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U.S. CHAMBER OF COMMERCE

Regulatory Cooperation in the EU-U.S. Trade and Investment Agreement

U.S. Chamber of Commerce and BUSINESSEUROPE

Introduction and Summary:

The United States and the European Union are the world's largest economies, each producing about \$15 trillion in goods and services a year. Each is also the other's largest trading partners, with more than \$1.5 trillion in goods, services, and income receipts flowing across the North Atlantic annually.

Despite the depth and breadth of this commercial relationship, differences in regulation are overwhelmingly cited as the primary obstacle to enhanced trade between them. An exhaustive study of these differences in 23 different sectors¹ estimates that reducing even half of these divergences would lead to GDP increases for the EU and the U.S. of over \$200 billion per year, with exports increasing substantially in both. Many of these regulatory differences are 'unnecessary,' as the U.S. and EU, democratic societies with comparable levels of income and wealth, strive to provide similar levels of consumer, environment and investor protection; that is, their regulatory outcomes are similar, even if procedures and details differ.

The European Union and the United States should adopt an ambitious approach to regulatory issues in the context of a comprehensive transatlantic trade and investment agreement, with the purpose of enhancing regulators' efficiency and thus effectiveness in fulfilling their domestic regulatory mandates. In particular, in addition to strong and binding technical barriers to trade (TBT) and sanitary/phyto-sanitary (SPS) provisions, the EU and the U.S. should agree on regulatory cooperation provisions that will:

- Establish a **clear goal** of having counterpart U.S. and EU regulators determine where their regulatory regimes aim for compatible regulatory outcomes, such that a product or service that can be sold in one market can be made available for purchase in the other; and
- Provide **new tools and a governing process** to guide regulatory cooperation on both a cross-cutting and sector-specific basis, which will help address divergences in both existing regulations and future regulatory measures.

Obviously, a determination that specific regulatory approaches are compatible can come only after intensive study and establishment of full trust and confidence between counterpart regulators. This will take time, and a U.S.-EU agreement should allow for this, creating an 'evergreen' process with a continuous agenda for advancement. Further, in some sectors, the goal of full recognition may not be feasible or even desirable, but the process of studying the issue will likely lead to other benefits, such as simplification of reporting or data sharing requirements, elimination of duplicative testing, simplification of conformity assessment procedures, etc. Finally, the scope of coverage for regulatory cooperation should include financial regulations.

¹ ECORYS Nederland BV, *Non-Tariff Measures in EU-US Trade and Investment – An Economic Analysis* (2010).

The U.S. Chamber of Commerce and BUSINESSEUROPE have developed the following proposal to elaborate how a regulatory component could be developed by describing the provisions that should be included in the agreement, including:

- **Preamble** which affirms the importance and benefits of regulatory cooperation to enhancing regulator efficiency and effectiveness, while recognizing their mandate to protect their consumers, investors and the environment;
- **Regulatory Principles** that emphasize and endorse regulatory best practices both accepted and agreed by the U.S. and the EU;
- **Regulatory Outcomes** that establish a clear goal of compatible regulatory regime determinations;
- **Transatlantic Regulatory Tools** including transparency, information and data sharing, confidentiality, processes for identifying proposed measures with a significant impact on transatlantic trade, and a new Regulatory Compatibility Analysis procedure;
- **Institutional Provisions** to establish an oversight body to address cross-sectoral issues, promote best practices, and oversee an ‘evergreen’ process of enhancing regulatory compatibility; and
- **Preserve Regulator Decision-Making Authority** to maintain respect for sovereignty.

Preamble

Although FTAs generally avoid chapeaux to individual chapters, it is, however, important that a U.S.-EU agreement break from this mode in regard to how it approaches regulation. A U.S.-EU agreement charting a course for regulatory cooperation must be guided by a unified vision in order to sustain a continuous high-level commitment. It would also signal to third countries the importance the U.S. and the EU place on high quality, least trade restrictive approaches to regulation. The level of ambition in a U.S.-EU agreement requires a clear statement of how deep EU-U.S. regulatory cooperation benefits consumers, investors and the environment by allowing regulators to devote scarce resources to enforcement against higher-risk jurisdictions, without diminishing their ability to regulate or achieve their regulatory mandate. This will give U.S. and European citizens greater confidence in traded products and services even as it helps regulators ensure optimal allocation of their scarce resources. It would also establish regulatory predictability and help small and medium sized businesses in particular to engage in transatlantic trade.

