



# Transatlantic Regulatory Cooperation: Background and Analysis

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## Summary

Commercial ties between the United States and the 27-member European Union are substantial, growing, and mutually beneficial. However, differences in regulatory approaches limit an even more integrated marketplace from developing. To deal with this situation, a variety of government-to-government efforts have been created to dismantle existing regulatory barriers and to prevent new ones from emerging. These efforts fall under the rubric of transatlantic regulatory cooperation (TRC) and are at the heart of today's U.S.-EU economic relationship.

This report is intended to serve as an introduction and primer on a complicated, broad, and often highly technical set of issues. Since the mid-1990s, both U.S. and European multinational companies have viewed divergent ways of regulating markets for both goods and services as the most serious barriers to transatlantic commerce. The primary reason why these companies seek to achieve greater harmonization in standards and regulatory procedures is to reduce costs imposed by having to comply with two different sets of regulations and standards.

TRC must deal with a number of key differences between the United States and EU concerning approaches to regulation. These differences involve political support for regulation and public attitudes towards risk and transparency. Until they converge or are re-aligned, a transatlantic gap in regulatory policies is likely to persist.

Regulatory cooperation is an umbrella concept that incorporates a broad range of activities. At one end of the spectrum are information exchanges and dialogues among regulators that are designed to build trust and confidence. At the other end of the spectrum are activities designed to harmonize regulatory approaches through acceptance of common principles and standards. In between are activities that involve varying degrees of intrusion into the autonomy of regulators.

TRC initiatives have made progress in reducing costs to businesses and consumers in some sectors, but not in others. One of the key obstacles to more extensive cooperation frequently cited is the domestic orientation of regulatory agencies involved in the process. To promote more effective TRC, two policy options are commonly advanced: (1) attracting high-level political support and (2) increasing dramatically the involvement of legislators (Congress and the European Parliament). The Transatlantic Economic Council (TEC), which was created in April 2007, was designed, in part, to generate the kind of high-level political support that previous initiatives may have lacked.

At the last TEC meeting, held in November 2011, the two sides agreed to avoid creating new and unintended barriers to trade and investment, especially in emerging technologies, such as nanotechnology, biobased food, and cloud computing. The leaders also encouraged regulators on both sides to implement common regulatory principles and best practices.

TRC has been mostly an executive branch driven process. Yet, through authorization and appropriations of the many different regulatory agencies involved in TRC, Congress could play a more central role if it decided to move in this direction. As domestic regulation takes place in an increasingly integrated transatlantic marketplace, Congress will be called upon to balance the often competing demands of trade expansion and barrier reduction against domestic health and safety concerns.

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## Introduction

The United States and the 27-Member European Union (EU) share a huge, dynamic, and mutually beneficial economic partnership.<sup>1</sup> Not only is the U.S.-EU commercial relationship, what many call the transatlantic economy, the largest in the world, it is also arguably the most important.<sup>2</sup> While the transatlantic market is today highly integrated due in large part to a massive amount of foreign direct investment by both U.S. and European companies in each other's markets, differences in regulatory approaches, standards, and philosophies militate against the development of an even tighter and more integrated marketplace. Regulatory differences are also behind some of the most politically sensitive bilateral trade disputes.

To deal with this situation, a variety of government-to-government efforts and transatlantic dialogues have been created to increase understanding between policymakers and regulators on both sides of the Atlantic, to minimize existing regulatory barriers, and to prevent the emergence of new regulatory barriers. These efforts, falling under the rubric of transatlantic regulatory cooperation (TRC), are seen as being important to today's U.S.-EU economic relationship. Proponents maintain that TRC undertakings can not only prevent disruptive and costly trade disputes from occurring, but also spur trade and investment flows by reducing costs for producers and consumers on both sides of the Atlantic.

Since the establishment of the New Transatlantic Agenda (NTA) in 1995, there have been a number of new TRC initiatives, all aimed at removing or reducing regulatory barriers to trade.<sup>3</sup> While each of these initiatives has made some progress toward reducing regulatory burdens, many U.S. and European companies heavily engaged in the transatlantic marketplace maintain that the results have not been materially significant.

At the 2007 U.S.-EU Summit, leaders of the EU and United States committed their governments to increasing the efficiency and transparency of transatlantic economic cooperation and to accelerating the reduction and elimination of barriers to international trade and investment with the ultimate objective of achieving a barrier free transatlantic market. They also agreed on a Framework for Advancing Transatlantic Economic Integration (the Framework) and created a new institutional structure, the Transatlantic Economic Council (TEC), to advance the process of regulatory cooperation and barrier reduction. Headed on both sides by ministerial-level appointees, the TEC is designed to oversee the efforts outlined in the Framework, with the goal of accelerating progress and guiding work between the Summits.<sup>4</sup>

Whether the TEC will herald a new era of more effective cooperation remains to be seen. Much could depend upon whether the TEC can exert enough political leverage to convince regulators to make reforms that will result in reduction of regulatory barriers between the EU and the United

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<sup>1</sup> For background on the European Union, see CRS Report RS21372, *The European Union: Questions and Answers*, by (name redacted) and (name redacted).

<sup>2</sup> For background on EU-U.S. commercial ties, see CRS Report RL30608, *EU-U.S. Economic Ties: Framework, Scope, and Magnitude*, by (name redacted); and CRS Report R41652, *U.S.-EU Trade and Economic Relations: Key Policy Issues for the 112th Congress*, by (name redacted).

<sup>3</sup> The NTA committed the United States and EU to work together to achieve four major goals, including the expansion of world trade and closer economic relations. Implementation of the agenda is guided by a joint EU-U.S. Action Plan which is coordinated by a group of senior level officials.

<sup>4</sup> For background on the 2007 U.S.-EU Summit and the TEC, see <http://www.whitehouse.gov/infocus/eusummit/2007/>.

States, as well as increase the role that legislators on both sides of the Atlantic play in the process. Six TEC meetings have been held since it was established in 2007, the most recent in November 2011 in Washington, DC.

This report is intended to serve as an introduction and primer on a complicated, broad, and often highly technical set of issues. It is presented in seven parts: the first section describes the nature and scope of U.S.-EU regulatory barriers; the second section explains the rationale for regulatory cooperation; the third section highlights the differences in U.S.-EU regulatory approaches; the fourth section examines the various forms of regulatory cooperation; the fifth section evaluates the results of past initiatives at regulatory cooperation; the sixth section analyzes the creation and operation of the Transatlantic Economic Council; and the last section highlights the role of Congress in transatlantic regulatory cooperation. This report will be updated as events warrant.

## **U.S.-EU Regulatory Barriers**

Since the mid-1990s, both U.S. and European multinational companies (MNCs) have viewed divergent ways of regulating markets for both goods and services as the most serious barriers to transatlantic commerce. Redundant standards, testing, and certification procedures are seen by these companies as far more costly and harmful than any trade barriers imposed at the border, such as tariffs or quotas. While the purpose of many regulations is to protect consumers and the environment, divergent domestic regulations and standards can affect the competitive position of firms, helping some and disadvantaging others by affecting the importation of products not produced or grown according to those requirements.<sup>5</sup>

To the extent that product standards differ, exporters may find their goods prohibited from certain markets or subject to expensive re-labeling, re-packaging, or re-testing. For example, European winemakers intending to sell in the U.S. market must label their bottles according to U.S. requirements, which are different than EU requirements. Similarly, U.S. exports to the EU of poultry washed with anti-microbial treatments have been blocked for years by different health and safety standards.

Different regulations add to the cost of doing business on both sides of the Atlantic and serve as non-tariff barriers to trade in many different economic activities and sectors. These include but certainly are not limited to differences in accounting and financial reporting requirements, antitrust or competition procedures, consumer protection (safety and health) standards, environmental regulations, and personal data transmission. Each of these divergences can materialize into politically charged disputes and threaten the functioning of the transatlantic market.

