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**MOSSAVAR-RAHMANI CENTER**  
for Business and Government

# **Regulatory Cooperation – A Reality Check**

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# **Regulatory Cooperation – a Reality Check**

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**Abstract:** Regulatory cooperation is seen as an effective way to in foster further trade liberalisation and reduce unnecessary red tape in international exchange. The European Union Single Market shows the benefits of such cooperation, contributing to an estimated 8.5% of EU GDP. Through Association Agreements, EU neighbours have aligned with EU law to access the EU market. Yet, despite impressive estimates of potential benefits, other trading partners have set a low level of ambition for regulatory cooperation and the benefits have been modest thus far. Given that regulatory cooperation is a long-haul exercise and that the EU Free Trade Agreements with regulatory cooperation provisions have only recently gone into force, the full potential of regulatory cooperation may only be seen in coming years.

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## I. Introduction

Regulatory cooperation is at the heart of the European Union (EU) project and a key component of EU enlargement, partnership and trade agreements. It figures prominently in current discussions between the EU and the United Kingdom (UK) as they work out their future relationship. The drive for regulatory cooperation is based on a range of presumed trade enhancing and cost reduction benefits. The following explores whether these benefits have materialised in practice.

Given low and decreasing tariff levels, efforts to boost trade (and economic growth) are increasingly focused on regulatory cooperation to reduce unnecessary regulatory divergences which represent ‘behind the border’ barriers to trade.<sup>1</sup> Beyond trade, regulatory cooperation offers efficiency gains for both businesses and the public sector in so far as it reduces administrative costs by eliminating duplicate testing and inspections.<sup>2</sup> Business also finds it less costly and more conducive to economies of scale to comply with one set of rules and formalities across export markets. Governments see regulatory cooperation as a way to ensure global financial stability and avoid global systemic risks<sup>3</sup> and tackle cross border externalities (e.g. climate change) which cannot be dealt with in isolation. With globalisation, governments have a strong interest in regulatory cooperation to ensure that inputs along the supply chain respect domestic environmental, health and safety standards. Likewise, governments want to engage in regulatory cooperation to achieve a level regulatory playing field so that industry does not locate to jurisdictions with lower regulatory requirements. For countries seeking accession to the EU, regulatory alignment is a condition of membership. For others, it is a means to access the EU single market and thus facilitate trade and growth. Regulatory cooperation is not without cost. In addition to the resources required to manage cooperative ventures, there may be costs related to regulatory alignment that is not suited to local circumstances and political costs related to the loss of regulatory autonomy.<sup>4</sup>

Regulatory cooperation can range from informal information exchange, to mutual understanding about good regulatory practices to legislative harmonisation, mutual recognition agreements and equivalency arrangements. The latter types of cooperation, where rules are either the same or have similar policy goals and deliver equivalent outcomes, have greater potential to generate benefits compared to informal exchanges.<sup>5</sup>

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<sup>1</sup> OECD (2017), *International Regulatory Co-operation and Trade: Understanding the Trade Costs of Regulatory Divergence and the Remedies*, OECD Publishing, Paris, p.3.DOI: <https://doi.org/10.1787/9789264275942-3-en>,

<sup>2</sup> OECD (2017), *International Regulatory Co-operation and Trade: Understanding the Trade Costs of Regulatory Divergence and the Remedies*, OECD Publishing, Paris, p.9..DOI: <https://doi.org/10.1787/9789264275942-3-en>

<sup>3</sup> OECD (2017), *International Regulatory Co-operation, Addressing Global Challenges*, OECD Publishing, Paris, .DOI: <https://doi.org/10.1787/9789264200463-en>

<sup>4</sup> Bull, Reeve T., Mahboubi, Neysun A., Stewart, Richard B., & Wiener, Jonathan B. (2015). New approaches to international regulatory cooperation: The challenge of TTIP, TPP, and mega-regional trade agreements. *Law and Contemporary Problems*, 78(4), p. 7.

<sup>5</sup> Hoekman, Bernard. (2015). *Trade Agreements and International Regulatory Cooperation in a Supply Chain World*. 2015/04, RSCAS Working Paper, European University Institute, Florence, p.7.

The EU itself is the clearest example of regulatory convergence between sovereign states, with EU Member States<sup>6</sup> bound by law to eliminate regulatory differences that impede the free movement of people, goods, service and capital and to exercise mutual recognition in goods and services markets. Since the 1990s, regulatory cooperation has been an important component of EU association agreements with its near neighbours and has emerged as a key element in recently concluded ‘new generation’ free trade agreements with Korea, Canada and Japan. It has been pursued through sectoral agreements, for example, with the USA. In addition to formal agreements, EU standards and rules are inspiring third countries and companies to adopt similar legislation in an informal, often market driven process termed ‘the Brussels effect’.<sup>7</sup>

There is a growing body of research on the trade impeding aspects of divergent regulation and its estimated costs<sup>8</sup> as well as on the scope and methods of diffusion of the ‘Brussels effect’.<sup>9</sup> There is less coverage of the results of regulatory cooperation and whether it has generated foreseen benefits and/or cost savings. This paper contributes to filling that gap by examining the results of formal and informal regulatory cooperation and reviewing available analyses of the impacts of that alignment. It explores the limitations and challenges of cooperation between ‘rule-makers’, using EU-US regulatory cooperation as an illustration. Conditions for the success of formal regulatory cooperation/convergence ventures are outlined.

The paper shows that the integration motivation (e.g. accession to the EU and access to the EU single market) has driven the closest alignment to EU rules and processes. The EU’s ‘new generation’ of free trade agreements which include regulatory cooperation provisions do not aim at alignment but focus on information exchange, adoption of good regulatory practices and mutual recognition agreements in certain sectors. As these agreements have only recently entered into force, it is too early to judge results. While they have good potential, they are limited by design. They focus on goods which are diminishing in importance relative to services in most developed economies and within the goods sector, on conformity assessment, which represents a relatively small part of ‘behind the border’ barriers to trade. The agreements also explicitly emphasise regulatory autonomy or voluntary cooperation. These factors could restrain the scope and hence impact of regulatory cooperation activities.

Regulatory cooperation between the EU and the US is sectoral and patchy, with modest results. The EU and the US, as two ‘rule-makers’<sup>10</sup>, have found it difficult to adjust to and mutually recognise each other’s regulatory approaches and practices. This is related to diverging policy objectives (e.g. on climate change, the use of genetically modified organisms, data protection/privacy), different institutional/governance structures (e.g. federal/state responsibilities, EU/Member State competences) and regulatory policy orientations (e.g.

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<sup>6</sup> Austria, Belgium, Bulgaria, the Czech Republic, Croatia, Cypress, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Romania, the United Kingdom.

<sup>7</sup> Bradford, A. (2012). The Brussels Effect. *Northwestern University Law Review* 107(1), 1-67.

<sup>8</sup> OECD (2017), *International Regulatory Co-operation and Trade: Understanding the Trade Costs of Regulatory Divergence and the Remedies*, OECD Publishing, Paris, <https://doi.org/10.1787/9789264275942-en>  
The benefits of regulatory cooperation were quantified prior to the launch of the TTIP negotiations by Ecorys (2009), *Non-tariff Measures in EU-US Trade and Investment – An Economic Analysis*, Final Report, 11 December 2009

<sup>9</sup> Alasdair R. Young. (2015) [The European Union as a global regulator? Context and comparison](#). *Journal of European Public Policy* 22:9, pages 1233-1252.

<sup>10</sup> ‘Rule makers are major issuers of regulation as contrasted with countries that are ‘rule-takers’, adopting the same or similar rules to those of the ‘rule-makers’.

related to risk assessment, the application of the precautionary principle), fluctuating political commitment to cooperation and a certain lack of trust between regulators.

Voluntary alignment with EU regulations by companies, third countries and international organisations, the so-called ‘Brussels effect’ is taking place, showing that the EU regulatory reach extends well beyond formal agreements in specific areas. But alignment in these instances has often been partial thus potentially diminishing trade enhancing and cost reduction effects.

EU regulatory harmonisation and application of mutual recognition has required a solid legal and institutional framework with strong judicial oversight and enforcement. Where third country alignment with EU rules has been most successful, the partner country has accepted the one-way direction of regulatory convergence (i.e. that third countries align with EU law, not the other way around) and the supremacy of the European Court of Justice (ECJ) in interpreting EU law. It has also required an institutional and legal framework to steer, manage, monitor and report on the regulatory alignment process. Because EU legislation undergoes ongoing review and updating, regulatory convergence is a ‘living’ exercise and it demands continual updating of the relevant rules in the aligning country.

Experience has shown that the process of regulatory alignment is a long-term exercise and may involve incremental phases, with alignment of processes, methodologies and procedures in a first instance, with alignment of the rules themselves at a later stage. A ‘learning and socialisation process’<sup>11</sup> often prepares the ground for regulatory alignment. The legislative approximation process in the EU neighbourhood, for example, required considerable institution and administrative capacity building, supported by EU technical assistance, funding and exchange of experts.

The process of bilateral regulatory alignment is often facilitated by agreeing first on global standards in international organisations. That is, the EU actively participates and provides input to international organisations in their rule making processes and then transposes the adopted global norms back into EU law. If other countries have done the same, the process of bilateral mutual recognition or equivalence is much more straightforward.

Outside of studies of the EU internal market, empirical evidence on impacts of regulatory cooperation (e.g. in terms of increased trade, cost savings on public expenditure related to the reduction in inspections, paperwork etc.) is limited. While it is understandably difficult to separate the impacts of regulatory cooperation from other factors affecting trade, this area would seem to offer fruitful ground for further research. Further thought needs to be devoted to indicators and monitoring frameworks to facilitate the evidence building exercise. The expected withdrawal of the United Kingdom (UK) from the EU has generated new scholarly interest in the implications of regulatory divergence<sup>12</sup> and provides fertile ground for assessment of the costs of non-alignment.

The following paper sets out the context for regulatory cooperation (i.e. definitions and main drivers). It examines the results of regulatory cooperation for two types of formal agreements between the EU and third countries – those having an integration aim and those with a

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<sup>11</sup> Lavenex, S. (2014), The power of functionalist extension: how EU rules travel, *Journal of European Public Policy*, 21:6, 885-903.

<sup>12</sup> Armstrong, Kenneth A. (2018) Regulatory alignment and divergence after Brexit, *Journal of European Public Policy*, 25:8, 1099-1117, DOI: [10.1080/13501763.2018.1467956](https://doi.org/10.1080/13501763.2018.1467956)

predominantly trade orientation. It reviews EU-US regulatory cooperation, as a illustration of the limitations and challenges of regulatory cooperation. The paper looks at informal regulatory convergence (i.e. the “Brussels effect”) and concludes with observations on the outlook for regulatory cooperation.

## II. The Context

### 2.1 What is regulatory cooperation?

The OECD provided an early definition of regulatory cooperation as ‘the range of institutional and procedural frameworks within which national governments, sub-national governments, and the wider public can work together to build more integrated systems for rule-making and implementation, subject to the constraints of democratic values, such as accountability, openness and sovereignty.’<sup>13</sup> It has since refined the definition by developing a typology of forms of international regulatory cooperation:<sup>14</sup>

- Supranational Organisations – integration/harmonisation (EU)
- International Organisations/rule making (International Maritime Organisation, International Labour Organisation, World Trade Organisation)
- Trans governmental Networks of Regulators (Basel Committee on Banking Supervision)
- Specific Negotiated Agreements (EU Agreements for Conformity Analysis and Assessment)
- Regional Trade Agreements with regulatory cooperation provisions (EU Free Trade Agreements; EU Association Agreements, EU Economic Partnership Agreements)
- Formal requirements in domestic administrative procedures to consider IRC when developing regulations (US Executive Order 13609, Commission Better Regulation Guidelines)
- Formal regulatory cooperation partnerships (Canada-US Regulatory Cooperation Council)
- Mutual Recognition Agreements (1998 EU-US Agreement on Conformity Assessment)
- Recognition and incorporation of international standards in domestic law (direct transposition of International Standards Organisation (ISO), United Nations Economic Commission for Europe (UNECE))
- Soft law/guidelines/codes of conduct (OECD Tax Convention)
- Dialogue/informal mechanisms (EU-US Trans-Atlantic Economic Council, Transatlantic Business Dialogues, Transatlantic Consumer Dialogues)

Within each form, different tools ranging from ad hoc exchanges of information to procedural and legislative harmonisation may be deployed. The latter can be done bilaterally or by bringing national measures into conformity with international standards. Short of harmonising law, countries may choose to mutually recognise each other’s laws, standards, measures or processes. This is usually done by way of formal bilateral agreement. ‘Equivalence’ is another form of cooperation which involves the recognition by two parties that their regulatory objectives are the same and that the institutional system through which to attain these objectives

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<sup>13</sup> OECD (1994) Regulatory Cooperation for an Interdependent World (Paris: OECD, 1994), p.15.

