Managing U.S.-EU Trade Relations Through Mutual Recognition and Safe Harbor Agreements: 'New' and 'Global' Approaches to Transatlantic Economic Governance

Gregory C Shaffer, Loyola University Chicago

Available at: https://works.bepress.com/gregory_shaffer/22/
Reconciling Trade and Regulatory Goals: The Prospects and Limits of New Approaches to Transatlantic Governance through Mutual Recognition and Safe Harbor Agreements

by Gregory Shaffer, Univ. of Wisconsin Law School

final version published in 9 Columbia Journal of European Law 29-77 (Fall 2002)

Abstract. A central goal in governing the interface of the economies of the United States and European Community (EC) is to reconcile the objectives of protective social regulation, on the one hand, and free competition facilitated through open trade policies, on the other. These policies can be both complementary and conflicted. This Article examines how these issues have been addressed bilaterally in a number of economic sectors through mutual recognition agreements and a hybrid form, the safe harbor principles on data privacy protection. The Article provides an overview and analysis of the 1997 Mutual Recognition Agreement and the 2000 agreement on Safe Harbor Principles (for data privacy protection). The Article assesses what spurred these agreements, which actors participated in their negotiation, what constrains their implementation (in terms of both political and market forces), and, ultimately, what are the prospects and limits for their adoption in other areas. Although neither of these agreements directly prescribe harmonization of U.S. and EC laws or regulatory approaches, they have led to some de facto harmonization by regulatory authorities and firms. The Article concludes that, overall, transatlantic institutional adaptation has been slow (and often creeping), but where it has occurred, it has been rather unidirectional, and will likely continue to be so. Simply stated, the United States has made most of the changes, whether through adoption of international standards that mirror those of the EC, through delegation of testing and certification responsibilities to private laboratories reflecting the EC’s “global approach,” or through coordination and oversight of these laboratories under a new U.S. national program analogous to those operating in the EC for over a decade. Overall, in light of the relative absence of government coordination, the private sector likely will continue to take the lead in coordinating arrangements to meet disparate transatlantic regulatory requirements through private sub-contracting and other networking arrangements.

1 Professor, University of Wisconsin Law School; Director, UW European Union Center of Excellence; Co-Director and Senior Fellow, UW Centre on World Affairs and the Global Economy (WAGE). Correspondence e-mail: gshaffer@wisc.edu. Support for this project came from the Stephen P. Jarchow Faculty Research Award of the University of Wisconsin Law School and the University of Wisconsin European Union Center, which is in turn supported by a grant from the European Commission. This was complemented by support from the UW CIBER fund (U.S. Title VI grant) and the UW Center on World Affairs and the Global Economy. Earlier versions of this paper were presented at a conference at the European University Institute on Transatlantic Dispute Settlement and Avoidance (Florence, July 2001), the biannual conference of the Conference of Europeanists (Chicago 2002), the University of Michigan Law School (2002), and the Law and Society annual conference (Vancouver 2002). Thanks go to Ambassador David Aaron, Kalypso Nicolaides, and David Vogel for their comments on earlier drafts, and to Benjamin Rickert and Rebecca Perlmutter for invaluable research assistance. All errors of course remain my own.
I. Introduction

By the late 1990s, the value of trade between the United States and European Community (EC) combined with sales of U.S. and EC affiliates in each other’s markets had expanded to exceed $1.7 trillion. With this rise in transatlantic trade and investment, developments on one side of the Atlantic increasingly affect citizens, business enterprises and interest groups on the other, and, in turn, these groups’ demands on their respective government representatives. With tariff rates at historic lows for most categories of goods, transatlantic trade issues increasingly have become regulatory ones—that is, divergent regulatory laws and procedures in themselves not only restrain trade, and thus transatlantic competition, but they can do so in an asymmetrical discriminatory manner. A central question facing national legislators, executives and administrative officials is how to govern transatlantic economic interdependence while maintaining social standards responsive to their respective constituencies’ demands.

The United States and EC thus increasingly face the difficult task of reconciling the objectives of protective social regulation, on the one hand, and free competition facilitated through open trade policies, on the other, in a complex, rapidly changing environment. Depending on the context, these objectives can be complementary or in conflict. For example, the goals of domestic regulatory and free trade policies are both to protect and benefit citizen-consumers, in which sense they are complementary. Social regulatory policies, at least in their ideal form, are to protect consumers from the risk of market failures through state regulatory intervention. Open trade policies, at least in their ideal form, intend to offer consumers a wider selection of goods at lower prices, thereby expanding their consumption possibilities and increasing their standard of living.

Regulatory and trade policies, however, may conflict for two primary reasons. First, domestic lawmakers and regulators typically do not take account of the impact of domestic regulations on foreigners, primarily because foreigners do not have a voice in domestic political and regulatory processes. Even absent a discriminatory intent, regulatory requirements can be duplicative, redundant or otherwise disproportionately affect traded products, in part because

---

2 The term EC is used in this Article instead of EU (or European Union) because it is EC institutions that enter into bilateral agreements with the United States under the “first pillar” of the Treaty of European Union (TEU) of 1992. The TEU changed the name of the European Economic Community to the European Community to denote that the European Community had integrated beyond purely economic matters. The TEU also created three separate pillars of activities for the regional block. The first pillar concerned all traditional EC matters, as expanded by the TEU to cover, in particular, European economic and monetary union. The 1997 U.S.-EC Mutual Recognition Agreement thus refers to the EC as a party, and not to the EU. Commentators, however, often use the term EU because it is broader in scope, covering all three pillars of activities.


5 As Miguel Maduro writes, “National polities have a twofold deficit: on the one hand, they do not control many decision-making processes which impact on those national polities but take place outside their borders; on the other hand, national polities exclude from participation and representation many interests which are affected by [their] decisions.” Miguel Poiares Maduro, Europe and the Constitution: What if this is As Good as it Gets, in RETHINKING EUROPEAN CONSTITUTIONALISM (eds. J. Weiler & M. Wind: 2001).
domestic regulators do not take account of these impacts.\textsuperscript{6} In an economically interdependent world, domestic politics thus generates both input discrimination (from the lack of representation of foreigners in domestic political processes) and output discrimination (from the greater burden of duplicative regulations on cross-border traders) because of foreigners' lack of representation in domestic political processes.

Second, regulatory divergence reflects genuine difference in constituent preferences and different regulatory strategies, and there is no reason why these differences must be harmonized or made compatible. In an environment characterized by high numbers, complexity, rapidly changing technology and indeterminacy between regulatory strategies and outcomes, harmonization policies can be inappropriately rigid, not permitting for needed experimentation and learning. Top-down command and control regulation can be ineffective from multiple perspectives. Thus, the challenge confronting political leaders is to reduce redundant regulatory barriers to trade, where possible, without sacrificing democratic choice regarding the appropriate allocation of risks and the appropriate procedures for addressing them.\textsuperscript{7} The task is far from easy. To attempt to meet this challenge, U.S. and EC political leaders, under the aegis of the New Transatlantic Agenda,\textsuperscript{8} have begun to devise structures for transatlantic political and regulatory cooperation so that domestic regulatory processes are more likely to reflexively take account of the impact of domestic regulatory choices on non-constituents.

This Article provides an overview of how the tension between the goals of domestic regulatory protection and liberalized trade have been addressed by the United States and EC through transatlantic mutual recognition agreements and a hybrid form, the U.S.-EC safe harbor principles on data privacy protection. The Article assesses the prospects and limits, both politically and in the marketplace, of these new governance mechanisms promoted by the U.S.-EC Mutual Recognition Agreement (MRA) and its six sectoral annexes (of 1997), the U.S.-EC Mutual Recognition Agreement on Marine Safety (initialed in June 2001), and the U.S.-EC understanding on Safe Harbor Principles for data privacy protection (of 2000).\textsuperscript{9} The Article assesses what spurred these agreements, which actors participated in their negotiation, what constrains their implementation, and, ultimately, what are the prospects and limits for their adoption in other areas.

The Article advances four primary findings. First, transatlantic mutual recognition agreements need to be seen in the context of domestic and global business strategies to reduce regulatory compliance costs, to get new products quickly to market in a changing technological environment and thereby to enhance profits. Second, the agreements’ implementation has been much more difficult than envisaged by business and government leaders due to reactions in the marketplace, wariness of independent regulatory officials, and a lack of committed resources for transatlantic regulatory collaboration. Third, the agreements and understandings nonetheless have spurred some domestic regulatory change, as well as some mutual recognition of product

\textsuperscript{6} Whereas products intended solely for domestic markets need comply only with domestic testing, certification and related regulatory requirements, exported products need comply with those of the producing and importing jurisdictions.

\textsuperscript{7} As Christian Joerges writes, “risks, especially those caused by internationally produced and marketed products, cannot be meaningfully attributed to just one legally defined territory and the political confines of nation-states.” Christian Joerges, \textit{Law, Science and the Management of Risks to Health at the National, European and International Level– Stories of Baby Dummies, Mad Cows and Hormones in Beef}, \textit{7 Columbia J of European L.} 1, 3 (2001)

\textsuperscript{8} See discussion in \textsc{Pollack and Shaffer, Transatlantic Governance}, supra note 3 at 14-17.

\textsuperscript{9} The analysis is based on a review of relevant documentation coupled with interviews of regulatory and trade officials and private bodies within the United States and EC.
approvals. They also could spur some de facto harmonization of regulatory approval procedures and substantive standards, thereby reducing the potential for intergovernmental conflict in these sectors. Fourth, and perhaps most controversially, where there has been convergence, the convergence has tended toward EC–and not U.S.–regulatory practices. As this Article will show, the EC now has a sustained record under its single market program of easing trade barriers among fifteen EC member states working in eleven different languages, while retaining relatively high regulatory standards. This practical experience, coupled with the EC’s growing market power, has enabled EC regulators to put forward regulatory models that can be both attractive to firms and more pragmatic to adopt than those of their U.S. counterparts.

II. Harmonization and Mutual Recognition: Can the EC’s “New” and “Global” Regulatory Approaches Be Applied to the Transatlantic Marketplace?

There exist three primary options for easing regulatory barriers for trading firms: harmonization, mutual recognition and national treatment (albeit subject, of course, to multiple variants).10 Under a policy of harmonization, regulators in separate jurisdictions agree to adopt identical substantive standards and procedures.11 Such harmonization facilitates cross-border trade as well as cross-border regulatory cooperation because of regulators’ greater comfort with similar standards. Under a policy of mutual recognition, regulators retain separate standards for internally-produced products, but agree to recognize the other jurisdiction’s standards for products imported from it, albeit sometimes subject to significant conditions and controls.12 Mutual recognition agreements pose much greater challenges for regulatory cooperation because of regulators’ unfamiliarity and unease with divergent foreign standards. Under a policy of national treatment, each jurisdiction maintains its own standards and is proscribed only from applying more stringent standards to foreign products. A national treatment regime removes fewer regulatory barriers, especially those that are non-discriminatory on their face, since regulators are not required to “mutually recognize” the other’s standards.13 These three policy


11 On the limitations of harmonization policies, see David Leebron, Lying Down with Procrustes: An Analysis of Harmonization Claims, in FAIR TRADE AND HARMONIZATION: ECONOMIC ANALYSIS 393 (Jagdish Bhagwati & Robert Hudec eds., 1996). Some commentators point out how harmonization tends to demand more than mutual recognition agreements, although, as will be seen, the negotiation and implementation of mutual recognition agreements also demand significant resources. See Michelle Egan, Mutual Recognition and Standard Setting: Public and Private Strategies for Governing Markets, in MARK POLLACK AND GREGORY SHAFFER, TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY 179, 195 (2001).


13 Nikolaidis refers to “policed national treatment” as a third approach. See Kalypso Nikolaidis, Mutual Recognition of Regulatory Regimes: Some Lessons and Prospects, in REGULATORY REFORM AND INTERNATIONAL MARKET OPENNESS, 171, 173 (OECD 2001). A narrow interpretation of national treatment permits for considerable regulatory diversity and, in consequence, a greater likelihood of regulatory barriers to trade. However, courts have ruled against regulations that provide for national treatment on their face where the regulations lack a “scientific” basis or cover foreign production processes (as opposed to product characteristics). Such judicial oversight can lead to controversial outcomes, as in the WTO shrimp-turtle case (concerning an import ban imposed on account of foreign production processes) or the WTO meat-hormones case (concerning an import ban imposed without
options can be complementary, sometimes working in tandem.

A. Overview of the EC’s Coordination of National Regulatory Systems. Since 1985, the EC has adopted what it terms “new” and “global” approaches to European regulation, under which EC institutions only legislate “essential requirements,” delegate the determination of more-detailed standards to quasi-public European standards organizations (the “new approach”), and then coordinate quasi-public national certification bodies to certify products produced in any one member state for sale throughout the EC market (the “global approach”).

In 1985, the European Commission issued a bulletin that set forth its “new approach” to harmonization in response to the market-distorting and market-segregating impact of multiple national standards and the difficulty of appropriately overcoming them at the EC level, especially in light of rapidly changing technologies. Under this “new approach,” the Council of Ministers (the Council) enacts framework directives for technical standards covering “essential requirements.” The 1987 Single European Act modified voting rules for the enactment of EC internal market legislation to a “qualified majority” vote (as opposed to unanimity), thereby eliminating member state veto rights in the Council. This combination of qualified majority voting and the reduction of EC-prescribed standards to “essential requirements,” together with the EC’s highly-publicized push to “complete” an EC internal market by 1992, led to the adoption of a series of EC harmonization directives.