In no area has this been a greater problem than in chemicals. In this sector, the United States and EU have fundamentally different regulations on issues such as genetically modified organisms (GMOs), hormones, and the registration and restriction of chemical substances. In the case of GMOs, these differences have translated into longer authorization times and stricter standards for approval, release, and marketing of GMOs in the EU than in the United States. Moreover, GMOs

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<sup>5</sup> Daniel C. Esty, "Regulatory Competition in Focus," *Journal of International Economic Law* (2000), pp. 215-217.

have been the subject of a long and bitter trade dispute brought before the World Trade Organization.<sup>6</sup>

Pharmaceuticals is another sector where regulatory differences have been described as not only significant, but also bewildering. Just in the area of drug approvals, primary regulatory elements governing testing protocols, submission of clinical data, and certification of good manufacturing practices vary considerably between the United States and EU. Moreover, within the EU, where public health policy is still a national prerogative, rules and protocols can vary greatly from member state to member state. Because each member state has its own rules and protocols, it can be quite expensive for pharmaceutical companies to achieve marketing authorization throughout the EU or even a subset of countries.<sup>7</sup>

Another example comes from the automotive sector, where American and European car makers sell similar products in the United States and Europe. But there are different standards and testing requirements for all kinds of parts, ranging from headlights, wiper blades, light beams, and seat belts to crash standards—which critics maintain are without measurable differences in safety benefits. There are even multiple crash test dummies of the same or similar size and purpose—a clear example of where regulatory requirements diverge.<sup>8</sup>

Despite the salience of regulatory barriers in transatlantic commerce, a comprehensive, sector-by-sector study or inventory of regulatory barriers has not been undertaken. Proponents argue that such a report could identify regulatory differences that impose substantial burdens on transatlantic commerce and possibilities for their reduction or convergence without compromising either U.S. or EU health and safety priorities. In 2003, the European Commission (EC) proposed that such a study be undertaken and jointly funded, but the U.S. government did not back the initiative. Both sides, however, note the major regulatory divergences that are considered trade barriers in their respective annual trade barrier reports. In the 2008 U.S. trade barriers report, for example, 12 pages are devoted specifically to EU regulatory barriers.<sup>9</sup>

## **Rationale for Transatlantic Regulatory Cooperation**

Efforts to enhance TRC draw on both economic and political justifications and are strongly supported by business interests and governments on both sides of the Atlantic. At the same time,

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<sup>6</sup> Reinhard Quick, “Transatlantic Regulatory Cooperation on Chemicals—An Idealist’s Dream?,” German Marshall Fund Academic Research Conference, Ford School, University of Michigan. Available at [http://www.fordschool.umich.edu/news/events\\_details/re\\_coop\\_and\\_comp\\_08/](http://www.fordschool.umich.edu/news/events_details/re_coop_and_comp_08/), and Gregory C. Shaffer and Mark A. Pollack, “Reconciling Regulatory Differences: The Ongoing Transatlantic Dispute over the Regulation of Biotechnology,” in *The Future of Transatlantic Economic Relations*, edited by David M. Andrews, Mark A. Pollack, Gregory C. Shaffer, and Helen Wallace, Robert Schuman Centre for Advanced Studies, 2005, pp. 220-221.

<sup>7</sup> Keith Maskus and Yin He, “Trans-Atlantic Regulatory Cooperation in Pharmaceuticals: An Intellectual Property and Trade Perspective,” German Marshall Fund Academic Policy Research Conference, May 8-9, 2008, Ford School, University of Michigan, p. 8. Available at [http://www.fordschool.umich.edu/news/events\\_details/reg\\_coop\\_and\\_comp\\_08/](http://www.fordschool.umich.edu/news/events_details/reg_coop_and_comp_08/).

<sup>8</sup> Vann H. Wilber and Paul T. Eichbrecht, “Transatlantic Trade, the Automotive Sector: The Role of Regulation in a Global Industry, Where We Have Been and Where We Need To Go, How Far Can EU-US Cooperation Go Toward Achieving Regulatory Harmonization,” German Marshall Fund Academic Policy Research Conference, Ford School, University of Michigan, p. 7. Available at [http://fordschool.umich.edu/news/events\\_details/re\\_coop\\_and\\_comp\\_08/](http://fordschool.umich.edu/news/events_details/re_coop_and_comp_08/).

<sup>9</sup> Office of the U.S. Trade Representative, 2008 National Trade Estimate Report on Foreign Trade Barriers, pp. 9-21. Available at <http://www.ustr.gov>.

within the United States, some interests, mostly academics, see greater benefits derived from regulatory competition and independence, whereby each side is free to maintain its own approach to regulating consumer, health, and environmental issues. The case for non-cooperation or at least caution is also based on concerns that domestic health and safety standards may be compromised by a process that is driven substantially by business interests and stakeholders and could be affected by a “race to the bottom” regarding U.S. and EU standards.

## **Economic Rationale**

The primary reason why many export industries seek to achieve greater harmonization in international standards is to reduce costs associated with complying with two different sets of regulations and standards. To the extent that transatlantic regulatory standards and procedures differ, the costs of engaging in transatlantic commerce increase.<sup>10</sup>

A good example comes from the auto industry. According to a trade association, a U.S.-based producer of light trucks looked into exporting a model to Europe and found that its design was incompatible with a European regulation on exterior edge projection (the United States has no comparable standard). The truck was never exported because it would have required a major and costly re-design. The same truck manufacturer then undertook to ensure that another model on the drawing boards would have maximum export potential built into its design. In order to sell this product in Europe, the manufacturer reportedly utilized 100 unique parts, incurred an additional \$42 million in design and developmental costs, and committed an additional 130 people to the program. Yet, the performance of the vehicle, in terms of safety, was unchanged. European-based manufacturers face the same issues in reverse when contemplating selling a European-designed model in the United States. These separate regulations, in turn, may cost manufacturers millions of extra dollars to comply with, but may result in no changes in the vehicle in terms of safety or fuel economy.<sup>11</sup>

A 2005 OECD study is often cited to illustrate how costly regulatory barriers are to producers and consumers on both sides of the Atlantic. This study estimates that regulatory divergences between the United States and Europe costs the United States a sum that is equivalent to 1%-3% of GDP annually.<sup>12</sup>

In addition to cost savings that might be derived from the harmonization of regulations so as to facilitate open markets, it is argued that regulatory cooperation between states will help ensure that regulatory standards will not serve as obstacles to freer trade or unfair trade advantages.<sup>13</sup>

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<sup>10</sup> David Vogel, “Can it be done? Suggestions for better regulatory cooperation between the US and Europe,” *Transatlantic Thinkers #7*, BertelsmannStiftung, p. 3. Available at [http://www.bertelsmann-stiftung.de/cps/rde/xchg/bst\\_engl/hs.xsl/prj\\_7072-7084.htm](http://www.bertelsmann-stiftung.de/cps/rde/xchg/bst_engl/hs.xsl/prj_7072-7084.htm).

<sup>11</sup> Vann H. Wilber and Paul T. Eichbrecht, “Transatlantic Trade, the Automotive Sector: The Role of Regulation in a Global Industry, Where We Have Been and Where We Need To Go, How Far Can EU-US Cooperation Go Toward Achieving Regulatory Harmonization,” German Marshall Fund Academic Policy Research Conference, May 8-9, 2008, p. 5. Available at [http://fordschool.umich.edu/news/events\\_details/re\\_coop\\_andcomp\\_08/](http://fordschool.umich.edu/news/events_details/re_coop_andcomp_08/).

<sup>12</sup> OECD Working Paper No. 432, *On the Benefits of Liberalizing Product Markets and Reducing Barriers to International Trade and Investment: The Case of the United States and European Union* May 26, 2005.

<sup>13</sup> The initial impetus for promoting a transatlantic dialogue on regulatory standards was the European Community’s 1992 internal market program. At the heart of this program was an effort to establish European-wide standards. Progress along these lines raised concerns in the U.S. business community that the new standards and regulations could be used to disadvantage U.S. exporters and products.

Just as internal regulatory divergences can become a source of competitive advantage or trade tension, proponents of regulatory convergence assert that differences in emissions standards, labeling requirements, and attitudes towards public health risks between countries can become a market access barrier for foreign products or provide domestic producers with “unfair” competitive advantages.

Proponents of regulatory cooperation maintain that it could have the effect of preventing a welfare-reducing “race to the bottom” as jurisdictions seek to advance the competitiveness of their own industries through lax regulation or lower standards. This rationale for regulatory cooperation served to justify a large expansion of federal legislation and institutions in the United States in the areas of environmental regulation, consumer protection, health and safety, and labor protections. Similar fears of trade distortions and races to the bottom led to the implementation of sweeping harmonization programs and centralized legislation in the EU.<sup>14</sup>

Cast in the context of the global economy, some view TRC as a way for the United States and EU to promote global regulatory standards. In the absence of world standards, the United States and Europe are often competing for acceptance of their respective regulations in third markets. Proponents of TRC indicate that the net effect of this competition is that India and China can play the United States off against Europe, developing their own technical standards and financial regulations, complicating world trade for everyone.<sup>15</sup>

## **Political Rationale**

Supporters of TRC note that since the end of the Cold War, the United States and Europe have been searching for various ways to bolster the foundation of the relationship. Absent the common enemy embodied in the threat posed by the former Soviet Union, both sides have felt freer to pursue their own narrow economic and political interests. In the process, trade disputes have appeared to increase in frequency, focusing often on differences in regulation, rather than the traditional barriers of tariffs and subsidies.