<sup>14</sup> <http://www.oecd.org/gov/regulatory-policy/irc.htm>



is effective.<sup>15</sup> Each party takes a unilateral decision within its jurisdiction to give effect to the recognition of equivalence. Cooperation may be formal or informal; binding or non-binding/voluntary. Formal arrangements usually include institutional provisions to settle disputes, monitor the implementation of agreed obligations, provide a forum for exchange of information and consultations and facilitate further negotiations.

The EU is specifically identified in the OECD typology as an example of extensive regulatory harmonisation through a supranational institutional and legal framework.

EU regulatory cooperation with third countries falls into most of the other categories in the OECD typology. It can be broadly defined as the EU working together with a third country, by exchanging information and technical expertise, to make regulations more compatible with each other so that conditions for mutual recognition or equivalence of legislation and/or procedures can be met. It is a process aimed at reducing unnecessary regulatory differences; eliminating duplicative administrative requirements and processes; achieving regulatory alignment (when appropriate) and; sharing information and expertise. It often takes inspiration and is guided by international standards. Regulatory cooperation in the form of either harmonisation or mutual recognition/equivalence has the most potential to generate trade enhancing and cost reducing effects, creating a level playing field in which all market participants in global supply chains comply with public policy (e.g. health, safety, environment) requirements.

## 2.2 Why is regulatory cooperation important? The Drivers

Regulatory cooperation is seen to reduce non-tariff barriers and hence increase trade and economic growth<sup>16</sup>. Both the WTO Agreement on Technical Barriers to Trade (TBT) which covers technical regulations, standards and testing and certification procedures and the Agreement on Sanitary and Phyto-Sanitary Measures (SPS) which covers food safety and animal health aim to reduce discriminatory non-tariff barriers to trade.<sup>17</sup> The TBT agreement prompted the EU to engage actively in exploring and concluding mutual recognition agreements in the late 1990s/early 2000s.<sup>18</sup> It also initiated the idea of that countries could unilaterally adopt technical standards of other countries, if they considered them suitable for achieving domestic policy aims.<sup>19</sup>

Neither the TBT nor the SPS agreements specifically address efficiency (i.e. the elimination or reduction of processes or measures that are unnecessarily costly or duplicative). This cost

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<sup>15</sup>Hoekman, Bernard. (2015). *Trade Agreements and International Regulatory Cooperation in a Supply Chain World*. 2015/04, RSCAS Working Paper, European University Institute, Florence, p.4..

<sup>16</sup> In the Sustainability Impact Assessment conducted for TTIP (Ecorys 2017), it is estimated that GDP would be 0.5 percent higher each year for the EU and 0.4 percent higher for the US if the Trans-Atlantic Trade and Partnership Agreement were to be concluded. 76 percent of the total economic impact was estimated to come from regulatory cooperation.

<sup>17</sup> Marakesh Agreement Establishing the World Trade Organisation, 1867 UNTS Annex 1 (Agreement on Technical Barriers to Trade) and Annex 1A (Agreement on the Application of Sanitary and Phytosanitary Measures, 1 January 1995.

<sup>18</sup> The TBT agreement encouraged WTO members to explore mutual recognition agreements for conformity assessment bodies Marakesh Agreement Establishing the World Trade Organisation, 1867 UNTS Annex 1 (Agreement on Technical Barriers to Trade) Art. 6(3), 1 January 1995

<sup>19</sup> Marakesh Agreement Establishing the World Trade Organisation, 1867 UNTS Annex 1 (Agreement on Technical Barriers to Trade) Art.2(7), 1 January 1995



cutting rationale has stimulated the drive for deeper regulatory cooperation. For business it is a way to reduce compliance costs entailed by producing to different product and service specifications in different markets and administrative costs relating to duplicative procedures and processes. It facilitates economies of scale. For the public sector, it is a means to cut costs through sharing inspections, avoiding duplicate testing and so on. In periods of ongoing budget restraint, public authorities cannot afford to spread their resources thinly across the globe and are therefore looking to prioritise inspections and testing in countries of high risk and therefore recognise the enforcement decisions of partner countries exercising equivalent levels of rigour in testing and inspection.

In terms of policy objectives, governments pursue regulatory cooperation bilaterally and through multi-lateral fora (e.g. the United Nations Framework Conference on Climate Change, the World Health Organisation, the International Maritime Organisation) to more effectively tackle externalities such as pollution or epidemics. They want to ensure that regulations on products and services produced in global supply chains are being applied and implemented correctly to meet health, safety, consumer and environmental protection goals and thereby increase protection for their citizens. They may also seek regulatory compatibility or convergence to level the regulatory playing field to reduce the risk of relocation of factories and businesses to countries with lower standards (e.g. so-called ‘carbon leakage’ in relation to strict greenhouse gas emission standards).

For countries aiming to become EU member states, regulatory alignment (i.e. the so-called approximation of legislation) is a condition for membership. For countries wanting to have access to the EU market to facilitate trade and exchange, alignment to EU internal market rules is required.

Finally, there is a strategic motivation – if like-minded rule makers’ (e.g. the EU and the US), cooperate to set standards, there is greater potential for global acceptance of their standards and mitigation of the risk of wider acceptance of lower standards.

Regulatory cooperation may not always be seen to be beneficial. It may generate costs by requiring the country which has accepted alignment to adopt or amend legislation, with related administrative and compliance (e.g. investment) costs. It may entail expenditure on the development of administrative and institutional capacity, including the costs of setting up coordination structures and monitoring mechanisms. Importantly, it may infringe on political preferences and a country’s desire for regulatory autonomy may override the perceived benefits of cooperation. Certain stakeholders may be very reticent about regulatory cooperation as they may perceive it as an ill-disguised attempt to deregulate and reduce levels of environmental, health and/or safety protection. Cultural, legal and institutional constraints may make regulatory cooperation difficult. Finally, on a strategic level, there is also an element of competition between ‘rule-makers’. The export of regulation by a rule maker may be seen as a way to pursue competitive advantage in third country markets and as a means to promote and protect the interests of the rule-maker in both domestic and third country markets.

### III. Formal Agreements with an Integration Orientation

#### 3.1 The EU

The EU is a supranational organisation whose Member States (MS) pool sovereignty in specific areas and agree to respect supranational law, judicial overview and adjudication by a supranational court (the European Court of Justice) and enforcement by the European Commission (the Commission). The EU is based on the free movement of goods, capital, persons and services. Free movement within the single market goes hand in hand with a customs union having a common external tariff, a single customs code and common IT systems. The EU does not harmonise all product legislation.<sup>20</sup> Rather, it harmonises in a few key internal market areas (e.g. vehicles, chemicals, medical devices, protective equipment) and relies on the application of the mutual recognition principle for market opening in other areas.<sup>21</sup> Applying the mutual recognition principle means that products legally marketed in one MS can be sold in other MSs even though they may not meet all the technical specifications of the MS in which the goods are sold.<sup>22</sup> To work, it demands a robust system of enforcement and dispute settlement, involving respect for EU law and the arbitration of the European Court of Justice.

Regarding harmonised product legislation, the European Union adopts laws that define essential requirements which should be satisfied by products and services being sold in the Single Market. At the request of the Commission, detailed technical standards that facilitate compliance with these essential requirements are then developed by the European Standardization Organizations (ESO) (i.e. CEN, the European Committee for Standardisation, CENELEC, the European Committee for Electro-technical Standardisation and ETSI, the European Telecommunications Standards Institute).<sup>23</sup> The ESOs are private organisations which bring together industry, other stakeholders (business associations, public authorities, professional bodies, trade associations, consumer organizations, environmental organizations, trade unions, enforcement bodies, testing and inspection bodies, etc.) and the national standardisation bodies of EU/EEA and of some neighbouring countries. Some 20% of European standards relate to EU harmonised product legislation. Once a European standard is developed and agreed, the EU national standardisation bodies accept it as a national standard and withdraw all conflicting national standards. European standards are voluntary and there is no legal obligation to apply them. When businesses make use of harmonized standards they benefit from a 'presumption of conformity' with the requirements set out in the relevant European legislation which means that they can sell their products or services throughout the Single Market. A manufacturer can only place a product on the EU market however when it

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<sup>20</sup> The EU approach to harmonisation has evolved from the 'old approach' in which technical specifications were set out in detail in legislation (still applicable to cars and chemicals) to the 'new approach' where harmonisation is done only in specific sectors (e.g. electronic and electric equipment, machinery, lifts, medical devices) where legislation is needed to set out common health, safety, and environmental protection requirements. Other sectors are non-harmonised, not subject to common EU rules and may come under the national rules. The mutual recognition principle is applied in these sectors.

<sup>21</sup> The Cassis de Dijon judgment meant that extensive regulatory harmonisation could be avoided while still tackling behind the border barriers to internal trade. See European Court of Justice, Judgment of the Court of 20 February 1979. *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein*. Reference for a preliminary ruling: *Hessisches Finanzgericht - Germany*. Measures having an effect equivalent to quantitative restrictions. Case 120/78. *European Court Reports 1979 -00649* ECLI identifier: ECLI:EU:C:1979:42.

<sup>22</sup> See [http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition\\_en](http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition_en)

<sup>23</sup> See <https://www.cenelec.eu/standards/ESOs/Pages/default.aspx>

meets all the applicable requirements. A procedure, termed conformity assessment, is carried out before the product can be placed on the market to ensure that it meets these requirements. The procedure for each product is normally specified in the applicable product legislation and may entail testing, inspection and certification. It can be carried out by the manufacturer, or, if the applicable legislation requires it, by a conformity assessment body.

### 3.1.1. Results: deep integration

The EU single market illustrates how sovereign nations have achieved regulatory convergence as well as agreement on how to manage regulatory divergence through mutual recognition. This has been a long term, incremental process which remains challenging, particularly in the area of services and the digital economy and in regard to the application of the mutual recognition principle.

The European Commission monitors developments in the Single Market. The most recent report on the Single Market indicates that regulatory barriers have been removed for over 80% of industrial products through the adoption of common rules and the principle of mutual recognition.<sup>24</sup> While it is difficult to draw a causal relationship between the removal of these barriers and trade and economic performance, the report shows that intra-union trade in goods and services has grown from 27% relative to the size of EU Gross Domestic Product (GDP) in 2004 to 33% in 2017. The economic benefits of the single market are estimated at 8.5% of EU GDP.<sup>25</sup>

The report is complemented by the European Commission's Single Market Scoreboard<sup>26</sup> which examines market openness/integration using a set of key indicators. Infringements (legal cases brought against a Member State for failing either to transpose or apply EU law correctly) are one indicator, showing where there are difficulties in regulatory alignment. An excerpt from the scoreboard (below) shows a decreasing trend in infringements of EU law in the Member States. This data suggests improving application of EU law and therefore closer regulatory alignment.

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<sup>24</sup> European Commission (2018) Communication on the Single Market in a changing world – a unique asset in need of renewed political commitment. COM(2018) 772 final, November 11, 2018, Brussels, p.6..

<sup>25</sup> [https://ec.europa.eu/commission/sites/beta-political/files/factsheet\\_single\\_market.pdf](https://ec.europa.eu/commission/sites/beta-political/files/factsheet_single_market.pdf)

<sup>26</sup> [http://ec.europa.eu/internal\\_market/scoreboard/performance\\_overview/index\\_en.htm](http://ec.europa.eu/internal_market/scoreboard/performance_overview/index_en.htm)



**Figure 1 Trend in numbers of infringement cases<sup>27</sup>**

Source:

[http://ec.europa.eu/internal\\_market/scoreboard/performance\\_by\\_governance\\_tool/infringements/index\\_en.htm#maincontentSec3](http://ec.europa.eu/internal_market/scoreboard/performance_by_governance_tool/infringements/index_en.htm#maincontentSec3)

On the functioning of mutual recognition, a recent evaluation illustrates challenges.<sup>28</sup> It points out that while there are few official notifications of breaches in applying the principle, its it is not being fully exploited across all EU Member States (MSs) and sectors. Trade of products which rely on the mutual recognition principle because there are no harmonised Union rules is below trade of products which are subject to such rules.<sup>29</sup> There is a lack of awareness and even if economic operators are aware, many have difficulties in understanding whether a product can benefit from the principle. Companies surveyed raised concerns about the lack of uniformity in the implementation of the principle and divergent national rules and related procedures and practices.

<sup>27</sup> The numbers show the pending cases: legal proceedings that have been launched if a Member State has not transposed an EU directive correctly or on time or if a Member State is considered by the Commission to be applying Single Market rules incorrectly. Infringement proceedings start when the Commission sends a letter of formal notice to the Member State in question. The Commission and the Member State engage in a process of investigation and clarification. If the result is not satisfactory the case is referred to the European Court of Justice which is the only body that can rule definitively that a breach of EU law has occurred.

