulatory dialogue and that, since RC falls within the powers granted to the executive, and RC is voluntary, parliament retains its usual oversight mechanisms and RC is a legitimate exercise of power by the executive. The next sub-sections address these counterarguments in more detail.

5.2.4 *The 'voluntary' argument*

When arguing that RC is voluntary and thus consists of nothing more than a 'talking shop', the main argument is that RC does not require a certain outcome or prevent a party to regulate measures differently or to pursue different initiatives 'for reasons including different institutional or legislative approaches, circumstances, values or priorities', as stated in the CETA, for example.⁷⁹⁶ The RC models consider RC a voluntary effort, however, when a party refuses to cooperate it must explain the reasons for doing so.⁷⁹⁷ Essentially this comes down to what this research refers to as the 'cooperate or explain' principle. Surely the fact that refusal of cooperation needs to be explained raises questions about the voluntary element of RC. Whilst it is unclear what the consequences are if a party does not explain, as O'Brien argues, a refusal to cooperate can have political and/or economic consequences for the party refusing to cooperate, especially when dealing with powerful actors such as the US.⁷⁹⁸ The argument here is that it indeed results in political pressure to engage in RC when refusal to cooperate must be explained and has political and/or economic consequences.

Furthermore, it is important to consider other provisions in the RC models that *do* result in certain commitments. For example, in the CETA firstly both the EU and Canada are committed to furthering RC which seems to point in the direction of RC being an obligation.⁷⁹⁹ Moreover, the CETA explicitly states that the EU and Canada *shall* strengthen their cooperation as set out in the RC chapter.⁸⁰⁰ The USMCA requires its regulatory authorities to encourage

⁷⁹⁶ CETA, art. 21.5.

⁷⁹⁷ See, for example, CETA, art. 21.2.6; see further chapter 2.

⁷⁹⁸ O'Brien, 'Moving Regulation out of Democratic Reach: Regulatory Cooperation in CETA and its Implications', 5.

⁷⁹⁹ CETA, art. 21.2.4; O'Brien, for example, also considers RC to have a compulsory nature, see O'Brien, 'Moving Regulation out of Democratic Reach: Regulatory Cooperation in CETA and its Implications', 5.

⁸⁰⁰ CETA, art. 4.5.

cooperation.⁸⁰¹ Encouraging RC is not a strong obligation. There is, however, another element to consider. The USMCA's GRP Committee monitors the implementation and operation of the USMCA through, amongst others, updates on regulatory practices and processes, exchanging information on approaches to RC and considering developments in RC.⁸⁰² The CETA's RC Forum has similar obligations and generally both the USMCA's Committee and the CETA's Forum promote and facilitate RC.⁸⁰³ Consider the following:

*Through the GRP Committee, the Parties shall enhance their communication and collaboration in matters relating to (...) encouraging regulatory compatibility and regulatory cooperation, with a view to facilitating trade between the Parties.*⁸⁰⁴

This provision leads to the conclusion that RC *will* take place, even if only through the Committee or Forum – that is if Parties decide not to engage in RC. The government officials that in these Committees will engage in RC as its part of their functions. Moreover, GRP are often equally phrased in an obligatory manner in the sense that parties *shall* publish lists of planned regulatory measures.⁸⁰⁵ So, whilst RC is generally presented as voluntary or is 'simply' encouraged it *will* take place through the bodies created by the FTAs or at the minimum result in a discussion on the reasons for refusal. Moreover, GRP assure the transparent development of regulations which enables access to regulatory procedures and subsequent possibilities for parties to comment on planned regulatory measures.⁸⁰⁶ This could lead to a debate and possible attempts to influence a decision not to engage in RC – an issue that becomes more pressing depending on the parties as it is expectedly (politically) easier for the EU to refuse cooperation with Canada than with the US.

Yet, in 2004, the Court of Justice of the European Union (hereinafter the Court) decided that RC is non-binding.⁸⁰⁷ In this case the French government contested the EU-US *Guidelines on Regulatory Cooperation and Transparency* based on the arguments that i) the Commission was not competent to adopt the Guidelines as they amounted to an international agreement, i.e., that

⁸⁰¹ USMCA, art. 28.17.

⁸⁰² USMCA, art. 28.18.3.

⁸⁰³ CETA, art. 21.6.1; USMCA, art. 28.18.2.

⁸⁰⁴ USMCA, art. 28.18.2.

⁸⁰⁵ See, for example, 'TTIP - EU proposal for Chapter: Good Regulatory Practices', art. 5 (21 March 2016) <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154380.pdf> accessed 20 April 2020; USMCA, art. 28.9; CETA, art. 27.1.

⁸⁰⁶ See below, section 5.3.2.

⁸⁰⁷ See *Case C-233/02, France v. Commission*, [2004] ECR I-2759; chapter 2, section 2.3.2; EU-US Guidelines on Regulatory Cooperation and Transparency at <<https://obamawhitehouse.archives.gov/sites/default/files/omb/oir/irc/2002-guidelines-on-reg-coop-and-transparency.pdf>> accessed 6 October 2021.

the Guidelines should have been concluded by the Council rather than the Commission and ii) that the Guidelines amounted to a legal instrument sufficiently detailed to reflect a commitment subject to international law with binding force.⁸⁰⁸ Important for the purpose of this research is the second argument relating to whether or not RC in the Guidelines is voluntary.

Regarding the voluntary nature of RC in the Guidelines, the French Government argued that the Guidelines, at the very least, contain a commitment to cooperate as demonstrated by the fact that the Guidelines state that implementation and progress *will* be reviewed – which ultimately infringes on the Commission’s right of initiative as the Guidelines would affect the legislative process as whole.⁸⁰⁹ The Commission did not view the Guidelines as a legally binding agreement, ‘as confirmed by analysis of the intention of the parties.’⁸¹⁰ More precisely, the Commission argued that, since the Guidelines were to be applied on a voluntary basis: ‘they will be applied on a voluntary basis and the fact that the actions which the parties propose to adopt voluntarily as a result are described by use of the English terms 'should' and 'will' rather than 'shall' are decisive in that regard.’⁸¹¹

The Court ruled that the EU and the US did not have the intention of entering into a legally binding commitment when concluding the Guidelines – and as such considered it unnecessary to consider the specific importance of the use of the terms 'should' or 'will' rather than 'shall'.⁸¹² The Court continued that the Guidelines do not ‘impose obligations on the Commission in carrying out its role of initiating legislation.’⁸¹³ The Court argued that included in the Commissions power to initiate legislation is ‘the possibility of engaging in prior consultation and gathering all necessary information before submitting appropriate proposals.’⁸¹⁴ Essentially, the Court argues that RC in the Guidelines is voluntary based on the intention of the EU and the US when conducting the Guidelines and that ‘the mere fact’ that the Guidelines provide for possibilities to engage in prior consultation and gather the necessary information before submitting proposals do not undermine the Commission’s power of initiative.⁸¹⁵

Whilst the Guidelines are a policy tool for the EU and the US, the RC models are stipulated in legally binding FTAs, i.e., international agreements. Where the Court ruled that in this case,

⁸⁰⁸ *Case C-233/02, France v. Commission*, [2004] ECR I-2759, at 28, 38.

⁸⁰⁹ *Ibid*, at 31, 47.

⁸¹⁰ *Ibid*, at 32.

⁸¹¹ *Case C-233/02, France v. Commission*, [2004] ECR I-2759, at 33.

⁸¹² *Ibid*, at 43.

⁸¹³ *Ibid*, at 50.

⁸¹⁴ *Ibid*, at 51.

⁸¹⁵ *Ibid*, at 51.

considering the specific importance of the terms ‘should’ or ‘will’ rather than ‘shall’ was unnecessary, the argument here is that in case of RC in FTAs, considering these terms *is* important. However, from a strictly legal perspective, the expectation is that Court would consider RC non-binding even when established in an internationally binding agreement due to the voluntary nature of RC. Based on the intention of the parties, whilst the Court would arguably decide that the FTA itself is a legally binding agreement, RC in a legally binding agreement would most likely be considered voluntary by the Court.

This decision by the Court is rather formalistic, but at the same time arguably legally valid. Indeed, the Commission holds the power to initiate legislation and that includes possibilities to engage in prior consultation and gather all necessary information before submitting a draft proposal. Nonetheless, the argument here is that RC is not as voluntary *politically* as it is presented *legally*. Whilst RC can be considered legally non-binding, the argument here is that the *political* pressure that follows from establishing RC in a legally binding treaty, i.e., from the provisions of RC and the treaty context, result at a minimum in political pressure to engage in RC – as well as the fact that RC *will* take place through the bodies created by the FTAs and that GRP provisions assure that parties publish planned regulatory measures accompanied by possibilities for the other party to provide comment on these planned regulatory measures.

Moreover, the *outcome* of the RC process can have legally binding consequences in the sense that regulatory measures that are a result of the RC process have legal effect. In other words, the executive engages in RC, allows and considers comments of the other party when drafting a regulatory measure with a view to facilitate trade and ultimately, the draft proposal is influenced by the RC process. The *procedural requirements* of RC are voluntary, but the *outcome* of RC can lead to binding norms. It is therefore important to have democratic control since RC leads to an exercise of power – even if only power of persuasion – that ought to be legitimate and held accountable and considering that that democratic control on RC is insufficient, RC faces a legitimacy problem.⁸¹⁶

5.2.5 *The agenda-setting phase: the argument that nothing really changes*

Another counterargument against the claim that the RC has a legitimacy deficit, as for example Hoekman and Sabel argue, is that participating parties in RC remain subject to domestic oversight mechanisms and that parliament holds the power to approve or reverse decisions

⁸¹⁶ Slaughter, 'Agencies on the loose? Holding government networks accountable', 532; See below, section 5.2.5 and section 5.3.

when needed.⁸¹⁷ In other words, RC takes place in the agenda-setting phase and is within the powers of the executive thus parliament retains their usual oversight mechanisms. Slaughter argues that it is reasonably expected that normal oversight functions are extended to transgovernmental activities.⁸¹⁸ As seen above (section 5.2.4), The European Court of Justice has indeed confirmed that RC falls under the Commissions right of initiative which includes ‘the possibility of engaging in prior consultation and gathering all necessary information before submitting appropriate proposals’⁸¹⁹ The Commission (or any executive power) *should* gather all necessary information before submitting proposals to the legislative bodies – and the RC process does not undermine the power of initiative. However, gathering information through RC expands the authority of the executive by engaging in a dialogue *with foreign governments* with a focus on facilitating trade – and *without* assigning any role to parliament and with weak participation rights at best.

The exchange of information in the ongoing regulatory dialogue created by RC results at a minimum in exerting influence over regulatory decisions made by the RC partner thus influencing the regulatory discourse (and at a maximum in the setting of standards cooperatively).⁸²⁰ The argument here is that the regulatory discourse is affected when engaging in RC – and there is some political pressure to engage in RC. In other words, the RC process creates a shared regulatory space that demands legitimisation.⁸²¹ To further this argument, the fact that RC takes place in the agenda setting phase without oversight by parliament and sufficiently balanced participatory rights is the essence of RC’s legitimacy deficit.⁸²² It is not the issue that the executive gathers information but the fact that this can result in the regulatory discourse being affected at the start of the regulatory process in cooperation with a foreign government without parliamentary oversight and sufficiently balanced participatory rights. To conclude, in summary, RC affects the regulatory discourse and results in political pressure to engage in RC.

⁸¹⁷ Bernard Hoekman and Charles F. Sabel, 'Trade Agreements, Regulatory Sovereignty and Democratic Legitimacy' (July 2017) Robert Schuman Centre for Advanced Studies Research Paper No RSCAS 2017/36

⁸¹⁸ Slaughter, 'Agencies on the loose? Holding government networks accountable', 528.

⁸¹⁹ *Case C-233/02, France v. Commission*, [2004] ECR I-2759 at 51.

⁸²⁰ See section 4.3 and section 5.2.1; Siles-Brügge and Gabriel, *Policy Briefing: The Neglected Side to TTIP – Horizontal Regulatory Provisions*, 9 <<https://documents.manchester.ac.uk/display.aspx?DocID=28672>> accessed 9 February 2022.

⁸²¹ See section 5.2. on the shared regulatory space.

⁸²² See below, section 5.3.

5.2.6 *Throughput-legitimacy and the legitimacy deficit of RC*

The legitimisation of RC is – at best – achieved by a combination of input- output- and throughput-legitimacy. In other words, all three types of legitimacy can contribute to enhancing the legitimacy of RC.

At the start of this chapter the key argument summarised the causes of the legitimacy deficit of RC. The various elements contributing to the throughput-legitimacy deficit were elaborated on in this chapter. This chapter thus shows that the three factors which affect the throughput-legitimacy of RC are the creation of a shared regulatory space, thereby transforming the role of the executive (section 5.2.1) combined with the influence of foreign governments (section 5.2.2) and the influence of business and lobbying groups on the RC process (section 5.2.3). As throughput-legitimacy focuses on how decisions are made, influencing the regulatory discourse (or setting standards cooperatively) via RC prior to adopting a draft regulatory measure by engaging in a dialogue with foreign governments with a focus on facilitating trade results in a legitimacy-deficit.⁸²³ The key argument in this thesis is that the legitimacy deficit of RC must be addressed by strengthening input- and output-legitimacy whilst expertise enhances the throughput-legitimacy of the RC process.⁸²⁴

5.3 Parliamentary oversight and participatory rights in RC

Throughput-legitimacy is not isolated from input- and output-legitimacy, or in other words, input- and output-legitimacy are not redundant when focusing on the throughput-legitimacy of the RC process. Notably, this thesis focuses on the role of expertise in enhancing the throughput-legitimacy of the RC process. There is not a one-size-fits-all answer to legitimacy, or in other words, it is not possible to simply proclaim a regulatory process is (il)legitimate without analysing legitimacy from a broad perspective. Howse argues that RC should be more transparent, inclusive, and participatory.⁸²⁵ Building on that, the basis of legitimate authority in RC can flow from the RC *process* ensuring transparency and deliberation in decision-making (i.e., throughput-legitimacy) whilst establishing parliamentary oversight and ensuring public participation (input-legitimacy). Consequently, the key argument in this section is that

⁸²³ See chapter 1, section 1.2; Schmidt, 'Democracy and Legitimacy in the European Union Revisited: Input, Output and 'Throughput'', 7; Steffek, 'The limits of proceduralism: Critical remarks on the rise of 'throughput legitimacy'', 786.

⁸²⁴ For expertise see chapter 6.

⁸²⁵ Robert Howse, 'Transatlantic regulatory cooperation and the problem of democracy' in George A. Bermann, Matthias Herdegen and Peter L. Lindseth (eds), *Transatlantic regulatory cooperation: legal problems and political prospects* (Oxford University Press 2000), 480; also see, for example, Ibid; Peel, *Science and Risk Regulation in International Law*, 341.

establishing parliamentary oversight mechanisms and participatory rights that guarantee a balanced representation of interests in RC can enhance the input-legitimacy of the RC process.