To deal with the joint task of giving the relationship a new rationale as well as bolstering overall ties, numerous attempts have been made since the 1995 NTA to enhance transatlantic economic cooperation. In this context, efforts to advance regulatory cooperation have been part of attempts to reinvigorate and upgrade the bilateral relationship. Annual summits, attended by the U.S. President, the President of the European Commission, and the President of the European Council, have been the venue for bringing high-level political attention and focus on efforts to enhance transatlantic regulatory cooperation. Regulatory cooperation, now entailing an expanding group of stakeholders and networks, has become a significant component of the U.S.-EU economic relationship. Supporters argue that through such cooperation the partners may be able to find ways to amicably and expeditiously resolve commercial disputes, as well as establish joint approaches to a number of common regulatory challenges that have global importance.<sup>16</sup>

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<sup>14</sup> Daniel C. Esty and Damien Geradin, “Regulatory Co-opetition,” *Journal of International Economic Law* (2000), 235-255, p. 236.

<sup>15</sup> Transatlantic Policy Network (TPN), *Completing the Transatlantic Market*, February 2007, pp. 6-7. Available at <http://tpnonline.org>.

<sup>16</sup> Simon J. Everett and Robert M. Stern, “Condemned To Cooperate?,” German Marshall Fund Academic Policy Research Conference, May 8-9, 2008, University of Michigan, p. 7. Available at [http://www.fordschool.umich.edu/news/events\\_details/re\\_coop\\_08/](http://www.fordschool.umich.edu/news/events_details/re_coop_08/).



Because the United States and European Union collectively represent over 50% of global production, in areas where they can agree on a common regulatory policy or approach, they are well-positioned to promote it globally. Where they disagree, there is often deadlock, reflecting the equal size of their economies and markets.<sup>17</sup>

While there are other forums (such as the World Trade Organization and international treaties) to promote regulatory cooperation, they are seen as having shortcomings. The WTO, for example, promotes regulatory cooperation by giving some international standards legal effect, nudging WTO Members to actively participate in international standardization bodies. It also puts national provisions to the test in various committees and offers its members a platform to facilitate regulatory cooperation.<sup>18</sup> But the number of transatlantic regulatory differences that fall within the scope of WTO rules constitute a relatively small proportion of the regulatory policies and procedures that involve firms on both sides of the Atlantic. Moreover, the few regulatory-based trade disputes that the WTO has decided sometimes exacerbate rather than lessen tensions between the United States and EU.<sup>19</sup> For this reason, it is argued that the United States and EU need to develop bilateral mechanisms for coordinating their regulatory policies.<sup>20</sup>

## Counter-Arguments

Although there is strong support for TRC among business and government leaders on both sides of the Atlantic, the concept and rationale have their critics. This opposition is based, in part, on an alternative view of the benefits of regulatory competition as opposed to a centrally adopted regulatory framework constructed through regulatory cooperation. These mostly academic critics see benefits in variations in regulatory approaches across jurisdictions (either intra-state or interstate) as a way of disciplining overarching governments and creating incentives for bureaucratic efficiency. They argue that regulatory competition leads to the adoption of standards of varying stringency that efficiently match the needs and desires of each jurisdiction. Because conditions, tastes, and incomes tend to vary across jurisdictions, this school of thought maintains that an optimal regulatory policy for one jurisdiction will not necessarily be optimal for another.

Some consumer groups caution against the influential role that business groups play in transatlantic regulatory cooperation. The concern is that safety and health concerns may be compromised if business groups play such a prominent role in negotiations over testing requirements and standards for their own products. Rather than reducing barriers per se, the Trans Atlantic Consumers Dialogue maintains that the purpose of regulatory cooperation between the United States and EU should be to promote higher health and safety standards, thereby improving consumer welfare on both sides of the Atlantic.<sup>21</sup>

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<sup>17</sup> Gregory Shaffer and Mark Pollack, "How Hard and Soft Law Interact in International Regulatory Governance: Alternatives, Complements or Antagonists?," German Marshall Fund Academic Policy Research Conference, May 8-9, 2008. University of Michigan, p. 5. Available at [http://www.fordschool.umich.edu/news/events\\_details/reg\\_coop\\_andcomp\\_08](http://www.fordschool.umich.edu/news/events_details/reg_coop_andcomp_08).

<sup>18</sup> Reinhard Quick, "Regulatory Cooperation—A Subject of Bilateral Trade Negotiations or Even for the WTO?," *Journal of World Trade Law* 42(3), 2008, p. 405.

<sup>19</sup> David Vogel, *op. cit.*, p. 4.

<sup>20</sup> *Ibid.*, p. 5.

<sup>21</sup> Trans Atlantic Consumer Dialogue, "Position Paper and Resolution on Horizontal Regulatory Initiatives in EU-U.S. Regulatory Cooperation," February 2007. Available at <http://www.tacd.org/cgi-bin/db.cgi?page=view&config=admin/docs.cfg&id=322>.

Opponents of TRC assert from this perspective that a great number of centralized regulatory programs should be dismantled and regulatory powers should be decentralized. They believe that regulatory cooperation also reaches its limits where there is lack of institutional architecture to enforce decisions.<sup>22</sup>

## **U.S.-EU Differences in Regulatory Approaches**

Transatlantic regulatory cooperation must deal with a number of key differences between the United States and EU concerning approaches to regulation. Key differences bear on political cycles affecting regulation, public preferences and tolerance for risk, attitudes towards transparency, and institutional capacities to undertake regulatory reforms. These key differences—whether they pertain to product safety, environmental protection, securities trading, or customs procedures—in how regulations are developed and applied, in turn, raise challenges about whether and how to merge, harmonize, or converge the varied approaches. Until the regulatory structures themselves become more convergent or aligned, the major divergences in regulatory policies are unlikely to disappear.

### **Political Cycles**

Over the last 50 years, the political cycles of regulatory policy stringency and expansion in the EU and the United States have not moved together. In the process, many important European and American regulations have diverged.<sup>23</sup>

Beginning in the 1960s, many U.S. regulatory standards were likely more comprehensive and stringent than those adopted by the EU and most member states. The United States was typically first to identify new consumer and environmental risks and more likely to adopt relatively risk-averse or precautionary standards for dealing with those risks. For example, from the early 1960s through the mid-1980s, American standards for the approval of new pharmaceutical products were more stringent than in any EU member state, and American automobile emission standards were consistently more stringent than those adopted in Europe. The United States also restricted the use of lead in gasoline more rapidly than did Europe and also acted more aggressively to restrict the use of ozone-depleting chemicals.<sup>24</sup>

But over the last 15 years, a number of European standards have become more stringent and comprehensive than U.S. standards.<sup>25</sup> For example, European standards for the approval and labeling of genetically modified (GM) foods and seeds are far more stringent than those adopted by the United States. Recently approved legislation on chemicals (Registration, Evaluation, and Authorization of Chemicals or REACH) has made European standards for the approval of both existing and new chemicals much more demanding than in the United States. The EU has also

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<sup>22</sup> Reinhard Quick, *op. cit.*, p. 401.

<sup>23</sup> David Vogel, *op. cit.*, p. 14.

<sup>24</sup> *Ibid.*, p. 7.

<sup>25</sup> At the same time, in 1980s and throughout much of the 1990s, much of U.S. policy was driven by efforts to reduce the costs of protective regulations on American companies and, thus, improve the performance of the American economy.

moved more aggressively than the United States to impose restrictions on greenhouse gas emissions.

However, in the aftermath of rising concerns about the safety of imported products and the financial crisis caused by the proliferation of sub-prime mortgages, support for more aggressive regulatory actions is rising in the United States. If the pendulum in the United States swings back towards increased regulation, this may narrow some of the current transatlantic regulatory divergences.<sup>26</sup>

## **Values and Public Preferences**

Some transatlantic regulatory differences reflect different public preferences and values. For example, many European consumers tend to prefer “naturally produced” foods, while many American consumers are more accepting of products produced by advanced forms of agricultural production. This difference helps to explain, in part, why Europe has imposed restrictions on the use of growth hormones for both beef and dairy cows, while the United States has not. It also explains, in part, the relative lack of political controversy in the United States surrounding the introduction of biotechnology compared to the more negative response to this technology in Europe.<sup>27</sup>

The United States and EU also operate two different systems of risk management. As in the case of GMOs, the U.S. system is relatively science-based and prefers to regulate once significant problems have been identified. This approach has strong support of farmers, industry, and government officials. On the European side, the public tends to favor a more cautious approach, preferring to regulate out of precaution before a problem has occurred. The food safety scandals of the 1990s increased the resolve of EU member governments to put in place ever more strict regulation for the pre-approval, traceability, and labeling of all GMOs, independent of their individual safety characteristics.<sup>28</sup>

## **Transparency and Rule-Making**

The United States and EU provide for very different degrees of public participation in rule-making. In the United States, Congress passes laws, but generally grants broad authority to the administrative or regulatory agencies to implement those laws through regulations. On occasion, Congress also provides specific direction to these agencies.