Under this “new approach” to regulation, the Council delegates the task of drawing up more-detailed standards to industrial standardization bodies operating under the umbrella of three European standards organizations: CEN, CENELEC and ETSI. These European standards organizations are comprised of national standards bodies that, in turn, include representatives from government, industry and other social groups. The European standards bodies vote on a simple majority basis (following a first round of voting), facilitating the adoption of “non-essential” technical standards. These standards are not internally binding on the member states, so that member states retain some _de jure_ autonomy. However, these standards have become _de facto_ harmonized requirements for selling products within the EC because of their importance in conducting a sufficient risk assessment). Just as mutual recognition policies, such judicial challenges facilitate regulatory competition through which consumers implicitly choose among production processes when they purchase products on the market.

---


16 _Id._


18 CEN is the acronym for the Comite European de Normalisation (founded in 1961); CENELEC for the Comite European de Normalisation Electrontechnique (founded in 1959); and ETSI for the European Telecommunications Standards Institute (founded in 1988).

19 _See MICHELLE EGAN, CONSTRUCTING A EUROPEAN MARKET: STANDARDS, REGULATION AND GOVERNANCE_ 154-158 (2001) (noting two rounds of voting before decision by a majority vote, as well as other preliminary procedures).
the marketplace.\textsuperscript{20}

Under what is termed the EC’s “global approach” to regulation, products may be tested and certified within any member state in order to receive a “CE” marking (which indicates that they comply with “Communauté Européen” norms. All member states must recognize these certifications (i.e. mandatory mutual recognition), such that certified products may circulate freely throughout the EC market. In 1990, the member states formed the European Organization for Testing and Certification (EOTC) to coordinate national bodies engaged in the certification process and thereby help assure national authorities of the reliability of tests conducted in other member states.\textsuperscript{21} Each member state must approve and is responsible for overseeing the certification bodies within its jurisdiction and must notify the Commission’s Enterprise Directorate-General (DG) of its approvals. These testing and certification laboratories consequently are referred to as “notified bodies.”\textsuperscript{22} Member state authorities periodically meet and exchange information about the process’ operation through working groups and committees created pursuant to the respective directives. They thereby attempt to build and retain confidence in the system.\textsuperscript{23} This EC system can be characterized as governance by coordinated cross-border public-private networks.\textsuperscript{24}

Even though the CE marking alone is required for customs purposes, the trade names and trademarks of national notified bodies can remain advantageous for marketing purposes within member states. National distributors and suppliers sometimes prefer certification by national bodies within their own jurisdiction in order to reduce the risk of marketing products certified by a foreign body. Market barriers thus arise not only from government intervention and regulatory distrust, but also from the perceptions of private actors in the market. In short, the EC’s endeavors, while generally successful, have encountered setbacks, stalemates and ongoing challenges, despite the EC’s deployment of considerable institutional resources.\textsuperscript{25}

\begin{itemize}
\item \textsuperscript{20} See Giandomenico Majone, International Regulatory Cooperation: A Neo-Institutionalist Approach, in Regulatory Cooperation and Managed Mutual Recognition: Developing a Strategic Model, in TRANSAatlantic REGULATORY COOPERATION 596 (ed. George Bermann 2001) (“the voluntary standards produced by the European organizations become, de facto, binding”). As stated in the Commission’s 1985 Bulletin, “the authorities in the Member States will be obliged to recognize that products manufactured in accordance with harmonized standards [set by private bodies]... are presumed to conform to the ‘essential requirements’ laid down in the Directive; this means that any manufacturer will be free to produce goods which do not meet the standards, but the burden of proof that his products meet the essential requirements of the Directive will then fall upon him.” See Technical Harmonization and Standards: A New Approach, (art. 1.3.3(iv)), supra note....
\item \textsuperscript{22} The overall process is called the “global approach” because once a notified body certifies that a product meets EC standards, the product may be marketed in all fifteen member states.
\item \textsuperscript{23} Firms and laboratories also remain subject to post-marketing member state regulatory controls, as well as market-reputational constraints.
\item \textsuperscript{25} See Egan, CONSTRUCTING A EUROPEAN MARKET, supra note..., at 229 (“Firms continue to experience difficulties in persuading other economic operators or suppliers to accept the results of conformity assessment from bodies they do not know, or to accept national standards and marking arrangements that they are not familiar with.”); and DAVID Vogel, BARRIERS OR BENEFITS: REGULATION IN TRANSATLANTIC TRADE (1997), at 4. See also John Chai, Medical Device Regulation in the United States and the European Union: A Comparative Study, 55 FOOD & DRUG L.J. 57, 72 (2000) (noting that “no member state was able to meet the deadline” for implementing the 1993 Active
B. Harmonization and Mutual Recognition in the Transatlantic Context: Can the EC System Be Exported? While there has been little effort to harmonize standards on a purely transatlantic basis, the United States and European member states have negotiated through international fora. In turn, such international standards can facilitate the negotiation of bilateral mutual recognition agreements because, where parties operate under common standards and procedures, they more easily understand and develop trust in each other’s regulatory practices. For example, the 1997 U.S.-EC Mutual Recognition Agreement is based largely on the mutual recognition of test results by “Conformity Assessment Bodies,” which, in turn, are evaluated pursuant to international standards set forth in ISO/IEC Guides.

The EC has tended to look more favorably toward international harmonization efforts than the United States for two primary reasons. First, EC member states and European standards organizations have more experience in negotiating and implementing agreements with third parties in light of the EC’s own internal market process. Second, in international organizations where each country has one vote, the EC’s fifteen member states can work collectively so that, overall, they are more likely to promote EC-based standards in multilateral fora. For example, two of the most widely known ISO standards, ISO 9000 and ISO 14000 were developed initially within Europe.

Mutual recognition agreements, in contrast, have been negotiated not internationally, but bilaterally or through regional fora. For example, the United States and EC have or are in the process of negotiating mutual recognition agreements under the auspices of APEC and CITEL, as well as with individual countries, such as Canada, Australia, Japan, New Zealand and Israel.

Implantable Medical Devices Directive and “most member states were not able to designate their [notified bodies] in time”).

26 “Conformity Assessment Bodies” are the transatlantic analogue of “notified bodies” operating within the EC market in the context of the EC’s “global approach.”

27 The international standard-setting bodies relevant to the sectors covered by transatlantic mutual recognition agreements include: the International Standards Organization (ISO) (for a broad range of standards); the International Electrotechnical Commission (IEC) (for testing and certification standards); Codex Alimentarius (for food-related standards); the International Conference on Harmonization (for pharmaceutical standards); the Global Harmonization Task Force (for medical device standards); and the International Maritime Organization (for marine safety standards).

Codex Alimentarius, a joint undertaking of the World Health Organization and the Food and Agricultural Organization, is relevant to the U.S.-EC Veterinary Equivalence Agreement. This latter agreement is not yet operational and is not covered in this Article. The International Conference on Harmonization is a program that “harmonizes requirements and guidelines for testing drugs and biologies.” Its members are the Commission, the European Medicines Evaluation Agency, EC member state regulators, Japan’s health ministry and U.S. European and Japanese pharmaceutical trade industry associations. See Linda Horton, Mutual Recognition Agreements and Harmonization, 29 SETON HALL L. REV. 692, 717-718 (1998). The Global Harmonization Task Force consists of regulators from the US, EC, Canada, Japan and Australia, although the Task Force now admits observers from many other countries.

28 As Vogel writes in respect of harmonization of pharmaceutical guidelines and standards, “the experience the Europeans gained in harmonizing regulations among the EU’s member states has both enabled and encouraged it to play a leadership role in promoting international regulatory cooperation.” See David Vogel, The Globalization of Pharmaceutical Regulation, 11 GOVERNANCE 1, 14 (Jan. 1998).

29 Egan, Mutual Recognition and Standard Setting, supra note ... at 201

30 APEC is the Asia Pacific Economic Cooperation forum “is the primary international organization for promoting open trade and economic cooperation among 21 member ‘economies’ around the Pacific Rim.” See United States APEC Index (visited Feb. 28, 2002)<http://www.apec.org/>. CITEL is “an entity of the Organization of American States, is the main forum in the hemisphere in which the governments and the private sector meet to coordinate
The EC’s experience in harmonizing and coordinating fifteen national regulatory systems offers a model to be considered, and possibly exported, to these other contexts, including the transatlantic one. Yet, the EC’s own experience also highlights the challenges that the United States and EC face in governing the interface of their economies. As this Article will demonstrate, there is even more distrust between regulators on either side of the Atlantic, there are greater challenges of political legitimacy, and the marketplace imposes even more severe constraints on the effective implementation of mutual recognition agreements in the transatlantic context.

III. The 1997 U.S.-EC Mutual Recognition Agreement

A. What Gave Rise to the 1997 Mutual Recognition Agreement? The issue of transatlantic standards became more important to firms engaged in transatlantic trade for two primary reasons. First, as transatlantic tariff barriers decreased, firms became more concerned with, what they termed, duplicative regulatory compliance costs.31 They pressed for their removal. This pressure increased with rising transatlantic investment, since divergent U.S. and EC standards and certification requirements most directly affect transatlantic corporate groups, and these groups more easily coordinate lobbying on both sides of the Atlantic. Subsidiaries of U.S. firms in the EC account for about one-third of EC imports from the United States, while subsidiaries of EC firms in the United States account for about 38% of U.S. imports from the EC.32

Second, when the EC moved toward a single market, U.S. firms challenged that the EC was erecting a “fortress Europe” in which member states would use common “single market” standards and certification procedures to prejudice U.S. competition.33 U.S. firms feared that they would be disadvantaged because, under the EC’s “global approach,” only notified bodies located within the EC could test and certify products for marketing in the EC.34 Prior to the “global approach,” U.S.-based laboratories acted as subcontractors for the testing of products under member state standards, and firms feared that this option might be foreclosed.35

In response to these developments, U.S. and EC authorities began to seriously address issues of regulatory coordination at the beginning of the 1990s. In May 1989, U.S. Secretary of regional efforts to develop the Global Information Society according to the mandates of the General Assembly of the Organization and the mandates entrusted to it by Heads of State and Government at the Summits of the Americas.” See CITEL (visited Feb. 28, 2002) <http://www.citel.oas.org/).

The EC reports that it has concluded “six Mutual Recognition Agreements on conformity assessment between the European Community and third countries [which have] entered into force: on 1/12/98 with the United States, on 1/11/98 with Canada, on 1/1/99 with Australia and New Zealand, on 1/1/02 with Japan, and on 1/5/00 with Israel in the Sector of Chemicals Good Laboratory Practices (GLP).” See Mutual Recognition Agreements, (visited Feb. 26, 2002) <http://europa.eu.int/comm/enterprise/international/indexb1.htm#intro>.

31 Firms engaged in cross-border sourcing of products particularly are concerned with disparate standards. See also MARIA GREEN COWLES, THE LIMITS OF LIBERALIZATION: REGULATORY COOPERATION AND THE NEW TRANSATLANTIC AGENDA, 3 (1997).
32 Pollack and Shaffer, Transatlantic Governance in Historical and Theoretical Perspective, supra note..., at 14.
33 See Egan, Mutual Recognition and Standard Setting, supra note ..., at 186-187. Although firms have largely been assured that EC harmonization would not be used as a weapon to discriminate against U.S. firms, they would still prefer not to have to meet multiple U.S. and EC standards.
34 See discussion in supra notes [14, 21-24] and accompanying text (re global approach).
35 However, sub-contracting continues today, so that again, firms’ fears of the EC “global approach” have largely been assuaged. See infra notes [156-157].
Commerce Robert Mosbacher and Commission Vice-President Martin Bangemann agreed to explore the possibility of transatlantic mutual recognition agreements, as well as mechanisms to grant U.S. firms greater access to EC standard-setting procedures. In 1995, the United States and EC signed the New Transatlantic Agenda and its attached “Joint Action Plan” which contained a detailed list of items to address. However, at the NTA’s annual summits, transatlantic diplomats found it difficult to operationalize the action plan in concrete ways that benefited their constituents. Negotiators were soon in search of “deliverables” in order to show that the NTA was more than an empty symbol.

Large businesses on each side of the Atlantic, working under the auspices of the Transatlantic Business Dialogue (TABD), promoted the concept of mutual recognition agreements as a concrete policy initiative that would meet business needs. TABD rapidly became a significant independent voice, identifying areas of concern and coordinating pressure on officials to set time tables for the signature and implementation of mutual recognition agreements. As Paula Stern, former chair of the U.S. International Trade Commission and advisor to TABD, states, “TABD quickly established the Trans-Atlantic Advisory Committee on Standards, Certification and Regulatory Policy (TACS) to formulate recommendations, organized on a sectoral basis, for the elimination of regulatory barriers between the two economies.”