Whilst RC does not focus explicitly on legitimisation, if anything the RC process aims towards output-legitimacy by emphasising learning, discovering best practices, and cooperating via GRP.⁸²⁶ This focus of RC on output-legitimacy is not surprising considering that the EU itself relied heavily on output-legitimacy.⁸²⁷ To further this parallel to the legitimacy debate in the EU, Majone argues that the expansion of the EU's regulatory state was mainly justified through the argument of protecting EU citizens from health and environmental risks and the functioning of the Single Market.⁸²⁸ To protect the EU's citizens, the EU relied heavily on 'epistemic (output) legitimacy', or as Majone explains 'on the promise of scientifically sound and non-majoritarian expert-based regulation to tackle transboundary health and environmental problems so as to increase the welfare of EU citizens; and thereby to compensate for the shortcomings of a European welfare state and (input) democracy.'⁸²⁹ Whilst the RC models do not explicitly aim towards protecting citizens and focus on cooperatively developing a regulatory discourse that promotes trade, the output-legitimacy of the RC process can be achieved by emphasising on learning and discovering best practices.

The input-legitimacy of RC is enhanced by including strong participatory rights and parliamentary oversight mechanisms in the FTAs. The shared regulatory space and consequently the transforming role of the executive is problematic considering the lack of parliamentary oversight in the FTAs and the participation rights in RC that do not guarantee a balanced representation of interests. As seen above, whilst legally voluntary element, the FTAs results in political pressure to engage in RC and its outcomes are legally binding. Additionally, as O'Brien argues, if RC is completely voluntary, why is there a need to establish RC in a legally binding treaty?⁸³⁰ The ongoing regulatory dialogue takes place at a minimum on the FTA level – i.e., through the institutions created by the FTAs. The executive branches participate in these dialogues and officials discuss cooperation opportunities in the transnational institutions. When engaging in RC, government officials of the executive branch cooperate with

⁸²⁶ Also see chapter 4.

⁸²⁷ Scharpf, *Governing in Europe: effective and democratic?*, 11.

⁸²⁸ Majone, 'The regulatory state and its legitimacy problems'; Weimer and De Ruijter, 'Regulating Risks in the European Union: the Co-production of Expert and Executive Power', 4.

⁸²⁹ Weimer and De Ruijter, 'Regulating Risks in the European Union: the Co-production of Expert and Executive Power', 4.

⁸³⁰ O'Brien, 'Moving Regulation out of Democratic Reach: Regulatory Cooperation in CETA and its Implications', 13.

their counterparts and together, pave the way for the setting of regulatory standards that are least restrictive to trade. Considering that transnational parliamentary oversight mechanisms are absent in the RC models analysed in this thesis and participatory rights are weak (see below in sections 5.3.1 and 5.3.2), the executive has the possibility to exert influence on regulatory processes *beyond its borders* thus expanding its authority without accompanied oversight mechanisms for parliament.

It is argued in thesis that democratic checks and balances in RC are necessary. Democratic checks and balances should be included *in the FTAs* establishing RC via oversight mechanisms for parliament and participatory rights that guarantee a balanced representation of interests. If RC includes a role for parliament and creates strong participatory rights, the input-legitimacy of RC is enhanced – whilst at the same time a role for expertise enhances the throughput-legitimacy of the RC process.⁸³¹ As Alemanno concludes: ‘TTIP’s success will largely be determined by its ability to ensure parliamentary input to guarantee its legitimacy and accountability.’⁸³² The question is thus whether RC efforts adequately assure participatory rights or if RC establishes oversight mechanisms for parliament and if not, how should the FTA establish such parliamentary oversight and guarantee a balanced representation of interests? Or, in other words, how exactly does (or should) the regulatory dialogue created by RC assure input-legitimacy?

5.3.1 *The role of parliaments in RC*

Importantly, EU-US RC pays attention parliamentary cooperation in the preparatory stages of regulation. In an attempt to legitimise the transatlantic dialogues, the Transatlantic Legislators Dialogue liaises with the permanent dialogues.⁸³³ The Transatlantic Legislators Dialogue, a transatlantic parliamentary dialogue, was designed to ‘add a new level of democratic oversight to the expanding transatlantic relationship.’⁸³⁴ Effectively, this means the Transatlantic Legislators Dialogue operates against the background of other EU-US contacts.⁸³⁵ Essentially, representatives of the European Parliament and US Congress meet with representatives of the

⁸³¹ See chapter 6.

⁸³² Alemanno, ‘The Transatlantic Trade and Investment Partnership and the Parliamentary Dimension of Regulatory Cooperation’

⁸³³ Jancic, ‘The European Parliament and EU-US relations: revamping institutional cooperation?’, 54, 55.

⁸³⁴ See, for example, Transatlantic Legislators Dialogue, *Joint Statement of the 68th Interparliamentary Meeting* (Madrid, 2010) <https://www.europarl.europa.eu/cmsdata/210493/2010-06-06_68-TLD_Madrid_JS.pdf> accessed 21 May 2022; Jancic, ‘The European Parliament and EU-US relations: revamping institutional cooperation?’, 52.

⁸³⁵ See the Transatlantic Legislators Dialogue’s Website <http://www.europarl.europa.eu/intcoop/tld/default_en.htm> accessed 21 May 2022.

various dialogues – for example the Transatlantic Business Dialogue – to discuss regulatory issues or, in the case of the TTIP, as Jancic argues, possibly to ‘analyse the TTIP process and, significantly, ways in which the US Congress could be lobbied.’⁸³⁶ Alemanno argues that existing parliamentary cooperation in the Transatlantic Legislators’ Dialogue should be enhanced and extended to FTAs such as TTIP.⁸³⁷ The TTIP proposals itself acknowledged that the role of the Transatlantic Legislators Dialogue is ensuring that the TTIP and its implementation is accompanied ‘as appropriate, by a deepening of transatlantic parliamentary cooperation.’⁸³⁸ Subsequently, the parliamentary dimension of the TTIP would have drawn upon the experience of the Transatlantic Legislators Dialogue.⁸³⁹ Whilst acknowledging deeper parliamentary cooperation is important, the institutional provisions of the TTIP proposals do nothing more than that. They fail to address important questions such as; how will parliamentary cooperation affect the implementation of the TTIP? What is the role of both parliaments in RC? What are the powers of parliament to intervene in decisions made by the JC? Furthermore, the influence of the Transatlantic Business Dialogue is greater than any of the other transatlantic dialogues.⁸⁴⁰ Drawing upon experiences of the Transatlantic Legislators Dialogue also means acknowledging the prevalent influence of business in EU-US cooperative efforts.

The proposal for RC in the TTIP does devote explicit attention to political accountability by emphasising the need to involve the legislators, advocating regular reviews at the Ministerial level and full participation by relevant regulatory authorities.⁸⁴¹ In the proposal for the institutional provisions, released a couple of months after the RC proposal, these considerations are absent.⁸⁴² Whilst it is very positive that there was attention paid to the need for the

⁸³⁶ Jancic, 'The European Parliament and EU-US relations: revamping institutional cooperation?', 55; Steffenson, *Managing EU-US relations: actors, institutions and the new transatlantic agenda*, 72. Bignami and Charnovitz, 'Transnational Civil Society Dialogues', 274. Noteworthy is the Transatlantic Policy Network (TPN), a dialogue between legislators from US Congress and European Parliament with business leaders from both sides of the Atlantic, influential in getting European industries and officials involved in the transatlantic dialogues. More academic in nature than the other dialogues, TPN 'has working groups that cover the transatlantic marketplace, monetary issues, science and technical cooperation, the Ukraine, and NATO and security issues'. Through an 'extensive program' with conferences, forums, seminars and debates, the TPN aims to strengthen the transatlantic partnership.

⁸³⁷ For more on the Transatlantic Legislators’ Dialogue and ways it could participate in RC see, Alemanno, 'The Transatlantic Trade and Investment Partnership and the Parliamentary Dimension of Regulatory Cooperation'.

⁸³⁸ European Commission, *EU Proposal for Institutional, General and Final Provisions*, art. X.6 <https://trade.ec.europa.eu/doclib/docs/2016/july/tradoc_154802.pdf> accessed 22 October 2020.

⁸³⁹ Ibid.

⁸⁴⁰ See chapter 2, section 2.3.1.

⁸⁴¹ European Commission, 'TTIP - EU proposal for Chapter: Regulatory Cooperation' 21 March 2016 <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf> accessed 30 June 2020.

⁸⁴² European Commission, *EU Proposal for Institutional, General and Final Provisions* <https://trade.ec.europa.eu/doclib/docs/2016/july/tradoc_154802.pdf> accessed 22 October 2020.

involvement of legislators and thus parliamentary involvement in the TTIP, on trade negotiations and subsequently on RC, the opportunities for parliament to intervene are rather limited. This is problematic for both the EU, where parliament does not have a right of initiative, and the US, where the fast-track authority of the President in trade negotiations reduces involvement of Congress in negotiating FTAs, but also in general.⁸⁴³ Whilst a thorough analysis on the lack of a right of initiative for the European Parliament and the fast-track authority of the President of the US and its democratic implications are beyond the scope of this thesis, the fact that parliaments are not explicitly part of the RC process contributes to the overall legitimacy deficit of the RC process.

The other RC models similarly do not attribute an active role to parliaments in the RC process and the argument in this thesis is that the RC should include a parliamentary oversight mechanism. Neither the CETA nor the USMCA mention parliamentary involvement in RC – e.g., the CETA specifically calls for consultations with *private* (i.e., non-governmental) entities in its RC chapter – or in the rest of the FTA for that matter.⁸⁴⁴ In contrast, in the TCA a provision on the possibility to establish parliamentary cooperation is in the common and institutional provisions, specifically in the title on the institutional framework of the TCA.⁸⁴⁵ A possibility, considering that article 11 of the TCA states that the EU and the UK Parliament *may* establish a Parliamentary Partnership Assembly consisting of members of the respective Parliaments.⁸⁴⁶ This Assembly functions as a forum to exchange views on the EU-UK partnership; may request information regarding the implementation of the TCA; is informed of decisions and recommendations of the Partnership Council and can make recommendations to the Partnership Council.⁸⁴⁷ In the RC provisions of the TCA, there is no explicit role attributed to the Parliamentary Assembly. Nonetheless, it is a positive development that parliamentary cooperation is possible whilst the non-obligatory nature of the provision simultaneously leaves open questions about the existence and role of the Assembly. Furthermore, considering the functions of the Assembly, its role in RC is minimal. The Assembly is informed of RC under the TCA and can make recommendations at best but is not given explicit mechanisms to participate or intervene in the RC process. This limitation also appears in the CETA and the USMCA but seem starker since parliamentary cooperation is not mentioned in the RC

⁸⁴³ On the fast track authority of the President and how this is problematic from a democratic point of view see, Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power'.

⁸⁴⁴ CETA, art. 21.8. Also see below, section 5.3.2.

⁸⁴⁵ TCA, art. 11.

⁸⁴⁶ TCA, art. 11(1).

⁸⁴⁷ TCA, art. 11(2).

provisions of these FTAs. What remains is that in RC, cooperation takes place between the executives, setting the agenda for upcoming draft proposals. The point is not that this is illegitimate, after all the executive branch generally sets the agenda – especially considering the lack of a right of initiative for the European Parliament. However, as RC creates a shared regulatory space, the argument here is that parliament should be given oversight mechanisms in the FTAs that create the shared regulatory space.

Now a question is of course, what is the added value of including oversight mechanisms in an FTA considering the procedural requirements that follow when a draft is decided on by the executive? These procedures exist to assure democratic and public involvement and it is possible to argue that because of these oversight mechanisms, including an oversight mechanism in an FTA setting up RC is not necessary.⁸⁴⁸ The central argument here is that parliament exercises its oversight on a draft proposal as it usually does and thus, ‘extra’ oversight mechanisms are redundant. Whilst it is true that parliaments retain their usual oversight mechanisms, including oversight mechanisms for parliament in the FTA results in a democratic feature in a legally binding international treaty. The argument here is that it is important to include such a democratic feature in a legally binding FTA because when the authority of the executive is expanded through trade agreements, an accompanied expansion of parliamentary oversight should take place in the FTA itself. Considering that RC is a new, unpredictable, and quite possibly far-reaching process taking place between countries in the name of facilitating trade, existing oversight mechanisms simply do not cut it.

The expansion of the executive’s authority is problematic since it is not accompanied by an expansion of parliamentary oversight. RC is the strengthening of regulatory authority of the executive branch *without* an accompanied oversight mechanism for parliament. And whilst yes, democratic checks and balances can be found – i.e., parliament gets a say at the signing of the FTA and subsequently after the adoption of the draft proposal – in this way, parliament merely gets a say on the *existence* and the *outcome* of the RC process. Considering that the outcome of RC can be legally binding, it is positive that parliaments get a say on the outcome of the process, yet the issue is with the regulatory discourse that is affected by RC.

Specifically relating to the EU, Chase and Pelkmans provide a suggestion in that the Commission could stick with the current system but add the possibility for its RC partners to comment on proposals *after* publishing and thus after adopting a legislative proposal in the

⁸⁴⁸ This argument was elaborated on above in section 5.2.5.

College of Commissioners.⁸⁴⁹ This would result in the Commission adopting a draft legislative proposal in the College of Commissioners; publish the proposal online; accept comments on the proposal for a set amount of time and; make the proposal, the comments on the proposal and the response of the Commission available to Council and parliament when the legislative proposal is formally presented. In the EU, there are thus two options for the Commission to engage in RC. Either *before* adoption of a legislative proposal by the College of Commissions or *after* adoption. The solution presented by Chase and Pelkmans, i.e., that the draft is simultaneously sent to the European Parliament and published to engage in RC, results in foreign governments setting the agenda as less of an issue. However, if RC happens in parallel to deliberation in European Parliament without information on what is happening in RC, there is still a legitimacy issue. In other words, there is no guarantee in the FTAs that parliaments are made aware of the influence of RC on the draft proposal. From a legitimacy point of view this is hard to justify leading to the conclusion that an oversight mechanism for parliament must be included in the FTAs that sets up the RC dialogue. Additionally, it must be kept in mind that agreeing with a foreign government on certain proposals can lead to parliaments feeling political pressure to accept the proposal. Whilst legally, parliaments have the power to adopt, reject and amend, the question is if this is a situation that is desirable.