Regulations proposed by U.S. administering agencies are subject to considerable public input due in large part to the requirements of the U.S. Administrative Procedures Act (APA), the Freedom of Information Act, and the Government in the Sunshine Act, which permit public scrutiny of regulatory activity. A myriad of laws, executive orders, and bulletins ensure that transparency remains part of the regulatory process. Federal agencies are required to publish in the Federal Register, not just the proposed rule, but the supporting justification for the rule and the entire analytic justification behind it.

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<sup>26</sup> Jackie Calmes, “Both Sides of the Aisle See More Regulation,” *New York Times*, October 14, 2008, p. 1.

<sup>27</sup> David Vogel, *op. cit.*, p. 6.

<sup>28</sup> Gregory C. Shaffer and Mark A. Pollack, *op. cit.*, p. 221.

EU directives (which serve the same function as U.S. regulations) tend to be developed by the European Commission without as much input from either the public, business, or elected officials. The European Parliament, however, has to approve or pass the directives (legislation) proposed by the Commission. While the EU has a number of “better regulation” procedures and guidelines, it has no effective equivalent to the APA.<sup>29</sup>

Recognizing that the United States and EU have become each other’s most important stakeholder, both sides may have an interest in ensuring that the other will have the opportunity, method, and forum for participating constructively in each other’s regulatory process.

## **Institutional Capacity to Undertake Reforms**

There also major differences in institutional capacities to undertake regulatory reforms. The EU’s institutional framework is well suited to making regulatory changes. In broad terms, the EU has developed as a regulatory state with the European Commission taking a leading role in coordinating European wide regulatory policies in pursuit of building a Single Market. The Commission has ample authority to coordinate cooperation on transatlantic regulatory issues. The regulatory culture within the EU internal market is considered “trade friendly” because EU and national regulators operate with dual missions to promote free trade within the internal market while ensuring public safety. But enforcement is usually left to member states, which often results in a different levels of enforcement and different treatment of European and U.S. companies.<sup>30</sup>

In general, U.S. regulatory agencies have the mandate and funding to focus on domestic regulatory issues and they enjoy a fair amount of independence on policy and implementation matters. However, the United States lacks a clear-cut institutional mechanism to coordinate cooperative efforts. And neither the Commerce Department nor the Office of U.S. Trade Representative (USTR), the lead agencies for U.S. undertakings in the realm of transatlantic regulatory cooperation, have authority to overhaul domestic regulatory policymaking. While Commerce and USTR may bring the heads of U.S. regulatory agencies to the negotiating table, the regulatory agencies are not usually funded nor mandated to engage in TRC activities.<sup>31</sup>

An added structural complication on the U.S. side is the role that states play in regulating activities, particularly professional services. Insurance, banking, private pension fund management, and professional services such as engineering and architecture are all subject to state regulation (and some sectors exclusively).<sup>32</sup>

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<sup>29</sup> Testimony of Gerard Depayre, Deputy Head of Delegation, European Commission to the United States, “U.S.-EU Cooperation on Regulatory Affairs,” Hearing Before the Subcommittee on European Affairs of the Committee on Foreign Relations, U.S. Senate, 108<sup>th</sup> Congress, 1<sup>st</sup> session, October 16, 2003, p. 20.

<sup>30</sup> Kalypso Nicolaidis and Rebecca Steffenson, “Managed Mutual Recognition in the Transatlantic Marketplace,” in *The Future of Transatlantic Economic Relations*, p. 147.

<sup>31</sup> Maria Green Cowles, “Calming the Waters: The Rebirth of the Transatlantic Business Dialogue,” in *The Future of Transatlantic Economic Relations*, p. 285.

<sup>32</sup> Kalypso Nicolaidis and Rebecca Steffenson, p. 152.

## Forms of Transatlantic Regulatory Cooperation

Regulatory cooperation is an elastic concept that subsumes a broad range of activities. At one end of the spectrum, these activities may include simple discussions and sharing of information between regulators—most often on prospective regulations. At the other end of the spectrum, these activities may involve attempts at harmonizing regulatory approaches through acceptance of common principles and standards. In between are activities that involve varying degrees of intrusion into the autonomy of regulators. One such category is agreements that recognize each other's standards or certification procedures. These agreements are known as MRAs or mutual recognition agreements. The line between each category can be arbitrary and vague, and there are other activities associated with regulatory cooperation that may not fall neatly into one of the above categories.<sup>33</sup>

To date, most efforts at transatlantic regulatory cooperation have been associated with information exchanges and dialogues. Considerable efforts have also been made at negotiating MRAs for a range of goods, as well as other attempts to recognize the adequacy of each others standards in specific areas such as data privacy and accounting. Little has been undertaken in regard to harmonization of standards. What follows is a short elaboration of activities that apply to each of these regulatory activities.

### Information Exchanges and Dialogues

The most basic form of regulatory cooperation involves the establishment of a working group or dialogue for an exchange of information. The group, which may be comprised of technical experts or regulators from different jurisdictions, may meet on an ad hoc and informal basis or may be more structured. A primary objective of these consultations may be to better understand technical differences in standards or regulations and to consult with each other prior to new regulations becoming effective.

Making an effort to work with or consult with each other prior to new regulations becoming effective is viewed as one way to minimize unnecessary regulatory barriers. The exchange of people and information is also expected to build trust and confidence, with the hope of making for more informed and coordinated regulations and may eventually lead to agreement on what constitutes best regulatory practice.

While an exchange of views and a discussion of different issues will not necessarily bring about a meeting of the minds in the technical assessment of a certain field of regulation, it is a necessary first step if convergence is to take place. Where there is no attempt at dialogue, efforts to restrain unilateral legislative actions that could create new regulatory barriers are unlikely to be successful.<sup>34</sup>

In the transatlantic context, a number of U.S. regulatory agencies (e.g., the Securities and Exchange Commission, the Food and Drug Administration, the National Highway Traffic Administration, and the Occupational Safety and Health Administration) have engaged in these

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<sup>33</sup> Alan O. Sykes, "Regulatory Competition or Regulatory Harmonisation? A Silly Question?," *Journal of International Economic Law* (2000), pp. 257-264.

<sup>34</sup> Reinhard Quick, "Regulatory Cooperation," *op. cit.*, p. 402.

kinds of information exchanges and non-binding dialogues with their European counterparts over the past decade. These exchanges were encouraged by the *Guidelines on Regulatory Cooperation and Transparency* which the United States and EU negotiated as part of the 1998 Transatlantic Economic Partnership (TEP). The guidelines were intended to enhance cooperation between EU and U.S. regulators in the development of technical regulations and specifically referred to regular consultation, exchange of data and information, as well as informing one another at an early stage on planned new regulation.

Since 2004, the annual U.S.-EU summits have reinforced efforts at regulatory cooperation. A *Roadmap for Regulatory Cooperation* provides a framework of specific activities in 15 different sectors (e.g., pharmaceuticals, telecommunications equipment, food safety, and auto safety). Subsequent summits have prescribed cooperation for “lighthouse projects” in the fields of intellectual property rights, secure trade, financial markets, innovation, and technology, as well as the elimination of obstacles to investment. In addition, a *High Level Regulatory Cooperation Forum*, comprised of regulators from both sides, was established to find common ground on horizontal issues such as risk assessment, cost-benefit analysis, and impact analysis when promulgating regulations.

## **Mutual Recognition Agreements**

A stronger form of cooperation involves MRAs. This cooperation entails an agreement by regulators to accept products or services from another jurisdiction under specified conditions, so that actors complying with the regulations of one jurisdiction will be considered to be in compliance with the rules in another jurisdiction. These kind of agreements can focus on the mutual recognition of conformity assessment certifications or the alignment of relevant standards.