<sup>28</sup> EY with the support of Tech4i2, Time.lex, and CEPS (2008); Study on the costs and benefits of the revision of the Mutual Recognition Regulation (EC) No 764/2008; August 2017

<sup>29</sup> European Commission (2017), Executive Summary of the REFIT Evaluation accompanying the Proposal for a Regulation on the Mutual Recognition of Goods lawfully marketed in another Member State, SWD(2017) 476, December 19, 2017, Office of Publications, Luxembourg, p. 1

## 3.2 EU Multilateral Agreements

The EEA is a multilateral agreement between the EU and Norway, Iceland and Liechtenstein. It integrates these countries into the EU single market under the EU policy and legislative framework.<sup>30</sup> The agreement replicates articles of the EU Treaty: the four freedoms, related spheres such as competition, social policy, consumer rights, environment protection, statistics, intellectual property. The EEA does not cover common agriculture and fisheries policies (although the agreement contains provisions on trade in agricultural and fish products); customs union; common trade policy; common foreign and security policy; justice and home affairs (although the EEA EFTA States are part of the Schengen area which enables free movement); direct and indirect taxation; or economic and monetary union. The EEA countries accept incorporation of EU acts into domestic legislation. They do not participate in the EU legislative process but their representatives participate in expert committees and can submit comments and be briefed on legislative developments either within the EU-EEA institutional structure or on an ad hoc basis. The ECJ is recognised as the only body that can interpret EU law.

### 3.2.1 Results: replication and close alignment

The EEA countries have a good record in aligning to EU single market legislation. They are fully integrated into the EU single market and have adopted common rules with the EU on state aid, public procurement and competition. They have implemented EU legislation in a manner and at a speed at least as good as the average EU Member State.<sup>31</sup> Their record in applying EU single market and procurement legislation is monitored and recorded in the Commission's Single Market Scoreboard<sup>32</sup> and the EFTA Surveillance Authority Internal Market Scoreboard.<sup>33</sup>

## 3.3 EU Bilateral Agreements: An Integration Focus

The European Union has a long tradition of concluding association agreements<sup>34</sup> with countries seeking accession to the EU (Greece in 1961; the Europe Agreements covering the countries of Central and Eastern Europe that became members of the EU in 2004<sup>35</sup>; the Stabilisation and Association Agreements for the Balkans<sup>36</sup>). The Association Agreements with the Ukraine, Moldova and Georgia which include Deep and Comprehensive Free Trade Agreements (DCFTAs) have integration, short of accession, as their objective. Likewise, those with the Mediterranean neighbours<sup>37</sup> focus more on integration into the European economic space than accession.

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<sup>30</sup> See <https://www.efta.int/eea>

<sup>31</sup> Sverdrup, U., *The EEA is functioning well: True or False?*, in *The EEA and the Single Market, 20 years on*, EFTA Bulletin, EFTA Secretariat, September 2012

<sup>32</sup> [http://ec.europa.eu/internal\\_market/scoreboard/performance\\_overview/index\\_en.htm](http://ec.europa.eu/internal_market/scoreboard/performance_overview/index_en.htm)

<sup>33</sup> EFTA Surveillance Authority (2018), Internal Market Scoreboard (2018), No. 42. July 2018

<sup>34</sup> Association Agreements are referred to in Art. 217 Treaty on Functioning of the European Union (TFEU) “an association with reciprocal rights and obligations, common action and special procedures”.

<sup>35</sup> The ten countries of central and eastern Europe that had Europe Agreements are Bulgaria, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, Slovenia, Romania.

<sup>36</sup> Stabilisation and Association Agreements have been concluded with the former Yugoslav Republic of Macedonia, Albania, Montenegro, Serbia, Bosnia-Herzegovina and Kosovo.

<sup>37</sup> Euro-med Association Agreements have been concluded with Israel, Palestine (interim), Jordan, Tunisia, Morocco, Lebanon, Egypt and Algeria.

Association Agreements provide for privileged access to the EU single market, , reciprocal rights and obligations, and for institutions designed to implement and monitor the agreements. Under the agreements, the third country brings its laws closer to the EU (not the other way around). The institutional framework under the agreements normally includes an Association Council which can adopt binding decisions, make amendments to the annexes of the agreement and settle disputes and an Association Committee which assists the Council. The Council can delegate decision-making to the Committee. A European Parliament (EP) – associated country Committee is often set up under the agreements to make recommendations and exchange info. The European Court of Justice is recognised by associated countries as the source of legal interpretation of the provisions of the agreements.

The Stabilisation and Association countries are obliged to fully approximate EU primary and secondary law with a view to accession. This includes competition, intellectual, industrial and commercial property, customs, public procurement, standards and conformity assessment, banking and financial services, land and maritime transport, company law, accounting, consumer protection, environmental, agricultural, plant and animal health and safety, data protection, nuclear energy, occupational health and safety and SME legislation. Many of the articles of the agreements replicate the EU treaty. For example, articles prohibiting customs duties, quantitative restrictions on imports/exports or measures having equivalent effect replicate Art. 30, 34 and 35 of the Treaty on the Functioning of the European Union (TFEU).<sup>38</sup> Alignment is to be done over time, with the alignment of internal market legislation having priority under the agreements. The partner countries are required to align their legislation as legislative changes are made in the relevant EU laws. The institutions under the agreements are empowered to adopt binding acts.

The Deep and Comprehensive Free Trade Agreements while not having the accession goal also involve the approximation of the above-mentioned areas of EU legislation.

The agreements with neighbouring countries in north Africa and the Middle East have a more limited scope. Approximation is seen as a gradual process and does not cover the entire body of EU legislation. The selection of areas for approximation depends on the administrative, financial and institutional capacity to take on the legislation in any given area. The agreements provide for free trade in industrial goods and liberalisation of trade in agriculture, services, movement of capital.<sup>39</sup> Priority is given to approximation of law in the internal market area (standards; competition law, public procurement legislation, agricultural and phyto-sanitary standards, financial services). The specific areas for alignment are set out in the annexes to the agreements and are adjusted over time to reflect legislative developments in the EU. The agreements involve dialogue and exchange of information and good practice. Bilateral action plans are prepared, and progress is monitored through regular reporting.

The EU has many bilateral sector agreements with Switzerland, many of which require legislative approximation, facilitating access to the single market. The Swiss have aligned their industrial product legislation fully in order to access the EU's internal market.<sup>40</sup>

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<sup>38</sup> Muraviov, Viktor (2016), *The Supranational Character of EU Association Agreements with 3<sup>rd</sup>* in Arnold, & Arnold, Rainer. (2016). *Limitations of national sovereignty through European integration* (1st ed. 2016. ed., Ius gentium (Dordrecht, Netherlands) ; v. 51). New York: Springer., p. 189.

<sup>39</sup> See Harpaz, G. (2006). *When East meets West: Approximation of laws in the EU-Mediterranean context*. *Common Market Law Review*, 43(4), 993-1022.

<sup>40</sup> See [http://www.europarl.europa.eu/meetdocs/2009\\_2014/documents/deea/dv/2203\\_07/2203\\_07en.pdf](http://www.europarl.europa.eu/meetdocs/2009_2014/documents/deea/dv/2203_07/2203_07en.pdf)



The EU has customs unions (CUs) with San Marino, Andorra and Turkey.<sup>41</sup> The EU-Turkey CU was established on 1 January 1996. It removes tariffs and quantitative restrictions in bilateral trade between the EU and Turkey on industrial goods. It does not cover agriculture, coal and steel products, public procurement or services. It sets a single external tariff, (i.e. the EU and Turkey charge the same duties on imports from third countries). Turkey is obliged to harmonize its laws with the EU's in areas of direct relevance to the operation of the CU, including commercial (ie trade) policy and agreements with third countries on industrial products, legislation on the abolition of technical barriers to trade, competition policy and intellectual property rights and rules. Turkey must also adopt the EU's rules of origin for products covered by the CU. The provisions which mirror EU law in the CU must be interpreted in conformity with the relevant decisions of the Court of Justice of the European Union.

In addition to the association agreements and customs unions, there are many specialised agreements that the above-mentioned groups of countries are either party to or aspiring to join that more firmly anchor them in the EU internal market.<sup>42</sup> The Pan-Euro Med Convention for preferential rules of origin aligns the rules of origin of associated countries with that of the EU and the EEA, allowing for bilateral and diagonal accumulation. The associated countries are eligible to join the European Standards Associations. The EU also concludes Agreements for Conformity Analysis and Assessment (ACAAs) which provide for mutual recognition of technical standards. When an ACAA is concluded, goods placed on the market of one of the signatories gains automatic access to the other without further controls. The signatory to an ACAA must adopt the same standard as the EU and follow procedures identical to those in the EU for controlling access to its home market. The only ACAA that has been concluded is with Israel.<sup>43</sup>

### 3.3.1. Results: towards convergence

#### The Europe Agreements

The legislative alignment of the countries of central and eastern Europe that became EU Member States in 2004 illustrates the results of close regulatory cooperation under the association agreements in the pre-accession phase. When these countries entered the EU, they were considered to have both adopted the EU body of legislation and demonstrated the administrative capacity to implement it. An examination of their infringement record shows that this judgement seems to have stood the test of time. Except for the Czech Republic, Slovakia, Poland and Hungary, the number of infringements of the 'new member states' has been consistently below the EU average. Poland has been consistently above the average since it joined the EU. The Czech Republic, Slovakia and Hungary moved above the EU average in 2015 and 2106. This shows that the Member States which had association agreements prior to membership have kept up their performance in terms of legislative approximation.

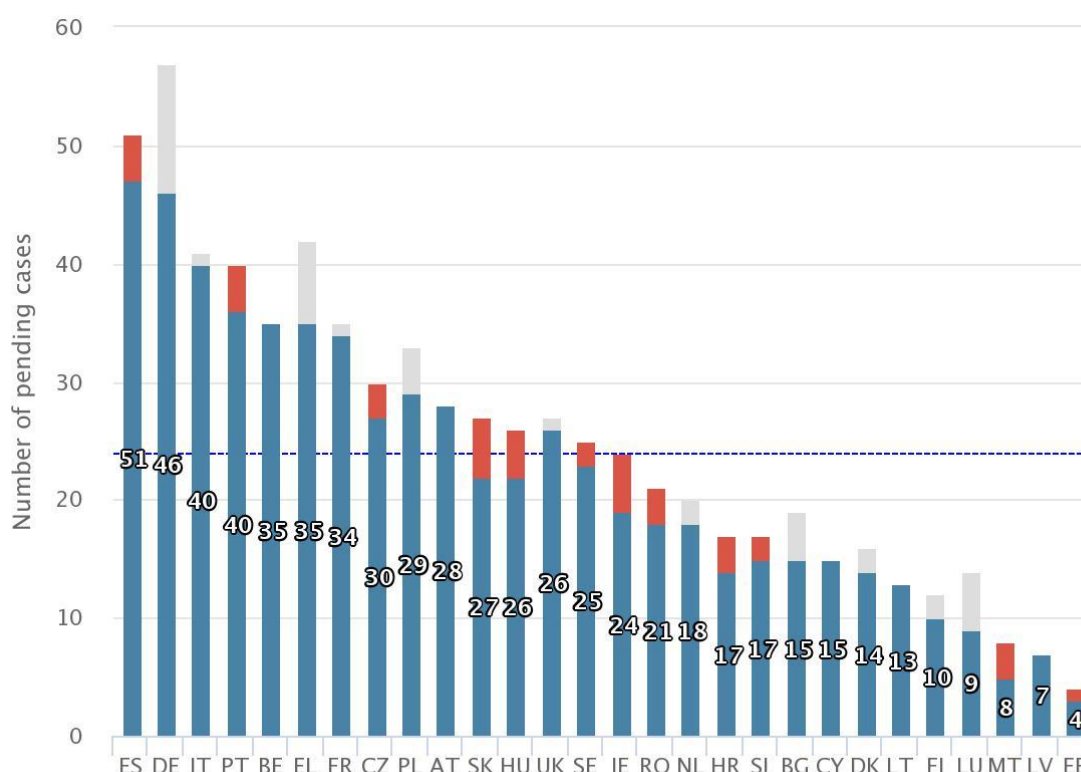
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<sup>41</sup> See <http://ec.europa.eu/trade/policy/countries-and-regions/countries/turkey/>

<sup>42</sup> See Emerson, M. (2018), The Strategic Potential of the Emerging Wider European Economic Area, CEPS, No. 2018/05, February 2018.