The argument in this thesis is that RC ought to establish an obligatory notification.⁸⁵⁰ By providing oversight to parliament, the input-legitimacy of RC is improved. More precisely the argument is that via a notification procedure for parliament, i.e., members of parliament ought to be informed about the RC process beforehand and must receive information on the influence of the RC process on the draft legislative proposal, the input-legitimacy of RC is enhanced. Improved throughput-legitimacy via expertise (chapter 6) contributes to better output-legitimacy, however, still needs to be balanced by better input-legitimacy. To improve the input-legitimacy of RC, the FTAs establishing RC must i) establish an obligatory notification procedure to the parliaments of the RC parties and ii) strengthen the participatory rights of interest groups (such as civil society, non-governmental organisations, or in short, a wide as possible arrange of interested persons).⁸⁵¹

⁸⁴⁹ Chase and Pelkmans, 'This time it's different: Turbo-charging regulatory cooperation in TTIP', 15.

⁸⁵⁰ See below, section 5.3.1; also see, chapter 6, section 6.4.1.

⁸⁵¹ See chapter 6, section 6.5.

5.3.2 *Participatory rights in RC*

To legitimise transnational governance, De Búrca developed a democracy-striving approach advocating for democratisation through broader participation rights via mandatory ‘provisionality and openness of the participatory system’, i.e., a regulatory cycle that is constantly revised to ‘include any new actors or interests who identify themselves as concerned stakeholders, or who have otherwise been identified in the course of the process as having a potential claim to be included’, i.e., what the RC models consider to be ‘interested parties’.⁸⁵² This research builds on De Búrca’s democracy-striving approach as the key argument of this research is that compensatory mechanisms contribute to the throughput-legitimacy of the RC process via expertise but that the RC process should *also* continuously strive to be democratically legitimate by enhancing input-legitimacy via parliamentary oversight and stronger participatory rights. RC thus requires strong participatory rights that result in a balanced representation of interests. This sub-section analyses how participatory rights are organised and balanced in the RC models.

Input-legitimacy can also flow from input by citizens through participatory rights. This section analyses participatory rights in RC. The need for participatory rights in RC requires little explanation. Since decisions made through RC *can* have substantive legal effects, guaranteeing a balanced representation of interest enhances the legitimacy of the RC process.⁸⁵³ If participatory rights are established so that interested parties have equal opportunities to influence RC decision-making, a balanced representation of interests follows which undeniably enhances the legitimacy of the RC process. The question is thus more precisely how RC organises and balances participatory rights and if participation as established in the FTAs contributes to the legitimacy of RC. The analysis of this section focuses on the RC models, specifically EU-US RC culminating in the TTIP proposals, the CETA, the USMCA and the TCA.

The need for strong participatory rights in RC – especially considering the absence of parliamentary oversight – is acknowledged in the literature. Mendes argues that RC decisions – and the authority given to the executive through RC – need to be accompanied by ‘suitable procedural constraints’ analogous to domestic procedural constraints in order to structure the

⁸⁵² See further chapter 6, section 6.4.2. De Búrca, ‘Developing Democracy Beyond the State’, 253. Also see, on the push for democratisation through participation, Maasen and Weingart, *Democratization of expertise? : exploring novel forms of scientific advice in political decision-making*, 3.

⁸⁵³ See chapter 2, section 2.4.1.

authority of the executive.⁸⁵⁴ Trujillo argues that protecting the public interest requires participatory rights for all interests.⁸⁵⁵ She includes participatory rights for representatives of developing countries in her argument considering that RC between the EU and the US will have external impacts on other countries.⁸⁵⁶ The impact of RC on developing countries is important to realise, but is outside of the scope of this thesis to discuss further. The point here is that the need for participatory rights in the RC process is crucial, perhaps more so since oversight mechanisms by parliament are notably absent.

The RC models analysed in this thesis include provisions aiming to set up participation by interested parties in their RC chapter or via GRP. The main issue here is that a common feature of the RC models is that participation takes place via a provision along the lines of publication a draft regulatory measure; allowing ‘any person’ to assess the affect the regulatory measure potentially has on their interests and that parties ought to guarantee opportunities to provide comments on the draft.⁸⁵⁷ Whilst this arguably allows participation of interested parties, these types of provisions establish that the parties engaging in RC can influence each other’s regulatory processes as transparency on planned regulatory measures and possibilities to comment on these measures contribute to creating the shared regulatory space. In other words, notice and comment procedures *enable* RC rather than ensuring that interested parties are heard. Furthermore, participation in the USMCA is reminiscent of the notice and comment procedure in the American administrative process under the Administrative Procedures Act, in which the influence of business and lobbying groups is apparent.⁸⁵⁸ These types of provisions, relating to giving notice of planned regulatory measures and allowing comments by interested parties, are found in most of the RC models. Rather than establishing a balanced representation of interests in the RC process, these provisions assure the creation of a shared regulatory space – i.e., by providing access to regulatory processes – and do not actively counter the influence of business and lobbying groups.

Whether such provisions are stipulated in the RC chapter itself or in the GRP chapter does not make much of a difference in view of participation in RC resulting in access to regulatory

⁸⁵⁴ See, Mendes, 'The External Administrative Layer of EU Law-making: international Decisions in EU Law and the Case of CETA' .

⁸⁵⁵ Trujillo, 'Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power', 412.

⁸⁵⁶ *ibid*, 412.

⁸⁵⁷ See, for example, European Commission, 'TTIP - EU proposal for Chapter: Regulatory Cooperation', art. x6.1 (21 March 2016) <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf> accessed 30 June 2020; TCA, art. 346; USMCA, art. 28.9.

⁸⁵⁸ See chapter 2, section 2.4.2; chapter 3, section 3.4.2; chapter 4, section 4.2.2.

procedures. For example, GRP in the TTIP provision aimed to establish stakeholder consultation when preparing regulatory acts.⁸⁵⁹ Surely, good governance provisions and stakeholder consultations are established in domestic laws and procedures. What exactly is the added value of including such a provision in an FTA? The proposed TTIP GRP chapter provides some insights as it states that the parties of the FTA ought to publish draft regulatory acts to allow not only any natural or legal persons to provide input, but also to allow the other party 'to assess whether and how their interests might be significantly affected.'⁸⁶⁰ The consequence again is access to regulatory procedures (without an attempt to balance the interests of business with the non-business interests) and the creation of a shared regulatory space rather than providing participatory rights with a view on legitimising the RC process.⁸⁶¹

Aside from the provisions on stakeholder consultations and GRP, other provisions in the RC models also establish participatory rights. For example, through GRP and the requirement of an IA which provides both expertise and broad consultation in the RC process. The RC models generally require an exchange of information on planned regulatory acts and their accompanying IAs.⁸⁶² In the CETA alone, the option of joint-IAs is created.⁸⁶³ Considering the minimal role of IAs in RC, however, its added value in view of participatory rights is similarly minimal.

The CETA contains a provision relating to participatory rights of non-governmental interests specifically but does not mention ensuring a balanced representation of interests. Canada and the EU 'may consult, as appropriate' stakeholders and interested parties such as 'representatives from academia, think-tanks, non-governmental organisations, businesses, consumer and other organisations', by any means deemed appropriate.⁸⁶⁴ As of 2018, the Commission and the federal government of Canada carried out consultations with stakeholders to identify areas of interest for RC.⁸⁶⁵ Whilst the CETA, on the one hand, includes no considerations on ensuring

⁸⁵⁹ European Commission, 'TTIP - EU proposal for Chapter: Good Regulatory Practices' (21 March 2016), art. 6 <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154380.pdf> accessed 20 April 2020.

⁸⁶⁰ Ibid, art. 6.1.b.

⁸⁶¹ See, European Commission, 'TTIP - EU proposal for Chapter: Regulatory Cooperation', annex (21 March 2016) <https://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf> accessed 30 June 2020.

Interestingly, the annex to the RC proposal states that the involvement of stakeholders is critical for the success of the TTIP's RC activities. The TTIP proposals do not refer to providing participation rights to legitimise the RC process but is evidently focused on its success.

⁸⁶² See chapter 4, section 4.2.2.

⁸⁶³ CETA, art. 21.4(f)(ii).

⁸⁶⁴ CETA, art. 21.8.

⁸⁶⁵ See chapter 3, section 3.4.1.5; European Commission, 'Call for proposals for regulatory cooperation activities in the Regulatory Cooperation Forum (RCF) under CETA' (February 2018) <http://trade.ec.europa.eu/consultations/index.cfm?consul_id=248> accessed January 5th 2021; Government of

a balanced representation of interests, the EU proposal for the TTIP's chapter on RC from March 2016, on the other hand, explicitly considers ensuring a balanced representation of interests. This proposal dictates that RC must take place in a transparent manner and therefore RC ought to foresee timely opportunities for interest parties to present their views on RC and propose new RC activities.⁸⁶⁶ Moreover, in the joint annual RC programme, an overview of ongoing and planned 'priority' RC would be published. Whilst it is unclear what *priority* RC initiatives are, in this annual programme, consultation with an advisory group 'composed by business including small and medium sized enterprises, trade unions and public interest groups ensuring a balanced representation of interests' takes place.⁸⁶⁷ This is evidence that the TTIP proposals evolved since 2015 considering that the earlier EU proposal on RC made no mention of ensuring a balanced representation of interests.⁸⁶⁸ Notably, the TTIP is the only RC model of the models analysed in this thesis to explicitly focus on ensuring a balanced representation of interests in its (proposed) RC chapter – whilst it is simultaneously the only RC model that is *not* in effect.

Whilst public input contributes to the legitimacy of the RC process, the problem that arises is the influence of business.⁸⁶⁹ The USMCA does not specifically address this concern when advocating for the transparency of procedures. Public input on expertise is the focus of the USMCA which creates an incentive for lobbying groups to make use of the USMCA's notice and comment procedure. When regulatory measures affect trade, it is plausible that lobbying groups will provide input on (planned) regulatory measures and relevant regulatory science, i.e., science supporting (planned) regulatory measures. Through public input, lobbying groups can attempt to establish similar regulations in the US, Canada, and Mexico and contest the science supporting (planned) regulatory measures. Strong participation rights, for example through a notice and comment procedure, enhance the input-legitimacy of the RC process however, a balanced representation of interests is vital.⁸⁷⁰ Since the US is the dominant party in the USMCA, and public input takes place regardless of domicile, it is not hard to imagine US business interests being similarly dominant in the notice and comment procedure. The

Canada, 'Consultations on the Canada-European Union Comprehensive Economic Trade Agreement, Regulatory Cooperation Forum' February 2018) <<https://open.canada.ca/data/en/dataset/c45c4cda-7134-4e65-8e99-5214eb07bcf3#wb-auto-6>> accessed January 5th 2021.

⁸⁶⁶ European Commission, 'TTIP - EU proposal for Chapter: Regulatory Cooperation', art. x.6.1 (21 March 2016) <http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf> accessed 30 June 2020.

⁸⁶⁷ *ibid*, art. x.6.2 and art.x.6.3.

⁸⁶⁸ See, European Commission, 'TTIP - Initial Provisions for Chapter [] Regulatory Cooperation' (4 May 2015) <http://trade.ec.europa.eu/doclib/docs/2015/april/tradoc_153403.pdf> accessed 20 April 2020.

⁸⁶⁹ See chapter 5, section 5.2.3.

⁸⁷⁰ See chapter 6, section 6.4.2.

USMCA does not address how the influence of business is balanced with other interests in the GRP chapter – neither that of civil society nor the influence of another government.

What stands out in the provisions on participatory rights in the RC models that *are* in effect, is that the parties *may* consult, *as appropriate*, with interested parties, by means considered appropriate by the parties. These type of participation provisions result in a system of participation that is decided based on the needs of the parties and does not guarantee participation nor provide ways to balance the representation of interests. In other words, further procedural rules are notably absent, and participation is predominantly set up in a non-obligatory manner. This does not guarantee participation, nor does it ‘structure or constrain’ the RC activities as observed by Mendes.⁸⁷¹ Mechanisms for guaranteeing participation of multiple, and perhaps conflicting interests in the RC models are frankly underwhelming. There is no guarantee of participation nor are the voices of citizens weighed against the input of business. Even when stakeholders or interested parties participate in RC, the non-obligatory nature of participation in the RC models is problematic.

Moreover, bias towards business under RC is arguably strengthened by the lack of strong participatory rights in RC. By allowing sufficient time for interested parties to provide comments in writing, the RC models open regulatory processes to the influence of lobbying groups and other countries.⁸⁷² In the USMCA, as the process mirrors the administrative process in the US, the specific problem is the influence of business and the lack of ways to protect the interests of the public against the influence of big business and lobbyists.⁸⁷³ As the RC models do not guarantee a balancing of interests, there is a danger that the influence of business will have a privileged position in RC.⁸⁷⁴ O’Brien explains that ‘basic democratic features’ are completely absent in the CETA, resulting in RC expectedly predominantly influenced by business.⁸⁷⁵ This conclusion can be applied to the other RC models. The RC models generally do not guarantee participatory rights and even if participation rights are guaranteed, the RC models do not explicitly counter the bias towards other trading partners and big business since

⁸⁷¹ Mendes, ‘The External Administrative Layer of EU Law-making: international Decisions in EU Law and the Case of CETA’, 511.

⁸⁷² See, for example, CETA, art. 21.4.e.

⁸⁷³ USMCA, art. 28.9; see further chapter 2, section 2.4.2.1.

⁸⁷⁴ See, for example, Ernst-Ulrich Petersmann, ‘Transformative Transatlantic Free Trade Agreements without Rights and Remedies of Citizens?’ (2015) 18 *Journal of International Economic Law* 579, 579; Trujillo, ‘Regulatory Cooperation in International Trade and Its Transformative Effects on Executive Power’, 411.

⁸⁷⁵ O’Brien mentions the publication of agendas or reports of meetings; lists of participants in meetings; openness of meetings to the public; availability of documents, and; representativeness of those invited to participate in meetings’, O’Brien, ‘Moving Regulation out of Democratic Reach: Regulatory Cooperation in CETA and its Implications’, 9.

provisions to balance interests are nowhere to be found in the agreement. Importantly, RC is focused on facilitating trade and thus the influence of business is an inherent problem of RC that is enhanced by the (lack of) shaping of participatory rights in RC.

Despite the lack of participatory rights ensuring a balanced representation of interests, the RC models have sought to bring civil society into the process through the institutionalisation as set up by the FTAs. Specifically, the FTAs aim to establish participation through establishing a ‘Civil Society Forum’. For example, the CETA facilitates a Civil Society Forum, however, it is limited to conducting a ‘dialogue on the sustainable development aspects’ of the CETA.⁸⁷⁶ The TTIP proposals show plans of establishing a Civil Society Forum to conduct a dialogue on the implementation and application of the TTIP in which the EU and US ought to ‘promote a balanced representation of all relevant interests.’⁸⁷⁷ The TCA obligates the EU and the UK to consult civil society on the implementation of the Agreement and any supplementing agreements, particularly through interactions with domestic advisory groups and the Civil Society Forum.⁸⁷⁸ As opposed to the other RC models, the TCA dedicates the most attention to participatory rights via institutionalisation, illustrating that the TCA seems to have taken certain criticism into account. Article 14 TCA states that:

The Civil Society Forum of the TCA conducts a dialogue on matters of trade, meets once a year and is open to participation of independent civil society organisations. Domestic advisory groups – article 13 TCA i.e., a representation of independent civil society organisations including non-governmental organisations, business and employers' organisations, as well as trade unions, active in economic, sustainable development, social, human rights, environmental and other matters’ – can participate in the Civil Society Forum and the recommendations of advisory groups must be considered. Operational guidelines for the conduct of the Forum are adopted by the TCA’s Partnership Council. Regarding the Forum, the TCA obligates the EU and UK to ‘promote a balanced representation, including non-governmental organisations, business and employers’ organisations and trade unions, active in economic, sustainable development, social, human rights, environmental and other matters.’