Under full recognition of standards, companies, for example, could sell pharmaceuticals in the United States after meeting European standards without first obtaining FDA approval. An agreement on conformity assessment procedures is a smaller step, requiring domestic regulators to accept the competency of their foreign counterparts to conduct product testing, inspection, or certification. The basic premise behind this kind of MRA is that products could be tested once and considered to have been tested in both markets.<sup>35</sup>

In 1998, the United States and EU completed an MRA for testing and certification requirements covering multiple sectors, including telecommunications and information technology equipment, pharmaceuticals, electronics, electromagnetic compatibility, sports boats, and medical devices. The MRA did not provide for mutual recognition of product standards, but it identified certification bodies in the exporting country that could assess the conformity of a range of traded goods with standards of the destination country. The MRAs, thus, introduced competition between assessors or certification bodies.

Competition among certification entities was familiar in Europe, where private firms had long provided certification, but was new in the United States, where government agencies had dominated the process. As a result, while some U.S. officials believed that the MRAs would lead

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<sup>35</sup> Testimony of Stuart Eizenstat, European-American Business Council, Hearing on U.S.-EU Cooperation on Regulatory Affairs, Subcommittee on European Affairs of the Committee on Foreign Relations, U.S. Senate, 108<sup>th</sup> Congress, 1<sup>st</sup> session, October 16, 2003, p. 29.

to cheaper and more rapid certification, others were concerned about its implications for product safety.<sup>36</sup>

The MRAs did not result in any kind of binding legal agreement between the United States and the EU. Rather they were accomplished through an exchange of letters between the heads of the relevant regulatory agencies. To be implemented successfully, MRAs require that regulators on both sides of the Atlantic have confidence that the other side will not try to attract more business by being deliberately lax. Similarly, regulators need to recognize that each other's safety standards and inspection requirements are basically equivalent.<sup>37</sup>

## **Harmonization/Agreement on Regulatory Standards**

The strongest form of regulatory cooperation involves harmonization or agreement on the same standards or rules applied across jurisdictions. This could extend not only to regulatory targets (e.g., the permissible level of a particular pollutant in each jurisdiction or reserve requirements among banks), but also to the manner by which regulators ensure compliance with their regulations.

In the transatlantic context, few precedents exist for acceptance or adoption of similar or identical standards. While there have been numerous political declarations calling for regulatory convergence and harmonization, few changes have been enacted in each side's existing laws that would move their regulatory regimes in this direction. The transatlantic market, of course, is not a single market with common institutions pushing for further economic integration. But various stakeholders, frustrated by the slow progress in transatlantic regulatory cooperation, have made proposals that could push the two sides in the direction of adopting a new institutional architecture, such as a binding regulatory cooperation agreement.<sup>38</sup>

Those who see a binding treaty or regulatory cooperation agreement as necessary institutional architecture to achieve a transatlantic single market point to EU integration as a model. In moving towards the completion of a Single European Market, the Commission issued a white paper that listed the pieces of legislation requiring harmonization, and simultaneously identified the institutional mechanisms to achieve specified ends.<sup>39</sup>

U.S. public support for such an approach could depend on whether the goal of such a treaty or legal agreement was the development of identical legislation or comparable legislation. If the goal was identical legislation, much resistance to this kind of deeper integration could be expected from a number of quarters. This is particularly true from stakeholders who view movement in this direction as leading to a loss of regulatory autonomy for U.S. authorities. If the goal was the

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<sup>36</sup> Charan Devereaux, Robert Z. Lawrence, and Michael D. Watkins, "The U.S.-EU Mutual Recognition Agreements," in *Case Studies in US Trade Negotiations*, in *Making the Rules*, Vol. 1, Institute for International Economics, 2006, p. 304.

<sup>37</sup> Stuart Eisenstadt, *op. cit.*, p. 24.

<sup>38</sup> The U.S. Chamber of Commerce, for example, has proposed an Agreement on Regulatory Cooperation (ARC), a legally binding regulatory cooperation agreement that would oblige both sides to operate under a common set of regulatory principles and core beliefs. The ARC would require regulators to assess the cost impact of forthcoming regulations on transatlantic commerce, adopt other's best practices where possible, and utilize a similar methodology to assess costs and benefits of proposed regulations. See Chamber of Commerce of the United States, Correspondence to U.S. Office of Management and Budget and to the Secretariat General, European Commission, February 8, 2008.

<sup>39</sup> Reinhard Quick, "Regulatory Cooperation," p. 401.

development of similar or comparable legislation that facilitates mutual recognition, much less resistance perhaps could be expected.<sup>40</sup>

## Results of Past Initiatives at Regulatory Cooperation

The United States and EU have pursued a variety of policy initiatives and new mechanisms over the past 15 years to reduce or eliminate regulatory barriers. The results have been mixed. A number of these initiatives have been successful in some regulatory areas, while transatlantic regulatory cooperation has not made material differences for businesses or consumers in some other sectors. Assuming it is concluded that stronger regulatory cooperation is desirable, an assessment of past efforts could be useful.

### Highlights of Past Initiatives

Beginning in 1990 with the Transatlantic Declaration, regular U.S.-EU summits were initiated to reinvigorate and upgrade the bilateral relationship. Attended by the U.S. President, the President of the European Commission, and the President of the European Council, the summits were intended to bring high-level focus to cooperative activities. Successive summits have led to a number of agreements relating to transatlantic regulatory cooperation:

- At the 1995 summit in Madrid, the United States and EU formally adopted the New Transatlantic Agenda (NTA) in an effort to provide a new foundation for the partnership. The NTA was accompanied by a detailed action plan. In addition, the NTA set up a comprehensive and regular government-to-government dialogue, as well as four dialogues between stakeholders on both sides of the Atlantic. These included the Transatlantic Business Dialogue (TABD), the Transatlantic Labor Dialogue (TALD), the Transatlantic Environmental Dialogue (TAED) and the Transatlantic Consumer Dialogue (TACD).
- Pursuant to the NTA, the two sides focused particular attention on problems posed by divergent standards and certification systems. In addition to promoting the convergence in regulatory systems, efforts were undertaken to negotiate MRAs covering several sectors. In 1998, MRAs affecting sectors such as electrical equipment, pharmaceutical products, telecommunications, and information technology equipment were reached.
- At the 1998 summit in London, the Transatlantic Economic Partnership (TEP) was created to improve bilateral economic and trade relations and to help create a more open world trading system. The TEP established deadlines for particular actions within the areas of regulatory cooperation, mutual recognition, and consumer product safety.
- At the Bonn Summit in June 1999, a Joint Statement on *Early Warning and Problem Prevention Mechanisms* was adopted. The warning system was designed to identify regulations, preferably still in draft form, that might contribute to non-tariff barriers to trade.

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<sup>40</sup> Ibid.



- At the 2000 U.S.-EU Summit in Lisbon, the Consultative Forum on Biotechnology was established to improve communication and understanding on the various concerns involved in biotechnology.
- At the May 2002 summit in Washington, the two sides reached agreements on *Guidelines for Regulatory Cooperation and Transparency*. These sought to take the idea of an early warning system a step further by encouraging U.S. and EU regulatory agencies to consult on a voluntary basis, sharing work plans that identify areas of anticipated regulatory action for the coming year and offering opportunities for reaction before regulations are finalized.<sup>41</sup>
- Moving towards a more systematic cooperative approach, a *Roadmap for EU-U.S. Regulatory Cooperation and Transparency* was developed in June 2004. It listed 10 specific projects for regulatory discussion and also expanded the approach to horizontal initiatives.
- The 2005 EU-U.S. Summit produced a second *Roadmap for EU-U.S. Regulatory Cooperation and Transparency* and expanded the list to 15 sector-specific projects. It also established two new dialogues. One was between the European Commission and Office of Management and Budget on transparency and methodologies for impact and risk assessment, in order to improve understanding of each other's regulatory systems. A second, a *High-Level Regulatory Cooperation Forum*, was tasked to develop a joint regulatory work plan based on mutual best practices. Its members include senior U.S. and European Commission officials, academics, business executives, and other officials.

## Accomplishments

Among the accomplishments are the following:

1. Most observers would agree that new mechanisms for dialogue and information exchange have improved mutual understanding and day-to-day working relationships among economic regulators in a wide range of sectors; Arguably, cooperation is now far deeper, broader, more decentralized and routine than it had been before in areas such as pharmaceuticals, medical devices, financial services, and marine equipment.
2. The NTA process and related efforts at regulatory cooperation fostered closer relationships among many stakeholders, including business people representing the major corporations investing in both Europe and the United States. In particular, the TABD, representing a transatlantic coalition of big businesses on both sides of the Atlantic, developed into an “effective framework for enhanced cooperation between the transatlantic business community and the governments of the European Union and the United States.”<sup>42</sup>
3. The NTA and subsequent summits enhanced on-going efforts to increase the compatibility of U.S. and EU approaches to competition policy. According to one observer, much convergence in

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<sup>41</sup> The Atlantic Council of the United States, *Risk and Reward: U.S.-EU Regulatory Cooperation on Food Safety and the Environment*, Policy Paper, November 2002, p. 7.