<sup>43</sup> Council Decision 99/662/EC, 19 July 1999, Official Journal L263, 9.10.1999, p.7





**Figure 2: Number of pending infringement proceedings in each Member State**

Source:

[http://ec.europa.eu/internal\\_market/scoreboard/performance\\_by\\_governance\\_tool/infringements/index\\_en.htm#maincontentSec3](http://ec.europa.eu/internal_market/scoreboard/performance_by_governance_tool/infringements/index_en.htm#maincontentSec3) Pending infringement proceedings as of 1 December 2017. The differences since the previous report (the July 2017 Single Market Scoreboard, with figures from December 2016) are shown at the top of each bar in the chart: the blank parts show a decrease in the number of pending cases, while the red parts show an increase in the number of pending cases.

### Association Agreements

The results of the Stabilisation and Association Agreements are captured in regular Commission reporting.<sup>44</sup> The countries are all at different stages of alignment but most have made progress in the areas of free movement of goods, company law, customs code, financial control, trans-European networks and science and research. Some progress has been made on intellectual property law, financial services, enterprise and industrial policy, consumer and health protection and plant and health safety but it varies considerably from country to country. Most have more to do on competition and state aid policy, public procurement, statistics, transport, environment and climate change. While there has been progress in putting the laws on the statute books, the Commission reports that for most of the partner countries effective implementation together with strengthening administrative capacity remain major concerns.

There is less evidence available on the extent to which the southern Mediterranean partners have managed to align their legislation with the EU. Reporting on the trade aspects of the Association Agreements points to regulatory issues which work to impede trade and

<sup>44</sup> European Commission (2018), Communication on Enlargement Policy, COM(2018)450 final, 17 April 2018, Strasbourg.

investment.<sup>45</sup> That, aside from Israel, no countries in the region have managed to conclude an Agreement on Accreditation and Conformity Assessment would suggest that alignment, even of the internal market legislation, remains a challenge.

### Customs Union (CU) – Turkey

The most recent European Commission report on Turkey's preparations for accession and an evaluation of the functioning of the Customs Union provide a consolidated view of Turkey's progress in legislative alignment.<sup>46</sup> Turkey is considered to be well advanced in the areas of company law and has achieved a good level of preparation in the areas of free movement of goods, intellectual property law, financial services, enterprise and industrial policy, consumer and health protection, customs union and financial control. Important gaps remain in its alignment to public procurement law and less progress has been made in the area of statistics, transport policy, environment and climate change.

## IV. Formal Agreements with a Trade Orientation

### 4.1 Free Trade Agreements

At the end of 2017, the EU had 35 major free trade agreements with 62 partners (i.e. including the EEA, the association agreements and the customs union agreements).<sup>47</sup> Classic free trade agreements mainly cover trade in goods but a new generation of agreements (i.e. those negotiated since 2006 when the Commission adopted its 'Global Europe' strategy to focus on bilateral trade and investment deals<sup>48</sup>) includes investment and services as well as alignment to international standards. The EU has such agreements with South Korea, Columbia-Peru, Central America, Canada, Singapore and Japan. The committees set up under these agreements enable regulators to exchange good practice, experience and information as well as identify areas to work together bilaterally and in international organisations.

The Comprehensive Economic and Trade Agreement with Canada (CETA) has both sectoral and horizontal regulatory cooperation provisions that go beyond WTO commitments.<sup>49</sup> The horizontal disciplines include good regulatory practices (publication of regulatory agendas, early information, public consultations, impact assessments, retrospective evaluations) and regulatory cooperation (enhancing compatibility of measures, preventing unnecessary barriers, exchanging information during regulatory cycle). Emphasis is placed on forward looking cooperation as measures are being developed. The EU and Canada set up a Regulatory Cooperation Forum, to enable regulators to exchange information and help identify areas where regulators could work together. It met for the first time in December 2018 and adopted a work plan which identified five fields of future cooperation – cyber-security and the internet of things, animal welfare, 'cosmetic like' drug products, pharmaceutical inspections and exchange of information between the EU's RAPEX product alert system and the Canadian system, RADAR. 13 committees and six specialised dialogues have as well been set up and

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<sup>45</sup> European Commission (2017), Report on the Implementation of Free Trade Agreements, Jan-Dec. 2017, COM(2018) 454final, 31 October 2018, pp. 113-159.

<sup>46</sup> European Commission (2017), Report on the Implementation of Free Trade Agreements, Jan-Dec. 2016, COM(2017) 654final. November 11, 2017, p. 12.

<sup>47</sup> European Commission (2017), Report on the Implementation of Free Trade Agreements, Jan-Dec. 2016, COM(2017) 654final. November 11, 2017, p. 7.

<sup>48</sup> European Commission (2006), Communication on Global Europe, COM (2006) 631 final, 24 October 2006

<sup>49</sup> <http://ec.europa.eu/trade/policy/in-focus/ceta/ceta-chapter-by-chapter/>

have been meeting. The agreement also includes a protocol on conformity assessment, which allows Canadian companies in many sectors (electrical and electronic equipment, including electrical installations and appliances, and related components; radio and telecommunications terminal equipment; toys; construction products; machinery; measuring instruments; hot-water boilers; explosive devices; noise equipment; recreational craft) to have their products tested and certified for the EU market in Canada (and vice versa).

The Japan-EU Economic Partnership Agreement which went into force on February 1, 2019 covers trade in goods and services as well as investment.<sup>50</sup> It has wide ranging provisions on regulatory cooperation. Like CETA, the Agreement provides for the establishment of a Regulatory Cooperation Committee to exchange good practice, experience and information; to identify possible areas for bilateral regulatory cooperation; and, enhance cooperation in international standards setting organisations. Japan commits to close alignment of its standards in key areas to those of international organisations. For example, it commits to fully aligning its standards on cars to (United Nations Economic Commission for Europe (UNECE) standards. It will recognise the International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) as the international standards setting body and use its guidelines as a basis for domestic legislation. Japan has agreed to adopt the international standards organisation (ISO) standards for textiles. Both parties commit to implementing the core labour standards of the International Labour Organisation (ILO) and international environmental agreements, including the UN Framework Convention on Climate Change, as well as the Paris climate agreement. Japan and the EU reached an agreement in July 2018 to recognise each other's data protection legislation as equivalent.

The EU has also concluded Economic Partnership Agreements with 29 countries of Africa, the Caribbean and Pacific (ACP) countries and is in negotiation with more of these countries.<sup>51</sup> These agreements have provisions on cooperation on sanitary norms and other standards, but their emphasis is on trade and development.

#### 4.1.1. Results: too early to judge

Although horizontal regulatory cooperation was not a focus of the 'new generation' FTAs with South Korea, Columbia/Peru and Central America, the agreements provide for sectoral regulatory cooperation on plant and animal health, intellectual property and public procurement.

An interim ex-post evaluation concludes that the EU-Korea FTA succeeded in the reduction of non-tariff barriers (NTBs), such as differences in technical standards, labelling requirements, double certification, and sanitary and phytosanitary trade barriers.<sup>52</sup> The evaluation showed that already before the provisional application of the EU-Korea FTA, the Korean government had proceeded with transposition of FTA commitments (e.g. on customs procedures, general import and export procedures, standards and technical requirements, sanitary and phytosanitary requirements) into domestic legislation and administrative rules. However, the study cautioned that the observed regulatory changes could not be causally ascribed to specific commitments under the EU-Korea FTA and concluded that as far as document requirements and times

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<sup>50</sup> [http://europa.eu/rapid/press-release\\_MEMO-18-6784\\_en.htm](http://europa.eu/rapid/press-release_MEMO-18-6784_en.htm)

<sup>51</sup> <http://ec.europa.eu/trade/policy/countries-and-regions/development/economic-partnerships/>

<sup>52</sup> European Commission (2017). Evaluation of the Implementation of the Free Trade Agreement between the EU and its Member States and the Republic of Korea Interim Technical Report Part 1: Synthesis Report, Prepared by Civic Consulting and the Ifo Institute, June 2017.

connected to trade relations as well as trade costs were concerned, they could neither identify a systematic change after the agreement came into force, nor any general time trend. The FTAs with Columbia/Peru and Central America show some progress on sanitary and phyto-sanitary issues but limited progress overall on intellectual property and public procurement commitments.<sup>53</sup>

CETA was provisionally applied from September 2017 and is being actively implemented with various committees and specialised dialogue groups meeting regularly.<sup>54</sup> It is too early to judge results. The same applies to the EU-Japan Economic Partnership. In contrast to the impact assessment for CETA, the impact assessment for the Japanese agreement<sup>55</sup> estimated potential gains from non-tariff barriers and hence should provide a good basis against which to measure results in a future ex-post evaluation.

## 4.2 EU – US Regulatory Cooperation

The EU and the United States (US) have tried for many decades to stimulate regulatory cooperation.<sup>56</sup> In 2002 they agreed on a set of non-binding guidelines on regulatory cooperation and transparency, followed by a roadmap setting out how the guidelines should be implemented. A High-Level Regulatory Cooperation Forum (HLRCF) was set up in 2005. It met on a number of occasions until 2013, issuing a ‘Common Understanding on Regulatory Principles and Best Practices’ in 2011.

There are only a few binding cooperation agreements. In 1998, the two parties concluded a EU-US Agreement on Mutual Recognition of Conformity Assessment.<sup>57</sup> The aim was to avoid duplication of conformity assessment procedures in six industrial sectors (telecommunications equipment, electromagnetic compatibility, electric safety, recreational craft, pharmaceutical ‘good manufacturing practice’ and medical devices). The initiative met with limited success. The annexes on telecommunication equipment and electro-magnetic compatibility of equipment and appliances were implemented in 2000. The annex on recreational marine craft was implemented but then discontinued following amendment of the EU legislation. The pharmaceutical annex under which EU and US regulators recognise the outcome of inspections of good manufacturing practices (GMPs) at production sites for certain human medicines was resuscitated in 2017.<sup>58</sup> It is being progressively implemented and will cover all Member States by mid-2019. Mutual recognition in the other sectors under the agreement proved difficult.<sup>59</sup>

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<sup>53</sup> European Commission (2017) Report on the Implementation of Free Trade Agreements, Jan-Dec. 2016, COM(2017) 654final. November 11, 2017, p. 12-13

<sup>54</sup> European Commission (2018), Report on the Implementation of EU Free Trade Agreements 1 January – 31 December 2017. EU Publications Office, p. 20

<sup>55</sup> European Commission (2018), The Economic Impact of the EU-Japan Partnership Agreement - An analysis prepared by the European Commission’s Directorate-General for Trade, Luxembourg: Publications Office of the European Union, 2018, ISBN 978-92-79-86621-0NG-02-18-799-EN-CDOI 10.2781/108936

<sup>56</sup> These efforts are documented in Garcia Bercero, I., G. Emberger and J. Vandenberghe, ‘EU-US Engagement on Regulatory Issues: Lessons Learnt, Notably in the Context of the TTIP Negotiations’ (2018) 23 *European Foreign Affairs Review*, Issue 2, pp. 149–165

<sup>57</sup> European Union, OJ L 31, 4.2.1999, Luxembourg, Office of Publications

<sup>58</sup> European Union (2017), Annex to the Commission Decision on determining the Union position for a Decision of the Joint Committee set up under Article 14 of the Agreement on Mutual Recognition between the European Communities and the USA, C(2017) 1323 final, March 1 2017.

<sup>59</sup> Pelkmans, J. and A. Correia de Brito (2015) Transatlantic MRAs – a lesson for TTIP?, Centre for European Policy Studies, No. 101, March 2015.

A separate MRA on marine equipment was signed in 2004. Designated products that comply with EU requirements are accepted on board US flagged ships without any additional testing or certification and vice versa. Both parties based their respective legislation on the conventions of the Internal Maritime Organisation (IMO) and other relevant international standards.

Air transport and aircraft certification are other areas where the EU and the US have successfully entered into binding agreements. The EU-US Air Transport Agreement (signed in 2007 and taken to a permanent second stage in 2010) covers safety, security, environment/climate, competition policy as well as business issues.<sup>60</sup> It removed restrictions on routes, prices, and capacity and in doing so increased the number of flights and stimulated competition. It represented a paradigm shift, opening regulatory cooperation across many areas of air transport from safety to air traffic management, to consumer protection. The regulatory cooperation provisions of the agreement provide for mutual recognition of regulatory decisions such that when US authorities are dealing with EU applications, they rely on the Member State's regulatory decision that an airline is financially fit and European owned. A Joint Committee is set up under the Agreement *inter alia* to develop reciprocal recognition of regulatory determinations and to consider issues such as conflicting regulatory requirements which create red tape.