What stands out is that the EU and the UK (and similarly the EU and the US in the TTIP proposals) must ‘promote’ balanced representation of interests, but it is not clear how this should take place. Nonetheless, promoting a balanced representation of interests via obligatory participation creates stronger participatory rights than the other RC models. However, whilst

⁸⁷⁶ CETA, art. 22.5.

⁸⁷⁷ European Commission, *EU Proposal for Institutional, General and Final Provisions*, 14 July 2016 at http://trade.ec.europa.eu/doclib/docs/2016/july/tradoc_154802.pdf, art. X.8.

⁸⁷⁸ TCA, art. 12.

the TCA emphasises most the balanced representation of interests, RC in the TCA is dependent on political will and thus a basic framework for RC is absent in the FTA – which is still problematic in relation to the legitimacy of the process.⁸⁷⁹

Weak participatory rights combined with the inherent focus of FTAs on business through facilitating trade raises a clear legitimacy deficit. As it stands, RC processes are open to multinationals while unclear how other (non-business) interests are weighed against business interests. This arguably results in a privileged position for business and commerce in RC. Considering the influence of foreign governments on (setting the agenda for) domestic regulatory processes, RC can allow for the (undue) influence of both business and foreign governments whilst insufficiently guaranteeing a balanced representation of non-business interests.⁸⁸⁰

This leads to the question: when is participation organised in RC in such a way that it ensures a balanced representation of interests? Whilst the focus of this thesis is on expertise and the throughput-legitimacy of RC, this thesis argues that the RC models demand stronger participation rights and consequently the RC models *must* stipulate that the parties *must ensure* a balanced representation of interests. Participation provisions in RC thus must i) be obligatory and ii) refer to *ensuring* a balanced representation of interests. Via such a provision, RC actors become obligated to explain in what way a balanced representation of interests is ensured in RC – i.e., a consideration in the draft regulatory proposal explaining how interests were balanced in the RC process. Specifically in view of RC, ensuring a balanced representation of interests results in a consideration that explains how the interests of business are weighed against the interests of other interest groups (such as civil society, NGO's etc). Considering that an issue in RC is the influence of business and foreign governments since RC aims towards facilitating trade, requiring a balanced representation of interests demands that the RC actors explain how the interests of business and foreign government was weighed against the interests of (non-business) interest groups.

5.4 Concluding remarks

RC, and transnational governance in general, requires legitimisation. As it stands, RC faces a legitimacy deficit. Whilst interested parties are given ways to express their views, its non-obligatory nature, and the absence of procedural rules in conjunction with a trade focused

⁸⁷⁹ See chapter 3, section 3.4.3.

⁸⁸⁰ See chapter 6, section 6.4.2.

regulatory dialogue leads to legitimacy problems. The RC process requires legitimisation. This chapter argues that establishing parliamentary oversight and ensuring a balanced representation of participatory rights in the FTAs will undoubtedly add to the legitimacy of the RC process.

At a minimum, interested parties ought to have access to the regulatory dialogue and provide input in a similar way to those mechanisms which apply at national level for domestic matters. Whilst the RC models do provide ways for interest groups to participate in RC, it remains unclear how the influence of business is weighed against the influence of other (non-business) interest groups. EU-US RC (prior to the TTIP) revealed that the influence of business is predominant in trade related matters and the RC models in effect do not guarantee that the preferential influence of business is weighed effectively against other interests. Moreover, the focus of RC on facilitating trade inherently draws in the influence of business which naturally seeks to protect and further its own interests. Seen through the lens of legitimacy, this lack of balance with other interests is problematic. To enhance the legitimacy of RC, participatory rights should be strengthened, and parliamentary oversight should be established in the FTAs setting up RC. By providing parliaments with a voice and guaranteeing that the RC actors provide a consideration on how participatory rights were balanced in the RC process, RC can become more legitimate than in its current form.

As it stands, RC is democratically problematic because it takes decision-making away from parliament and traditional input channels. There is a risk of ‘behind the door’ deals where it is unclear which interests are served – especially considering the focus on trade and the resulting influence of business. And if indeed a ‘global policy laboratory’ is established where multiple countries engage in RC and thus discuss how to set regulatory standards with a view on facilitating trade, parliaments need to be aware of such dialogues in the preparatory stages of regulation and subsequently extend democratic oversight on RC. By providing parliament with oversight mechanisms and ensuring a balanced representation of participatory rights of *all interests* in the FTAs, the risk of behind the door deals is reduced due to a democratic check on the ongoing regulatory dialogue. As RC is business and commerce focused the input-legitimacy problems of RC will not disappear unless parliamentary gains oversight mechanisms and RC actors explicitly consider how participatory rights are balanced in RC.

The next chapter assesses the role of expertise in enhancing the *throughput-legitimacy* of RC.

Chapter 6 Expertise and the Legitimacy Deficit of Regulatory Cooperation

6.1 Introduction

RC focuses on the regulation of risks through an ongoing regulatory dialogue aimed towards cooperatively setting regulatory standards at a transnational level. RC is *transnational (risk) governance* that requires legitimisation. This thesis argues that its legitimacy deficit demands addressing.⁸⁸¹ It is agreed, as Slaughter argues, that transnational risk governance cannot be held to the same standards as national processes.⁸⁸² Moreover, as Fisher explains, in general, perfect answers to the ongoing legitimacy problem of risk regulation do not exist due to the unelected nature of public administration.⁸⁸³ Drawing on Fisher's work on technological risk regulation it can be argued by analogy that RC, as a form of transnational (risk) governance, inherently faces ongoing legitimacy problems to which there are no perfect answers. A key question is, as Fisher asks: what is the role of law in constituting and limiting the power of administrative risk regulators?⁸⁸⁴ A key argument of this thesis is that the law constituting the RC process (i.e., the FTAs) ought to provide democratic checks and balances via parliamentary oversight and ensuring a balanced representation of interests.⁸⁸⁵ However, this research focuses the role of expertise in enhancing the throughput-legitimacy of RC and thus, whilst not providing the perfect answer, addresses a compensatory element that enhances the legitimacy of RC. As set out in the introductory chapter, the main question of this thesis is:

Can reliance on scientific expertise, and delegating to independent experts, address the legitimacy deficit of regulatory cooperation?

The key argument of this chapter expands on the arguments made in the previous chapter. As argued, parliamentary oversight creates a democratic check on the power of the executive when engaging in a regulatory dialogue with foreign governments and strong participatory rights counter the influence of business in RC and ensures input of the public at large i.e., the people ultimately affected by the regulatory norms that flow from RC.⁸⁸⁶ Establishing parliamentary oversight and participation rights that ensure a balanced representation of interests thus

⁸⁸¹ See chapter 5.

⁸⁸² Slaughter, 'Agencies on the loose? Holding government networks accountable', 526.

⁸⁸³ Fisher, *Risk regulation and administrative constitutionalism*, 247.

⁸⁸⁴ *ibid*, 247.

⁸⁸⁵ See below, section 6.4.

⁸⁸⁶ *Ibid*.

contribute to the *input-legitimacy* of the RC process, whilst at the same time, the *output-legitimacy* of RC is strengthened by focusing on learning and gathering best practices.

This chapter argues that expertise enhances the *throughput-legitimacy* of RC. A stronger role for expertise (see below, section 6.2.1) in RC enhances the throughput-legitimacy of RC because it places an obligation on decision-makers to make a reasoned and rational decision much earlier than the standard legal requirement in the law-making process (given the implications of RC). Additionally, by requiring decision-makers to make a reasoned and rational decision, expertise balances the influence of business and foreign governments in RC. In such a way, expertise enhances the quality of deliberation in RC which enhances the throughput-legitimacy of RC. In light of that, Joerges and Neyer developed the theory of 'deliberative supranationalism'.⁸⁸⁷ A thorough analysis of Joerges and Neyer's theory is beyond the scope of this thesis, but for the purpose of this research it is important that an argument in deliberative supranationalism is that a deliberative and science-based process enhances the quality of decision-making thereby compensating for the non-democratic nature of the process.⁸⁸⁸ The argument in this thesis is thus in line with the idea of deliberative supranationalism in the sense that expertise can, in principle, enhance the throughput-legitimacy of the RC process because a role for expertise in the RC process creates a deliberative and science-based process that enhances the quality of decision-making.

Importantly, it is argued that the solutions proposed in this thesis only work if there is *full* transparency. In other words, full transparency is a prerequisite for making the RC process more legitimate. Full transparency on the executives' part firstly requires full disclosure *prior* to engaging in the RC process via the notification procedure to parliament and stakeholders. Secondly, transparency requires disclosing all information on the RC process when the regulatory measure is proposed, i.e., the regulatory proposal ought to expressly include a consideration of the RC process and in what way RC influenced the proposal. Thirdly,

⁸⁸⁷ See Christian Joerges and Jurgen Neyer, 'Transforming strategic interaction into deliberative problem-solving: European comitology in the foodstuffs sector' (1997) 4 *Journal of European public policy* 609; Christian Joerges, 'Deliberative Supranationalism'-Two Defences' (2002) 8 *European law journal*: review of European law in context 133; Christian Joerges, 'Deliberative Political Processes' Revisited: What Have we Learnt About the Legitimacy of Supranational Decision-Making' (2006) 44 *Journal of common market studies* 779. Also see, Peel, *Science and Risk Regulation in International Law*, 48; Stijn Smismans, *Law, Legitimacy, and European Governance: Functional Participation in Social Regulation* (Oxford Studies in European Law, Oxford University Press 2004), 422.

⁸⁸⁸ *Ibid.*

transparency requires information on the expertise used and the experts consulted when conducting joint regulatory science.

Crucially, expertise alone is insufficient to enhance the throughput-legitimacy of RC.⁸⁸⁹ A stronger role for expertise enhances the throughput-legitimacy of the RC process by improving the quality of deliberation in RC. But this stronger role for expertise in RC requires balancing by improving the input-legitimacy via oversight by parliament and strong participatory rights.⁸⁹⁰ Transnational expertise also contributes to better output-legitimacy, however, a stronger role for expertise also requires balancing by better input-legitimacy *on the expertise used* via oversight by parliament and strong participatory rights, i.e., the democratisation of expertise in RC.⁸⁹¹ Consequently, the FTAs establishing RC must i) establish an obligatory notification procedure to the parliaments of the RC parties, announcing RC but also at a later stage clarifying in the draft proposal how RC influenced the regulatory discourse ii) strengthen participatory rights and ensure a balanced representation of interests and iii) require joint regulatory science to create a common scientific basis when cooperatively setting regulatory standards – and using i) and ii) to democratise expertise in RC.

This chapter emphasises that a stronger role for expertise must be accompanied by both parliamentary oversight and participation on the experts and expertise used in RC, both to contribute to the overall legitimacy of RC but also to balance the problems with the legitimacy claim of expertise, namely the issue of biased expertise and the problems with technocracy.⁸⁹² Consequently, this chapter firstly analyses the capability of scientific expertise to enhance the legitimacy of the RC process (section 6.2). Secondly, this chapter examines the problems with expert-based legitimacy (section 6.3), namely biased expertise (section 6.3.1) and technocracy (section 6.3.2). Lastly, this chapter focuses on solutions to these problems specifically by applying the democratisation of expertise to RC (section 6.4).

6.2 Expertise and legitimacy

This thesis argues that the legitimacy deficit of RC needs to be addressed and that expertise can enhance the throughput-legitimacy of the RC process. In general, expertise is often called upon to increase the legitimacy of decision-making.⁸⁹³ Transnational expertise in RC creates a need

⁸⁸⁹ See chapter 5, section 5.3.

⁸⁹⁰ See chapter 6, section 6.4.

⁸⁹¹ Ibid.

⁸⁹² See chapter 6, section 6.3.

⁸⁹³ See, for example, Peter M. Haas, 'Ideas, experts and governance' in Monika Ambrus and others (eds), *The Role of Experts in International and European Decision-Making Processes: Advisors, Decision Makers or Irrelevant*

for a justification of decision-making in a rational way. This enhances the throughput-legitimacy of cooperative decision-making by increasing the quality of deliberation in RC. Nonetheless, RC must be overseen by the respective parliaments of the parties and RC models must aim to secure a balanced representation of interests via participatory rights. A role of the latter is to control the expertise used to support to regulatory measures.⁸⁹⁴ After all, who gets the final say in governance? This should not be a group of scientific experts, but the people. Through providing oversight mechanisms for parliament and interest groups, democratic control on expertise can take place, increasing the legitimacy of both the expertise used and the RC process.

6.2.1 *The desired role for expertise in regulatory cooperation*

This research established the understanding of expertise and experts in this thesis and assessed the role of expertise and experts in RC.⁸⁹⁵ Expertise and experts in RC in this thesis are understood as:

- iii) Domestic expertise: co-produced by the *respective* executives and experts, used to support regulatory decision-making and part of the ongoing regulatory dialogue or
- iv) Transnational expertise: co-produced *through RC* resulting in joint co-produced regulatory science, i.e., containing two levels of cooperation, which can consist of aligning domestic expertise.

Subsequently, experts in RC are:

- iii) Domestic experts: actors contributing to evidence-based policymaking, i.e., by providing data, reports, information, IAs and RAs that support the regulatory measure which is subsequently discussed in the ongoing regulatory dialogue;
- iv) Transnational experts: actors who are directly involved in the RC process (for example via *joint RAs* or *joint IAs*), which can be domestic experts acting in a transnational setting.

The role of expertise in RC focuses predominantly on *domestic expertise* as part of the ongoing regulatory dialogue. In view of that, the experts included in RC are predominantly *domestic experts*. In the few cases that RC creates a role for *transnational expertise*, this type of expertise

Actors? (Cambridge: Cambridge University Press 2014); Ambrus and others, *The Role of 'Experts' in International and European Decision-Making Processes : Advisors, Decision Makers or Irrelevant Actors?*

⁸⁹⁴ See below, section 6.4.