<sup>42</sup> Maria Green Cowles, “Calming the Waters: The Rebirth of the Transatlantic Business Dialogue,” p. 278.

substantive standards has been achieved voluntarily through the exchange of ideas and institutional learning processes.<sup>43</sup>

4. MRAs (discussed previously) covering over \$50 billion in trade were implemented in three sectors, leading to significant cost savings for U.S. businesses; several of the agreements provided for U.S. and EU testing facilities to recognize each other's standards over time, thus allowing firms to have products tested only once on either side of the Atlantic. The Commerce Department estimated that the agreement would save U.S. industries more than \$1 billion in testing and certification costs.<sup>44</sup>

5. The 2002 *Guidelines for Regulatory Cooperation* promoted a number of procedural steps that most likely have facilitated a more effective dialogue. These steps included arrangements to permit sharing of non-public information between regulators. The *Roadmap for Regulatory Cooperation* now provides a framework for consultations and dialogue in 15 different sectors (e.g., pharmaceuticals, telecommunications equipment, food safety, and auto safety) with a focus on prospective regulations and reducing regulatory barriers.

6. The U.S.-EU Safe Harbor Agreement was implemented in 2002. This agreement provided an innovative mechanism whereby U.S. firms could be certified as meeting the EU's more demanding data privacy requirements for exporting personal data.

7. In February 2004, the United States and EU signed an MRA on marine safety equipment covering \$150 million to \$200 million annually in two-way trade.<sup>45</sup>

8. The *U.S.-EU High Level Regulatory Cooperation Forum*, established in 2005, has focused on methodologies for generating good regulatory practices. To the extent both sides are able to develop a methodological framework that ensures the comparability of regulatory reviews, with an emphasis on risk assessments, cost/benefit analysis, and trade and investment impacts, unilateral legislative initiatives, and the creation of new regulatory barriers can be curtailed.

9. By 2006 the Financial Markets Regulatory Dialogue had reported some progress on recognizing each others' financial standards in specific areas.<sup>46</sup> In particular, progress has been made on gaining the mutual acceptance by 2009 of the equivalence of accounting standards—that is, the U.S. Generally Accepted Accounting Principles (GAAP) and International Financial Reporting Standards (IFRS). This will make it easier for European companies to raise capital in the United States and for U.S. companies to raise capital in Europe.<sup>47</sup>

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<sup>43</sup> Robert Anderson, "Competition (Antitrust) Policy: What Balance of Cooperation and Regulation in the Transatlantic Sphere?," German Marshall Fund Academic Policy Research Conference, May 8-9, 2008, Ford School, University of Michigan, p. 5. Available at [http://www.fordschool.umich.edu/news/events\\_details/reg\\_coop\\_and\\_comp\\_08/](http://www.fordschool.umich.edu/news/events_details/reg_coop_and_comp_08/).

<sup>44</sup> Maria Green Cowles, "Calming the Waters: The Rebirth of the Transatlantic Business Dialogue," p. 280.

<sup>45</sup> Charon Devereaux, Robert Z. Lawrence, and Michael D. Watkins, "The U.S.-EU Mutual Recognition Agreements," p. 348.

<sup>46</sup> Elliott Posner, "Market Power without a Single Market: The New Transatlantic Relations in Financial Services," In *The Future of Transatlantic Economic Relations: Continuity Amid Discord*, July 2005.

<sup>47</sup> Andreas Noelke, Johan Wolfgang Goethe Universitat, "Transatlantic Regulatory Cooperation on Accounting Standards: A 'Varieties of Capitalism' Perspective," German Marshall Fund Academic Policy Research Conference, May 8-9, 2008, Ford School, University of Michigan. Available at [http://fordschool.umich.edu/news/events\\_details/reg\\_cop\\_and\\_comp\\_08/](http://fordschool.umich.edu/news/events_details/reg_cop_and_comp_08/).

## Disappointments

Specific disappointments include the following.

1. Enthusiasm for mutual recognition as a regulatory strategy faded when three of the six agreements failed to become operational by established deadlines.<sup>48</sup> In the view of some analysts, these MRAs were never implemented due to the U.S. reluctance to recognize the equivalency of European certifiers. In the pharmaceutical and medical device sectors, for example, the FDA had continuing doubts about the capability of some EU member states to oversee high pharmaceutical standards in laboratories. In the electrical equipment sector, OSHA refused to cede its right to designate which laboratories in Europe could evaluate and certify new electrical products for sale in the United States.<sup>49</sup> A related obstacle on the European side was the EU inclination to regulate at the European level, only to leave enforcement to Member States, which often results in different levels of enforcement and different treatment of European and U.S. companies.<sup>50</sup>
2. Irrespective of annual summits, the TEP, by some accounts, went into hibernation from 1998 to 2004. Despite the many recommendations and political declarations issued during this time period, there were few material accomplishments.<sup>51</sup>
3. Pieces of legislation adopted unilaterally by both sides in 2002 served to put a break on regulatory cooperation by violating the *2002 Guidelines on Regulatory Cooperation* and the “*Early Warning System*.” On the one side, the EU imposed its views on how to regulate chemicals by adopting legislation known as REACH, which affected the testing and approval of chemicals, without much input from U.S. stakeholders. On the other side, the United States adopted legislation (Sarbanes-Oxley), which reformed public accounting standards, without taking into account EU views. Both pieces of legislation created considerable difficulties for transatlantic businesses, from companies attempting to raise capital to firms that manufacture everyday goods.
4. Despite extensive efforts at cooperation for nearly two decades, the transatlantic regulatory divide remains large in the area of chemicals. The two sides still maintain fundamentally different regulations on issues such as hormones, genetically modified organisms (GMOs), cosmetics, and the registration and restriction of chemical substances. U.S. and EU regulators continue to operate with starkly different regulatory philosophies and styles. And the record of transatlantic regulatory cooperation in this sphere has been highly contentious, prompting the United States to file a legal complaint with the WTO.<sup>52</sup>

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<sup>48</sup> Kalypso Nicolaidis and Rebecca Steffenson, “Managed Mutual Recognition in the Transatlantic Marketplace,” p. 148.

<sup>49</sup> Gregory Shaffer, “Managing U.S.-EU Trade Relations Through Mutual Recognition and Safe Harbor Agreements: ‘New’ and ‘Global’ Approaches to Transatlantic Economic Governance?”, 9 *Columbia Journal of European Law*, 29-77 (Fall 2002), p. 43.

<sup>50</sup> Stuart Eizenstad, op. cit. p. 26.

<sup>51</sup> Reinhardt Quick, “Regulatory Cooperation,” p. 399.

<sup>52</sup> Reinhardt Quick, “Transatlantic Regulatory Cooperation on Chemicals—An Idealist’s Dream?,” German Marshall Fund Academic Policy Research Conference, May 8-9, 2008, Ford School, University of Michigan. Available at [http://fordschool.umch.edu/nas/events\\_details/reg\\_coop\\_and\\_comp\\_08/](http://fordschool.umch.edu/nas/events_details/reg_coop_and_comp_08/).

5. There has been lack of material progress in many other sectors, such as autos, and pharmaceuticals. Moreover, past TRC initiatives have tended to be fragmented, poorly coordinated, and lacking in political accountability for success and failure.<sup>53</sup>

## **Obstacles and Options for More Extensive Cooperation**

In evaluating the history of past initiatives, a number of observers have pointed to several key obstacles to more effective regulatory cooperation. High on this list are the independence of regulatory agencies involved, the lack of committed resources for transatlantic regulatory collaboration, and the sheer complexity of the undertaking. To promote more effective TRC by overcoming these obstacles, three policy options are often put forth: (1) attracting high-level political support for TRC; (2) increasing dramatically the involvement of legislators on both sides in the process; and (3) developing an institutional architecture that can prioritize the problems and challenges that need to be addressed.

Regulatory cooperation, particularly mutual recognition, requires domestic regulators to accept the competency of their foreign counterparts to conduct product testing. A key obstacle, however, is that regulators remain accountable to domestic legislators for the product standards that are applied both to domestic and foreign products. As a result, regulators on both sides of the Atlantic are generally reluctant to transfer authority to a foreign body, and the MRA negotiations demonstrated that some regulatory bodies are more reluctant than others.<sup>54</sup>

Based on the premise that enhanced regulatory cooperation, particularly through mutual recognition, will never happen if matters are left to individual regulatory agencies, high-level political pressure is commonly prescribed. Such pressure, either from the White House, the Congress, or both, may be employed to convince regulators to adopt reforms that result in a reduction of barriers between the United States and EU and/or to make greater efforts to accommodate transatlantic interests when promulgating new regulations.