EU-US Agreement on cooperation in the regulation of civil aviation safety went into force in 2011 after eight years of negotiation.<sup>61</sup> It allows for automatic acceptance of certain approvals issued within the other jurisdiction's certification system (i.e. an approval issued by one party constitutes a valid approval by the other party) and enables the reciprocal acceptance of findings of compliance during validation processes. Its scope covers the airworthiness approvals and monitoring of civil aeronautical products, the environmental testing and approvals of civil aeronautical products and the approval and monitoring of maintenance facilities.

In recent years, the EU has relied more on equivalence decisions than mutual recognition agreements with the US. This is the instrument of choice in the financial services sector where the Commission examines whether the rules applied by a third country are legally binding, effectively supervised by authorities and achieve the same results as the corresponding EU rules. Once the assessment is finalised and provided that all technical criteria are satisfied, the Commission can formally adopt an equivalence decision. 279 such decisions had been adopted by the end of October 2018.<sup>62</sup> 22 of these concern equivalence/adequacy decisions in the US financial services sector. These cover audits; credit rating agencies, central counterparties, trading venues for derivatives and shares, securities prospectus and prudential requirements for credit institutions and investment firms. The equivalence agreement for clearing houses (central clearing counterparties or CCPs)<sup>63</sup>, sets out that the legal and supervisory framework for American CCPs is equivalent to that of the EU which means that European clearing houses can operate in the USA complying with EU rules and US clearing

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<sup>60</sup> <https://ec.europa.eu/transport/sites/transport/files/2017-eu-us-air-transport-agreement-factsheet.pdf>

<sup>61</sup> European Union (2011), The EU-US Agreement on cooperation in the regulation of civil aviation safety, OJ L 291, 9.11.2011, p. 1–44.

<sup>62</sup> [https://ec.europa.eu/info/business-economy-euro/banking-and-finance/international-relations/recognition-non-eu-financial-frameworks-equivalence-decisions\\_en](https://ec.europa.eu/info/business-economy-euro/banking-and-finance/international-relations/recognition-non-eu-financial-frameworks-equivalence-decisions_en)

<sup>63</sup> European Commission (2016), IP-16-807\_EN, European Commission adopts equivalence decision for CCPs in USA, Brussels, 15 March 2016



houses can operate in the EU under American rules. These cooperation initiatives in financial services are overseen by a 'Joint EU-US Financial Regulatory Forum', created in 2016.<sup>64</sup>

An equivalence agreement was also reached between the EU and U.S. in organic farming in 2012.<sup>65</sup> Products certified organic by a USDA-accredited certifying agent or an EU Member State recognised control body or control authority may be sold and labelled as organic in both the U.S. and the EU.

Data protection is also covered by a type of equivalence agreement - an adequacy decision. The arrangement with the USA, entitled the 'Privacy Shield',<sup>66</sup> aims to ensure an adequate level of protection for personal data transferred from the EU to organisations in the USA. The arrangement does not take the form of a binding agreement but rather relies on self-certification and enforcement (unilateral implementing decisions). It sets out data protection obligations on companies receiving personal data from the EU as well as safeguards on US government access to EU data.

Against this background, regulatory cooperation was a centre-piece of the negotiations of the Trans-Atlantic Trade and Investment Partnership (TTIP) Agreement, launched in 2013.<sup>67</sup> The negotiations were inspired by preparatory work<sup>68</sup> which estimated that the benefits of the agreement would come mainly from reduction of "behind-the-border" obstacles to trade resulting from regulatory divergence.<sup>69</sup> Proposals were tabled by both sides on horizontal regulatory cooperation (e.g. enhanced TBT and SPS initiatives; good regulatory practices) and on regulatory cooperation in nine sectors.<sup>70</sup> Negotiators aimed to find ways to cooperate in the preparation of new regulations to achieve greater compatibility and to reduce duplicative regulatory requirements (double testing, certification, qualifications, audits, inspections, etc.). The EU proposal<sup>71</sup> suggested information sharing on regulatory planning (both impact assessment and reviews), taking each other's regulatory approaches into account before regulating and exploring possibilities for determining equivalence or mutual recognition of rules and processes. The EU proposed an institutional framework – a Joint Committee, chaired at ministerial level, was to be established to ensure the good functioning of the agreement, with an annual session devoted to regulatory cooperation. The EU side also suggested establishing

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<sup>64</sup>Joint Statement of July 2016 and exchange of letters, to be found at [https://ec.europa.eu/info/business-economy-euro/banking-and-finance/international-relations/bilateral-relations\\_en](https://ec.europa.eu/info/business-economy-euro/banking-and-finance/international-relations/bilateral-relations_en).

<sup>65</sup> European Commission (2015), Commission Implementing Regulation 2015/931, 17 June 2015, Official Journal L151/1

<sup>66</sup> European Commission (2017), Commission Implementing Decision (EU) 2016/1250 of 12 July 2016 pursuant to Directive 95/46/EC of the European Parliament and of the Council on the adequacy of the protection provided by the EU-U.S. Privacy Shield, OJ L 2017, 1.8.2016, p. 1

<sup>67</sup>Council of the European Union (2013), Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America, ST 11103/13, 17 June 2013.

<sup>68</sup> High Level Working Group on Jobs and Growth, Final Report (2013). To be found at [http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc\\_150519.pdf](http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf).

<sup>69</sup> For a review of the TTIP negotiations, see Garcia Bercero, I., Emberger, G., Vandenberghe, J., 'EU-US Engagement on Regulatory Issues: Lessons Learnt, Notably in the Context of the TTIP Negotiations' (2018) 23 *European Foreign Affairs Review*, Issue 2, pp. 149–165

<sup>70</sup>Cars, chemicals, cosmetics, engineering, information technology, medical devices, pesticides, pharmaceuticals and textile, European Commission, 'TTIP and Regulation: An Overview,' 10 February 2015.

<sup>71</sup>The proposal for a regulatory cooperation chapter in TTIP can be found at the website of the European Commission's DG TRADE, at [http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc\\_154377.pdf](http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf).

a "Transatlantic Regulators' Forum" (TRF) at senior level to identify areas for cooperation and engage with civil society stakeholders.

Although the TTIP discussions were brought to a halt under the Trump administration in early 2017, regulatory cooperation was raised in a meeting between Commission President Juncker and US President Trump in July 2018 when they announced a 'close dialogue on standards to ease trade, reduce bureaucratic obstacles, and slash costs.'<sup>72</sup> US negotiating objectives were issued by the US Trade Representative in January 2019.<sup>73</sup> The European Commission responded by tabling its proposal for negotiation of an equivalence agreement on conformity assessment bodies.<sup>74</sup> Supporting a timely adoption of this mandate, the March 2019 meeting of the European Council called "for the necessary steps to be taken towards rapid implementation of all elements of the U.S.-EU Joint Statement of 25 July 2018".<sup>75</sup> The directives for the negotiating mandate were adopted by the European Council on April 2019.<sup>76</sup>

#### 4.2.1. Results: below potential

Despite, the ambition on both sides to give the political and economic relationship a formal overarching framework,<sup>77</sup> the attempts to formalise horizontal regulatory cooperation between the EU and the US have had limited success and the overall approach regulatory cooperation approach between the EU and the US remains sector driven rather than strategic.

On horizontal agreements, as mentioned above, the 1998 Mutual Recognition Agreement on Conformity Assessment has not been fully implemented. The telecommunications annex is identified as being most successful due to the global and dynamic nature of the industry which has converged internationally around generally accepted standards because it sees clear benefits (e.g. no delays, more certainty and compatibility of inputs in global supply chains) in such cooperation.<sup>78</sup> While declarations on regulatory cooperation and non-binding guidelines on good regulatory practice have been adopted, the actual results of these efforts are modest. Both sides agreed, for example, to take trade impacts of new regulations into account in impact assessments and have adopted guidelines to that effect (e.g. the Commission's Better Regulation Guidelines<sup>79</sup> and the Executive Order 13609<sup>80</sup> which directs all US executive agencies to avoid unnecessary divergences between domestic regulation and that of main trading partners). But, with little monitoring or enforcement of these commitments, there has been little motivation for the Commission departments or the US executive agencies to apply

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<sup>72</sup> Europa Press Release, July 27, 2018

<sup>73</sup> Office of the United States Trade Representative (2019), United States – European Union Negotiations, Summary of Specific Negotiating Objectives, January 2019

<sup>74</sup> European Commission (2019), Recommendation for a Council Decision authorising opening negotiations on an agreement with the USA on conformity assessment, COM(2019) 15 Final, Brussels, 18 January 2019.

<sup>75</sup> To be found at <https://data.consilium.europa.eu/doc/document/ST-1-2019-INIT/en/pdf>, p.3

<sup>76</sup> To be found at <https://www.consilium.europa.eu/en/press/press-releases/2019/04/15/trade-with-the-united-states-council-authorises-negotiations-on-elimination-of-tariffs-for-industrial-goods-and-on-conformity-assessment/>

<sup>77</sup> Garcia Bercero, I., Emberger, G., Vandenbergh, J., 'EU-US Engagement on Regulatory Issues: Lessons Learnt, Notably in the Context of the TTIP Negotiations' (2018) 23 *European Foreign Affairs Review*, Issue 2, pp. 149–165

<sup>78</sup> Correia de Brito, Kaufmann, C. and Pelkman, J., 'The contribution of mutual recognition to international regulatory cooperation' OECD Regulatory Policy Working Papers, No. 2, OECD Publishing, Paris, p. 58

<sup>79</sup> European Commission (2017), Better Regulation Toolbox, p. 184 [https://ec.europa.eu/info/better-regulation-toolbox\\_en](https://ec.europa.eu/info/better-regulation-toolbox_en)

<sup>80</sup> Exec. Order 13609, 77 Fed. Reg. 26413 para 3, May 1, 2012



these provisions.<sup>81</sup> The EU's Regulatory Scrutiny Board reported that less than 20% of Commission impact assessments looked at trade impacts in 2016 and this decreased further in 2017.<sup>82</sup>

Sector agreements show better results. The air transport agreement has resulted in increased passenger traffic and reduced prices for consumers.<sup>83</sup> The aircraft certification agreement is reported to have limited the duplication of assessments, tests and controls to the greatest extent possible, but these cost savings have not yet been measured.

Equivalence agreements are being implemented. The data privacy arrangement is monitored and in the most recent report,<sup>84</sup> the European Commission indicates that the US is living up to its commitments. However, equivalence arrangements can run into difficulties if the law is changed or amended on either side in such a way as to alter the other side's assessment of equivalence. For example, concerns over the decision on equivalence of central clearing parties reached in 2016 between the Commodities Futures Trading Commission and the European Commission arose when proposals were made on the EU side to amend the legislation underlying the agreement.<sup>85</sup>

Finally, there are ongoing discussions between the EU and the US at multilateral level which have facilitated better mutual understanding and led to cooperation in certain sectors. Both the EU and the US have adopted the Globally Harmonised System for the classification and labelling of chemicals. This has led to compatible legislation being adopted in both jurisdictions.<sup>86</sup> EU-US cooperation in the International Maritime Organisation (IMO) facilitated the EU-US MRA on marine equipment. The EU-US MRA on 'good manufacturing practices' in pharmaceuticals was preceded by years of cooperative discussions under the International Conference on Pharmaceutical Harmonisation (ICH).

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<sup>81</sup> Bull, Reeve T., Mahboubi, Neysun A., Stewart, Richard B., & Wiener, Jonathan B. (2015). New approaches to international regulatory cooperation: The challenge of TTIP, TPP, and mega-regional trade agreements. *Law and Contemporary Problems*, 78(4), pp. 21-22.

<sup>82</sup> Regulatory Scrutiny Board, RSB Annual Report 2016, p. 13 and RSB Annual Report 2017, p. 18.

<sup>83</sup> European Commission, Fact Sheet on the EU- US Air Transport Agreement, at <https://ec.europa.eu/transport/sites/transport/files/2017-eu-us-air-transport-agreement-factsheet.pdf>

<sup>84</sup> European Commission (2018), Report on the 2<sup>nd</sup> Annual Review of the Functioning of the EU-US Privacy Shield, COM(2018)860 final, 19 December 2018

<sup>85</sup> <https://www.cftc.gov/PressRoom/SpeechesTestimony/opaquintenz9>

<sup>86</sup> A US Department of Labour rule from 2012 modified the Occupational Safety and Health Agency's Hazard Communication Standard to conform to the UN Globally Harmonized System of Classification and Labelling of Chemicals can be found here: <https://www.govinfo.gov/content/pkg/FR-2012-03-26/pdf/2012-4826.pdf>

## VI. Informal regulatory convergence - the “Brussels Effect”

The ‘Brussels Effect’ refers to the voluntary adoption by companies and third countries of EU laws and standards outside of the framework of formal agreements.<sup>87</sup> Studies have demonstrated how the EU exported its laws and regulation through market mechanisms (i.e. companies choosing to align voluntarily for market access and economy of scale reasons) and by providing a regulatory model for third countries.<sup>88</sup> Through this dissemination route, EU rules have become *de facto* global standards in certain areas.