U.S. and EC officials announced the 1997 MRA with fanfare as a “milestone” in U.S.-EC economic relations. Secretary Richard Daley of the U.S. Department of Commerce proclaimed that the MRA could save businesses over $1 billion annually in unnecessary regulatory compliance costs. The Transatlantic Business Dialogue estimated that about half of $110

---

36 See DAVID VOGEL, BARRIERS OR BENEFITS: REGULATION IN TRANSATLANTIC TRADE, at 9 (1997).
37 The Transatlantic Business Dialogue was launched in 1995 roughly at the time as the creation of the New Transatlantic Agenda. As documented by Cowles, the TABD consists of CEOs of over 100 of the largest firms on each side of the Atlantic. See Maria Green Cowles, The Transatlantic Business Dialogue: Transforming the New Transatlantic Dialogue, in POLLACK AND SHAFFER, TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY (2001), at 215.
38 To give one example of TABD’s work, see e.g. Mutual Recognition of the Food and Drug Administration and European Community Member State Conformity Assessment Procedures; Pharmaceutical GMP Inspection Reports, Medical Device Quality System Evaluation Reports, and Certain Medical Device Pre market Evaluation Reports, 63 Fed Reg. 17,744, 17,747 (Apr. 10, 1998) (noting views of TABD).
39 See Paula Stern, The Trans-Atlantic Business Dialogue: A New Paradigm for Standards and Regulatory Reform: Sector by Sector, in OECD PROCEEDINGS: REGULATORY REFORM AND INTERNATIONAL MARKET OPENNESS 155, 156 (1996). The advantage for firms under the 1997 MRA is that once a product is certified in the exporting country to conform to the standards set by the importing country, it need not be re-certified after importation. In theory, this could save testing, shipping and packaging costs, and perhaps lead to mutual recognition of substantive standards.
40 See e.g. statement of Charles Gaylord from the Office of International Programs in the FDA at a public meeting on the 1997 Mutual Recognition Agreement in Rockville, Maryland, Dec. 8, 1999: “When the Mutual Recognition Agreement was signed last year, it was a significant milestone that was the culmination of years of hard work by many people both within the EU and the FDA.” (visited March 12, 2002) <http://www.fda.gov/oia/dec8transcript/opening.html>.
41 Gary Yerkey, U.S., EU Conclude Standards Pact on Testing and Certification, Officials Say, 14 INT’L TRADE REP. 1068 (June 18, 1997) (citing Secretary of Commerce William Daley). Daley was likely taking his figures from industry. For example, ITI, which led “the efforts of information technology firms in the United States to press government for closure of talks in telecommunications and information technology,” estimated that a transatlantic “MRA on telecommunications and information technology products would save over $1.1. billion in costs for US manufacturers and consumers each year.” See John Sullivan Wilson, Eliminating Barriers to Trade in Telecommunications and Information Technology Goods and Services: Next Steps in Multilateral and Regional Liberalisation Efforts, in OECD PROCEEDINGS: REGULATORY REFORM AND INTERNATIONAL MARKET OPENNESS
billion of U.S. exports to Europe require some form of EC certification, which now could be accomplished in the United States. Officials announced plans for subsequent MRAs to cover an array of product and service sectors. The TABD estimated that a framework agreement for services would have an even greater impact in freeing up trade, affecting approximately $130 billion in transatlantic commerce. Yet, as will be seen, both transatlantic businesses and government officials have become less enamored with mutual recognition agreements in light of their experience with the 1997 agreement.

B. Transatlantic Business Practice before the 1997 MRA. In order to understand the limited scope of the 1997 MRA, it is helpful to briefly review how businesses often had their products certified before its negotiation, and how many continue to operate. Firms and laboratories have adapted over time to differing U.S. and EC regulatory requirements through entering into sub-contracting arrangements. Still today, private testing bodies often test products in the manufacturer’s place of production on one side of the Atlantic in accordance with standards set on the other, and then have these test results certified by an accredited body in the importing jurisdiction. The domestic testing body operates under a sub-contracting arrangement with the responsible certification body in the importing jurisdiction. For example, for the European market, laboratories in the United States can test U.S. products under EC standards and provide the paperwork to a “notified body” in Europe that certifies them. In addition, large European notified bodies, themselves, have invested in the United States to provide these testing services in an integrated manner. Now that U.S. regulatory agencies increasingly recognize testing by private laboratories, U.S. laboratories too have entered into sub-contracting arrangements with European counterparts for product certification under U.S. standards. Large U.S. laboratories similarly have invested in Europe, and in some cases, themselves become EC notified bodies. In consequence, the sectoral annexes to the 1997 MRA, assessed below, do not represent a significant change for many businesses, but rather a slight extension of sub-contracting practices that have already adapted to regulatory and commercial developments. In fact, sub-contracting is specifically contemplated in some of the MRA’s sectoral annexes, such as for telecommunications equipment, which provide that Conformity Assessment Bodies in one jurisdiction may sub-contract testing to laboratories in the other.

131, 141 (1996). See also Stern, The Trans-Atlantic Business Dialogue, supra note..., at 161 (citing same figure from TABD). Other estimates were more modest, but still considerable. See e.g. DAVID VOGEL, BARRIERS OR BENEFITS: REGULATION IN TRANSATLANTIC TRADE (1997), at 12 (citing figure of $172 million saved); and Egan, Constructing a European Market, supra note... (citing a figure of $47 billion in transatlantic trade affected by 1997 MRA).

42 See Stern, The Transatlantic Business Dialogue, supra note..., at 156.


45 Underwriters Laboratory, the largest U.S. private laboratory, acquired the largest Danish laboratory, and created a subsidiary in the United Kingdom that became a notified body in the 1990s. Telephone interview with representative of Underwriters Laboratories, Oct. 17, 2002; and interview with Commission Official in DG Enterprise, June 15, 2001.

46 See e.g. Section VII of the Telecommunication Equipment Annex.
C. The 1997 MRA Negotiations. U.S.-EC negotiators initially discussed negotiating mutual recognition arrangements in eleven sectors, but ultimately whittled this down to the following six: telecommunications equipment, electromagnetic compatibility, electrical safety, recreational craft, medical devices, and pharmaceutical good manufacturing practices. As with all trade negotiations, the EC and United States were concerned that the final results either favor their export industries or be “balanced.” The United States wished to conclude an agreement on telecommunications equipment first, but the EC refused because it felt that U.S. firms would benefit more if the agreement covered only this sector. The EC used its political leverage by threatening not to sign any MRA involving telecommunications equipment without inclusion of MRAs covering medical devices and pharmaceutical good manufacturing practices.

The MRA negotiations required the involvement of multiple executive agencies since the negotiations comprised an overall framework agreement and six annexes covering the six separate sectors. The Office of the United States Trade Representative and the Commission’s Trade Directorate-General (DG) led the negotiations of the MRA framework agreement. Each of the annexes, however, was negotiated by the regulatory agency responsible for the sector concerned. On the European side, this was a simpler process because of the centralization of the responsible agency officials within the Commission’s DG Enterprise and these officials’ long experience with coordinating the twin goals of regulatory protection and free trade within the single market. Because of this dual role, DG Enterprise officials are, in some ways, more analogous to the U.S. Department of Commerce than to independent U.S. regulatory agencies. On the U.S. side, in contrast, separate independent federal agencies negotiated the annexes. The Federal Communications Commission (FCC) handled the telecommunications and electromagnetic compatibility annexes; the Occupational Safety and Health Administration (OSHA), a division of the Department of Labor, negotiated the electrical safety annex; the Food and Drug Administration (FDA) negotiated the annexes for medical devices and pharmaceutical good manufacturing practices; and the Coast Guard oversaw the recreational craft annex. These U.S. agencies traditionally have focused only on protecting public health and safety, and thus were less receptive to arguments concerning trade facilitation.

The involvement of both trade officials and regulatory officials resulted in intra-U.S. agency conflicts, as well as transatlantic ones. Trade officials more aggressively pushed for an agreement, and U.S. regulatory officials, in particular the FDA and OSHA, were reticent about accepting foreign certification of safety standards. Since these agencies are relatively independent compared to their EC counterparts, they obstructed agreement where they believed that their regulatory missions might be compromised. In the fall of 1996, negotiations almost broke down over inclusion of the medical device and pharmaceutical annexes. Only Congress’ intervention, following intensive lobbying efforts by private firms and the U.S. Department of Commerce, overcame FDA opposition to their inclusion. In November 1997, Congress passed the FDA Modernization Act, which specifically directed the FDA to “support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements.”

---

47 See Rebecca Steffenson, EU-US Mutual Recognition Agreements, supra note 46, at 12 (concerning the role of different actors in the negotiations).
encouraged mutual recognition agreements “between the European Union and the United States” in all product areas under FDA competence.50

As the former EC Trade Commissioner Sir Leon Brittan states, “governments proved to be more eager than their agencies to cooperate.”51 Ultimately, it was trade officials, spurred by business constituents, who drove the negotiations. High-level trade officials in two coordinating bodies within the NTA framework—the Senior Level Group and TEP Steering Group52—identified goals, set deadlines and monitored progress. Nonetheless, the annexes required U.S. regulatory agency approval, which created delays, resulting in sharp and ongoing criticism from the Transatlantic Business Dialogue.53 In other words, the relation of independent agencies and transgovernmental regulatory cooperation was opposite that predicted by some leading commentators on regulatory coordination.54 The relative independence of U.S. agencies such as the FDA and OSHA, at least to date, has arguably not facilitated, but rather hindered, a coordinated partnership among transatlantic authorities.

D. The 1997 Mutual Recognition Agreement. The 1997 Mutual Recognition Agreement consists of a framework agreement and six annexes.55 Each of the annexes is, in fact, a separate agreement for a separate sector covering defined categories and lists of products. These annexes are briefly summarized in Table 1.

The 1997 MRA does not cover recognition of the adequacy or equivalency of transatlantic standards, but is rather much less ambitious. First, the EC and United States have not negotiated harmonized transatlantic standards for the concerned sector.56 Second, although each annex is unique, each of them only addresses mutual recognition by certification bodies (called “Conformity Assessment Bodies”) located in the exporting jurisdiction in accordance with the importing party’s required standards and procedures. Since neither the United States nor the EC relinquish sovereign control over the substance of their standards, transatlantic trading firms still must meet the separate requirements of the world’s two largest markets. Third, even


50 See FFDCA, sec. 383(c)(2). Nonetheless, under a Memorandum of Understanding between USTR and FDA, “FDA speaks for the government on discussions relating to FDA’s regulatory responsibilities and authority, in both the Joint Committee under the umbrella agreement and in the Joint Sectoral Committees for drugs and devices.” Linda Horton, Mutual Recognition Agreements and Harmonization, 29 SETON HALL L. REV. 692, 735 (1998)
52 TEP is the acronym for the Transatlantic Economic Partnership, a follow-up to the New Transatlantic Agenda signed in May 1998. The Senior Level Group was responsible for overseeing EC-U.S. relations and consisted of... The TEP Steering Group took primary responsibility for trade and investment issues and consisted of... See POLLACK AND SHAFFER, TRANSATLANTIC GOVERNANCE, supra note ..., at 16.
54 See e.g. Giandomenico Majone, 265-266 Regulating Europe (1996) (maintaining, in the EC context, that “agency independence is...the necessary condition for a reform of the regulatory process in the direction of a co-ordinated partnership among national and European authorities.”).
55 A single product may be covered by more than one annex. For example, some telecommunication equipment may be subject to the annexes on telecommunication equipment, electromagnetic compatibility, and electrical safety.
56 The sole minor exception to date is the mutual recognition agreement on marine equipment initialed in June 2001.
these assessment evaluations are subject to varying pre-approval and post-approval conditions. For example, in the case of medical devices, the relevant agencies need not accept the tests from foreign certification bodies if they find the reports deficient and delineate why, thus reducing businesses’ incentives to use these bodies. In the case of pharmaceutical good manufacturing practices, the tests are performed by regulatory bodies, and not private laboratories, and again, the agency in the importing jurisdiction may reject reports where it finds them deficient.

The MRA sets up a new transatlantic structure for overseeing its implementation. First, the MRA creates a Joint Committee, which consists of U.S. and EC trade officials who meet twice annually. Second, the annexes create Joint Sectoral Committees to oversee the annexes’ implementation. The Joint Sectoral Committees are of greatest importance for implementing the MRA since they consist of the actual regulatory authorities who must oversee the protection of health and safety on each side of the Atlantic. However, in some cases, these regulatory authorities are not effectively collaborating, as examined in the more detailed assessments of the six sectors.