⁸⁹⁵ See chapter 1, section 1.3; chapter 3.

is to be conducted by *domestic experts*. In other words, in the RC models analysed in this thesis, expertise is, at best, part of the information exchange.⁸⁹⁶ Studies and reports by domestic experts are (possibly) a topic of discussion in the ongoing regulatory dialogue. The development of EU-US RC over the years illustrates a movement towards including *transnational* expertise to facilitate cooperation and reduce regulatory divergence culminating in the Global Risk Assessment Dialogue (discussed in Chapter Three).⁸⁹⁷ This development towards a role for transnational expertise in RC goes further than discussing domestic expertise in RC, for example via joint RAs or joint IAs. Both joint RAs and joint IAs contribute greatly to providing a more prominent role to expertise in RC. Notably, joint IAs would result in both broad consultation *and* expertise which surely enhances the throughput-legitimacy of the RC process. Whilst the CETA creates possibilities for joint RAs and joint IAs, empirical research shows these possibilities are not utilised in RC.⁸⁹⁸ The role of transnational expertise in RC is minimal and thus, this chapter argues that the role of expertise in RC ought to be strengthened to enhance the throughput-legitimacy of RC.

More precisely, the stronger role for transnational expertise means requiring joint regulatory science to create a common scientific basis when cooperatively setting regulatory standards. This means that when the executive drafts a planned regulatory measure in cooperation with a foreign government, this draft measure ought to rely on *transnational expertise*. In view of the transformed role of the executive and the influence of foreign governments, transnational expertise addresses these issues by enhancing the quality of deliberation in RC. In other words, a role for transnational expertise can ensure that executives do not merely focus on the trade agenda but consider *transnational expertise* – thus enhancing the quality of deliberation in RC. Transnational expertise in this sense can consist of aligning domestic expertise, i.e., *domestic experts* can create *transnational expertise*. Importantly, the demand of joint regulatory science to create a common scientific basis when cooperatively setting regulatory standards does not necessarily mean that parties must start from scratch. The argument here is that it is sufficient to discuss *domestic expertise* conducted by *domestic experts* and that, by agreeing on the domestic expertise discussed in the ongoing regulatory dialogue, the RC actors can establish *transnational expertise*. In other words, aligning *domestic expertise* can result in *transnational expertise* by agreeing on the expertise and as such, creating a common scientific basis.

⁸⁹⁶ See chapter 3.

⁸⁹⁷ Alas, the Global Risk Assessment Dialogue did not amount to much, see chapter 3, section 3.3.3.

⁸⁹⁸ See chapter 3, section 3.4.1.5.

Additionally, a role for *transnational experts* is completely absent in the RC models analysed in this thesis. To strengthen the role of transnational experts in RC, alternatively the FTAs could create the possibility that the RC actors establish scientific committees. These scientific committees, parallel to the scientific committees in the EU, can be appointed by the RC actors and provide scientific advice on drafting and amending legislation.⁸⁹⁹ By mutually appointing scientific committees, RC can create transnational expertise by transnational experts – notwithstanding the fact that participation and parliamentary oversight must also extend on the work of these scientific committees.⁹⁰⁰ Surely, transnational experts can be domestic experts *acting in a transnational setting*. Furthermore, aligning domestic expertise to create transnational expertise can also enhance the throughput-legitimacy of RC without needing to establish transnational experts. Thus, the requirement of transnational expertise argued in this thesis can consist of i) aligning domestic expertise *or* ii) including transnational experts in the RC process by establishing scientific committees on the transnational level (which can consist of domestic experts acting in a transnational setting).

Elaborating further on the legitimacy-claim of expertise, experts are included in decision-making processes to enhance the legitimacy of governance by increasing the quality of decisions, increasing transparency, and adding to the inclusiveness of the decision-making process.⁹⁰¹ Expertise plays an increasingly important role in contemporary society and is used in several ways – i.e., instrumentally, strategically, or even symbolically – to fulfil various roles in the policymaking process.⁹⁰² Generally, as Ambrus and others explain, scientific experts are included in decision-making processes to enhance the legitimacy of governance.⁹⁰³ Gruszczynski argues that scientific experts are an important feature of decision-making processes due to increasing complexity of issues faced but also because science, as a ‘higher

⁸⁹⁹ Daniel Guéguen, *Comitology and other EU committees and expert groups: the hidden power of the EU: finally a clear explanation* (Brussels: Europe Information Service 2004), 27.

⁹⁰⁰ See below, section 6.4.

⁹⁰¹ Ambrus and others, 'The role of experts in international and European decision-making processes: setting the scene', 5.

⁹⁰² On the various ways to use expertise see: Lorna Schrefler, 'Reflections on the different roles of expertise in regulatory policy making' in Monika Ambrus and others (eds), *The Role of Experts in International and European Decision-Making Processes : Advisors, Decision Makers or Irrelevant Actors?* (Cambridge : Cambridge University Press 2014), 66; also see chapter 1, section 1.4.

⁹⁰³ Ambrus and others, 'The role of experts in international and European decision-making processes : setting the scene', 5. See further below, section 6.2.

form of rationality', has a legitimising role.⁹⁰⁴ Whilst expertise can thus, in principle, enhance the throughput-legitimacy of RC, the legitimacy claim of expertise is not unchallenged.

Science cannot be the leading principle in RC due to the issues with biased expertise and the problem of technocracy.⁹⁰⁵ Peel argues that science has been given an unjustifiably privileged position in the management of SPS risks and ascribes failure of the WTO dispute settlement process to not taking into account domestic processes and principles such as the precautionary principle in the EU.⁹⁰⁶ Wickinoff and others similarly argue that scientific expertise in the WTO has been given too much of a pivotal role in dispute settlement at the cost of cultural and political factors, which are not considered justifications for regulations under the WTO system.⁹⁰⁷ Furthermore, it is not unthinkable that the same science results in different regulatory responses.

6.2.2 *The same science, different regulatory responses*

As set out in the introduction of this thesis, when countries work with similar assumptions on the scientific level, including expertise in the RC process increases the chances of convergence.⁹⁰⁸ In other words, scientific expertise can take RC to the next level. It is therefore not surprising that the focus in EU-US RC shifted to cooperation on matters of expertise, despite the fact that cooperation on expertise is not yet realised.⁹⁰⁹ Alemanno explains that a reason for cooperating 'at the scientific stage of risk analysis is that in regulatory regimes, risk assessment is a central element, something like a *Grundnorm* of the risk analysis paradigm.'⁹¹⁰ Atik further explains that 'scientific traditions may promote regulatory convergence based not on trade efficiencies but on the happenstance of received scientific traditions.'⁹¹¹ In principle, the inclusion of expertise in RC can increase the chances of convergence and thus it was expected that expertise would play an important role in the RC models. However, against these expectations the role for transnational expertise in RC is minimal, whilst expertise *is* considered

⁹⁰⁴ Lukasz Gruszczynski, 'The role of experts in environmental and health-related trade disputes in the WTO: deconstructing decision-making processes' in Monika Ambrus and others (eds), *The Role of Experts in International and European Decision-Making Processes : Advisors, Decision Makers or Irrelevant Actors?* (Cambridge : Cambridge University Press 2014), 216.

⁹⁰⁵ See below, section 6.3.

⁹⁰⁶ See, Peel, 'Risk regulation under the WTO SPS Agreement: Science as an international normative yardstick?'

⁹⁰⁷ See, Wickinoff and others, 'Adjudicating the GM Food Wars: Science, Risk and Democracy in World Trade Law'.

⁹⁰⁸ See chapter 1, section 1.3.

⁹⁰⁹ The most prominent example of this shift in focus is the Global Risk Assessment Dialogue, see chapter 3, section 3.3.3.

⁹¹⁰ Alemanno, 'How to get out of the transatlantic regulatory deadlock over genetically modified organisms?', 218.

⁹¹¹ Atik, 'Science and international regulatory convergence', 755.

a facilitating factor as seen in the development of EU-US RC.⁹¹² Whilst unclear what role may be assigned to expertise in the future, the central argument of this thesis is that expertise *should* become more important in RC in view of enhancing the throughput-legitimacy of the RC process. Crucially, however, expertise or joint regulatory science is presented as a solution to the *legitimacy deficit* of RC and not to further RC to the extent that national processes become unimportant.

Regulatory responses vary from country to country, even with a common scientific basis, due to different legal cultures and underlying principles. Legal cultures, as Fisher explains, result in different approaches or answers to certain regulatory problems.⁹¹³ The precautionary principle, for example, is often considered one of the major differences between EU and US regulatory styles.⁹¹⁴ Whilst an elaboration of the precautionary principle is beyond the scope of this thesis, a ‘common basis of scientific *understanding*’, as Alemanno argues, does not exist, neither globally or on the transatlantic level, and there are no distinguishable attempts to achieve a common scientific understanding.⁹¹⁵ A common scientific understanding relates to underlying principles and, as Meuwese explains, there is ‘a lack of (discussion on) shared underlying principles’ in RC.⁹¹⁶ The ‘common law of scientific considerations’, as Atik considered in view of the WTO, is therefore hard to find.⁹¹⁷ The only RC model that works towards establishing a common scientific basis and that creates possibilities to conduct cooperative research agendas is the CETA.⁹¹⁸ However, whilst this provides a stronger role for expertise, the CETA also does not refer specifically to developing a common scientific understanding. Transnational expertise can provide a common scientific basis for specific regulatory measures but due to a lack of a common basis of scientific understanding or discussions on shared underlying principles, national differences will continue to frustrate RC efforts. One of the most well-known examples is the Beef Hormone dispute:

The EU and the US have a longstanding history when it comes to controlling whether hormone-treated beef can enter their respective markets.⁹¹⁹ Starting all the way back in 1981,

⁹¹² See chapter 3.

⁹¹³ Fisher, *Risk regulation and administrative constitutionalism*, 253.

⁹¹⁴ For a comparison on precaution in the EU and the US see, Jonathan B. Wiener and Michael D. Rogers, ‘Comparing precaution in the United States and Europe’ (2002) 5 *Journal of Risk Research* 317.

⁹¹⁵ Alemanno, ‘The Transatlantic Trade and Investment Partnership and the Parliamentary Dimension of Regulatory Cooperation’, 36. Emphasis added.

⁹¹⁶ Meuwese, ‘EU–US horizontal regulatory cooperation: mutual recognition of impact assessment?’, 264.

⁹¹⁷ Atik, ‘Science and international regulatory convergence’, 755; chapter 3, section 3.2.1.

⁹¹⁸ See chapter 3, section 3.4.1.

⁹¹⁹ On beef hormones see, for example, Joerges, ‘Law, Science and the Management of Risks to Health at the National, European and International Level - Stories on Baby Dummies, Mad Cows and Hormones in Beef’; Peel,

the beef hormone dispute has been a major EU-US trade dispute.⁹²⁰ Affecting transatlantic trade relations for decades, the dispute between the EU and the US concerns a wide range of legal and procedural issues. Moreover, Johnson argues that a lack of consensus regarding the safety of hormone-treated beef and the disagreement over scientific evidence has resulted in a dispute that continues beyond the conclusion of formal dispute resolution processes.⁹²¹ The risk on human health due to hormone-treated beef is subject to scientific controversy.⁹²² Whilst a formal dispute resolution was reached under the WTO, the divergence in regulatory standards still exist and cooperative efforts have not resulted in a solution to the cause of the divergence, namely scientific uncertainty. This results in different regulatory measures being adopted in the EU and the US respectively.

Essentially, whether growth-hormone residue in bovine meat poses a threat to human health is subject to scientific uncertainty. Either the risk to human health is considered negligible or unknown – as assessed by the European Food Safety Authority review.⁹²³ The EU and the US deal with the resulting scientific uncertainty differently. According to Hornsby, the EU uses an affirmative position – i.e., even negligible risk is a risk. In contrast, the US uses a negative argument – i.e., there is no proof that there is a risk to human health.⁹²⁴ The variance in the regulatory measures adopted in response to scientific uncertainty are generated by different administrative traditions and principles which shape the regulatory systems of the EU and the US. The question is if these difficulties can be overcome through RC by including expertise or if indeed, as Meuwese states, a lack of shared underlying principles result in these tensions being unsolvable.⁹²⁵

Consequently, Alemanno concludes that EU-US RC should specifically focus on a mutual understanding of the regulatory frameworks in the EU and the US.⁹²⁶ The question here is whether it is desirable to eliminate national differences to facilitate RC? Should RC ultimately change underlying systems and principles? In the end, regulatory responses are the responsibility of governance institutions that are, in turn, responsible to their constituencies.⁹²⁷

'Of apples and oranges (and hormones in beef): science and the standard review in WTO disputes under the SPS Agreement'.

⁹²⁰ Johnson, 'The U.S.-EU Beef Hormone Dispute', 30 ff.

⁹²¹ Ibid., 1.

⁹²² Charlier and Rainelli, 'Hormones, Risk Management, Precaution and Protectionism: An Analysis of the Dispute on Hormone-Treated Beef between the European Union and the United States'.

⁹²³ See, for example, Sang-Hee Jeong and others, 'Risk Assessment of Growth Hormones and Antimicrobial Residues in Meat' (2010) 26 *Toxicological research* 301; European Food Safety Authority, Opinion of the Scientific Panel on Contaminants in the Food Chain on a Request from the European Commission Related to Hormone Residues in Bovine and Meat Products, Question N° EFSA-Q-2005-048, *the EFSA Journal* (2007) 510, 1-62, <<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2007.510>> accessed 1 May 2022.

⁹²⁴ David J. Hornsby, *Risk regulation, science and interests in transatlantic trade conflicts* (New York : Palgrave Macmillan 2014), 3.

⁹²⁵ Meuwese, 'EU-US horizontal regulatory cooperation: mutual recognition of impact assessment?', 264.

⁹²⁶ Alemanno, 'How to get out of the transatlantic regulatory deadlock over genetically modified organisms?', 221.

⁹²⁷ Gruszczynski, 'The role of experts in environmental and health-related trade disputes in the WTO: deconstructing decision-making processes', 220.

Essentially, and perhaps especially so in controversial policy-areas, ‘the substance of decision-making is determined by politics and not expertise.’⁹²⁸ As Schrefler states, ‘we have to accept that a portion of regulatory policy-making is political.’⁹²⁹ Gruszczynski also acknowledges that ‘highly politicised disputes tend to remain politicised, irrespective of the criteria that one uses (scientific or non-scientific).’⁹³⁰

Furthermore, scientific legitimacy or expert-based legitimacy alone is not sufficient due to various problems with expert-based legitimacy, namely the problems of biased expertise or technocracy. Relating to the latter, for example, in T-13/99 *Pfizer Animal Health v. Council*, the European Union’s General Court stated that ‘scientific legitimacy is not a sufficient basis for the exercise of public authority’ since a legitimate exercise of authority requires democratic legitimacy or political responsibility.⁹³¹ The following section elaborates on the issues with expert-based legitimacy, namely the issue of biased expertise (section 6.3.1) and the problem of technocracy (section 6.3.2).