The pioneering work done by Anu Bradford<sup>89</sup> explains that because companies need to comply with EU legislation in the internal market, many find it more efficient to adopt the same standards globally. Multi-national companies in the waste and chemicals field, for example, have decided to apply the EU waste (Restrictions on Hazardous Substances -ROHs and Waste of Electronic Equipment - WEE) legislation and chemicals legislation REACH (Registration, Evaluation, Authorisation of Chemicals), respectively, globally. The major internet platforms are increasingly complying with the EU’s General Data Protection Regulation (the GDPR) in their international operations.<sup>90</sup>

Third countries are as well taking inspiration from EU rules, even if not obliged to do so under formal trade agreements. Because EU law draws on different national traditions, it is viewed by third countries as having the propensity to suit a variety of regulatory environments. The EU has not shied away from regulating in new areas such as data protection and digital services and is thus regarded as having ‘up to date’ legislation which responds to current regulatory challenges. EU chemicals legislation, REACH, is often referred to as illustrating how the EU has inspired third countries in their development of national laws.<sup>91</sup> REACH requires the collection of data and risk assessment from the supplier before a substance can be produced, transported and placed on the market. The burden of proof rests with manufacturers and importers. REACH has inspired the development of chemical legislation in Japan, Turkey, Taiwan, South Korea and China.

The EU also diffuses its regulatory orientations and practices through active participation and decision-shaping in multilateral organisations. Once agreed at global level, the EU transposes international standards back directly into EU law. For example, the EU, the USA and Japan launched the International Conference on Pharmaceutical Harmonisation (ICH) in the 1990s. It has now become the internationally recognised issuer of guidelines in the area and has been successful in promoting the harmonisation of forms and procedural requirements globally. The

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<sup>87</sup> See Bradford, A. (2012). The Brussels Effect. *Northwestern University Law Review*, 107(1), 1-67.

<sup>88</sup> See Bradford, A. (2015). Exporting standards: The externalization of the EU's regulatory power via markets. *International Review of Law and Economics*, 42, 158-173; Gady, F. (2014). EU/U.S. Approaches to Data Privacy and the "Brussels Effect": A Comparative Analysis. *Georgetown Journal of International Affairs*, 12-23; Lavenex, S. (2014), The power of functionalist extension: how EU rules travel, *Journal of European Public Policy*, 21:6, 885-903; Young, A. (2015) The European Union as a global regulator? Context and comparison, *Journal of European Public Policy*, 22:9, 1233-1252, DOI: 10.1080/13501763.2015.1046902; Müller, Patrick, Kudrna, Z. and Falkner, G. (2014) EU–global interactions: policy export, import, promotion and protection, *Journal of European Public Policy*, 21:8, 1102-1119, DOI: 10.1080/13501763.2014.914237

<sup>89</sup> See Bradford, A. (2012). The Brussels Effect. *Northwestern University Law Review*, 107(1), 1-67.

<sup>90</sup> Gady, F. (2014). EU/U.S. Approaches to Data Privacy and the "Brussels Effect": A Comparative Analysis. *Georgetown Journal of International Affairs*, 12-23.

<sup>91</sup> International Risk Governance Council (2017), Trans-Atlantic Patterns of Risk Regulation, Implications for International Trade and Cooperation, Ecole Polytechnique Fédérale de Lausanne (EPFL), Lausanne, Switzerland.

EU shared its early experience in ‘step by step’ construction of the internal EU market regulation for pharmaceuticals (i.e. starting with forms and procedures) in this organisation. This cooperative effort in the ICH paved the way for EU bilateral agreements with Australia, Canada, Israel, Japan, New Zealand, Switzerland and the USA on mutual recognition of ‘good manufacturing practice’ in medicine production.

Despite these many illustrations; the scope and depth of the ‘Brussels effect’ is being questioned in the scholarly literature<sup>92</sup>. EU climate change policy is used to illustrate its limitations. Tackling climate change is a key policy priority of the EU. It is an area where regulatory cooperation efforts at both bilateral and multi-lateral level could generate benefits. Yet despite strong advocacy bilaterally and at multilateral level, the EU has had difficulties in influencing global action. This was most visible at the Copenhagen Climate Summit in 2009 when the EU was effectively side lined. Also, in relation to CO<sub>2</sub> emissions and aviation, EU initiatives prompted the International Civil Aviation Organisation (ICAO) to examine the matter, but it is not yet clear as to whether the outcome of discussions (expected in 2020) will align with the EU approach.<sup>93</sup> The question arises as to whether the situation has changed in recent years. The following looks at two specific areas of climate change action to see whether the EU emissions trading system is being used as model for third countries and if EU action on CO<sub>2</sub> and vehicle emissions is having an impact on global standard setting.

## 6.1 EU Emissions Trading – a model for other systems?

*“Developments in 2017 bring the global ETS count to 21 systems in operation in early 2018, at different levels of government. With the launch of the Chinese national ETS, the share of global emissions covered by a domestic ETS has reached almost 15%. Now, economies with an ETS in place produce more than 50% of global GDP and are home to almost a third of the global population. These figures reflect the steady expansion of ETS policy and the strengthening of implementation around the world.”*<sup>94</sup>

Emissions trading has become a key instrument in the fight against climate change. It is profiled as an efficient market-based way to reduce carbon emissions. Given the EU’s lengthy experience in experimenting with the instrument, it would seem well placed to serve as a model for third countries. Some cap and trade emissions trading systems (Norway, Iceland, Liechtenstein, Switzerland, China, Korea) have indeed taken inspiration from the EU regulatory model. This has been facilitated through ongoing EU-third country bilateral dialogues and active EU participation in international fora on climate change. It may lead, over time, to the linking of emissions trading systems. At present the emissions trading systems of the EEA member states (Norway, Iceland and Liechtenstein) and Switzerland (where a formal agreement was signed in 2017 after seven years of negotiation) are linked to the EU system.

The Chinese Emissions Trading System provides an example of partial uptake of the EU model. The EU has been cooperating with China since 2014 to provide technical assistance for capacity building and support for the seven regional pilot systems as well as for the establishment of a national emissions trading system. In July 2016 the EU and China signed a

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<sup>92</sup> Young, A. (2015) The European Union as a global regulator? Context and comparison, *Journal of European Public Policy*, 22:9, 1233-1252, DOI: 10.1080/13501763.2015.1046902;

<sup>93</sup> Birchfield, V. (2015), Coercion with Kid Gloves? The European Union’s role in shaping a global regulatory framework for aviation emissions, *Journal of European Public Policy*, 22:9, 1276-1294, DOI: 10.1080/13501763.2015.1046904

<sup>94</sup> ICAP. (2018). Emissions Trading Worldwide: Status Report 2018. Berlin: ICAP.

Memorandum of Understanding and a new project, “Platform for Policy Dialogue and Cooperation between EU and China on Emissions Trading”, was agreed for the period up to 2020. It provides further support for capacity building and training, particularly for the implementation and further development of the national system. While China has taken inspiration from the EU ETS model, there are differences between the systems relating to the definitions of the cap, administrative capacity (the carbon market infrastructure), coverage (e.g. of only the power sector), metrics (i.e. use as a performance standard) and monitoring and verification. These are important factors in the ongoing discussions about linking the EU and the Chinese ETS.

The South Korean government has also worked with the EU in the design of its emissions trading system (KETS) which was launched in 2015 and covers around 66% of Korea's total greenhouse gas emissions. The EU provided technical assistance for capacity building to implement the KETS.

The EU actively participates in other dialogues on emissions trading. It announced in December 2018 that it was stepping up its cooperation with New Zealand, to meet more regularly at policy and technical levels to discuss issues of design and implementation of their respective systems and explore how to deepen the links between them. The EU brings its experience and extends training through the International Carbon Action Partnership, launched in 2007 as a platform bringing together countries with a mandatory cap and trade system. This complements the work of a World Bank platform, Partnership for Market Readiness, which is assisting some 17 countries in their preparation and implementation of carbon markets.

Designing compatible emissions trading systems would make the accounting of the contribution of these systems to the nationally determined contributions (NDCs) under the Paris Agreement more straightforward.<sup>95</sup> Article 6.2 of the Paris Agreement allows countries to engage in international carbon market mechanisms and count that action towards meeting their NDC. Emissions trading is seen as one of these mechanisms. If it can be demonstrated that compatible systems make linking more feasible, the systems currently being designed may tend towards the EU model as it is the largest player in the market and its design has been tested over time. However, experience has shown that the path towards increased compatibility and linking is neither linear nor technically driven. The EU and Australia looked at linking up their trading systems, but a change in the political climate resulted in the repeal of the Australian system in 2014, bringing the linking exercise to a standstill.

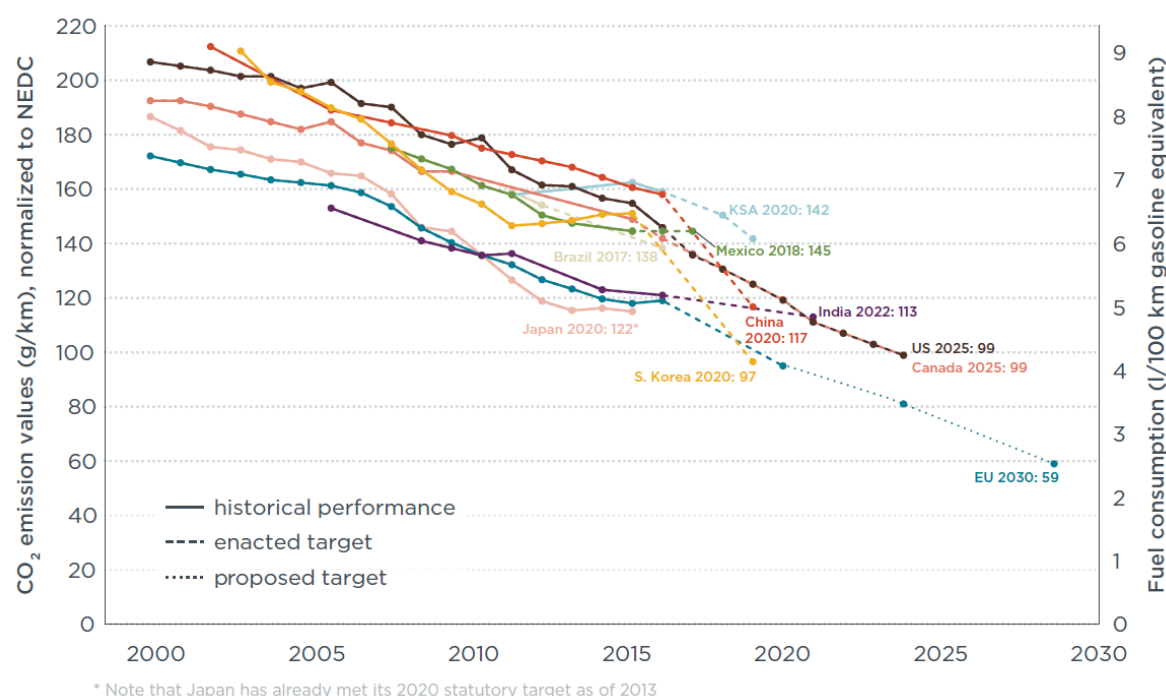
## 6.2 Diffusion through international action

The way in which the EU influences global standard setting in the area of vehicle emissions is illustrated by the EU interaction with the United Nations Economic Commission for Europe (UNECE) on global norms for vehicles. The EU has set the pace for global action on CO<sub>2</sub> vehicle emissions by agreeing internally on targets and deadlines which have in turn served to inspire third countries. An early voluntary agreement between the EU and selected associations

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<sup>95</sup> For further analysis of linking systems see Mehling, M. A., Metcalf, G. E., & Stavins, R. N. (2018). Linking heterogeneous climate policies (Consistent with the Paris Agreement). *Envtl. L.*, 48, 647. <https://heinonline.org/HOL/LandingPage?handle=hein.journals/envlnw48&div=31&id=&page=>

of car manufacturers (e.g. the European Automobile Manufacturers Association-ACEA: the Japanese Car Manufacturers Association- JAMA and the Korean Automobile Manufacturers Association - KAMA) did not produce desired results. So, the EU decided in 2007 to set mandatory CO<sub>2</sub> emission standards for newly registered light duty vehicles (domestic and imported). By 2017, the legislation covered more than 15 million passenger cars representing around 19% of global registrations.<sup>96</sup> The EU has recently set targets for 2030.<sup>97</sup> This has inspired other countries to set ambitious targets (see graph below which illustrates the recent adoption by China and South Korea of ambitious targets and timelines). Importantly cooperation in UNECE has also resulted in agreement on methods of measurement. The most recent EU targets incorporate metrics agreed in the UNECE test cycle “Worldwide Harmonized Light Duty Vehicle Test Procedures (WLTP)” which was developed in 2014 and directly transposed and applied in EU law in 2017. Agreement on such metrics sets a stronger foundation for discussions on alignment of emissions targets.