As of September 2002, only the three annexes of greatest initial interest to U.S. negotiators were fully operational—those covering telecommunications equipment, electromagnetic compatibility and recreational craft. In contrast, implementation of the annexes for electrical safety equipment, medical devices and pharmaceutical good manufacturing practices remain in dispute. The transitional period for the medical device annex was extended for two years. Regarding the pharmaceutical annex, the FDA maintained that it was willing to recognize the “equivalency” of only two member state regulatory systems by the end of the 2001 transition period, and it set no fixed date for reviewing the others. The EC, which must act on behalf of all fifteen member states, rejected this offer because it would prejudice manufacturers in the other thirteen member states, who would still be subject to duplicative EC and FDA inspections. The EC’s negotiation stance has been complicated by the fact that the U.S. executive has less control over independent agencies such as the FDA and OSHA. The Commission, displeased that the unimplemented annexes are those that the EC initially imposed as conditions for the 1997 MRA, is reviewing its options, including termination of the entire MRA, or suspension or withdrawal from certain of the agreements. In May 2002, the EC indicated that it was “likely to suspend participation in the agreement [concerning electrical equipment] because of OSHA’s continuing failure” to comply with its terms. The United States

57 For example, Section VII.2 of the Telecommunications equipment annex provides for post-market surveillance (including via labeling and numbering requirements) and border and internal checks, provided that the latter are not done in a discriminatory manner. See also infra note [90] (re controls under the medical devices annex).
60 The two targeted states were the United Kingdom and Ireland, with some indication from FDA that France and Germany would be reviewed next.
61 Article 11 of the annex does contemplate that FDA may not approve all member state systems as “equivalent,” at least by the end of the transition period, in which case FDA agreed to “accept for normal endorsement... inspection reports generated as a result of inspections conducted jointly by that authority on its territory and another authority listed as equivalent,” provided further that enforcement of the inspections’ findings would be guaranteed. However, as Commission officials state, the EC did not contemplate that one or two member state regulatory authorities would engage in all fifteen member states. Interview with Commission official in DG Trade, June 13, 2001.
62 See Gary Yerkey, EU Set to Withdraw from Agreement with U.S. to Boost Trade in Electrical Goods, 19 Int’l Trade Rep. (BNA) 956 (May 30, 2002). See also, EU Still Weighs Withdrawal from MRA, Will Raise it this Month,
and EC have held similar discussions about whether the agreement concerning the certification of pharmaceutical manufacturing processes can be salvaged.63

1. Telecommunications and Electromagnetic Compatibility MRA: Has it Become Superfluous? The telecommunications and electromagnetic compatibility annexes should be viewed together because they both involve telecommunications equipment and their inclusion was sought by the telecommunications industry. These annexes’ complementarity is reflected structurally, in that the parties have formed a “Joint Sectoral Committee,” consisting of members of the U.S. Federal Communications Commission and the EC’s DG Enterprise to monitor the annexes’ implementation.64 Under both annexes, the parties agree to recognize test reports and conformity assessment certificates issued by Conformity Assessment Bodies located in the exporting jurisdiction, “without any further conformity assessment.”65 As with all of the annexes, however, assessments are made in respect of the standards and in accordance with the procedures of the importing jurisdiction.

Both annexes are now operational and, compared to the other annexes, their implementation has been relatively successful.66 Nonetheless, these annexes themselves have become less important than when originally negotiated, since the EC has moved to a system of manufacturer self-certification for telecommunications equipment. In 1998, the EC Council enacted a new directive concerning telecommunications equipment pursuant to which manufacturers now may self-certify that their equipment complies with EC requirements.67 Similarly, in regards to electromagnetic compatibility, firms must prepare files on which EC “competent bodies” state “opinions,” but these bodies do not prepare assessment certificates.68
The EC’s move to manufacturer self-certification has been much more dramatic for access to the EC market than the MRA itself. Telecommunications firms now lobby U.S. authorities to adopt the EC’s decentralized system, viewing the MRA as a potential catalyst for U.S. domestic regulatory change.69

2. Electrical Safety: Regulatory Tensions. For EC authorities, the (at least relative) success of the telecommunications and EMC annexes has been undermined by the United States’ failure (on account of OSHA) to implement the electrical safety annex, which, in the EC’s view, is also necessary for EC telecommunications and other firms to gain freer access to the U.S. market. EC negotiators insisted that the MRA include an annex concerning electrical safety standards because the EC market has long been relatively deregulated and thus more open to U.S. products. In contrast, the U.S. system calls for regulatory reviews and approvals by OSHA, a division of the U.S. Department of Labor. EC authorities, acting on behalf of EC firms, desired to ease the regulatory burden for EC imports into the U.S. market that required OSHA approvals.70 They hoped to do so by having OSHA recognize product testing and certification, under OSHA standards by Conformity Assessment Bodies located in Europe. In addition, at least certain sectors of the telecommunications industry desired an MRA that covered not only all aspects of telecommunications product approvals, but also might lead to adoption within the United States of a decentralized EC system.71

This annex has not been implemented, however, because of disputes with OSHA over the designation of European Conformity Assessment Bodies. OSHA has found implementation of the MRA to be a “headache” since it has been pressed to accept, without significant review, applications forwarded to it by fifteen different member state authorities, all or part of which may be in any one of the EC’s eleven official languages.72 To ensure its regulatory mission, OSHA has insisted that it control the designation of European Conformity Assessment Bodies under the electrical safety equipment annex, rather than relying on European member state designations. OSHA has rejected a number of Conformity Assessment Bodies designated by member state authorities on different grounds, including on account of the language of the submission and the submission’s incompleteness.73 The Commission maintains that OSHA’s assertion of control over the designation of European Conformity Assessment Bodies is in violation of the agreement’s letter and spirit.74

They are likewise accredited pursuant to member state procedures. In the context of the U.S.-EC MRA, U.S. Conformity Assessment Bodies may perform the roles of “competent bodies” for U.S. products marketed in the EC, on account of the electromagnetic compatibility annex.

69 Interview with representative of Underwriters Laboratories, October 18, 2002.
70 One Commission official, for example, characterizes OSHA’s system as “antiquated.” Interview with Commission official from DG Enterprise, June 15, 2001 in Brussels.
71 According to one FCC official, “the purpose of the MRA from a manufacturer’s perspective was to bring about regulatory change.” Telephone interview, June 8, 2001. See also telephone interview with representative of Underwriters Laboratories, Oct. 17, 2002 (confirming perspectives of telecommunications firms).
72 OSHA has not wished to be forced to accept, without significant review, applications forwarded to it by fifteen different member state authorities, all or part of which may be in any one of the EC’s eleven official languages. OSHA also has insisted that it conduct on-site reviews of these bodies. OSHA even began charging an application fee in October 2000 because of the burden of the application process, which further raised tensions with European regulatory authorities. Telephone interview with OSHA official, June 7, 2001.
73 Telephone interview with OSHA official, June 7, 2000.
74 The Electrical Safety annex reads that European member state authorities (defined as “EC Designating Authorities,” of which there is one for each state) “shall designate conformity assessment bodies located in the EC”
The tensions between OSHA and the Commission’s enterprise directorate-general stem, in large part, from differences in U.S. and EC regulatory structure and culture in this specific area. Since the EC’s 1973 Council Directive on electrical safety equipment, EC member states permit manufacturers to self-certify their compliance with EC electrical safety requirements, subject to post-marketing member state surveillance and controls. The member states have agreed on the harmonization of approximately 600 standards for electrical safety equipment, which largely transpose international standards. In contrast, all electrical safety equipment that may be used in the workplace in the United States must be approved by a laboratory recognized and overseen by OSHA, known as an NRTL (or Nationally Recognized Testing Laboratory). Under the U.S. system, workplace owners must comply with, and are reviewed under, OSHA electrical safety equipment requirements.

From the perspective of European regulators, the United States lacks the political will to provide for mutual recognition in this annex. As one Commission official states, “OSHA never wanted this annex and is not committed to it.” OSHA officials indirectly concur, arguing that this annex was included as a “political gesture” to the Europeans and the telecommunications industry.” U.S. and EC regulatory authorities are now skeptical of the benefits of the electrical safety MRA. According to one Commission official, this MRA annex has been “counterproductive” for overall efforts at U.S.-EC regulatory cooperation. Another Commission official claims that the EC may exercise its right not to apply the other MRAs on account of OSHA’s alleged violations of the agreement.

3. Recreational Craft: A Simple Annex. The recreational craft annex was the simplest to
negotiate and implement from the perspective of the regulators on either side of the Atlantic. In
the United States, the applicable regulatory body, the U.S. Coast Guard, already permitted firms
to self-certify their products, so that there was no need for any European conformity assessment
bodies. In contrast, products must be certified by a “notified body” within the EC, so that
European recognition of U.S. Conformity Assessment Bodies could (at least in theory) reduce
costs for U.S. firms. However, U.S. firms have largely continued to use pre-existing sub-
contracting arrangements for European product certification.82

4. Medical Devices: Disappointment and Delay. The United States and EC agreed to
include the annexes for medical devices and pharmaceutical good manufacturing practices in the
MRA only after the EC, U.S. trade officials, business lobbyists and Congress placed
considerable pressure on a reticent FDA.83 Although the medical device annex was eventually
included, the FDA insisted that the annex’s coverage be more limited, even though the parties
only agreed to mutually recognize testing reports and not each other’s standards. First, the
medical device annex only applies to less stringently regulated medical devices, subject to
possible expansion based on an FDA “pilot program.”84 Second, designated Conformity
Assessment Bodies are not selected by an authority of the exporting country, but rather by “joint
assessment.”85 Third, implementation of the Annex was made subject to a three-year transition
period (to have ended in December 2001), during which the FDA organized a “joint confidence
building program.” In the fall of 2001, the parties agreed to extend this transition period for a
further two years.86 Fourth, designated Conformity Assessment Bodies are not permitted to
perform all tests contemplated by the MRA, but only those in which the regulatory authority
determines that they are competent.87 Fifth, while the annex uses the terminology of “Conformity
Assessment Bodies,” domestic regulatory bodies retain ultimate authority to recognize the testing
results.88 Thus, Conformity Assessment Bodies provide testing and systems evaluation services

82 Only one U.S. laboratory, Underwriters Laboratory, has applied to be a U.S. Conformity Assessment Body under
this annex, primarily because there is, in fact, little market demand for new notified bodies in this sector. Telephone
interview with Joe Dhillon, supra note..., June 7, 2001.
83 See Section III.C.
84 Appendix 2 of the medical device annex specifies that the agreement only covers class 1 products (such as
bandages) and certain listed class 2 products. FDA can expand this list following its review of a “pilot program,”
although in no case does the agreement cover “any US Class II-tier 3 or any Class 3 product.” FDA categorizes
medical devices under three classes, while the EC divides them into four. See John Chai, Medical Device Regulation
an overview of these classification systems).
85 This situation is unlike that in any of the other annexes, subject to one’s interpretation of the Electrical Safety
Annex. In particular, the FDA is concerned by what it finds to be laxer conflict-of-interest rules in Europe in a
context in which private bodies henceforth will be paid by the manufacturing firms that they are testing, and on
whose data the FDA is to rely. See Chai, Medical Device Regulation, supra note..., at 65. FDA officials also note
some problems within Europe based on approvals by notified bodies in one jurisdiction resulting in harm in another,
such as in regards to breast implants. The FDA thus remains more wary than the FCC and Coast Guard in respect of
86 See Gary Yerkey, Standards: U.S., Europe Near Agreement on Plan to Boost Trade in Marine Safety Equipment,
19 INT’L TRADE REP (BNA) 313 (Feb. 21, 2002). This confidence-building program includes mandatory seminars,
workshops, joint training exercises and observed inspections, requiring a considerable investment by applicant
laboratories.
87 Although the FDA has trained and inspected Conformity Assessment Bodies in conducting U.S. quality system
evaluations, the FDA had yet to train them to conduct pre-market 510k approvals by mid-2001. However, the FDA
may do so in the future, pending results of its pilot program. Telephone interview with FDA official, June 8, 2001.
88 Articles 11 and 12 of the annex provide that “reports prepared by the CABS listed as equivalent will normally be
for regulatory authorities, but do not make definitive determinations for marketing purposes. In addition, regulators must create a transatlantic “alert system” and exchange “post-market vigilance reports” as integral parts of the program.89

Implementation of even this relatively limited MRA program nonetheless has encountered serious obstacles. The primary difficulty lies in the wariness of the FDA, stemmed in large part by the very different nature of the U.S. and EC regulatory systems. The European regulatory system for medical devices is much more decentralized under the EC’s “new” and “global” approaches.90 Firms are offered a choice in the EC of how to meet EC “essential requirements,” which choice varies depending on the product and its risk.91 In contrast, the U.S. system is more heavily regulated, as the FDA often requires (depending on the product) both quality systems evaluations (which it terms “surveillance/post-market and initial/pre-approval inspection reports”) and pre-market product evaluation reports (which it calls “510(k) reports”).92 Even under the FDA’s new pilot program with private laboratories, the FDA retains ultimate authority over whether or not to accept laboratory reports or to require further information or testing, so that reliance on private laboratory certification is not automatic.

5. Pharmaceutical Good Manufacturing Practices (GMPs): FDA Reticence. The least ambitious and furthest from implementation of the six annexes is that for Pharmaceutical Good Manufacturing Practices. “Good manufacturing practices,” at least as defined by the EC, are those aspects “of quality assurance which ensures that products are consistently produced and controlled to quality standards.”93 The parties’ intention in the pharmaceutical GMPs annex, the
only annex not to rely on private Conformity Assessment Bodies, is to permit regulatory authorities on one side of the Atlantic to rely on regulatory authorities on the other to conduct on-site visits of manufacturing facilities. After the inspection, the foreign regulatory authority is to provide an inspection report regarding the manufacturers’ compliance with good manufacturing practices. These inspection reports should “normally be endorsed by the authority of the importing authority, except under specific and delineated circumstances.”

The pharmaceutical annex originally was, in large part, an agreement to agree, since many of the key provisions required further drafting. Initially, the parties could not even agree on a definition of good manufacturing practices, noting definitions from each of their legislative texts and adding that “the US and EC have agreed that the parties will “revisit this” issue.” Similarly, the parties left open the content of their programs “for assessing equivalence,” as well as the content of the “information which must be present in inspection reports.” However, in each case, these issues apparently have been resolved, with the parties agreeing to retain their own inspection forms listing the items that the other party’s regulatory authority must evaluate and the information that it must provide.