Successful regulatory cooperation also requires resources for the necessary meetings and dialogues to take place. At least on the U.S. side, the regulatory agencies have no dedicated budgets to support these activities. Accordingly, some stakeholders, such as the U.S. Chamber of Commerce, have proposed that Congress consider the creation of specifically funded mandates to enable U.S. agencies better participate in these transatlantic dialogues.

The scope of the transatlantic regulatory agenda is also extremely broad and technical. Encompassing most regulatory agencies, ranging from the Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC) to the National Highway Traffic Safety Administration (NHTSA) and the Environmental Protection Agency (EPA), and diverse sectors, ranging from pharmaceuticals and cosmetics to telecommunications and marine safety, the status of the agenda at any one time is not easy to ascertain. To move issues forward that are by their nature abstract and technical, some observers have called for creation of a institution that is capable of setting priorities and deciding on which issues are ripe for resolution with the help of higher-level political intervention.

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<sup>53</sup> Testimony of Kathryn Hauser, U.S. Executive Director of the Transatlantic Business Dialogue, House Committee on Financial Services, "The U.S.-EU Economic Relationship: What Comes Next?," June 16, 2005, p. 9.

<sup>54</sup> Kalypso Nicolaidais and Rebecca Steffenson, p. 145.

## The Transatlantic Economic Council

Predicated on the notion that past initiatives failed to make significant progress in enhancing regulatory progress, the Transatlantic Economic Council (TEC) was established in April 2007 at the U.S.-EU Summit as a key component of the *Framework for Advancing Transatlantic Economic Integration*. Created as a new entity by German Chancellor Angela Merkel (then EU Council President), European Commission President Barroso, and President Bush, the TEC is designed to provide minister-level political guidance for implementation of a work program as outlined by the *Framework* to foster regulatory cooperation and to reduce or eliminate regulatory burdens to trade. The Summit leaders also created an advisory group to the TEC and invited the U.S. Congress, along with the European Parliament, to accept a new, more substantive role in transatlantic regulatory cooperation by becoming part of an advisory group. In short, the TEC and the *Framework* are designed to deal with some of the suggested shortcomings (described above) of previous transatlantic regulatory initiatives: lack of high level political leadership and not enough involvement of legislators and other stakeholders in the regulatory process.

The TEC consists of two co-chairs (ministerial-level appointees with cabinet rank) from each side, as well as a number of EU Commissioners and U.S. Cabinet members for the broad-ranging policy areas covered in the *Framework*. Permanent members of the TEC include the Secretaries of the Treasury and Commerce and the U.S. Trade Representative and the European Commissioners for External Relations, for Trade and Internal Market and Services. In addition, other U.S. Cabinet members and European Commissioners may participate when the agenda covers issues falling under their jurisdiction.<sup>55</sup>

Given that the two TEC leaders are cabinet-level appointees, the TEC was expected to have the kind of high-level political support that previous efforts at economic integration may have lacked. Such clout, it is argued, may be needed to persuade domestic regulators to yield some of their authorities or to better cooperate with their counterparts across the Atlantic in harmonizing regulatory approaches.<sup>56</sup>

TEC efforts to foster cooperation and reduce regulatory barriers focus on two main types of issues: (1) differences in regulatory processes and approaches; and (2) sectoral or bilateral barriers and disputes. The goal in the first issue area is to find ways to reduce barriers to transatlantic economic integration posed by new regulations and or prevent them from happening. The primary avenue for accomplishing this objective entails efforts to reform, harmonize or converge regulatory processes, both through the development of comparable methodologies to assess risk and do cost-benefit analysis and intensified interactions among regulators. How regulations are developed and applied can have a large impact on the how companies do business not only in the transatlantic marketplace, but in third markets as well.

The goal in the second issue area is to reduce barriers to transatlantic integration caused by regulations in specific sectors. This is to be accomplished by intensified sector-by-sector cooperation, including the promotion of the 2002 U.S.-EU Guidelines for Regulatory Cooperation

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<sup>55</sup> To co-chair the TEC, the Obama Administration appointed Michael Froman, Deputy National Security Advisor for International Economic Affairs, National Economic Council. The EU co-chair is the EU Trade Commissioner, Karel De Gucht.

<sup>56</sup> For more information on the TEC, see Section IV in the U.S.-EU Framework for Advancing Transatlantic Economic Integration, April 2007, available at <http://www.whitehouse.gov/releases/2007/04/20070430-4.html>.

and case-by-case examination of specific projects called for by the Roadmap for Regulatory Cooperation.<sup>57</sup>

In the first three years (2007-2009) of its five-year history, the TEC was used primarily as a mechanism to try to resolve a number of longstanding bilateral trade disputes, most notably the EU's ban on imports of chlorine-washed poultry. Efforts to harmonize regulations on a sector-by-sector basis also proved difficult due to political and bureaucratic resistance on both sides to revise existing laws and regulations. In late 2010, the two sides agreed to focus future efforts on aligning regulations and standards in emerging or new technologies, (such as nanotechnology or electric cars) well before laws or regulations have been promulgated. Accordingly, at their fifth recent meeting, held in Washington on December 17, 2010, the TEC agreed to a work program focusing on sectors where regulatory cooperation can help preclude unintended trade barriers.

Among the highlights of this TEC meeting, the two sides agreed to develop a process to implement compatible approaches for the regulation of new and innovative sectors, with the hope of avoiding trade disputes due to different regulations. The meeting also provided new impetus for regulatory cooperation in specific sectors such as electronic health records, energy-saving products, and electric vehicles, as a way of reducing costs and preempting unnecessary obstacles to exports. Finally, the TEC meeting launched an Innovation Action Plan designed to strengthen joint efforts to promote innovation and the commercialization of emerging technologies.<sup>58</sup>

At its sixth meeting held in November 2011, TEC leaders reviewed accomplishments in 2011 and established priorities for 2012. Among the accomplishments, the TEC noted a number of steps taken to develop a transatlantic market for electric vehicles and endorsed a work plan for e-mobility, electric vehicles, and related infrastructure. As in many other areas supported by the TEC, it remains to be seen whether the results will prove tangible and commercially significant. This is due, in part, to the fact that regulatory cooperation is difficult and technically demanding work, with wide differences between the two sides concerning approaches to regulation.<sup>59</sup>

## Role of Congress<sup>60</sup>

Since it began nearly two decades ago, transatlantic regulatory cooperation has been for the most part a wholly run undertaking between the executive branches and independent regulatory agencies on both sides of the Atlantic. By and large, TRC exchanges and dialogues have been confined to regulators and officials of the executive branches on both sides of the Atlantic. The *Guidelines on Regulatory Cooperation and Transparency*, in fact, do not apply to Congress or the European Parliament.

The role of Congress in transatlantic regulatory cooperation in the past has been limited mostly to oversight hearings (see **Appendix A** for a listing) and the introduction of a few resolutions.<sup>61</sup> But

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<sup>57</sup> The Regulatory Cooperation Roadmap provides a framework of dialogues in 15 different sectors, including pharmaceuticals, telecommunications equipment, food safety, and auto safety.

<sup>58</sup> International Trade Reporter, "Transatlantic Council Meeting Advances Regulatory Cooperation, Innovative Strategies," 27 ITR 1963, December 23, 2010.

<sup>59</sup> See CRS Report RL34717, *Transatlantic Regulatory Cooperation: Background and Analysis*, pp. 7-9.

<sup>60</sup> For additional information, CRS Report RL34735, *Transatlantic Regulatory Cooperation: A Possible Role for Congress*, by (name redacted) and Vincent Morelli.

Congress has on occasion taken actions that have both thwarted and facilitated regulatory cooperation. For example, on the one hand, some Members of Congress became concerned in the late 1990s that the MRAs the administration was negotiating could harm consumers and undermine health and safety standards. As Representative Henry Waxman (D-CA) put it, “there is no question that international agreements of this kind can enhance the efficiency of commerce, but it is equally clear that they can potentially depress American health and safety standards.” According to one observer, such concerns made some U.S. regulators reluctant to participate in the MRA negotiations.<sup>62</sup>

On the other hand, Congress also passed legislation directing the FDA to support efforts of the Department of Commerce and USTR to implement MRAs. In the Food and Drug Administration Modernization Act of 1997 (P.L. 105-115), a bill to speed the FDA approval process for new drugs and medical devices, a provision directed the FDA to support the efforts of Commerce and the Office of the U.S. Trade Representative to implement MRAs. According to the same observer, inclusion of the MRA language in the legislation was an important step toward finishing the agreement.<sup>63</sup>

These examples highlight a larger and more pivotal role Congress could play in regulatory cooperation if it chose to become more involved. To the extent that an overwhelming domestic orientation of regulatory agencies is a problem in moving TRC initiatives forward, Congress has the power through both the authorization and appropriations process to mandate that U.S. regulators cooperate. Congress can also ensure that the U.S. agencies involved in regulatory cooperation have the necessary budgetary and organizational resources to get the job done. Conversely, if Congress views transatlantic initiatives as moving too far in the direction of trade expansion at the expense of safety and health concerns or other priorities, Congress can make it difficult for U.S. agencies to continue on that course of action.