**Figure 3 CO<sub>2</sub> Emissions and Cars**

Source: International Council on Clean Transportation, 2019

There are other examples where the EU has influenced global standard setting in UNECE. The ‘Group of Rapporteurs on Pollution and Energy (GRPE)’, for example, has taken inspiration from EU norms on electric cars and transposed them into UNECE standards. By taking a lead in another UNECE group, the ‘World Forum for Harmonization of Vehicle Regulations’, the EU, together with Japan and Korea, is leading the effort to develop a harmonized procedure to perform real driving emission testing on open roads. This is particularly important in light of the 2015 revelations that Volkswagen had cheated in emissions testing conducted in

<sup>96</sup>ACEA (2018), The Automobile Industry Pocket Guide 2018/2019, Brussels

<sup>97</sup> The new standards have been agreed by the Council (<https://data.consilium.europa.eu/doc/document/ST-5091-2019-EXT-1/en/pdf>) and the European Parliament committee.



laboratories. The UNECE effort aims to improve emissions testing in both laboratory and real driving conditions.

## VII. Weighing up the evidence

The EU itself has shown the clearest results of substantial and procedural regulatory cooperation and convergence. The system is not based on full harmonisation of legislation but rather allows regulatory divergence provided that the mutual recognition principle is applied such that goods legally marketed in one Member State can be marketed in another. This works because EU Member States accept ECJ adjudication. The EU experience shows however that even with a strong and stable legal, institutional and administrative framework, regulatory cooperation and convergence remain a challenge.

Other than the EU itself, EU-third country formal agreements with an integration focus involving either potential accession to the EU or access to the single market have been most successful in promoting regulatory alignment. The alignment is in one direction, with the partners aligning to EU law, not the other way around. Accepting EU law without having a say in its development and adoption and respecting the arbitration of the ECJ is the price that they pay for access to the EU market. The countries of the European Economic Area<sup>1</sup> (Norway, Iceland, Liechtenstein) and Switzerland have most fully aligned their laws to those of the EU internal market. Countries with EU Association Agreements and Customs Unions are at different stages of alignment, implementing the laws with varying degrees of success. If the laws are not implemented, the full benefits of alignment in terms of access to the EU market and cost reduction may not materialise.

The ‘new generation’ free trade agreements with South Korea, Canada and Japan look promising. But, an ex-post evaluation of the EU-Korea Agreement shows that while non-tariff barriers have been reduced under the agreement, the related changes in domestic legislation cannot be directly attributed to regulatory cooperation under the FTA. It is too early to judge results of the EU-Canada and EU-Japan Agreements.

The regulatory cooperation provisions of EU-third country free trade agreements have limitations inherent in their design. First, they have covered mutual recognition of conformity assessment and/or good manufacturing practices, not mutual recognition of the rules themselves. An OECD study points out that such a reduction in the costs of duplicative testing and certification, while important, represents a small portion of total costs of non-tariff barriers.<sup>98</sup> The same study also indicates that the largest part of non-tariff barriers in the pharmaceutical sector is the cost of market approval, something that is not addressed in the EU-US mutual recognition arrangement which focuses on good manufacturing practice.

Second, the focus of regulatory cooperation in these agreements has been mainly on ‘goods’ legislation. While important, is not in keeping with the changing nature of the economy where services account for a larger part of the economy. In the service sectors, regulatory heterogeneity, as measured by differences in the OECD Service Trade Restrictiveness Index,

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<sup>98</sup> Correia de Brito, Kaufmann, C. and Pelkman, J., ‘The contribution of mutual recognition to international regulatory cooperation’ OECD Regulatory Policy Working Papers, No. 2, OECD Publishing, Paris, p. 53

is estimated to generate costs equivalent to tariffs of between 20% and 75%.<sup>99</sup> Another study on the costs of regulatory divergence in financial services<sup>100</sup> concludes that regulatory divergence costs between 5-10% of annual turnover of the companies surveyed (251 financial sector institutions ranging in size from less than \$US 10 million to \$1 billion+ annual turnover with operations throughout the Americas, Europe, Africa, Asia, Oceania, and the Middle East). Inconsistencies in supervisory interpretations and practices, fundamentally different regulatory frameworks, and different regulatory or data definitions were found to be the most significant barriers. These studies point to the need to more deeply examine the dimensions of regulatory divergence in the area of services and explore the benefits of its possible reduction.

Third, regulatory cooperation is voluntary under the FTAs. It is understandable that the partners want to retain regulatory autonomy and not submit disagreements to a dispute settlement mechanism. But EU experience has shown that results depend on giving up some regulatory sovereignty and respecting the decisions of a supranational court.

Despite the limited scope of the new generation of FTAs, the modest actions foreseen under the agreements could act as stepping stones to more ambitious forms of regulatory cooperation in the future. Progress in regulatory cooperation requires a certain familiarisation process under which regulators develop an understanding of the partner's practices and procedures and build trust over time. This process may lead to mutual reliance, if not mutual recognition.

EU-US regulatory cooperation is an example of this incremental approach. While there is no overarching or strategic approach to cooperation and areas of 'soft' cooperation such as agreement on good regulatory practices have shown only modest results, cooperation has been successful in specific sectors. These achievements could serve as a model for other sectors and pave the way for a more formal horizontal strategic agreement in the future.

The informal spread of EU rules, the 'Brussels' effect, is taking place in sectors where the EU has taken a distinct lead in regulating (e.g. chemicals, waste, data protection). This raises the question of whether formal agreements are necessary. Alignment has been partial however in most cases and hence the trade and cost reduction benefits may not be fully realised.

The process of bilateral regulatory alignment is often facilitated by agreeing first on global standards in international organisations. The EU is an active participant in international organisations. It transposes the adopted global norms back into EU law. When other countries have done the same, bilateral mutual recognition or equivalence is much more straightforward. This has been clearly demonstrated in the area of pharmaceuticals and marine equipment.

There is little empirical evidence on the cost-savings or benefits of either informal ('Brussels effect') or formal regulatory cooperation. While trade has expanded significantly under association and free trade agreements,<sup>101</sup> it is difficult to say how much of this increase is related to enhanced regulatory cooperation. For example, trade with countries having SAAs in the Western Balkan region has more than doubled since 2007: in 10 years, exports to the EU have increased by 142% against a more modest increase of EU exports to the region of 84%. EU trade with South Korea grew at 5.7% per annum on average over the seven years (2010-

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<sup>99</sup> OECD (2017), *International Regulatory Co-operation and Trade: Understanding the Trade Costs of Regulatory Divergence and the Remedies*, OECD Publishing, Paris, <https://doi.org/10.1787/9789264275942-en>

<sup>100</sup> International Federation of Accountants and Business at the OECD (2018) *Regulatory Divergence: Costs, Risks, Impacts*.

<sup>101</sup> European Commission (2018), *Report on Implementation of EU Free Trade Agreements*, 1 January 2017 - 31 December 2017, European Publications Office, Luxembourg, pp. 12-23.



2017) that the FTA has been in force. EU trade with South Korea grew at 5.7% per annum on average over the seven years (2010-2017) that the FTA has been in force. Exports of goods from the EU to Korea have increased by about 60 percent from the period before application of the FTA to the period after and strongly outperformed exports to other regional trade partners of the EU (Japan, Taiwan). In the first 9 months of the application of CETA (October 2017 to June 2018) EU exports of goods to Canada increased by 7%, Trade between EU and Ukraine under the DCFTA has been growing strongly. EU exports to and imports from Ukraine grew by 22% and 27%, respectively, in 2017. EU imports from the Mediterranean countries increased from €133.6 billion in 2015 to €148.3 billion in 2017.

Further analysis is needed to separate the impact of reduction of non-tariff barriers/enhanced regulatory cooperation on these trade flows to get a better idea of the gains of regulatory cooperation. Likewise, in the context of regulatory cooperation promoting a more even playing field and acting to reduce delocalisation, while some scholarly work has been done to show that EU environmental regulation is not producing a race to the bottom<sup>102</sup> and that trade agreements are leading to regulatory convergence in the environment field,<sup>103</sup> there is less assessment of these effects in other sectors.

The prospect of assessing ex-post results would be enhanced if there were a more systematic treatment of the estimation of the gains of regulatory cooperation in the reduction of non-tariff barriers in European Commission impact assessments. While the quality of trade impact assessments is improving, few attempts have been made to estimate the gains of regulatory cooperation and no impact assessments have been conducted in some cases due to time constraints and/or methodological challenges.<sup>104</sup>

The withdrawal of the UK from the EU may provide some insight into the benefits of EU regulatory cooperation or the costs of non-alignment. A recent study looks at the tariff and non-tariff costs of a WTO arrangement relative to the situation where the UK is still in the EU.<sup>105</sup> They estimate the cost at £27 billion or equivalent to 1.5 percent of Gross Value Added annually. The report estimates that 70 percent of the extra costs arising from trade barriers are faced by five sectors: financial services; automotive; agriculture, food and drink; consumer goods; and chemicals and plastics and that firms which are highly integrated into EU supply chains (aerospace, chemicals & plastics, metals and mining and life sciences) will be hit most directly. Most of these sectors are regulated at EU level and the costs presumably arise due to regulatory divergence.

## 7.1 Limits to Formal Regulatory Cooperation

Outside of those countries aspiring to membership of the EU, most third countries are not willing to give up regulatory autonomy or submit disagreements on the applicable law to a

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<sup>102</sup> Vogel, D. (1997). Trading up and governing across: Transnational governance and environmental protection. *Journal of European Public Policy*, 4(4), 556-571. Kelemen, R.D. and Vogel, D., 2010. Trading places: the role of the United States and the European Union in international environmental politics. *Comparative Political Studies*, 43 (4), 427-456.

<sup>103</sup> Bastiaens, Ida and Evgeny Postnikov (2017) Greening up: the effects of environmental standards in EU and US trade agreements, *Environmental Politics*, 26:5, 847-869.

<sup>104</sup> For example, there was no impact assessment of the most recent EU-US negotiating directive on conformity assessment bodies due in part to time constraints but also to the difficulty in modelling and measurement of effects.

<sup>105</sup> See [https://www.oliverwyman.com/content/dam/oliver-wyman/v2/publications/2018/march/Oliver-Wyman\\_Clifford-Chance-The-Red-Tape-Cost-of-Brexit.pdf](https://www.oliverwyman.com/content/dam/oliver-wyman/v2/publications/2018/march/Oliver-Wyman_Clifford-Chance-The-Red-Tape-Cost-of-Brexit.pdf)

supranational court – two key features of the more successful EU/third country regulatory cooperation ventures. Third countries may legitimately resist giving up regulatory autonomy and find that EU norms are not suited to domestic circumstance. Some question whether the legislative approximation process agreed through trade agreements is sufficiently democratic.<sup>106</sup> Governments may meet the regulatory obligations under trade agreements by directly transposing EU law into domestic law through blanket or omnibus mechanisms which may be seen to short-cut deliberative legislative procedures. The requirement under the agreements for the third country to mandatorily align when changes are made to EU law may further exacerbate this problem.

There is also a fundamental question of whether regulatory cooperation leading to convergence is realistic between ‘rule-makers’. The EU-US experience reflects this challenge. It has been difficult to achieve results due to:

*Diverging policy objectives, institutional set-up and regulatory policy orientations:* Negotiations run into difficulties where the EU and the US have different policy objectives (e.g. climate change and privacy/data protection) and where they have dwelled on products that are politically and culturally ‘off bounds’ such as GMOs in Europe or horsemeat in the USA. Institutional differences related to US federal/state structure and EU/Member State responsibilities have presented difficulties in some discussions such as those on public procurement. There are differences in enforcement practices, with the US tending to rely more on litigation as a means of enforcement than is the case in the EU. On regulatory policy orientations, even though scholarly work has shown that orientations on risk regulation are not dissimilar between the EU and the USA<sup>107</sup>, there is still a strong perception in the US that the EU is overly precautionary and, in the EU, that the USA is overly deregulatory. These differing perceptions colour negotiations and work to diminish stakeholder support for regulatory cooperation. Indeed, regulation and deregulation have different connotations in each jurisdiction. Deregulation has a negative connotation in Europe and a positive one in the USA. The deregulatory and ‘America First’ agenda of the Trump administration has exposed those differences and has tended to dampen stakeholder enthusiasm for regulatory cooperation.