The “cornerstone” of the pharmaceutical GMP annex is each party’s determination of the equivalence of the regulatory system of the other party, which they “aimed” to conclude by December 31, 2001. The FDA, however, refused to recognize the equivalence of all but two member state systems, and thus the agreement was not implemented by the agreed date. The FDA faces a much more burdensome task to implement the MRA than do its European counterparts, who only need to adapt to one additional regulatory authority. In the FDA’s view, to determine equivalence, it must review not only multiple EC directives and related EC documents, but also each member state’s implementing legislation, regulatory structures and regulatory practices. The FDA requires that it engage in joint training and joint inspections.

---

94 The pharmaceutical GMP annex is the only annex not to be based on the use of private Conformity Assessment Bodies, since public authorities alone certify pharmaceutical manufacturers’ GMPs on each side of the Atlantic under relevant U.S. and EC legislation. Thus, the annex provides for “inspection reports generated by authorities” (i.e. public ministries), provided that the parties deem them to be equivalent “in terms of quality assurance of the products and consumer protection” (article 6).

95 These could be “pre-approval inspections” (i.e. before a product is first marketed) or “post-approval inspections” (i.e. after a product is first marketed).

96 See article 12 of the pharmaceutical GMP annex.

97 See article 1.3.

98 See article 6.

99 See article 8.

100 Interview with Commission official from DG Enterprise, June 18, 2001.

101 See article 2 (Purpose). In other words, the agreement itself does not recognize the “equivalence” of the parties’ regulatory systems for purposes of evaluating “good manufacturing practices,” but rather provides for a three-year transitional period during which the parties’ regulatory authorities aimed to make this determination.

102 The member state implementing legislation was translated for FDA at the Commission’s expense. Interview with Commission official in DG Enterprise, June 18, 2001.
with regulatory officials in each member state before recognizing that state’s “equivalence.” The FDA claims that Congress has failed to allocate sufficient budgetary resources for the FDA to implement the 1997 MRA in a manner that ensures U.S. public safety.\footnote{In the words of one FDA official, FDA has “refused to compromise its mission of protecting public health for balance of trade purposes.” Telephone interview with FDA official, June 7, 2001.}

E. New MRA for Marine Equipment: Initialed June 2001: Broadest in Scope. On June 12, 2001, the United States and EC initialed an Agreement on Mutual Recognition of Certificates of Conformity for Marine Equipment.\footnote{(footnote to include official citation of Agreement)} Unlike the 1997 Mutual Recognition Agreement and its six annexes, this new agreement provides for mutual recognition of each parties’ standards and procedures as “equivalent” for purposes of certifications issued by conformity assessment bodies located in either parties’ territory.\footnote{See articles 3 and 4 of the MRA for Marine Equipment. The relevant EC legislation is Council Directive 96/98/EC of 20 December 1996 on marine equipment, as amended by Commission Directive 98/85/EC. This directive is based on the “new approach” and “global approach.” The relevant U.S. legislation is 46 U.S.C. 3306, as implemented in 46 CFR Parts 159-165. The relevant regulatory authorities are the U.S. Coast Guard and the relevant agencies in the fifteen member states.} Although the initialed annex only covered five marine products, the parties plan to expand this list before they submit the agreement for final adoption under their respective legislative and administrative procedures.\footnote{Interview with Commission official in DG Trade on June 13, 2001 in Brussels.}

Pre-existing harmonization of standards in this sector, agreed under the auspices of the International Maritime Organization (IMO) in Geneva, made possible the parties’ mutual recognition of the “equivalence” of each other’s standards. This new mutual recognition agreement should be much easier to implement because testing bodies will not be certifying under separate standards and procedures, and thus less training and information exchange is required. Moreover, the parties agreed up-front to recognize each other’s existing certification bodies so that no applications are required for implementation.\footnote{See article 6 of the MRA for Marine Equipment.} Thus, while this agreement is relatively narrow in product coverage, it is much broader in scope.

IV. The 1997 MRA in Context: Multi-level Business Strategies, Divergent Regulatory Cultures, Unexpected Market Barriers

A. The 1997 MRA in the Context of Domestic and Global Business Strategies. Bilateral regulatory cooperation cannot be viewed outside of domestic and global business strategies. At the domestic level, trading firms hope that the MRA will promote domestic adoption of harmonized standards, on the one hand, and deregulated certification requirements, on the other. Firms’ main target has been U.S. independent regulatory authorities. They have had some success. Since 1998, the FCC has instituted a new program pursuant to which private testing laboratories may certify new telecommunications equipment, whereas formerly only the FCC could do so.\footnote{Since the MRA telecommunications and electromagnetic compatibility annexes rely on recognition of foreign Conformity Assessment Bodies, the United States (at a minimum) needed to adopt a program permitting the use of private testing laboratories were it to enter into the MRA.} With business’s encouragement, the EC has moved even further in some sectors, permitting manufacturer self-certification of most telecommunications equipment since 1998. Also since 1998, the FDA has instituted a program for private testing and certification of large categories of medical devices, starting with a pilot program that it plans to expand. As John Chai notes, U.S. manufacturers saw the EC system as a friendlier one in which to launch new products.
and urged Congress and the FDA to adopt many of its flexible features. Allegedly, some “U.S. manufacturers were moving their capital, resources, and facilities to Europe” as a result.109 In response to primarily domestic demands, the FDA Modernization Act expressly authorized the FDA to rely on private testing bodies in its oversight of medical devices.110

Although the original goal of the MRA annexes may have been to facilitate transatlantic trade, firms simultaneously focused on the deregulation of domestic product approvals.111 For example, deregulation of product marketing approvals is a core item on the Transatlantic Business Dialogues’ agenda. TABD, in its 2001 Mid Year Report, called for a model “linked to a wider use of Supplier’s Declaration of Conformity,” and stressed the need for transatlantic adoption of the EC’s global approach under the motto: “Approved Once, Accepted Everywhere.”112 Firms are primarily interested in reducing costs and getting new products to market in a rapidly changing technological environment.113 A primary means to do so is to reduce pre-marketing regulatory requirements. The 1997 MRA annexes for telecommunications equipment and electromagnetic compatibility facilitated advancement of businesses’ regulatory objectives. Many telecommunications firms continue to hope that the relevant U.S. agency, OSHA,114 might relax its pre-market controls of electrical safety equipment by adopting a system of self-certification used in the EC since 1973.115

As for Europe, U.S. firms hope to use transatlantic proposals for regulatory cooperation to change EC and member state legislative and regulatory procedures. In this case, firms would prefer that Europe adopt more of a U.S. procedural model, as set forth in U.S. administrative

---

109 See John Chai, Medical Device Regulation in the United States and European Union: A Comparative Study, 55 Food & Drug L.J. 57, 60 (2000). See also MICHELLE EGAN, CONSTRUCTING A EUROPEAN MARKET: STANDARDS, REGULATION AND GOVERNANCE 195 (2001) (“many multinational firms are pursuing a Europe-first marketing strategy” because “European governments are able to approve advanced medical devices more than three times faster than the FDA.”).

110 See 21 U.S.C.A. 360(m). See also Linda Horton, Mutual Recognition Agreements and Harmonization, 29 SETON HALL L. REV. 692, 707 (1998) (providing overview of FDA pilot program and its codification and expansion under the FDA Modernization Act). Nonetheless, as Horton points out, FDA continues to decide which devices are eligible, accredits the participating bodies, and makes final approval decisions in all cases. Id. As Chai states, “The utilization of private third parties is limited to their role in the preliminary assessment of low- and medium-risk devices. FDA gives the manufacturers the option of engaging qualified third-parties in the 510(k) submissions of the applicable devices.” Chai, supra note __, at 63. Business has not been able to prevail over the FDA not only because of the FDA’s relative independence, but also because the FDA has significant allies among consumer advocates and Congressional representatives in retaining its current regulatory controls. See e.g. U.S.-EU Mutual Recognition Agreement (MRA)- Congressional Hearing (visited March 11, 2002) <http://www.citizen.org/trade/harmonization/MRA/articles.cfm?ID=6156>.

111 Interview with FCC official, June 8, 2001. EC officials state that deregulation was likely not the initial goal with the MRA, but agree that this goal has become more central for firms. Interview with two officials from DG Enterprise, June 15, 2001, in Brussels.


113 Firms, of course, also maintain that such regulatory flexibility, in turn, benefits consumers on account of enhanced innovation and competition.

114 Telephone interview with representative of Underwriters Laboratories, Oct. 17, 2002. OSHA has long been challenged by U.S. business, which has been partially successful in preventing OSHA from efficiently doing its job. As Terry Moe writes, “Interest groups representing business actually did participate in the design of OSHA,... [and] OSHA is an administrative nightmare, in large measure because some of its influential designers fully intended to endow it with structures that would not work.” Terry Moe, The Politics of Structural Choice: Toward a Theory of Public Bureaucracy, in ORGANIZATION THEORY, 116 (ed. Oliver Williamson: 1990).

law. As TABD argues, “A key element for further discussion between business and governments... is how to ensure transparency in the regulatory process... The rulemaking and implementation process must be open thereby permitting industry to participate meaningfully in the regulatory process.” TABD urges, in particular, “greater use of ‘impact assessment’ on regulations...[which] should include estimating the costs and benefits of regulation as well as any regulatory alternatives.” The United States, in this case, has taken up TABD’s proposals in the negotiation of a U.S.-EC agreement on regulatory cooperation and transparency. In a 2001 draft, the United States proposed addressing “transparency” in regulatory processes through such mechanisms as “notice and comment rulemaking procedures,” mandatory assessments of the “potential benefits, costs and other impacts for all parties, domestic and non-domestic,” “public explanations... for the proposal and the alternatives,” and “access to documents containing supporting research, data and analysis.”

Businesses also view transatlantic mutual recognition agreements in a global context. Firms, together with some government representatives, hope that transatlantic arrangements may be a stepping stone for reaching mutual recognition agreements with third countries, thereby offering increased access to lucrative Asian and South American markets. The WTO Agreement on Technical Barriers to Trade and the General Agreement on Trade in Services explicitly encourage and lend legal support to the expansion of transatlantic MRAs. Under WTO rules, countries that do not “give mutual satisfaction” to third countries offering “equivalent” procedures or standards are subject to WTO anti-discrimination claims under WTO most-favored nations clauses. While the prospect of these claims remains relatively remote at this stage, business organizations, such as the TABD, already can use the WTO agreements as additional leverage.

Much more importantly than potential legal claims, each new mutual recognition agreement places pressure on third countries to enter into negotiations so that their firms are not disadvantaged—what Kalypso Nicolaidis refers to as a potential “contagion effect.” Transatlantic and third country negotiations thereby have reciprocal effects. Each MRA provides

---

116 On differences between the U.S. Administrative Procedure Act and EC administrative law, see e.g. Martin Shapiro, *Codification of Administrative Law: The US and the Union*, 2 EUROPEAN L. J. 26 (March 1996); and Francesca Bignami, *The Democratic Deficit in European Community Rulemaking: A Call for Notice and Comment in Comitology*, 40 HARVARD INT’L L. J. 451 (1999). Other U.S. legislation of interest to business includes the 1993 Government Performance and Results Act and the 1995 Unfunded Mandates Act. The Unfunded Mandates Act creates procedural hurdles for Congress to impose new requirements on local regulators without providing federal funds. The Government Performance and Results Act requires agencies to justify funding that they receive, with the implied threat that funding will be reduced if they do not perform efficiently (a form of agency cost/benefit analysis).


118 *Id.*, at 16 (also adding “Business consultation and the consultation of other interested stakeholders should be part of the assessment process”). In addition, TABD proposes that all regulation be subject to a separate “trade impact statement” at the cost-benefit analysis phase of regulatory activities and in the development of legislation.” 2001 Mid Year Report, *supra* note..., at 8.

119 Draft agreement on file with author.

120 Telephone interview with official from the FCC, June 8, 2001.


leverage to domestic firms to demand new MRAs (with transatlantic or third country counterparts, as the case may be) to equalize market access. The telecommunications industry has sought MRAs for other lucrative markets in Asia and Latin America, which U.S. and EC authorities respectively have signed through APEC and CITEL. The EC has signed MRAs with Australia, Canada, Israel, Japan, Switzerland and New Zealand, in addition to those signed with the United States. The transatlantic MRA can, in this way, be seen as a step for the extension of MRAs globally, helping ensure that not only transatlantic markets, but also other foreign markets, will remain open to foreign entry.

Business’ global and domestic strategies are interlinked. The telecommunications industry, in particular, has promoted global and U.S. regulatory change toward the EC’s self-certification model. If the industry can spur further regulatory change in the United States, it will increase its leverage in using the transatlantic MRA as a catalyst for its global deregulatory strategies. The EC and United States are in the process of implementing or negotiating MRAs for the telecommunications sector throughout the world.