Regulatory Principles

Here the text of an agreement is relatively straightforward. It essentially would draw from the various core regulatory best practices that are embodied in U.S. and/or EU administrative law. It would also reaffirm and formalize work already done in the June 2011 *Common Understanding on Regulatory Principles and Best Practices* and April 2002 *Guidelines on Regulatory Cooperation and Transparency*, developed bilaterally between the U.S. and the EU.

Much of this has arguably already been negotiated between the two parties, therefore, its inclusion would be easy and it would serve:

- To make the regulatory component of the overall agreement comprehensive;
- As a model for other trade negotiations for how regulatory best practices have linkages to the same market liberalization goals that serve as the impetus for trade negotiations; and
- To demonstrate a commitment from both the U.S. and the EU to go beyond any level of regulatory coherence or cooperation in current or in-process trade agreements.

Regulatory Outcomes

The U.S.-EU agreement should create a clear goal that encourages regulators to evaluate the body of regulation and corresponding conformity assessments governing various sectors to determine to what degree each regulatory framework delivers compatible regulatory outcomes. Once this is determined, regulators can implement a ‘sliding scale’ of regulatory cooperation enhancements to maximize the desired level of coherence, which can include full recognition.

The creation of the mandate in the agreement and corresponding implementing legislation should help ensure any statutory barriers to cooperation are removed. Where compatibility of regulatory outcome is acknowledged, regulators would grant recognition of products and services found to be in compliance with either regulatory regime. These decisions would need to be evidence based; unlike traditional trade negotiations, decisions should not be based on tradeoffs.

This process should allow stakeholders as well as regulators to identify entire sectors and regulations within sectors that are potentially ripe for a compatibility evaluation. Such a component will add a proactive requirement directing and empowering regulators to seek full recognition, as well as a process by which regulators would be required to respond to stakeholder-identified opportunities to examine compatibility – neither of which currently exists in the EU or the U.S. Further, embarking on the exercise of examining compatibility can yield benefits even if the regulators are unable to arrive at full recognition. For example, regulators can increase efficiency by enhancing mutual reliance through information and resource sharing or removal of duplicative testing and reporting requirements. Examining compatibility can identify barriers or other issues preventing progress and lead to the development of the pathways needed to arrive at full recognition, if desirable.

This process will also support regulatory reform in both the U.S. and the EU, which is increasingly putting a premium on conducting ex-post assessments or look-backs of existing regulation; these assessments are still very much in their infancy. However, an agreement that directs regulators to explore whether regulatory frameworks in the U.S. and the EU achieve compatible outcomes ties together and enhances the current ex-post assessment trend and would aid in the development of a greater capacity and ability to assess how regulation is working in what is often a globalized market.

Transatlantic Regulatory Tools

Working within the existing EU and U.S. regulatory promulgation process, an agreement would adopt new procedures that create a formal consultative role between the U.S. and the EU for select regulations consideration by either Party to be ‘significant.’ These ‘significant’ regulations can be defined to cover issues of key importance to conducting business on either side of the Atlantic or

to understanding how a regulatory mandate (e.g. health or safety) is being met when the regulated good or service will be traded across the Atlantic.

Possible factors that might trigger the formal consultative role are:

1. Where regulation will impact goods or services where the volume of such bilateral trade or investment is significant;
2. Any new regulation or change relevant to a sector where an existing regulatory cooperation arrangement between the EU and the U.S. will be impacted; and
3. Regulation is being considered in an emerging policy area or developing sector that has great potential for growth.

Regulatory Compatibility Analysis (RCA)

An important element of this process relates to the right of each side to be consulted early in the domestic regulatory process. This is particularly relevant given the apparent structural differences in the US and EU legislative and regulatory systems. These different structures will require some innovative thinking on how stakeholders, and regulators, on both sides can provide meaningful input into the process, where justified.

Such an approach is certainly feasible. In fact, in the 1980s the Administrative Conference of the United States (ACUS) made two recommendations endorsing a process called “regulatory negotiation” which put stakeholders at the table with regulators to essentially co-write regulation. Similarly, the EU has a longstanding policy to promote regulatory cooperation, and where possible convergence, with its major trading partners. This discussion paper posits a modified hybrid international version of the existing ACUS recommendations and the realization of the EU’s regulatory cooperation ambitions.

While some consultation already occurs, an agreement would serve to add a well articulated and developed methodology to elevate and formalize those efforts. The formalization will create a cohesive system between regulators and also assure continuous progress.