*Difficulty or unwillingness to recognise the merits of differing regulatory policy systems and approaches:* Both the EU and the US as ‘rule makers’ have reputations of applying their own MRA (‘my rules apply’) approach to negotiations. Both have sought approximation to their respective rules.<sup>108</sup> For the US, this relates not only to substantial rules but to negotiations on good regulatory practices as well. That is, the US has long championed its own regulatory system of ‘notice and comment’ and regulatory impact assessment and has argued in international trade negotiations that it be replicated.<sup>109</sup> This met with some success in terms of the transparency provisions of its agreements negotiated in the western hemisphere (NAFTA, Chile, Peru, Panama, Columbia, Dominican Republic/Central America), the middle east

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<sup>106</sup> Harpaz, G.(2006), When East Meets West, Common Market Law Review, p. 993–1022, 2006.

<sup>107</sup>See International Risk Governance Council (2017), Trans-Atlantic Patterns of Risk Regulation, Implications for International Trade and Cooperation, Ecole Polytechnique Fédérale de Lausanne (EPFL), Lausanne. Switzerland; Jonathan B. Wiener & Michael D. Rogers, Comparing Precaution in the United States and Europe, 5 *Journal of Risk Research* 317-349 (2002) Available at: [https://scholarship.law.duke.edu/faculty\\_scholarship/1191](https://scholarship.law.duke.edu/faculty_scholarship/1191)

<sup>108</sup> See Ching-Fu Lin and Han Wei Liu (, Regulatory Rationalisation clauses in FTAs: A Complete Survey of the US, EU and China, p. 162

<sup>109</sup> See Ching-Fu Lin and Han Wei Liu, Regulatory Rationalisation clauses in FTAs: A Complete Survey of the US, EU and China, (2018) *Melbourne Journal of International Law* 5; 19 (1) *Melbourne Journal of International Law* 149 p. 162

(Morocco, Oman, Bahrain), Australia and Singapore. It was less successful during the TTIP negotiations.

During those negotiations, the American side stressed that regulatory impact assessment and transparency (particularly as related to the calculation of costs and benefits of regulation), openness and participation in rule making were key elements of their regulatory system that they wanted to find back in the EU system.<sup>110</sup> The US negotiators felt that the EU side was not sufficiently transparent and did not permit participation in the rule-making system equivalent to the American notice and comment system in so far as draft impact assessments and draft proposals are not put out for comment prior to their adoption by the Commission.<sup>111</sup> A close examination of the EU system, particularly following the adoption of the May 2015 Better Regulation package<sup>112</sup> shows that the European Commission provides ample opportunities for participation in the decision-making process.<sup>113</sup> A preliminary impact assessment is put on-line for feedback. Impact assessments (and ex-post evaluations) must be accompanied by a 12-week public consultation. After the Commission adopts a proposal, both the proposal and the impact assessment are put out for feedback for an eight-week period before the documents are transmitted to the legislature. Implementing and delegated acts are as well put out for feedback for four weeks. Impact assessments, most of which include quantification of costs/benefits, are systematically conducted on all initiatives that have significant economic, social and environment impacts. In contrast to the US where regulatory impact assessment (and related transparency provisions) is conducted only on rules with economic impacts of over \$100 million promulgated by the executive agencies (i.e. neither independent agencies nor the Congress), the Commission conducts impact assessment (and related consultations/feedback) on both primary and secondary legislation. In short, the Commission system compares favourably to the American system, but this was not recognised as such during the TTIP negotiations.

*Little trust* in each other's ability to deliver: Confusion about the Commission's institutional role (i.e. that the Commission proposes and the legislature - Council and Parliament - decides on laws) has created the perception among US regulators that the Commission is unable to deliver. The example most often referred to in this context was a Commission commitment to allow the import of American chickens. This required a change in legally prescribed processing methods to allow chicken carcasses to be bathed in chlorine. The Commission made a proposal<sup>114</sup> to this effect. It was soundly rejected by the EU legislature.<sup>115</sup> A second example was the hesitation shown by the US Food and Drug Administration to recognise the EU medicines regulatory system in the late 1990s as being able to deliver to an equivalent standard as the American system. This meant that a mutual recognition agreement on good manufacturing practices did not enter into force as initially planned. It took nearly twenty

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<sup>110</sup> United States. Congress. House. Committee on Ways Means. (2016). President Obama's trade policy agenda with U.S. trade representative Michael Froman : Hearing before the Committee on Ways and Means, U.S. House of Representatives, One Hundred Thirteenth Congress, second session, April 3, 2014. Washington: U.S. Government Publishing Office.

<sup>111</sup> Hancock, B. (2013) U.S., EU Negotiators Out of Sync On TTIP Regulatory Cooperation Approach, Inside US Trade, Arlington (Sep 26, 2013).

<sup>112</sup> European Commission (2015), Communication 'Better Regulation for Better Results, COM(2015)215 Final, May 19, 2015, Luxembourg, Publications Office of the EU.

<sup>113</sup> The OECD Regulatory Policy Outlook ranks the EU highly in terms of its composite indicators that look at methodology, adoption/use, transparency and scrutiny of impact assessment, evaluation and stakeholder consultation. OECD (2018), Regulatory Policy Outlook,

<sup>114</sup> <http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%2016163%202008%20INIT>

<sup>115</sup> See <https://www.euractiv.com/section/health-consumers/news/outrage-at-plans-to-lift-chlorine-chicken-ban/>;

years, a maturing of the EU system, years of cooperation between regulators, evaluation and auditing of each other's processes and the development of an understanding on sharing of information and rules on conflict of interest to develop the trust needed for successful implementation of the agreement.

*The lack of a strong institutional framework and resources to enforce cooperation have meant that regulators on both sides of the Atlantic have little incentive to devote resources to closer regulatory cooperation with the other party.*

## 7.2 Ingredients for success

The elements which contribute to the success of regulatory cooperation ventures have been widely discussed in the literature<sup>116</sup> and the converse of the limiting factors mentioned above. They include,

*A shared understanding and application of good regulatory practices* (impact assessment, periodic review of regulatory measures, and facilitation of stakeholder participation in the regulatory process) is a prerequisite for regulatory cooperation. Transparency is particularly important – making sure that regulatory requirements and procedures are accessible to all interested parties and that the latter have enough time to respond to consultations. Respect for the role of international institutions and international standard setting also facilitates bilateral cooperation.

*Shared objectives and the institutional and administrative capacity to deliver on them.* The policy goals of the EU and the partner seeking regulatory cooperation need to be aligned. Regulatory cooperation is more likely to be successful at an early stage of policy development, notably for sectors involving emerging technologies (e.g. artificial intelligence, regulation of technology platforms, cyber security etc) or for those such as telecommunications and information technology where business has agreed on the need for a common set of standards.<sup>117</sup> Once a certain economic sector or new technology has become regulated, altering existing rules or regulatory practices becomes much more difficult, at least up to the point when the regulation becomes the subject of review/ex-post evaluation. Legal, institutional and administrative systems and procedures need to be at a similar level of maturity to be able to deliver on the agreed policy objectives. Technical assistance and funding are often required to build the capacity in partner countries for meaningful regulatory cooperation. Where business is active on a global scale, it will

*Commitment from all levels.* If there is no political commitment to cooperation ventures and if regulators do not have a clear mandate, cooperation with third countries will inevitably take back seat to domestic priorities.

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<sup>116</sup> Various authors have identified main elements needed for successful regulatory cooperation. See Bull, Reeve T., Mahboubi, Neysun A., Stewart, Richard B., & Wiener, Jonathan B. (2015). New approaches to international regulatory cooperation: The challenge of TTIP, TPP, and mega-regional trade agreements. *Law and Contemporary Problems*, 78(4), and; Correia de Brito, Kaufmann and Pelkman in 'The contribution of mutual recognition to international regulatory cooperation' OECD Regulatory Policy Working Papers, No. 2, OECD Publishing, Paris, p. 56-57

<sup>117</sup> Recent EU-US agreement on the development of a common testing method for charging devices and smart grids for electric vehicles is an illustration of early cooperation as identified in Garcia Bercero, I., Emberger, G., Vandenberghe, J., 'EU-US Engagement on Regulatory Issues: Lessons Learnt, Notably in the Context of the TTIP Negotiations' (2018) 23 *European Foreign Affairs Review*, Issue 2, pp. 149–165

*An institutional framework both at political and administrative/technical level with adequate resources* is needed to guide the process, take decisions and arbitrate where domestic preferences clash with the partners' regulatory cooperation goals. Some sort of horizontal steering body is needed to identify and deal with problems, keep work programmes on track and discuss cross cutting issues such as innovation and data sharing. Resources are key. Regulatory cooperation demands professionals with a knowledge of the working of the respective systems to elaborate a meaningful regulatory cooperation work programme and follow through (monitoring and reporting to political level).

*A long-term time horizon.* Successful regulatory cooperation is not a one-off exercise. Experience has shown that fruitful cooperation may involve a focus on good practices and procedures in specific sectors as a first step and the move to more substantial policy or legislative alignment at a later stage, often decades after the launch of exploratory discussions. Regulatory cooperation is a 'living' exercise. As the body of EU legislation evolves, third countries which have aligned with EU law or have reached some sort of equivalence agreements, need to continuously align or at the very least work to find mutually acceptable solutions to divergent regulation. Given this time horizon, there is a question as to whether regulatory cooperation should be negotiated as part of trade agreements. On the one hand, trade concessions can be made conditional on regulatory alignment which is a driver for cooperation. But trade negotiations and regulatory cooperation discussions are by their nature very different. The former is characterised by confrontational methods and a short term 'bargaining chip' approach which may be counterproductive if applied to regulatory cooperation discussions which by their nature tend to be longer term and consensual.

Most importantly, *trust is needed at all levels*: political/negotiators; regulators; stakeholders; general public. Regulatory cooperation demands good personal relationships between the regulators concerned; the building of networks of practitioners; and frequent contact.

## VIII. Conclusions

Regulatory alignment has taken place within the EU and between the EU and partner countries aspiring to EU membership or seeking access to the EU single market. Regulatory cooperation between the US and the EU has been successful in a few sectors but is below its strategic potential. The ‘new generation’ EU free trade agreements with extensive regulatory cooperation provisions have promise and as knowledge, understanding and trust builds up between regulators under these agreements, there is a good prospect of closer regulatory alignment and/or the conclusion of mutual recognition/equivalence agreements.

In the absence of empirical analysis, however, it is difficult to conclude that regulatory cooperation initiatives have generated the estimated trade enhancing, efficiency and delocalisation mitigation benefits which have prompted their negotiation (and inclusion in some preferential trade agreements). While trade between countries having preferential agreements with the EU has increased substantially, the impact on regulatory cooperation on trade and investment flows or on cost reduction has not been measured.

The potential benefits of the new generation FTAs need to be put in perspective. The level of ambition in the regulatory cooperation provisions is low, with regulatory cooperation remaining voluntary and the focus being on goods (and within that, conformity assessment). While important, these provisions represent a small part of the costs of non-tariff barriers and do not cover services which are a growing component of global trade.

Further thought should be given to how to meaningfully measure results and impacts of regulatory cooperation initiatives. Should the exit of the UK from the EU generate regulatory divergence, it would provide fertile ground for the measurement of the costs of non-alignment. It would also be insightful to examine how the US position as a global standard setter has changed under the current administration and what effect, if any, this has had on American trade and investment. A related avenue of analysis would be to examine if the American reliance on good regulatory practices alone, without institutional or enforcement provisions, has generated expected gains of reduction of regulatory divergence. The dimensions of regulatory barriers to trade in services also need to be more deeply assessed.

The destiny of international regulatory cooperation is closely tied to continued respect for a rules-based international trade and investment system. The latter has come under severe strain in recent years. China has been reticent to include regulatory cooperation in its free trade agreements. It is however emerging as a global regulatory standard setter in areas where it is a market leader such as information technology (IT).<sup>118</sup> Chinese companies, for example, have been actively shaping standards for 5G in European and international standard-setting bodies. The ‘China effect’ may spread to other areas where China occupies a position of market dominance or chooses to set market access conditions for its domestic market. The deregulatory agenda of the Trump administration combined with lukewarm appreciation of multilateral governance may work to diminish the American role in global standard setting. The EU, with its continued commitment to multilateral governance and to the conclusion of

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<sup>118</sup> European Policy Strategy Centre (2019), EU Industrial Policy after Siemens-Alstom, to be found at [https://ec.europa.eu/epsc/sites/epsc/files/epsc\\_industrial-policy.pdf](https://ec.europa.eu/epsc/sites/epsc/files/epsc_industrial-policy.pdf), p.16.

Free Trade Agreements which have strong regulatory cooperation commitments, will likely continue to occupy the global regulatory stage for some time. It is an open question as to whether other countries will choose to follow the EU model and/or join forces in setting standards for global regulatory excellence.



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