B. The Challenge of Implementation: Reconciling Regulatory Systems and Cultures. The significant institutional asymmetries between the United States’ and EC’s respective regulatory systems and cultures creates a major challenge for transatlantic regulatory cooperation and the implementation of transatlantic mutual recognition agreements. Where regulators adopt similar regulatory structures and systems, and enact similar substantive standards, they more easily understand and accept each other’s regulatory determinations. Regulatory symmetry facilitates regulatory trust and confidence, enabling regulatory cooperation to occur. For example, U.S. and EC regulatory authorities each have supported a more decentralized process for pre-marketing approvals of telecommunications equipment, which explains the relative ease of this annex’s implementation.

Although the U.S. system is often characterized as fragmented and decentralized, its actual nature varies by sector. At times, the U.S. system is relatively highly centralized, as when Congress delegates regulatory authority to an independent federal regulatory body, such as the FDA. At other times, the U.S. system is more fragmented, with regulation consisting of a patchwork of federal, state, and private voluntary standards with no overarching framework, as in the case of data privacy protection. Significant for transatlantic mutual recognition agreements, U.S. private standard-setting bodies remain highly fragmented, since the American National Standards Institute (ANSI), which is the closest analogue to a U.S. national standards body, does not serve as an administrator or coordinator of private standard-setting.

While some commentators maintain that the United States grants private actors relatively

---

124 See supra note [33]. The transatlantic MRA, of course, was also signed in the context of these other negotiations.  
126 Firms view self-certification as an even more important goal in countries where regulatory certification requirements result in significant delays or protection for domestic competitors.  
127 See supra notes [33. 126-127].  
130 See Egan, Mutual Recognition and Standard Setting, supra note...(?), at 199.
more flexibility than in Europe, this stereotype is belied in practice by a number of the sectors covered by the 1997 MRA. For example, the FCC certified all telecommunications equipment until the negotiation of the transatlantic MRA, at which time it adopted a more decentralized EC model. The U.S. Occupational Safety and Health Administration requires OSHA-accredited laboratories to certify all electrical safety equipment used in the workplace, whereas the EC has permitted manufacturers to self-certify the equipment’s conformity with EC requirements since 1973. The U.S. Food and Drug Administration continues to certify most medical devices, whereas EC authorities have permitted testing by private notified bodies since 1994.

U.S. and EC regulators work in different regulatory cultures, ones which (in the case of the MRA) makes EC institutional adaptation easier. EC and European national regulators operate under the dual mission of ensuring free trade within the internal market, on the one hand, while ensuring public safety through high product and process standards, on the other. They thus are quite accustomed to interacting with foreign regulators and testing bodies on an on-going basis. Consequently, the Commission’s DG Enterprise and DG Trade units rarely tussled when negotiating and implementing the 1997 Mutual Recognition Agreement. In contrast, the U.S. Food and Drug Administration traditionally has defined its role solely as that of protecting U.S. public health, and has not operated under a dual mission of also facilitating market exchange. Although FDA officials participate in the International Conference on Harmonization and although Congress expanded the FDA’s mission in 1998 to include trade facilitation, FDA authorities have developed U.S. standards and procedures over time in relative isolation from other regulators. FDA officials often consider their practices as superior, constituting what the FDA’s General Counsel has characterized as “the gold standard.” Because the FDA is an independent regulatory authority anxious to protect its regulatory autonomy, U.S. trade and commerce authorities encounter more difficulties in negotiating bilateral agreements concerning areas within the FDA’s jurisdiction. Because of OSHA’s and FDA’s wariness of relinquishing regulatory controls, the United States and EC have so far been unable to implement the MRAs for electrical safety equipment, medical devices and pharmaceutical good manufacturing practices.

Implementation of transatlantic MRAs also has been much easier for the EC because EC regulatory authorities only have to adapt to one new regulatory system (the United States’) that is

---

131 It is sometimes maintained that the U.S. provides greater flexibility for firms to set standards through self-regulation or through the competitive market place, subject to ex post review under tort law, while the EC takes a more precautionary ex ante approach, setting more stringent standards overseen by regulatory bodies. See e.g. Michelle Egan, Constructing a European Market: Standards, Regulation and Governance 131 (2001) (calling the EC system more “state-directed” and the U.S. system more “market-oriented”). The divergent approaches of the United States and EC to data privacy protection, genetically modified foods and hormone-injected beef also reflect this perception. See Shaffer, Ratcheting Up U.S. Privacy Standards, supra note ...; AND Mark Pollack and Gregory Shaffer, Food Safety and GMOs in the Transatlantic Relationship, supra note ...(?)

132 See discussion of new FDA pilot program in supra note [112].


134 See Linda Horton, Mutual Recognition Agreements and Harmonization, 29 SETON HALL L. REV. 692, 708 (1998) (noting the 1998 FDA Modernization Act, calling on FDA to “participate... with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements”).

overseen in one language (English), whereas U.S. authorities must adapt to fifteen different regulatory structures operating in eleven different languages within the EC. EC regulatory authorities already are accustomed to dealing with other national regulators in the context of the EC’s single market. Member state regulators are well-acquainted to working in English, the language in which U.S. certification bodies will submit their applications and testing reports. Expansion of the EC system to include the United States is a less significant change for them.

C. The Unexpected Challenge of Market Barriers to Implementation. Transatlantic trade officials and businesses that first touted the benefits of U.S.-EC mutual recognition arrangements now realize their underestimation of the difficulties of implementation. These constraints involve not just regulators and regulatory cultures, but market forces as well. The market has not reacted favorably to the recognition of new Conformity Assessment Bodies under the 1997 MRA. From the perspective of manufacturers, they typically develop long-term working relationships with certifying laboratories, which constitute a form of cost-effective firm-laboratory partnership. Because manufacturers invest in educating these laboratories about their products and manufacturing processes, and the relationship of these products and processes to applicable regulatory requirements, the cost of changing laboratories may be significant. Moreover, a laboratory’s mark itself may be important in some markets, so that firms may continue obtaining formal certification from EC notified bodies for the EC market and U.S. laboratories for the United States. As a result, most firms may continue using the same laboratories even though these laboratories cannot directly certify products as Conformity Assessment Bodies, but must work through sub-contracting arrangements with accredited laboratories on the other side of the Atlantic.

Similarly, laboratories will not invest in the accreditation procedures required to become a Conformity Assessment Body if they fear that the prospects for future profitable business are too uncertain. Accreditation costs can be substantial, involving seminars, workshops, training programs, audits and joint inspections with authorities across the Atlantic. While twelve European notified bodies initially applied to be recognized as Conformity Assessment Bodies under the medical device annex, two subsequently withdrew on account of costs. Private laboratories and manufacturing firms have become, in the words of one Commission official, “a bit cool on the MRA.” This industry reaction, in turn, suits those regulators who were not enthusiastic about the MRA in the first place.

The MRA’s success, in consequence, may require considerable market promotion, including through government subsidies and promotional programs. As Commission representatives assert, “the MRA should contain sufficient commercial incentives for potential CABs [Conformity Assessment Bodies] and industry to show interest. Use of the MRA cannot

---

136 In contrast, even if European regulatory bodies submit documents to U.S. regulatory authorities in English, the texts can be difficult to comprehend since they are prepared by regulators writing in a second language.


138 Some U.S. manufacturers state that it is cheaper for them to use a notified body, with testing conducted through a sub-contracting arrangement, than to use a Conformity Assessment Body. Moreover, firms continue to predominantly use free FDA inspections in the United States, even though they now are authorized to use private testing bodies. Interview with FDA official, June 8 2001.

139 Interview with Commission official from DG Enterprise, June 15, 2001 in Brussels (concerning medical devices).

140 Interview with official from DG Enterprise, June 15, 2001, in Brussels.
be imposed.” The Transatlantic Business Dialogue supports such promotional efforts.

Some domestic firms, however, also benefit from domestic regulatory barriers to their transatlantic competitors. When no domestic business constituency actively presses for domestic regulatory change, implementation of an MRA faces greater hurdles. For example, no U.S. constituency is presssing for implementation of the electrical safety MRA. As a Commission official points out, this is not a “balanced” MRA, since U.S.-based firms do not require conformity assessment to sell electrical safety equipment in the EC market. In addition, most U.S. producers encounter relatively less difficulty with OSHA’s program because of their experience with OSHA-certified laboratories, and thus may gain an advantage against European competitors. Similarly, laboratories already certified by OSHA have a relatively protected market. They would not benefit from new competition from laboratories certified by European authorities. Thus, there is little U.S. constituent pressure on OSHA to concede to the EC and recognize laboratories designated by EC member state authorities.

V. U.S.-EC Understanding on Principles for Data Privacy Protection: Managing Conflict and Maintaining Free Trade through A Hybrid Institutional Development

In July 2000, the United States Department of Commerce and European Commission formalized an agreement creating a set of “Safe Harbor Principles” (the Principles) on data privacy protection. Under the Safe Harbor understanding, U.S.-based firms may self-certify that they will abide by the Principles. In doing so, they may avoid European restrictions on data transfers to the United States imposed pursuant to EC law. The Principles constitute a unique development in the governance of U.S.-EC economic relations. To some, they represent the EC’s exercise of coercive market power in an extraterritorial fashion in an attempt to leverage up privacy standards within the United States. To others, they represent a capitulation by EC

---

141 Minutes from the Thirteenth US/EU MRA Medical Device Annex Stakeholders Teleconference (Nov. 7, 2001) (on file with author). The need for promotional efforts also confirmed in interview with Commission official in DG Enterprise, June 13, 2001. Commission officials also confirm that they will likely subsidize some efforts to promote some of the MRA annexes, in particular those in which they feel U.S. regulators are cooperating.

142 See e.g. TABD Mid Year Report, at 43.

143 The U.S. National Electrical Manufacturers Association, “which represents some 450 U.S. companies,” initially “opposed conclusion of the electrical safety MRA.” An industry source confirms that U.S. “companies manage to have their products tested and certified without much difficulty” and “that the MRA, in fact, was having little impact on the ‘day-to-day operations’ of companies that manufacture products covered under the agreement.” See EU Set to Withdraw from Agreement, Int’l Trade Rep (BNA) supra note...

144 Interview with official in DG Enterprise, June 13, 2001 in Brussels.

145 Interview with official in DG Enterprise, June 13, 2001 in Brussels.

146 Rather, the best hope for European firms may be that a Republican administration might deregulate OSHA’s premarket approval process by permitting manufacturer self-certification. If this occurs, however, the electrical safety annex’s provision of mutual recognition of testing bodies would have served little purpose other than (possibly) to help foment U.S. domestic regulatory change.

147 The agreement was formalized through an exchange of letters between Robert LaRussa, the Acting Secretary of the Department of Commerce and John Mogg, the Director of DG Internal Market (formerly DG XV) in the European Commission. See Joel R Reidenberg, E-Commerce and Trans-Atlantic Privacy, 38 HOUSTON L. REV. 717, 739 (2001).

trade bureaucrats to U.S. trading concerns through a weak agreement filled with loopholes.\textsuperscript{149} And finally, to some, including this author, they represent a compromise through new institutional development pursuant to which free transatlantic information flows may be preserved while satisfying legitimate EC concerns. The EC is justifiably wary of the export of personal information concerning EC residents in a technology-intensive, interdependent globalizing economy.\textsuperscript{150}

Unlike the mutual recognition agreements assessed above, the Safe Harbor Principles constitute a loose form of de facto harmonization of social standards. The Principles go beyond current regulatory requirements in the United States, and thereby constitute a regulatory floor with which trading firms must comply if they wish to receive data from Europe without threat of challenge. This harmonization, however, is designed to affect only trading firms, and otherwise to create no legal obligations within the United States. The United States and EC may thereby claim that they formally retain autonomy to enact whatever privacy legislation they deem appropriate. However, any firm that engages in cross-border exchange is subject to pressure to abide by the Principles. In this way, Europe’s regulatory approach may have spillover effects within the United States, leading to some convergence in data privacy practices, despite differing U.S. and EC regulatory systems.

Although the extent of the Safe Harbor Principles’ implementation remains an open question, the U.S.-EC dispute and efforts at cooperation demonstrate the inherent interrelation between social regulation and open trade policies where regulation (or the lack thereof) has external effects. Alleged U.S. under-regulation can jeopardize the privacy interests of EC residents. Alleged EC over-regulation can limit the commercial operations of U.S. enterprises. In an interdependent transatlantic economy, U.S. and EC authorities attempt to manage the ensuing conflicts of norms and interests, and mesh, where possible, their divergent regulatory systems.

A. Pooled Sovereignty: The EC’s Market Clout in an Interdependent Transatlantic Economy. The U.S.-EC agreement was spurred by the creation of the EC single market, on the one hand, and the interdependent nature of the U.S. and European economies, on the other. The creation of the single market led to the EC’s regulation of data privacy in the first place. Among the ironies inherent in the U.S.-EC dispute is that the original purpose of the EC’s data privacy directive was not just to increase data privacy protection within the European Community. It was also to ensure the uninhibited flow of data within the EC from the threat of unilateral restrictions by individual EC member states on account of their differing data privacy protection regimes.\textsuperscript{151}

\textsuperscript{149} See e.g., Joel R Reidenberg, \textit{E-Commerce and Trans-Atlantic Privacy}, 38 \textit{Houston L. Rev.} 717, 743-746 (2001).

\textsuperscript{150} Some commentators have distinguished an EC state-based approach to a U.S. market-based approach. See e.g. Egan, Constructing a European Market, supra note..., at 131. Yet, this is an overstatement, for as shown above, the EC itself has adopted novel institutional means to reconcile free movement of goods and social protection through the EC’s new and global approaches to harmonization, which include self-certification and oversight by self-regulatory organizations.