6.3 Problems with expert-based legitimacy

There are two main issues with expert-based legitimacy. Firstly, technocracy, as Maasen and Weingart call it, is ‘the dark side of expertise’ relating to the issue of experts as de-facto decisionmakers.⁹³² Secondly, the idea of science legitimising regulatory decisions is fundamentally based on the idea that science is a neutral arbiter providing an objective basis to regulatory measures. However, Werner explains that regulatory science is often seen not as finding ‘the truth’ but as establishing a foundation that justifies regulatory choices.⁹³³ Expertise is thus sometimes politically manipulated when policy-makers pick and choose certain scientific claims or results on which to base their regulatory actions. In other words, it is not uncommon that policy-makers interpret regulatory science to fit their regulatory goals.

⁹²⁸ Steinar Andresen, ‘The role of scientific expertise in multilateral environmental agreements: influence and effectiveness’ in Monika Ambrus and others (eds), *The Role of Experts in International and European Decision-Making Processes: Advisors, Decision Makers or Irrelevant Actors?* (Cambridge: Cambridge University Press 2014), 124.

⁹²⁹ Schrefler, ‘Reflections on the different roles of expertise in regulatory policy making’, 76.

⁹³⁰ Gruszczynski, ‘The role of experts in environmental and health-related trade disputes in the WTO: deconstructing decision-making processes’, 220.

⁹³¹ Case T-13/99 *Pfizer Animal Health SA v. Council of the European Union* [2002] ECR II-3305 at 201; also see Peel, *Science and Risk Regulation in International Law*, 54.

⁹³² Maasen and Weingart, *Democratization of expertise? : exploring novel forms of scientific advice in political decision-making*, 3. On the democratisation of expertise, see below section 6.4; also see, Nowotny, ‘Democratising expertise and socially robust knowledge’; Jacqueline Peel, ‘International law and the legitimate determination of risk: is democratising expertise the answer?’ (2007) 38 *Victoria University of Wellington Law Review* 363.

⁹³³ Werner, ‘The politics of expertise: applying paradoxes of scientific expertise to international law’, 48, 59; also see Salter, *Mandated science : science and scientists in the making of standards*, 2.

Consequently, regulatory science is perceived as biased. Walker, for example, considers science as a ‘neutral arbiter’ to be a myth.⁹³⁴ This is the problem of biased expertise. Biased expertise is essentially the problem of the politicisation of regulatory science which ultimately results in distrust in expertise. This section addresses these problems, starting with biased expertise (6.3.1) followed by technocracy (6.3.2). The following section (6.4) then proposes the solution to these problems via the democratisation of expertise and applies this to regulatory science in RC.

6.3.1 *Biased expertise*

In global risk governance, scientific expertise can provide expertise-based legitimacy to international regimes.⁹³⁵ Expertise is particularly important in global risk regulation (or global risk governance) since risk regulation is primarily a technical activity.⁹³⁶ Consequently, as Peel explains, practically all global governance institutions dealing with risk regulation involve scientific expertise in their process.⁹³⁷ In the WTO specifically, expert knowledge is seen as the definition of legitimacy functioning as a ‘neutral’ or ‘scientific’ check on what could be deemed illegitimate rule-making by its members.⁹³⁸ In the WTO’s SPS Agreement, scientific expertise functions as a justification for national regulatory measures that affect trade.⁹³⁹ Regulations under the SPS Agreement must be based on science, non-discriminatory and the least trade restrictive option.⁹⁴⁰ Experts are thus a ‘defining structural feature’ of WTO governance considering how it, as Lawrence explains, ‘employs statistical, scientific and economic logic to regularize the international trading system.’⁹⁴¹ Whether or not scientific experts can enhance legitimacy raises questions about bias or political manipulation. Lawrence summarises the concerns neatly in this quote:

(...) experts do not enhance the legitimacy of decision making because they reproduce the status quo. Experts do not enhance the legitimacy of decision making because they imply

⁹³⁴ See Walker, 'The Myth of Science as a "Neutral Arbiter" for Triggering Precautions'

⁹³⁵ Peel, *Science and Risk Regulation in International Law*, 49.

⁹³⁶ *ibid.* Also see, Joerges, 'Law, Science and the Management of Risks to Health at the National, European and International Level - Stories on Baby Dummies, Mad Cows and Hormones in Beef', 2, 3; and in general Fisher, *Risk regulation and administrative constitutionalism*.

⁹³⁷ Peel, *Science and Risk Regulation in International Law*, 50. Steinar Andresen, *Science and politics in international environmental regimes: between integrity and involvement* (Manchester: Manchester University Press 1999), 182, 183.

⁹³⁸ See chapter 3, section 3.2; Lawrence, 'The structural logic of expert participation in WTO decision-making processes', 179, 180.

⁹³⁹ Peel, *Science and Risk Regulation in International Law*, 50. SPS Agreement art. 2.2, 3.1 and 3.2.

⁹⁴⁰ See chapter 2, section 2.2; SPS Agreement, art. 2; TBT Agreement, art. 2. Also see, Colyer, 'The Role of Science in Trade Agreements'.

⁹⁴¹ Lawrence, 'The structural logic of expert participation in WTO decision-making processes', 185, 186.

*neutrality and consensus where there is really contestation and choice. Experts do not enhance the legitimacy of decision making because they replace democratic politics with technical reasoning. Or, to oversimplify, according to these critiques, experts do not enhance the legitimacy of decision making because their vocabulary and epistemology hide the fact that their contributions are also suffused with politics and value judgements.*⁹⁴²

Expertise in policymaking is a widely discussed topic in academic literature, pioneered by Jasanoff in her studies on scientific advice in politics.⁹⁴³ Indeed, scientific expertise is, as Werner describes, often ‘partial, conditional and contested’ thus the use of expertise may result in the opposite of what it is trying to achieve (provide legitimacy by shaping well-informed decisions) and instead increase complexity, contest decisions, and argue over alternative definitions of the problems or risks at hand.⁹⁴⁴ As Klabbers explains, expert knowledge in policymaking is often not universally valid but dependent on time, place, and cultural systems, which compromises the ‘truth-claim’ of expertise.⁹⁴⁵ Wickinoff and others state that ‘risk assessment always incorporates policy and value judgments, and it is far from a one-size-fits-all scientific endeavour.’⁹⁴⁶ Peel argues that ‘dependence on science as a universal arbiter and legitimator places unrealistic demands on scientific knowledge and experts.’⁹⁴⁷ Atik explains that mandated science has the risks of becoming ‘another politicized ideology explicitly directed by money and power.’⁹⁴⁸ Christoforou focuses his criticism on the selection and utilisation of expertise as he explains that ‘scientists coming from [specific] organisations may be unfairly biased in favour of maintaining their organisation’s standards and recommendations.’⁹⁴⁹ The claim that expertise is biased is thus an inherent problem to scientific legitimacy. Whilst many discussing expertise in policymaking argue that expertise enhances its

⁹⁴² Jessica Lawrence, 'The structural logic of expert participation in WTO decision-making processes' in Monika Ambrus and others (eds), *The Role of 'Experts' in International and European Decision-Making Processes : Advisors, Decision Makers or Irrelevant Actors?* (Cambridge: Cambridge University Press 2014), 173, 174.

⁹⁴³ See Jasanoff, *The Fifth Branch : Science Advisers as Policymakers* ; Jasanoff, *Science at the bar law, science, and technology in America* ; Sheila Jasanoff, '(No?) Accounting for expertise' (2003) 30 *Science & Public Policy* 157; Jasanoff, 'Constitutions of Modernity: Science, Risk and Governable Subjects', ; also see Weimer and De Ruijter, 'Regulating Risks in the European Union: the Co-production of Expert and Executive Power', .

⁹⁴⁴ Werner, 'The politics of expertise: applying paradoxes of scientific expertise to international law', 47, 48.

⁹⁴⁵ Jan Klabbers, 'The virtues of expertise' in Monika Ambrus and others (eds), *The Role of Experts in International and European Decision-Making Processes: Advisors, Decision Makers or Irrelevant Actors?* (Cambridge: Cambridge University Press 2014), 83.

⁹⁴⁶ Wickinoff and others, 'Adjudicating the GM Food Wars: Science, Risk and Democracy in World Trade Law', 95.

⁹⁴⁷ Peel, *Science and Risk Regulation in International Law* , 383. Also see, Walker, 'The Myth of Science as a "Neutral Arbiter" for Triggering Precautions'.

⁹⁴⁸ Atik, 'Science and international regulatory convergence', 758.

⁹⁴⁹ Christoforou, 'Settlement of science-based trade disputes in the WTO: A critical review of the developing case law in the face of scientific uncertainty'. 630; also quoted in Gruszczynski, 'The role of experts in environmental and health-related trade disputes in the WTO: deconstructing decision-making processes', 227.

legitimacy and acknowledge that expert knowledge ‘often forms the bedrock of legal and political decision making’ there are also valid points of criticism relating to biased expertise.⁹⁵⁰

Does relying on expertise increase its legitimacy? The argument here is that it does. Lawrence argues that more rational, better informed, and more representative decisions increase legitimacy – and as she explains, most WTO scholars agree with this conclusion.⁹⁵¹ Arguably, more rational, and better-informed decisions provide valuable input and increases output legitimacy as decisions are based on science rather than political will. For that to be the case, however, expert input must be ‘impartial, transparent, well informed and representative’, as Lawrence acknowledges.⁹⁵² Lawrence consequently argues that ‘well-designed expert governance is the definition of legitimate governance.’⁹⁵³ From her view – in the sense of seeing governance in general as expertise – it makes sense to claim legitimacy on that basis.⁹⁵⁴ This thesis offered a different view by focusing on experts that are not integral part *of* the system but experts that are relied upon *by* the system – often through advice.⁹⁵⁵ From the point of view of experts playing an advisory role, as Jasanoff writes: ‘expertise has legitimacy only when it is exercised in ways that make clear its contingent, negotiated character and leave the door open to critical discussion. In other words, expertise, like other forms of democratically delegated power, is entitled to respect only when it conforms to norms of transparency and deliberative adequacy.’⁹⁵⁶ By focusing on expertise enhancing the throughput-legitimacy of RC, the argument here is that more rational, better-informed deliberations improve the throughput-legitimacy of RC since discussions are based on science rather than political will or trade agendas.

Nonetheless, there is an accompanying problem to biased expertise namely the loss of authority and consequently more distrust in said science. Beck writes, ‘the more science and technology

⁹⁵⁰ Werner, ‘The politics of expertise: applying paradoxes of scientific expertise to international law’, 47.

⁹⁵¹ Lawrence, ‘The structural logic of expert participation in WTO decision-making processes’, 180.

⁹⁵² *ibid*, 179.

⁹⁵³ Lawrence, ‘The structural logic of expert participation in WTO decision-making processes’, 179.

⁹⁵⁴ To be clear, this does not imply that Lawrence sees no role for parliament. But from her point of view, governance is done by experts which would include parliament and thus result in a different view on the legitimacy of such an expert system.

⁹⁵⁵ See for example Andresen, ‘The role of scientific expertise in multilateral environmental agreements: influence and effectiveness’, 124, who argues that scientific experts are most important in the agenda-setting (i.e., preparatory) stages through giving advice – and their influence declines as politics takes over the decision-making process.

⁹⁵⁶ Jasanoff, ‘(No?) Accounting for expertise’, 160; Fischer, *Democracy and Expertise: Reorienting Policy Inquiry*, 45.

permeate and transform life on a global scale the less expert knowledge is treated as a given.⁹⁵⁷ The distrust in science is (at least partially) explained by the fact that regulatory science is often politicised. Scientific experts liaise with firms, interest groups and political parties and the public increasingly realises that the implementation of scientific knowledge into regulatory standards is not a neutral enterprise per se:

*The point of involving experts in decision making, after all, is not to find 'the truth' as such, but rather to establish a factual basis that makes it possible to take action and justify choices. The advice provided by experts is thus shaped by the selection of experts, the composition of expert groups, the questions posed to experts and the language they need to speak in order to be heard by those in power.*⁹⁵⁸

Legal and political decisions rely increasingly on experts whilst the authority of experts to provide evidence for decisions and justify policymaking has decreased as Werner explains.⁹⁵⁹ In general, in the 21st century where information is at everyone's fingertips, trust in experts has eroded and everyone is an expert at the click of a button. This overstatement is used here to illustrate an important point: the trust in experts has eroded over time. Nichols wrote a book entitled 'The Death of Expertise' in 2017 and in recent years, 'the death of expertise' has become more and more tangible.⁹⁶⁰ Consider the COVID-19 pandemic. At the start of the pandemic in 2020, experts such as virologists became increasingly important in shaping public policy. As the pandemic lingered on, Nichols's thesis came to life before our eyes as more and more people became distrusting of science.⁹⁶¹ This 'paradox of scientific authority' where science still shapes policymaking and 'scientific advice can still bear authority while the status of many institutions has been eroded', does not prevent scientific expertise from playing an important role in policymaking but is nonetheless important to take into account.⁹⁶² When discussing expertise in policymaking, it is (and should be) acknowledged that, as Werner argues, expert knowledge 'often forms the bedrock of legal and political decision making.'⁹⁶³

⁹⁵⁷ Beck, *World at risk*, 6. Werner, 'The politics of expertise: applying paradoxes of scientific expertise to international law', 47, 48.

⁹⁵⁸ Werner, 'The politics of expertise: applying paradoxes of scientific expertise to international law', 48, 49.

⁹⁵⁹ *ibid.*, 45.

⁹⁶⁰ Thomas M. Nichols, *The Death of Expertise: The Campaign Against Established Knowledge and why it Matters* (Oxford University Press 2017).

⁹⁶¹ See an interview with Nichols during the COVID-19 pandemic <<https://observatory.tec.mx/edu-news/devaluation-expertise>> accessed January 18, 2022.

⁹⁶² Wiebe E Bijker, Roland Bal and Ruud Hendriks, *The Paradox of Scientific Authority: The Role of Scientific Advice in Democracies* (The MIT Press 2009), 153. Ambrus and others, 'The role of experts in international and European decision-making processes: setting the scene', 15.

⁹⁶³ Werner, 'The politics of expertise: applying paradoxes of scientific expertise to international law', 47, 48.