In particular, the agreement would develop a process and methodology for consultation called a Regulatory Compatibility Analysis (RCA). An RCA should be overseen by OIRA or Sec Gen level, and for financial services in the newly created Financial Stability Oversight Committee (FSOC) in the U.S. and the Sec Gen or other appropriate venue for the EU.

RCA Methodology

The agreement should also spell out a RCA methodology to use as a baseline for avoiding unnecessary divergence of new regulations. The RCA is meant to inform regulators’ final decision and is not meant to be determinative.

Much consultation with regulators and stakeholders will need to be done to properly calibrate this methodology. But as a rough starting point, some questions to be considered as part of the methodology include, but are not limited to:

1. What are the costs/savings to the private sector (if any) of complying with a single set of regulations compared to the costs of complying with two or more sets of divergent regulations?
2. What are the budgetary savings to the two regulatory authorities of developing, inspecting, and enforcing two sets of regulations compared to one?
3. How much is transatlantic trade likely to increase as a result of the lower transaction costs from the elimination of the divergent rules?
4. How much would estimated benefits increase if regulatory spillover benefits to the transatlantic partner are included in the benefit estimates?
5. Would there be a change in the regulatory alternative recommended if the net-benefits are increased relative to the baseline of divergent regulations?
6. What are the quantitative and qualitative benefits of a transatlantic regulatory alternative compared to the domestic-oriented regulation?
7. Whether existing measures have become unnecessary or outdated by reason of changed circumstances, such as fundamental changes in technology and if the requirement can be removed or redeveloped more effectively through a cooperation activity.

Information Sharing

For many industries there is an enormous amount of data required by regulators as part of conformity assessment or product approval processes. However, this information is often business sensitive. The agreement should contemplate ways to incentivize and structure, perhaps on an industry by industry basis, information sharing arrangements that give both regulators' and stakeholders' confidence in data sharing, while addressing any other hindrances to open communication and information sharing. Further, the agreement should include harsh penalties for the release of confidential business information outside of a regulator-to-regulator context. Such assurances would be helpful to encourage industry to sign confidentiality waivers.

Transparency

Provisions should also be drafted to:

1. Provide for a central registry of all regulatory cooperation agreements between the U.S. and the EU as well as with third parties; and
2. Create transparency and stakeholder engagement guidelines to govern any U.S.-EU bilateral dialogue (e.g. U.S.-EU Investment Dialogue, Financial Markets Regulatory Dialogue, Energy Dialogue, IPR Dialogue).

Institutional Provisions

An oversight/implementation group(s) will be needed to manage and provide political oversight of the regulatory cooperation obligations included in the agreement. Accommodations need to be made so that any oversight group appropriately addresses the challenges on the U.S. side presented by independent agencies and structural differences of financial versus non-financial regulatory bodies. Similar corresponding accommodations would need to be made on the EU side. An oversight body would:

1. Develop methods to govern and coordinate both inter and intra-governmental communications.
2. Oversee and manage the RCA and sector compatibility evaluation processes.
3. Finalize concrete and feasible timeframes for regulators to achieve certain objectives and keep a publicly available ‘scorecard’ to track progress. Even if full recognition cannot follow a preset timeframe or be achieved at all, the oversight body should still set ‘small victories’ to improve compatibility on regulatory actions, like information and resource sharing.
4. Periodically, at preset intervals, examining existing and newly developed recognition arrangements to ensure enforcement and implementation of regulatory changes are in fact interoperable (particularly when faced with mismatched authorities, i.e. U.S. federal agency, EU Member State, sub-federal/sub-EU/sub-national regulation, failures of regulatory compliance).
5. Work with stakeholders to ensure they are engaged at regular intervals during a RCA or compatibility examination.
6. Develop outreach to make sure SMEs and NGOs are actively engaged.
7. Develop procedures to conduct, where and when relevant, joint/transatlantic scientific analyses of risk to facilitate common understanding between regulatory agencies across the Atlantic.

Preserve regulator decision-making authority

This agreement must not undermine the sovereign right to regulate or force the hand of regulators in determining the final form a regulation takes. The agreement must preserve a regulator’s right to regulate even after new tools like a regulatory compatibility assessment has been employed, but also:

1. Reserve the right for regulators to reject an individual product/service (at anytime, if available by sector) from the scope of coverage afforded by a regulatory cooperation/recognition arrangement (a “veto” authority). When this is done regulators should be required to notify their counterpart and provide rationale.
2. Provide for the unconditional immediate suspension and, after consultation, termination within a short period of time (say 90 days) of any regulatory cooperation/recognition arrangement.