\textsuperscript{151} The Directive was negotiated within the context of the threat of data transfer bans from certain member states with protective data privacy laws (such as France and Germany) to other member states with less stringent laws (such as Italy). By requiring similar data privacy protection throughout the European Union, the Directive concurrently removed the threat to unhindered data flows between member states. To ensure the economic benefits of trade liberalization through the creation of a single market, EC member states collectively agreed to guarantee more stringent protections of data privacy. See Greg Shaffer, \textit{Globalization and Social Protection: The Impact of EU
The interlinked nature of social protection and liberalized trade in a single European market gave rise to the Directive.

Similarly, data privacy protection became a transatlantic issue because of the growing interdependence of the U.S. and European economies and the rising importance of information technology. U.S. affiliates in Europe produce over a trillion dollars of goods and services annually, constituting “over half of all the foreign production of U.S. companies.” These companies depend on information flows, not only with third party suppliers, customers, consultants, marketers and other service providers, but also internally, within their complex networks of affiliates, joint ventures and partnerships.

The U.S.-EC dispute over the adequacy of U.S. data privacy protection affects U.S. privacy policies and practices because the EC exercises political and market power. In a globalizing marketplace, the EC’s single market initiative has reinforced the European Commission’s position as a global actor. The EC’s huge internal market enables the Commission to exercise considerable political clout in the negotiation of international and transatlantic rules, including harmonized rules governing firm behavior.

The shift of European regulation to the EC level has strengthened the EC’s ability to represent the interests of its constituents vis-a-vis the United States. The EC member states have not simply “lost” sovereignty in working through centralized EC authorities; they have reallocated it in a manner which effectively enhances their negotiating authority (and in that way their autonomy) vis-a-vis the United States. In pooling their sovereignty, EC member states now speak with a more powerful voice transatlantically on economic regulatory matters. The timing of the United States’ reaction to the threat of bans on data transfers from Europe demonstrates the EC’s relative clout. It was not until the EC’s privacy directive went into effect that U.S. authorities drafted Safe Harbor Principles and increased pressure on companies to raise their internal privacy standards. When the threat moved to the EC level, the United States took the threat more seriously.

Processing of Personal Data and the Free Movement of such Data\footnote{See Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L 281) 1 [hereinafter Directive].} became effective. The EC, through its Directive, takes primarily a regulatory approach to data privacy protection, as opposed to private ordering through market processes. The Directive is noteworthy for its broad scope of coverage. Except for public security, criminal law and related exceptions, it covers all processing of all personal data by whatever means, and is not limited to action by government, business sector or field of use.\footnote{See Directive, arts. 2 and 3.} The Directive prohibits data controllers from processing information unless the individual “unambiguously” consents to the processing and that consent is informed.\footnote{See Directive, arts. 7, 8, 10, 14.} Information subject to the most stringent controls includes “personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life.”\footnote{See Directive, art. 8.}

The Directive provides multiple means for enforcement. It requires member states to grant individuals a permanent right of access to obtain copies of the data about them and have it corrected or its use enjoined.\footnote{See Directive, arts. 12, 28.} It obliges member states to provide a judicial remedy for infringements of data privacy rights, including the right to receive damages.\footnote{See Directive, arts. 22-24.} To support effective enforcement, each member state must designate an independent public authority “responsible for monitoring the application within its territory” of the Directive’s provisions.\footnote{See Directive, art. 28.} These supervisory authorities are to be granted significant powers, including the power to investigate processing operations, to deliver “opinions before processing operations are carried out,” to order “the blocking, erasure or destruction of data,” to impose “a temporary or definitive ban on processing,” and “to engage in legal proceedings” against violators of the rights guaranteed by the Directive.\footnote{See Directive, arts 18, 28.}

The Directive also addresses the adequacy of foreign data protection law. It thus has explicit extraterritorial scope. Article 25 of the Directive provides that member states shall prohibit all data transfers to a third country if the Commission finds that the country does not ensure “an adequate level of protection” of data privacy. Pursuant to article 29 of the Directive, an EC Working Party prepared a series of documents that identified core principles under which the adequacy of a country’s protections should be gauged.\footnote{In July 1998, the Working Party incorporated earlier papers in a Working Document entitled Transfers of personal data to third countries: Applying Articles 25 and 26 of the EU data protection directive.} These principles are in line with the EC’s internal requirements and include the following: processing must be limited to a specific purpose made known to the concerned individual, together with other information to ensure fair processing; the individual must have access to the data and the right to object to its processing; the individual must have procedural mechanisms available to effectively enforce the protections.

In contrast to the EC, the United States has stressed “self-regulation” by the private sector backed by regulation which tends to be sector-specific and less stringent. Congress’ targeting of specific sectors and concerns is reflected in such statutory titles as The Driver’s Privacy Protection Act of 1994, and the Video Privacy Protection Act of 1988.\footnote{See also The Electronic Communications Privacy Act of 1986, the Cable Communications Policy Act of 1984,} Overall, the U.S.
approach is fragmented, involving standard-setting and enforcement by a wide variety of actors, including federal and state legislatures, agencies and courts, industry associations, individual companies and market forces. To a certain extent, the United States’ handling of data privacy issues reflects Americans’ traditional distrust of a centralized government. U.S. legislation provides citizens with significantly greater protection against the collection and use of personal information by government, in particular the federal government, than by the private sector. Since it appeared that the United States might not provide for “adequate” data privacy protection under the Directive’s criteria, U.S. and EC authorities engaged in intensive negotiations to avoid a ban on data flows to the United States. These negotiations culminated in the U.S.-EC understanding on Safe Harbor Principles pursuant to which, the EC agreed that the Principles only would address the adequacy of companies’ data protection practices, and not those of the United States as a whole. Under Safe Harbor, EC member states formally recognized that U.S. firms’ adherence to the Principles would be sufficient to protect firms from EC member state challenge.

Member state authorities, however, retain jurisdiction to challenge transfers to firms that do not adopt the Safe Harbor Principles. Privacy rights associations can trigger these proceedings by filing claims with supervisory authorities. Even before implementation of the Directive, data transfers to the United States were barred by British, French, German and Swedish courts and administrative authorities.

and The Fair Credit Reporting Act of 1971. In many cases, Congress has simply reacted to public scandals. In passing the Fair Credit Reporting Act, it responded “to consumer horror stories of dealings with credit reporting agencies.” It enacted The Video Privacy Protection Act after the video rental records of Judge Robert Bork were published by a news reporter in the course of a campaign against his Supreme Court nomination.

The fragmented, decentralized nature of the U.S. regulatory process is described in Steven Vogel, Freer Markets, More Rules: Regulatory Reform in Advanced Industrialized Countries, 217 (1996).


The Privacy Act of 1974 is the only federal omnibus act that protects informational privacy. Yet despite the legislation’s broad title, the Privacy Act only applies to data processing conducted by the federal government, not by state governments or private entities. The vast majority of states lack omnibus privacy acts, and rather offer scattered statutes applying to specific sectors or concerns. Nonetheless, demands for privacy legislation covering the private sector within the United States have increased. In the fall of 1998, the Federal Trade Commission (FTC) successfully lobbied for greater online data privacy protection for children. See Pub. L. No. 105-277, 112 Stat. 2681 Title XIII (1998). In May 2000, a divided FTC, by a 3-2 vote, called for Congress to enact on-line privacy protection for all persons within the United States. Federal Trade Commission, Privacy Online: Fair Information Practices in the Electronic Marketplace: A Report to Congress, May 2000. With a change to a Republican administration, the FTC has backed away from recommending legislation.

In an attempt to ward off EC action, U.S. officials implicitly threatened to challenge any ban imposed by the EC before the WTO’s Dispute Settlement Body. For example, Ira Magaziner, formerly responsible for U.S. discussions on electronic commerce issues, including privacy protection, stated that, “In general, we in the U.S. don’t recognize an extra-territorial attempt to shut down the electronic flow of data between countries. According to principles of international trade, I think that’s a violation of WTO rules.” Kenneth Cukier, ‘U.S. Under Fire over ‘Aggressive’ Net Tax Stance,’ Comm. Wk. Int’l, March 2, 1998. However, WTO rules have shielded the EC from a U.S. retaliatory threat since the Directive arguably is in compliance with WTO rules. For an analysis of the Directive’s extraterritorial scope under WTO law, see Shaffer, Globalization and Social Protection, supra note…, at 46-55.

Privacy International, a London-based privacy organization, has threatened to file claims against American Express and EDS for failing to provide adequate data privacy protection. See ‘Will Amex and EDS Face Privacy Lawsuits in Europe?’, Computergram Int’l, July 2, 1998.

See Fred Cate, The EU Data Protection Directive, Information Privacy, and the Public Interest, 80 Iowa L. Rev._____
C. The Safe Harbor Program.

Table 2

The Safe Harbor program sets forth seven core data privacy principles for industry to follow. Because the EC formally acknowledged the Principles as “adequate” under the Directive’s criteria, the Principles provide U.S. businesses with a “safe harbor.” The seven Principles are:

(i) “Notice”: An organization must provide “clear and conspicuous” notice to individuals “about the purposes for which it collects and uses information about them, how to contact the organization with... complaints, the types of third parties to which it discloses the information, and the... means... for limiting its use and disclosure”;
(ii) “Choice”: An organization must provide individuals with a “clear and conspicuous” choice to “opt out” of how their personal information may be used and to whom it may be disclosed; “for sensitive information (i.e, personal information specifying medical or health conditions, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership or information specifying the sex life of the individual), they must be given affirmative or explicit (opt in) choice if the information is to be disclosed to a third party or used for a purpose other than those for which it was originally collected or substantively authorized...”;
(iii) “Onward Transfer”: To disclose information to a third party, an organization must apply the “Notice and Choice principles”;
(iv) “Security”: Organizations must take reasonable measures to protect information from disclosure, misuse, alteration or loss;
(v) “Data Integrity”: Organizations “may not process personal information in a way that is incompatible with the purposes for which it has been collected or subsequently authorized,” and “take reasonable steps to ensure that data is... accurate, complete and current”;
(vi) “Access”: An organization must grant individuals access to personal information held about them and the opportunity to have it corrected, except where the burden would be disproportionate to the privacy risks in the case in question;
(vii) “Enforcement”: There must be “mechanisms for assuring compliance” and “consequences” for non-compliance, which must include “readily available and affordable independent recourse mechanisms” and “sanctions [that] must be sufficiently rigorous to ensure compliance.”

The meaning of the principles is further specified in a document entitled

“Frequently Asked Questions” which the U.S. Department of Commerce also negotiated with the Commission, and which specify the scope of certain exceptions.

An overview of the Safe Harbor Principles is set forth in Table 2. Companies join the Safe Harbor program by annually certifying to the U.S. Department of Commerce that they will comply with the Principles. The Department of Commerce then places the company’s name on its web site list of certifying firms. The firms’ primary benefit from certifying is that EC member states may not challenge them under member state law or otherwise condition any data transfers to them. U.S. law applies to the Principles’ interpretation, and U.S. courts and administrative bodies hear all claims (although European courts and administrative bodies may still challenge the online collection of information from European residents by U.S.-based firms).

Self-regulatory organizations (such as BBBOnLine and TRUSTe), backed by the U.S. Federal Trade Commission, offer the primary means for the Principles’ enforcement. In this way, the Principles’ application resembles the EC’s new and global approaches to internal market harmonization. As under the new approach, the Safe Harbor Principles set forth “essential requirements” that firms (although in this case, only self-certified firms) must meet. As under the global approach, quasi-public-private bodies oversee their compliance. This oversight ultimately is backed by the authority of the state. If a company adopts the safe harbor principles and fails to comply with them, it subjects itself to challenge by the FTC for “using unfair or deceptive acts or practices in or affecting commerce.” In a letter to the Commission date July 14, 2000, the FTC committed itself to “give priority to referrals of non-compliance with self-regulatory guidelines... [and] safe harbor principles” respectively referred to it from certifying organizations and EC member state authorities. As documented in this letter, the FTC has already brought enforcement actions against firms for failure to comply with their posted privacy policies. In this backhanded way, the Directive informally shapes U.S. data privacy requirements, potentially

---

173 To the extent U.S.-based firms gather information on-line from web sites in Europe, they may be subject to enforcement in Europe under the Directive despite their signing onto the Safe Harbor Principles, an issue about which U.S. and EC authorities have argued, but which remains unresolved. See Joel R Reidenberg, E-Commerce and Trans-Atlantic Privacy, 38 HOUSTON L. REV. 717, 743 (2001) (citing inter alia EC Article 29 working group report maintaining that EC authorities have jurisdiction over such activities).
174 See infra notes [214-215].
175 See supra notes [14-24].
177 In the fall of 1998, the FTC brought an enforcement action against GeoCities, which has “one of the most popular sites on the Web,” for having suggested that GeoCities was collecting personal information, when the personal information was rather going directly to third parties. In 1999, the FTC announced a second enforcement action against Liberty Financial Companies, Inc., operator of the Young Investor Web site, for falsely representing that information collected would be maintained anonymously. Another complaint was brought by the FTC against the online auction site ReverseAuction.com, which resulted in a consent agreement in January 2000. A description of these cases is set forth in Letter from the FTC to John Mogg, Director of DG Internal Market (formerly DG XV) of the European Commission, dated July 14, 2000.
becoming a baseline standard. Yet, it does so in a relatively flexible manner that respects U.S. legal sovereignty and use of private oversight bodies.