Beyond providing guidance to U.S. regulatory agencies on TRC initiatives, Congress also could play a bigger role in preventing new legislation from causing new transatlantic regulatory barriers. Currently, taking the transatlantic impact (trade and investment effects) into account is not considered in any structured or formal fashion during the legislative process. Yet, political declarations from past U.S.-EU summits backed by the transatlantic business community, have urged a more institutionalized process for making Congress more aware of the potential impact of new legislation on transatlantic trade.

How this could be done is the subject of considerable speculation. One of the factors that has to be considered is the wide range of congressional committees that have primary jurisdiction over issues that are high on the agenda of TRC. As shown in **Appendix B**, many different authorizing committees have primary jurisdiction over some of the main regulatory agencies involved in TRC

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(...continued)

<sup>61</sup> In December 2006, the Senate passed a resolution (S.Res. 632) calling for the completion of the Transatlantic Market by 2015. The resolution also called for a jointly funded, cooperatively led study of existing barriers to transatlantic trade and investment, including sector-by-sector estimates of the costs and benefits of removing such obstacles and a timetable for their removal.

<sup>62</sup> Congressman Henry Waxman, Hearing before the House Subcommittee on Oversight and Investigations of the Committee on Commerce, “Imported Drugs: U.S.-EU Mutual Recognition Agreement on Drug Prescriptions,” 105<sup>th</sup> Congress, 2<sup>nd</sup> session, October 2, 1998, p. 4.

<sup>63</sup> Charan Devereaux, Robert Z. Lawrence, and Michael D. Watkins, “The U.S.-EU Mutual Recognition Agreements,” p. 339.

activities. On the House side, the Energy and Commerce, Transportation, Judiciary, and Agriculture Committees all have important oversight roles. Counterpart committees on the Senate side include Commerce, Science, and Transportation, Health Education, Labor, and Pensions, Energy and Natural Resources, Environment and Public Works, and Agriculture. Notably absent from this list are the committees charged with overall responsibility for oversight of transatlantic relations, the Senate Foreign Relations and the House Foreign Affairs Committees, and the committees that have primary jurisdiction over trade and investment issues, Senate Finance and the House Ways and Means.

Currently, the only formal institutional link between Congress and transatlantic regulatory cooperation is through the Transatlantic Legislators Dialogue (TLD), an inter-parliamentary exchange between selected Members of the House of Representatives and the European Parliament. The TLD serves as an advisor to the TEC, but its membership and function have raised questions concerning how well it can carry out its role as an advisor to the TEC.<sup>64</sup>

Much of this begs the question whether Congress should be an advisor or a participant in the TRC process, including the annual U.S.-EU Summits. While a more proactive role for Congress would likely enhance the political basis of support for transatlantic regulatory cooperation, it is by no means certain that there is a consensus in favor of developing the necessary mechanisms and mandate to move in this direction.

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<sup>64</sup> The TLD as currently structured does not include members of the Senate on the U.S. side. For more information on the role of the TLD, see pp. 10-16 of CRS Report RL34735, *Transatlantic Regulatory Cooperation: A Possible Role for Congress*, by (name redacted) and Vincent Morelli.



## Appendix A. Congressional Hearings on Transatlantic Regulatory Cooperation

House Committee on Commerce. *Imported Drugs: U.S.-EU Mutual Recognition Agreement on Drug Prescriptions*. October 2, 1998, 32p.

House Committee on Commerce. *The EU Data Protection Directive: Implications for the U.S. Privacy Debate*. March 8, 2001, 48p.

House Committee on Financial Services. *The EU's Financial Services Action Plan and Its Implications for the American Financial Services Industry*. May 22, 2002, 122p.

House Committee on Financial Services. *U.S.-EU Regulatory Dialogue and Its Future*. May 13, 2004, 106p.

House Committee on Financial Services. *U.S.-EU Regulatory Dialogue: The Private Sector Perspective*. June 17, 2004, 79p.

House Committee on Financial Services. *U.S.-EU Economic Relationship: What Comes Next?* June 16, 2005, 86p.

House Committee on International Relations. *Transatlantic Trade Agenda: Conflict or Cooperation?* September 29, 1999.

House Committee on International Relations. *Recognizing the Continued Importance of the Transatlantic Relationship and Promoting Stronger Relations with Europe by Reaffirming the Need for a Continued and Meaningful Dialogue Between the U.S. and Europe*. October 29, 2003, 16p.

Senate Committee on Foreign Relations. *U.S.-EU Cooperation on Regulatory Affairs*. October 16, 2003, 55p.

Senate Committee on Foreign Relations. *U.S.-EU Regulatory Cooperation on Emerging Technologies*, May 11, 2005, 62p.

## Appendix B. U.S.-EU Regulatory Cooperation by Sector, U.S. Regulatory Agency, and Committee Oversight

Sector <sup>a</sup>	U.S. Regulatory Agency <sup>b</sup>	Committees <sup>c</sup>
Pharmaceuticals	Food and Drug Administration (FDA)	House: Energy and Commerce; Senate: Health, Education, Labor, and Pensions and Commerce Science and Transportation
Automobile Safety	National Highway Traffic Safety Administration (NHTSA)	House: Energy and Commerce; Senate: Commerce, Science and Transportation
Information and Communications Standards in Regulations	Department of Commerce, National Institute of Standards and Technology (NIST)	House: Energy and Commerce; Senate: Commerce, Science and Transportation
Cosmetics	FDA	House: Energy and Commerce; Senate: Health, Education, Labor, and Pensions
Consumer Product Safety	Consumer Product Safety Commission (CPSC)	House: Energy and Commerce; Senate: Commerce, Science, and Transportation
Consumer Protection Enforcement Cooperation	Federal Trade Commission (FTC)	House: Energy and Commerce, and Judiciary; Senate: Commerce, Science and Transportation, and Judiciary
Unfair Commercial Practices	FTC	House: Energy and Commerce, and Judiciary; Senate: Commerce, Science, and Transportation, and Judiciary
Nutritional Labeling	FDA	House: Energy and Commerce, and Agriculture; Senate: Health, Education, Labor and Pensions, and Agriculture
Food Safety	FDA	House: Energy and Commerce Agriculture; Senate: Commerce, Science, and Transportation, and Agriculture
Marine Equipment	U.S. Coast Guard	House: Transportation and Infrastructure; Senate: Commerce, Science, and Transportation

Sector <sup>a</sup>	U.S. Regulatory Agency <sup>b</sup>	Committees <sup>c</sup>
Eco-Design	Environmental Protection Agency (EPA); Department of Energy Office of Efficiency and Renewable Energy	House: Energy and Commerce and Science;  Senate: Energy and Natural Resources
Chemicals	Environmental Protection Agency	House: Energy and Commerce ;  Senate: Environment and Public Works
Energy Efficiency	EPA and Department of Energy	House: Energy and Commerce  Senate: Energy and Natural Resources
Medical Devices	FDA	House: Energy and Commerce;  Senate:
Telecommunications and Radio Communications Equipment	Federal Communications Commission and Department of Commerce, National Institute of Standards and Technology	House: Energy and Commerce ;  Senate: Commerce, Science, and Transportation

**Source:** CRS.

- a. These sectors are identified in the 2005 *Roadmap for Regulatory Cooperation*, [http://www.ustr.gov/World\\_Regions/Europe\\_Middle\\_East/Europe/US\\_EU-Regulatory-C](http://www.ustr.gov/World_Regions/Europe_Middle_East/Europe/US_EU-Regulatory-C).
- b. These agencies are also identified in the 2005 *Roadmap for Regulatory Cooperation*.
- c. Depending on the focus of each sectoral initiative, other committees could also have oversight responsibilities. Regarding appropriations, the appropriations subcommittees would tend to vary as well. For example, the House and Senate Appropriations subcommittees on agriculture have jurisdiction over FDA's appropriations. This arrangement reflects, in part, the agency's origin within the Department of Agriculture as the Bureau of Chemistry in 1862.

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