Whilst a general distrust in government cannot be addressed by including expertise in RC, biased expertise resulting from politicisation can be countered by providing mechanisms for oversight to parliaments and participatory rights on the expertise used in RC. More precisely, in RC this means that transnational expertise ought to be subject to oversight by parliament *and* interest groups through participatory rights. The key argument of this chapter is that RC requires transnational expertise that can consist of of i) aligning domestic expertise *or* ii) including transnational experts in the RC process by establishing scientific committees on the transnational level (which can consist of domestic experts acting in a transnational setting). Subsequently, the parliaments of the RC actors *and* interest groups (such as civil society, non-governmental organisations, or in short, a wide as possible arrange of interested persons) should receive information on the selection of experts, how the reports are undertaken (i.e., on matters such as methodology) to assure that RC aims to employ a broad range of experts on regulatory matters to avoid biased expertise as much as possible.⁹⁶⁴ Specifically stronger participatory rights (of for example interest groups, civil society, non-governmental organisation and in general, interested parties) can counter biased expertise – albeit that the problem with biased expertise cannot be completely banished when using expertise in policymaking.

6.3.2 *Technocracy: experts as de-facto decisionmakers*

A further issue with expertise is the problem of technocracy. On both sides of the Atlantic, the debate about scientific advice to politics and the problem of technocracy has existed since the 1960s. Maasen en Weingart has described technocracy as ‘the dark side of expertise’.⁹⁶⁵ Essentially, the problem of technocracy relates to experts becoming de-facto decision-makers. A good example is the WTO where international standards are set by international standard-setting bodies but which lack the support of participating states.⁹⁶⁶ The WTO has received criticism for allowing scientific expertise to play such a crucial role in its decision-making and the dispute settlement process.⁹⁶⁷ Decision-making by experts results in *technocratic*

⁹⁶⁴ See further 6.4.

⁹⁶⁵ Maasen and Weingart, *Democratization of expertise? : exploring novel forms of scientific advice in political decision-making*, 3. On the democratisation of expertise, see below section 6.4; also see, Nowotny, 'Democratising expertise and socially robust knowledge'; Peel, 'International law and the legitimate determination of risk: is democratising expertise the answer?' .

⁹⁶⁶ See chapter 2, section 2.2.2; Peel, *Science and Risk Regulation in International Law* , 26. Ambrus and others, 'The role of experts in international and European decision-making processes : setting the scene', 15.

⁹⁶⁷ See above, section 6.2.2; also see, Herwig, 'Health risks, experts and decision making within the SPS Agreement and the Codex Alimentarius', 195; Wickinoff and others, 'Adjudicating the GM Food Wars: Science, Risk and Democracy in World Trade Law'; Colyer, 'The Role of Science in Trade Agreements'; Christoforou, 'Settlement of science-based trade disputes in the WTO: A critical review of the developing case law in the face of scientific uncertainty'; Peel, 'Risk regulation under the WTO SPS Agreement: Science as an international normative yardstick?'

governance and whilst the argument in this thesis is that expertise ought to be important in RC, this thesis does not argue in favour of technocratic governance.

Experts predominantly fulfil an advisory role in regulatory decision-making processes. Andresen argues that ‘scientific expertise is most important in the agenda-setting phase, and gradually declines in significance as politics and governments take control over the relevant decision-making processes.’⁹⁶⁸ Which means experts ought to be important as RC happens in the preparatory stages of the regulatory process. As Haas writes, in RC – and arguably in policymaking in general – states are the primary decision-makers and scientific experts deliver framing and advice thus fulfilling an advisory role.⁹⁶⁹ However, admittedly RC faces a triple edged sword regarding its legitimacy because complex questions, globalisation, economic interdependence, technological progress and transnational risks create a need for expertise which could perceivably result in elected politicians losing their decision-making authority to technocrats and experts whilst, at the same time, science is at a risk of being biased and RC takes place on the transnational level through a process which – as Chapter Five argued – has an inherent legitimacy deficit. Surely, expertise alone is not sufficient. Not in general, as argued in this section, but also not in RC.

Maasen en Weingart explain that drawing scientific expertise into the process was once seen as the solution to legitimise decision-making processes, the debate has changed due to a push for democratisation through broader participation rights; the politicisation of science resulting in a growing distrust of the public towards experts as policy advisors and; the democratisation of expertise, resulting in legitimacy questions addressed through participatory rights rather than scientific legitimacy.⁹⁷⁰ The arguments presented in this thesis are in line with legitimisation through participation rather than scientific legitimacy alone. To address the claim that technocracy is ‘the dark side of expertise’, the democratisation of expertise is presented as the solution by, for example, Peel.⁹⁷¹ The next section elaborates on the democratisation of expertise and applies this to RC specifically.

⁹⁶⁸ Andresen, ‘The role of scientific expertise in multilateral environmental agreements: influence and effectiveness’, 124.

⁹⁶⁹ Haas, ‘Ideas, experts and governance’, 21.

⁹⁷⁰ Maasen and Weingart, *Democratization of expertise?: exploring novel forms of scientific advice in political decision-making*, 2.

⁹⁷¹ *ibid.*, 3. On the democratisation of expertise, see below section 6.4; also see, Nowotny, ‘Democratising expertise and socially robust knowledge’; Peel, ‘International law and the legitimate determination of risk: is democratising expertise the answer?’.

6.4 The democratisation of expertise in RC

The democratisation of expertise is presented as a solution to the various points of criticism on the role of scientific expertise in WTO decision-making and dispute settlement practices.⁹⁷² Essentially, democratising expertise results in including non-scientific considerations that influence public perception into the decision-making process, even when decisions are based on science.⁹⁷³ The overarching problem in WTO decision-making, for example, is too much science and not enough public involvement.⁹⁷⁴ If expertise is to play a more prominent role in RC, the problems with expert-based legitimacy need to be addressed through democratisation. After all, as is the case with politics in general, RC requires the support of interest groups and the general population because in the end, 'all politics is local'.⁹⁷⁵

6.4.1 Parliamentary oversight

The idea that parliament needs to be involved in RC or that EU-US parliamentary ties need to be enhanced is not new. There are at least two scholars arguing that enhancing the EU-US parliamentary ties through the Legislators Dialogue. Alemanno argues, for example, that existing forms of parliamentary ties require enhancing to tackle the legitimacy issues that occur in any effort aiming at RC.⁹⁷⁶ Jančić makes a similar point in his analysis of TTIP, rightfully arguing that RC in TTIP requires extra mechanisms to guarantee democratic participation and that parliaments should not be isolated from RC.⁹⁷⁷ He provides policy recommendations to this end, which can best be summarised as a) establishing a formal warning mechanism with a view on the Annual Regulatory Cooperation Programme established within TTIP's RC system, i.e., consulting the EU Parliament and US Congress before publication of said programme to get them involved in RC; b) involve the Transatlantic Legislators Dialogue to oversee RC under TTIP and as such, provide new ways for members of the European Parliament and members of Congress to participate in RC; c) enabling national parliaments within the EU to participate in the Legislators Dialogue.⁹⁷⁸ As Jančić focuses on TTIP specifically, it must be kept in mind that this thesis assesses broader RC models based on common characteristics found in various

⁹⁷² E.g., Peel, *Science and Risk Regulation in International Law*; Caroline E. Foster, 'Public Opinion and the Interpretation of the World Trade Organisation's Agreement on Sanitary and Phytosanitary Measures' (2008) 11 *Journal of International Economic Law* 427; Nowotny, 'Democratising expertise and socially robust knowledge'; Peel, 'International law and the legitimate determination of risk: is democratising expertise the answer?'

⁹⁷³ Peel, 'Risk regulation under the WTO SPS Agreement: Science as an international normative yardstick?', 66.

⁹⁷⁴ See chapter 3, section 3.2.

⁹⁷⁵ Macey, 'The 'demand' for international regulatory cooperation: a public-choice perspective', 165.

⁹⁷⁶ Alemanno, 'The Transatlantic Trade and Investment Partnership and the Parliamentary Dimension of Regulatory Cooperation', 56; also see, Haar, *Cooperating to deregulate*.

⁹⁷⁷ Jančić, 'Democratic Legitimacy of Enhanced Regulatory Cooperation in TTIP', 24.

⁹⁷⁸ For further details on Jančić's recommendations see *ibid*, 25 ff.

FTAs.⁹⁷⁹ Nonetheless, the policy-recommendations made by Jančić and Alemanno are valuable and taken into account in this thesis.

Considering the previous policy-recommendations and the argument made here that parliamentary oversight is necessary to legitimise RC, the question is what type of oversight mechanism contributes to enhancing the legitimacy of the RC process. It cannot be denied that, as Smismans explains relating to the EU Parliament in view of comitology, members of the European Parliament generally do not have the time or expertise to engage in extensive control over the RC process.⁹⁸⁰ In view of transnational RC it can certainly be argued that members of parliament, whether in the EU Parliament, Congress in the US or the House of Commons of Canada, similarly do not have the time or expertise to engage extensively in the RC process. However, this does not mean that parliament should be excluded or left out of the FTAs that establish the RC process entirely – as is the case now.

It is argued in this thesis that first the FTAs that establish RC should establish an *obligatory notification mechanism* to the involved parliaments before engaging in the RC process. Through this notification mechanism, parliaments are notified *before* engaging in the RC process, making way for Members of Parliament to participate in the RC process should they wish to do so. At a minimum, parliament should be notified so parliamentarians can decide whether they want to be involved in the RC process. Second, the draft regulatory proposal that follows should clearly state the influence of RC on the proposal. Essentially, when the authority of the executive is expanded, an accompanied expansion of parliamentary oversight should take place in the FTA that establishes the RC process. Notably, transparency works as a prerequisite because parliament will know what is going on. Otherwise, there is no use in oversight by parliament. Through establishing an obligatory notification mechanism, transparency on the RC process is extended to the respective parliaments as is currently done with a call for proposals to stakeholders but should be done explicitly towards the parliaments of the RC actors.

Noticeably, oversight through a notification procedure is less demanding than the policy-recommendations as made by Jančić who concludes that consultation before the publication of the RC programme to involve parliaments– and consultation is evidently more demanding (both for the executive as for the parliaments) than establishing an obligatory notification mechanism.

⁹⁷⁹ See chapter 4.

⁹⁸⁰ Smismans, *Law, Legitimacy, and European Governance: Functional Participation in Social Regulation*, 241.

The obligatory notification mechanism does not create a way for parliament to be involved in the setting of the agenda for the RC process but leaves this in hands of the executive – whereas one of the recommendations of Jančić seemingly aims to get parliament involved in setting the agenda. Jančić’s recommendations create stronger mechanisms than the oversight mechanism for parliament as argued in this thesis. In view of that, the presented notification mechanism does not result in mandatory involvement of members of parliament in the RC process. The reason for concluding to ‘merely’ a notification process is because the setting of the agenda is a competence that belongs to the executive as well as the fact that parliament, as mentioned above, does not have the time or the expertise to engage extensively in the RC process. During the negotiations of the TTIP, the European Commission expressed worries about parliamentary involvement in the consultation process.⁹⁸¹ Considering the essence of RC – i.e., an ongoing regulatory dialogue as early as possible – this concern is rather peculiar since the Commission focuses on the influence of parliament and its effect on its power of initiative but not on the influence of foreign governments. Consequently, oversight on the foreign influence embedded in the RC by establishing an obligatory notification procedure process is a must.

Aside from including an obligatory notification procedure, the FTA should stipulate a demand that parliament be informed in case a regulatory proposal came to existence in cooperation with a foreign government *and* information on the expertise used in the RC process, i.e., notified of the outcome of RC. In this way, the respective parliaments are notified that the executive is going to engage in RC and the proposal that results from the RC process must mention that this proposal was developed in cooperation with a foreign government. Whilst this does not change the process as such – i.e., parliament will stay out of setting the agenda – it makes sure that parliament knows what happened in the ongoing dialogue between participating executives. Moreover, such a recommendation may be easier to accept from the executive’s point of view as opposed to creating obligatory parliamentary involvement in the RC process – as the executive will claim that involvement of parliament will temper the effectiveness of RC and perhaps infringe on its right of initiative. Essentially, because parliamentary oversight is completely absent from RC and the FTAs setting up RC, the argument here is that parliament, at the very least, should be notified before engaging in RC and informed when a draft proposal is a result of RC and with which country. This should be guaranteed in the FTA itself by establishing an obligatory notification procedure on the initiation and the outcome of RC,

⁹⁸¹ See chapter 5, section 5.2.2.

increasing transparency which in turn allows for greater oversight, instead of relying on existing oversight mechanisms especially considering the possibly far-reaching consequences of RC.

In relation to expertise specifically, respective parliaments should extend its oversight to the selection of experts in RC and on matters such as methodology. Oversight by parliament on the expertise used assures that, whilst expertise fulfils an advisory role, the decision-making is ultimately in the hands of parliament. A notification procedure ensures that parliaments are aware of the plans to engage in RC, attain information about the use of expertise in RC and parliaments are informed of the outcome of the RC process. By notifying parliaments of the RC process, the use of expertise in the process and the outcome of the process, transparency is increased. The difference with the way RC is set up now is that parliament is guaranteed information about RC. In such a way, the legitimacy of the RC process is enhanced, members of parliament can decide whether to participate in the RC process but at a minimum, transparency on the influence of foreign governments on the legislative proposal is guaranteed thus enhancing the throughput-legitimacy of the RC process.

6.4.2 *Participatory rights in RC*

As opposed to the complete absence of parliamentary involvement, participation rights *are* established in the RC models.⁹⁸² The argument so far has been that participation rights as established in the RC models insufficiently see to ensuring a balanced representation of interests. There are three distinct ways in which the RC models organise participation, namely through i) notice and comment procedures, ii) stakeholder consultations and iii) through institutionalisation (i.e., establishing a Civil Society Forum).⁹⁸³ The problem with participation in RC is that i) notice and comment procedures aim towards *enabling* RC rather than ensuring participation, ii) stakeholder consultations do not clarify how interests are balanced and iii) the Civil Society Forum either relates to a small part of the FTA (CETA) or lacks procedural rules and constraints (TCA).⁹⁸⁴ Consequently, the RC models ought to foresee in obligatory participation by interested parties and ensure a balanced representation of interests and furthermore, to democratise expertise in RC, must see to establish participation rights on regulatory science supporting cooperatively set regulatory measures to balance the problem of biased expertise.

⁹⁸² See chapter 5, section 5.3.2.

⁹⁸³ Ibid.

⁹⁸⁴ Ibid.

The RC models require stronger participation rights and consequently, to strengthen participatory rights, firstly participation by interested parties (such as interest groups, civil society, or non-governmental organisations) must be made obligatory in RC and secondly, the RC models *must* stipulate that in RC, the parties *must ensure* a balanced representation of interests (as argued in Chapter 5), *including* on regulatory science that creates a common scientific basis when cooperatively setting regulatory standards. Participation provisions in RC thus must refer to ensuring a balanced representation of interests and extend to the use of transnational expertise so that interested persons (such as interest groups, civil society, or non-governmental organisations) can offer their views also on transnational expertise. By strengthening participatory rights on transnational expertise, for example on the selection of experts in RC and matters such as methodology, the problem of biased expertise can be addressed – albeit that the problem with biased expertise cannot be completely banished when using expertise in policymaking. Moreover, stipulating in the FTAs that parties must ensure a balanced representation of interests results in an obligation for the RC actors to provide a consideration in the draft proposal explaining how the interests were balanced. In view of RC, this requirement results in a consideration on how the interests of business and foreign governments and the aim to facilitate trade is weighed against non-business interests.

Essentially, this thesis argues that when the executive drafts a planned regulatory measure in cooperation with a foreign government, this draft measure ought to rely on *transnational expertise*. However, this stronger role for expertise also requires balancing by better input-legitimacy *on the expertise* used via oversight by parliament and strong participatory rights, i.e., the democratisation of expertise in RC. Notably, the democratisation of expertise can only work with *full transparency* (as argued in the introduction to this chapter).

6.5 Concluding remarks

The starting point of this thesis was that reliance on scientific expertise can increase the throughput-legitimacy of RC. Nonetheless, incorporating science into the decision-making process is frequently considered to be insufficient to legitimise transnational governance. Peel argues that ‘melding scientific knowledge with other inputs (...) overcome science’s deficiencies.’⁹⁸⁵ In essence, to come to an agreeable form of integrating scientific expertise into policymaking, ‘science must discipline politics and politics must discipline science.’⁹⁸⁶

⁹⁸⁵ Peel, *Science and Risk Regulation in International Law*, 384.

⁹⁸⁶ Jeremy Fraiberg, D. and Michael Trebilcock, J., 'Risk Regulation: Technocratic and Democratic Tools for Regulatory Reform'(1998) 43 McGill Law Journal 1835, 835.

Moreover, rules must be put in place to guarantee the influence and participation of interest groups, to establish oversight on the selection and utilisation of experts, to prevent biased scientific opinions and to generally deliver sound science which the public can agree with. Surely, to base transatlantic regulatory cooperation predominantly on science gives cause for concern. As the debate around scientific expertise in the WTO resulted in a cry for more democracy, science in transatlantic RC will inevitably be faced with similar criticism and a similar demand of more democratic decision-making.⁹⁸⁷

Transatlantic RC needs to be more than a science-based enterprise. Transatlantic RC ought to consider democratic standards and assure the voice of the people to be heard. Without the support of the people, transatlantic RC will be subject to heavy criticism or fail to be established at all. Thus, whilst the throughput-legitimacy of RC is enhanced by transnational expertise as it increases the quality of deliberation in RC, transnational expertise needs to be held to democratic standards. Legitimacy cannot flow from experts alone, especially not if experts are considered biased and politically manipulated. RC requires obligatory participatory rights in RC that must assure that interested persons (such as interest groups, civil society, or non-governmental organisations) participate in the RC process on the expertise used so that the expertise has not been biased. Through participatory rights that guarantee a balanced representation of interest, democratic control on expertise can take place, increasing the legitimacy of both the expertise used and the RC process.

Furthermore, considering experts as fulfilling an advisory role in the decision-making process leads to the conclusion that the substance of decision-making is essentially determined by politics and not expertise, in line with Andresen.⁹⁸⁸ In this view, states are the primary decision-makers and scientific experts deliver framing and advice thus fulfilling an advisory role through regulatory science.⁹⁸⁹ The issue with this view, however, is that when politicians copy the scientific experts under the claim that it is neutral, experts become decision-makers, which is the essence of the issue with technocracy. Consequently, by creating oversight mechanisms for parliaments and strengthening participation rights, both on the RC process and the expertise used in the RC process, experts are not the primary decisionmakers but fulfil an advisory role on which there are democratic checks and balances.

⁹⁸⁷ Peel, *Science and Risk Regulation in International Law*, 384.

⁹⁸⁸ Andresen, 'The role of scientific expertise in multilateral environmental agreements: influence and effectiveness', 124.

⁹⁸⁹ Haas, 'Ideas, experts and governance', 21.

The conclusion therefore is that integrating expertise into RC and transatlantic policymaking can, in principle, increase its throughput-legitimacy – but *only* if parliament and interested parties (such as interest groups, civil society, or non-governmental organisations) are given access to and oversight on the RC process *and* the expertise used. This requires transparency to the fullest, in the sense of disclosing which experts reached what decision, what these decisions are based on and the funding of the experts. If those requirements can be met, expertise can not only enhance the chances of regulatory convergence but also the throughput-legitimacy of the RC process.

Chapter 7 Conclusion and Lessons for the Transatlantic Experience

RC is the creation of procedural mechanisms in FTAs applicable to the preparatory stages of regulation, aimed at the convergence of standards. RC results in an ongoing regulatory dialogue between the executive branches of government to facilitate trade. The widening and deepening of RC ultimately create various policy laboratories across the globe in which countries learn from variation and best practices to work towards regulatory alignment. RC predominantly focuses on non-tariff barriers to trade and thus, essentially, RC is an expansion of the regulatory state in the risk society to the transnational level. In other words, RC is transnational (risk) governance.

Transnational (risk) governance requires legitimisation and this thesis argues that RC faces a legitimacy deficit. This thesis focuses on the *throughput-legitimacy* of RC and *the role of expertise* in addressing the legitimacy deficit of RC. Whilst RC is perhaps a matter of potential, RC creates a shared regulatory space that influences the regulatory discourse in the agenda-setting stages of the regulatory policymaking process and thus, RC ought to be legitimate. In this thesis, output-legitimacy is understood as the quality of the decisions made in RC. Input-legitimacy is understood as parliamentary oversight and participatory rights in RC. The throughput-legitimacy of RC focuses on how decisions are made in RC, or in other words, the RC *process*. Expertise is part of throughput-legitimacy considering that a scientific basis to regulatory measures creates a need for a justification of decision-making in a rational way thus enhancing the quality of deliberation in the RC process.

Expertise in this thesis relates to both *domestic expertise* (co-produced by the respective executives and experts, used to support regulatory decision-making and part of the ongoing regulatory dialogue) and *transnational expertise* (co-produced through RC resulting in joint co-produced regulatory science, i.e., containing two levels of cooperation, which can consist of aligning domestic expertise). Experts then, are either *domestic experts* (actors contributing to evidence-based policymaking, i.e., by providing data, reports, information, IAs and RAs that support the regulatory measure which is subsequently discussed in the ongoing regulatory dialogue) or *transnational experts* (actors who are directly involved in the RC process, which can be domestic experts acting in a transnational setting).

The starting point of this thesis was that expertise can enhance the throughput-legitimacy of RC *and* increase the chance of convergence. By considering expertise capable of enhancing the throughput-legitimacy of RC, this thesis relies on the compensatory approach to legitimise transnational governance. Expertise can enhance the throughput-legitimacy of RC considering that expertise is a compensatory mechanism that contributes to the throughput-legitimacy of RC by enhancing the quality of deliberation in the RC process. However, scientific legitimacy alone is insufficient to legitimise RC and thus, this research also relies on the democracy striving approach by arguing that the RC process should continuously strive to be democratically legitimate by creating parliamentary oversight on the RC process and strengthening participatory rights in RC so as to ensure a balanced representation of interests.

RC efforts build on the WTO framework. Consequently, this research analysed RC in the WTO followed by an assessment of transatlantic RC. The RC models analysed in this research are EU-US RC culminating in the TTIP proposals, the CETA, the USMCA and the TCA. By comparing these RC models, this thesis assessed the common characteristics of RC. Firstly, the RC models create an institutional framework to aid in developing RC or, in other words, support the creation of living agreements by allowing the ongoing regulatory dialogue to continuously develop. Secondly, RC takes places either through GRP or through explicit RC mechanisms that establish an ongoing regulatory dialogue. GRP build trust between governments. Two key GRP in RC are transparency and participation. Transparency functions as a prerequisite in RC as it assures that the RC actors are aware of each other's (planned) regulatory measures thus enhancing mutual awareness of respective regulatory frameworks. Participation assures that RC actors have access to each other's regulatory processes by allowing any person, regardless of domicile, to provide input on regulatory measures. Subsequently, RC mechanisms result in an ongoing regulatory dialogue since RC actors provide early notice of planned regulatory measures and allow other RC actors to provide input on these planned regulatory measures. Essentially, the focus of RC is on creating an ongoing regulatory dialogue with the purpose to align regulatory outcomes to facilitating trade. Thirdly, expertise is considered a facilitating factor in RC and predominantly domestic expertise is part of the ongoing regulatory dialogue.

The analysis of the RC models illustrated that RC faces a legitimacy deficit. The legitimacy deficit of RC is a consequence of the shared regulatory space created by RC caused by i) the transformation of the role of the executive in the setting of regulatory standards whilst ii) opening the RC process to the influence of foreign governments and iii) focusing on facilitating trade thus providing a privileged position to business influence in the RC process with iv) a

lack of parliamentary oversight and weak participatory rights in the FTAs establishing RC. Two counterarguments were analysed, namely the voluntary argument and the argument that RC takes place in the agenda-setting stages of RC and thus is subject to domestic oversight mechanisms. These counterarguments were addressed by arguing that RC is not as voluntary *politically* as it is presented *legally*. Moreover, the *outcome* of the RC process can have legally binding consequences in the sense that regulatory measures that are a result of the RC process have legal effect. The exchange of information that takes place in RC results, at a minimum, in exerting influence over regulatory decisions made by the RC partner thus influencing the regulatory discourse; at a maximum resulting in the setting of standards cooperatively. Essentially, RC affects the regulatory discourse and results in political pressure to engage in RC. It was further argued that it is not the issue that the executive gathers information but the fact that this can affect the regulatory discourse at the start of the regulatory process in cooperation with a foreign government without parliamentary oversight and sufficiently balanced participatory rights. Consequently, the shared regulatory space created by RC demands legitimisation.

Importantly, it is argued that the solutions proposed in this thesis only work if there is *full* transparency. A key argument of this thesis is that the law constituting the RC process (i.e., the FTAs) ought to provide democratic checks and balances by strengthening input-legitimacy via parliamentary oversight and guaranteeing a balanced representation of interests. This research thus argues that the first step to legitimise RC is i) strengthened input-legitimacy via parliamentary oversight and ii) guaranteeing a balanced representation of interested parties via participatory rights. In other words, this thesis argues that RC should continuously strive to be democratically legitimate and thus enhance the *input-legitimacy* of RC by parliamentary oversight and ensuring a balanced representation of interests – whilst at the same time focusing on learning and best practices enhances the *output-legitimacy* of RC. The RC models do not attribute a role for parliaments in the RC process and an argument in this thesis is that RC should include an obligatory notification mechanism to the parliaments of the RC actors. This increases transparency on the RC process and assures that parliaments are informed of the influence of foreign governments, business interests *and* information on the expertise used in the RC.

Additionally, the RC models do not guarantee participatory rights and where participation rights are guaranteed, the RC models do not explicitly counter the bias towards other trading partners and multinationals. Importantly, RC is focused on facilitating trade and thus the influence of

business is an inherent problem of RC that is enhanced by the (lack of) shaping of participatory rights in RC. Consequently, this research argues that participatory rights in RC must be i) obligatory and ii) must ensure a balanced representation of interests including on regulatory science that creates a common scientific basis when cooperatively setting regulatory standards. The argument here is that stipulating in the FTAs that parties must ensure a balanced representation of interests results in an obligation for the RC actors to provide a consideration in the draft proposal explaining how the interests of business and foreign governments is weighed against non-business interests.

This principal focus of this thesis is the role of expertise in enhancing the throughput-legitimacy of RC. The argument in this thesis is in line with the idea of deliberative supranationalism in the sense that expertise can enhance the throughput-legitimacy of the RC process because a role for expertise in the RC process creates a deliberative and science-based process which enhances the quality of decision-making by including experts in the RC process. As such, this thesis sees expertise as a compensatory element that enhances the throughput-legitimacy of RC. Thus, the desired role for expertise in RC is requiring cooperatively set regulatory measures to be based on transnational expertise. This requirement of transnational expertise can consist of i) aligning domestic expertise *or* ii) including transnational experts in the RC process by establishing scientific committees on the transnational level (which can consist of domestic experts acting in a transnational setting). In such a way, expertise can enhance the throughput-legitimacy by increasing the quality of deliberation in RC.

Whilst the key argument in this research is that expertise as a compensatory mechanism contributes to the democratic legitimacy of the RC process, scientific legitimacy alone is insufficient. Consequently, the democratisation of expertise requires parliamentary oversight and participatory rights *on the expertise used* in RC. Theoretically, science is universally valid. However, in the world of politics, scientific experts often do not represent *the* truth but rather *a* truth tailored to the request of those in power, shaped by their selection, the composition of their groups and the questions posed.⁹⁹⁰ Whilst a stronger role for expertise enhances the throughput-legitimacy of RC and simultaneously increases the output-legitimacy of RC, RC requires input-legitimacy on the expertise used in the RC process. Strengthening input-legitimacy on the expertise used in RC is essentially the democratisation of expertise. By establishing parliamentary oversight and strengthening participatory rights on the expertise

⁹⁹⁰ Werner, 'The politics of expertise: applying paradoxes of scientific expertise to international law', 48, 49.

used, the democratisation of expertise addresses the problems of biased expertise by strengthening participatory rights and balances the issue of technocracy by creating oversight mechanisms for parliaments and strengthening participation rights, both on the RC process and the expertise used in the RC process, resulting in a full-circle argument regarding the legitimacy of RC.

To conclude, in summary, to address the legitimacy deficit of RC this thesis presents three solutions: a more prominent role for expertise, establishing a role for parliament and making the process more inclusive and participatory by establishing strong participatory rights – with transparency being the prerequisite. In other words, if RC is to address its legitimacy problem, RC should i) assign a more prominent role to expertise by requiring joint regulatory science to create a common scientific basis when cooperatively setting regulatory standards thus strengthening the role of transnational expertise, ii) establish an obligatory notification procedure to the parliaments of the RC parties, announcing RC but also at a later stage clarifying in the draft proposal how RC influenced the regulatory discourse and iii) be more inclusive and participatory via obligatory participatory rights and referring in the FTA to ensuring a balanced representation of interests – and using ii) and iii) to democratise i). If these elements are kept in mind, scientific expertise can enhance the throughput-legitimacy of RC. Transparency works as a prerequisite for making the process more inclusive. After all, as Weiler asked, ‘if you do not know what is going on, which document will you ask to see?’⁹⁹¹ As a prerequisite, transparency is required for transnational governance to be able to be legitimate in the first place. But transparency alone does not result in legitimacy. The transatlantic experience teaches future RC endeavours that expertise, participatory rights, and parliamentary oversight are crucial to enhance the legitimacy of the RC process. To summarise in one sentence, as far as that is possible: RC needs more science, accompanied by more democracy.

⁹⁹¹ Joseph H. H. Weiler, 'To Be a European Citizen: Eros and Civilization', *The Constitution of Europe* (Cambridge University Press 1999), 349; also see, Slaughter, 'Agencies on the loose? Holding government networks accountable', 523.

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