The Safe Harbor Principles should not be viewed in isolation, since the Directive provides other ways to comply with it, although these other means are typically more stringent. For example, in January 2002, the Commission approved standard contract clauses covering privacy protection that can be applied to all data transfers from the EC, regardless of a firm’s adherence to the Safe Harbor Principles. U.S. financial services firms were particularly interested in the content of this model contract since they currently are ineligible for certification under the Safe Harbor Principles because no U.S. authority (such as the FTC) has competence to enforce them. When the draft model contract went beyond Safe Harbor requirements, the financial services industry reacted vehemently, pressuring the Treasury and Commerce Departments to send a joint letter to the Commission in protest, albeit to no avail. Firms also can sign ad hoc contracts with individual member state data privacy authorities. Alternatively, they can obtain the “unambiguous” consent of the “data subject” under the Directive, or sign contracts with affiliates or third parties when transferring personal information, in line with the Directive’s requirements.

The Safe Harbor Principles are still at an inchoate stage so that it remains too early to assess their definitive impact. Some commentators have questioned the effectiveness of the Principles given that only a few U.S. companies initially signed them, and that the number of certified companies had only reached about two hundred and fifty as of October 2002. A report of the Commission itself revealed serious flaws in the safe harbor agreement’s implementation. However, as practitioners point out, companies will not certify their

---

178 The Safe Harbor Principles are not intended, on their face, to affect U.S. law, but rather to provide a “safe harbor” to companies in respect of a foreign law, the EC Directive. Domestic parties, however, are aware of the spill-over effects these principles will have on data privacy policy and practice in the United States. While U.S. companies are not technically forced to adopt them, most large businesses should take them into account even if they do not formally certify that they are adopting them, in order to avoid EC restrictions on data transfers. Moreover, large businesses generally do not wish to be found in violation of law, since they are concerned about reputational effects in the product and capital markets.

179 The model contracts were prepared pursuant to Article 26 of the Directive. See Anandashankar Mazumdar, European Commission Gives Final Approval to Model Clauses to Protect Personal Data, 19 INT'L TRADE REP (BNA) 187 (Jan. 31, 2002). The Commission will likely supplement this universal model contract with other models tailored for transfers of specific types of information. Interview with Fabrizia Benini, DG Internal Market, June 13, 2001, in Brussels.

180 FTC jurisdiction does not cover the financial sector, so that other U.S. federal agency, such as the Office of the Comptroller of the Currency, would have to have the authority to make a similar commitment to the Commission to give priority attention to referrals. See e.g. Joel R Reidenberg, E-Commerce and Trans-Atlantic Privacy, 38 HOUSTON L. REV. 717, 743 (2001) (concerning FTC’s limited competence). The United States and EC continue to negotiate over the EC’s handling of the financial services sector. See Gary Yerkey, U.S., EU to Hold Talks on Including Financial Services Firms in Data Privacy Pact, 19 Int’l Trade Rep (BNA) 1087, June 20, 2002.

181 The content of the model contract ended up going far beyond both the relevant U.S. legislation (under the Gramm-Leach-Bliley Act) and the Safe Harbor Principles. See Joe Kirvin, EC Dismisses US. Worry that ‘Model Contract’ Will Hurt Safe Harbor Talks, 18 INTL. TRADE REP (BNA) 537 (April 5, 2001).

182 See Directive, art. 27.2.

183 See Directive, art 7 and art 25.1(a).

184 As of June 13, 2001, fifty two companies had certified. As of February 23, 2002, the number of certifications had expanded to one hundred fifty six. See US Department of Commerce: Safe Harbor (visited February 23, 2002) <http://www.export.gov/safeharbor>. As of October 6, 2002, the list had further expanded to two hundred forty nine companies. Id.

procedures until their operations are in compliance. For large companies, this can involve considerable re-engineering of their information systems, creation of new internal policies, and training of personnel. Moreover, many companies waited to see the content of the Commission’s “model contract,” which turned out to be more stringent than the Safe Harbor Principles themselves. A Commission representative admits that the number of U.S. certifying companies “are disappointing,” and that “it could be that companies feel there is a lack of enforcement of the EU data privacy law and therefore there is not a need to take part.” However, by 2002, the list of certified companies included major information technology companies such as Microsoft, Intel, Hewlett-Packard, Compaq, Acxiom and DoubleClick. In addition, the Commission started investigations of the practices of Microsoft and online music software companies, among others. Although some companies initially hesitated certifying under the Safe Harbor Principles in order to avoid being subject to an FTC challenge within the United States, most large companies receiving data from Europe likely will not reason in this manner. They would prefer to be in legal compliance with EC rules on both reputational and legal grounds. The Safe Harbor Principles are one way to proceed.

Whether or not they certify to the Safe Harbor Principles, companies engaged in transatlantic business operate in the shadow of the Directive’s potential enforcement. In this way, the EC Directive and Safe Harbor Principles can contribute to a gradual convergence in data privacy practices. Data privacy regulation in Europe has informed not only the tenor and context of debates in the United States; it has shaped interest groups’ appreciation of their options. Under the Directive, U.S. businesses face potential litigation before European courts and administrative bodies unless they adhere to the Safe Harbor Principles. Playing off the U.S.-EC regulatory conflict and its media coverage, privacy advocates have increased pressure on U.S. federal and state politicians, regulatory authorities and businesses. Even though privacy advocates have criticized the Safe Harbor Principles, privacy advocates will use them as part of their larger strategies. The context in which U.S. domestic debates over data privacy protection take place pursuant to Directive 95/46, SEC(2002) 196, Feb. 13, 2002. See also Alan Pedersen, Report Reveals Serious Flaws in Safe Harbor Agreement, Europemedia, Feb. 21, 2001, at http://www.europemedia.net/shownews.asp?Article. Telephone interviews with Barbara Wellbery of the law firm Morrison & Forester (previously Undersecretary of Commerce for Electronic Commerce in the Department of Commerce) and Robert Gellman (independent privacy consultant), June 5, 2001. U.S. and EC officials also had agreed on an implementation period during which firms would not be challenged, which period would be “reviewed in mid 2001.” See Letter from Robert LaRussa of the U.S. Department of Commerce to John Mogg, Director of DG Internal Market (formerly DG XV) of the European Commission, dated July 17, 2000 at US Department of Commerce Safe Harbor (visited April 2, 2002) <http://www.export.gov/safeharbor>. See Information Technology, EC Delays Revising Data Protection Edict; Survey Results to be Basis of New Proposal, 19 Int’l Trade Rep (BNA) 1169 (July 4, 2002). (containing quote from anonymous Commission official). See e.g. EC Delays Revising Data Protection Edict; Survey Results to be Basis of New Proposal 19 Int’l Trade Rep (BNA) 1169 (July 4, 2002) (noting that “the provisions of the EU data privacy law... have triggered an inquiry into the Microsoft .NET Passport system that allow companies to control access to their Web site,” and that “EU member states are also looking into the possibility the online music providers such as Real Audio are in violation of the EU data privacy law”); and Gary Yerkey, EU Data Privacy Officials Monitor Online Music Players, EC Confirms, 19 Int’l Trade Rep (BNA) 1087 (June 20, 2002).

Wellbery interview, supra note [197]. For example, in August 2002, Microsoft entered into a consent decree with the Federal Trade Commission, resulting in Microsoft’s agreement “to be monitored for 20 years” by the Commission, under the threat of severe civil penalties. The government charged Microsoft with not abiding by its privacy policies for users of its .NET Passport system. These privacy policies, in turn, were shaped by Microsoft’s agreement to adhere to the Safe Harbor
has been altered.

The Directive, in particular, has increased the demand for legal, consulting and other privacy services within the United States. The Better Business Bureau OnLine created a privacy seal program which incorporates the Safe Harbor Principles, and was revised to track “safe harbor” negotiations. The Electronic Frontier Foundation, a San Francisco-based public interest organization, has associated with information technology companies to launch a program named TRUSTe to rate the privacy protection of Internet sites, which program is certified under Safe Harbor. As smaller companies find these certification programs costly, trade associations such as the Direct Marketing Association designed their own enforcement programs for their members to comply with Safe Harbor requirements. In adapting to the Safe Harbor Principles, many businesses have found that compliance actually entails minimum costs. Legislation, in this case foreign legislation, has helped raise the standards to be certified and spurred more companies to use seal programs with oversight and sanctioning mechanisms.

The Directive also has helped spur the creation of a new corporate position—the chief data privacy officer in companies’ human resources divisions. These company employees attend conferences on the Directive and U.S. privacy legislation, write memoranda on privacy issues that they distribute within firms, and generally increase firm awareness of privacy issues. In formulating and overseeing the implementation of company policies, they foster company compliance with applicable legal requirements. Finally, outside law firms increasingly provide advice to firms regarding the Directive and the Safe Harbor Principles, thereby again promoting adaptation of U.S. business practice. This conjunction of lawyer, consultant and “privacy officer” advice, rendered in the context of the Safe Harbor Principles, can lead to some convergence of privacy policies over time, reducing the chance of a major transatlantic trade dispute over data privacy protection.

Concomitantly, in negotiating and operationalizing the Safe Harbor Principles, European officials have become more comfortable with the potential of U.S. governance approaches involving the use of private bodies, such as BBBOnLine, for the monitoring and certification of privacy practices. As Henry Farrell points out, European officials have indicated that they are willing to entertain the adaptation to the European context of less-centralized U.S. regulatory principles. See John Schwartz, Settling with F.T.C., Microsoft Agrees to Privacy Safeguards, NYT, at C6, August 9, 2002.


Telephone interview with Gary Laden, Director BBBOnLine Privacy Program, April 21, 1999.

Similarly, accountants, through their national organization, the American Institute of Certified Public Accountants (AICPA), created an analogous program entitled CPA WebTrust, under which they will evaluate web sites, conduct audits of firm’s privacy practices and recertify participating firms. See Web Trust: Online Businesses (visited April 2, 2002) <http://www.cpawebtrust.org/online.htm>.

mechanisms for data protection. The President of the European Parliament even called the Safe Harbor approach a “template for the future,” serving as a potential model for regulation in other policy areas.

D. Some Conclusions on Safe Harbor. While the Safe Harbor Principles do not formally apply to purely domestic data processing operations, U.S.-based enterprises recognize that it will be difficult for them to use two sets of data privacy practices, one for EC residents (providing for greater privacy protection), and one for U.S. residents (providing for less). Business databases will often include information about EC and U.S. residents, in which case businesses will be pushed to comply with the EC’s more demanding requirements. In addition, if businesses provide greater data privacy protection for EC residents than for U.S. residents, they may harm their public image. Privacy advocates have already exploited this argument, proclaiming that U.S. citizens should not be treated as second class citizens in their own country. This move toward convergence, in practice, should help relieve cross-border regulatory conflicts.

Most importantly, in a world of increased economic interdependence, the Safe Harbor Principles point to the importance of regulatory cooperation across borders involving public and private actors. Certification groups such as BBBOnLine meet with European data protection officials so that they become comfortable in the workings of an alternative U.S. approach. These private groups also negotiate contracts for joint seal programs in other jurisdictions, such as that concluded in 2001 between BBBOnLine and a Japanese counterpart. In this way, online businesses can meet criteria in multiple jurisdictions without the need for drawn-out treaty negotiations. Government officials realize that they do not have the resources to enforce the Directive’s provisions solely on their own, and thus rely on public-private networks in an attempt to ensure better global practices affecting EC constituents. The regulation of data privacy in a global economy will require the meshing of different regulatory systems and a commitment from the various actors to sustained interaction to ensure trust and confidence in each other’s efforts.

From a practical standpoint, the goals of protecting individual privacy, on the one hand, while ensuring trade liberalization, on the other, are inseparable. Regulation in a jurisdiction with less stringent data privacy controls has significant externalities, thereby affecting residents in

---

197 Speech of Pat Cox, Sept. 8, 2000, cited in Farrell, supra note ..., at 36.
198 As Kagan notes in his summary of case studies involving multiple industries, there is “evidence for a dynamic toward trans-national ‘corporation-level’ harmonization of regulatory compliance routines in multinational companies, keyed to compliance with the most stringent national standards (sometimes with a margin of error).” See Robert Kagan, Consequences of Adversarial Legalism, in REGULATORY ENCOUNTERS: MULTINATIONAL CORPORATIONS AND AMERICAN ADVERSARIAL LEGALISM, 374 (Robert Kagan & Lee Axelrod eds.).
199 See Comments of Mark Silbergeld on the Department of Commerce, Draft Safe Harbor Principles on behalf of a number of privacy advocate organizations, at http://www.ita.doc.gov/ecom/com1abc.html#silbergeld.
200 Telephone interview with Gary Laden of BBBOnLine, June 6, 2001, and interview with Fabrizia Benini, supra note...
201 The Japanese counterpart is named JIPDEC, a public-private body working with the Japanese Ministry of Trade and Industry. Telephone interview with Gary Laden, Director BBB OnLine Privacy Program, June 6, 2001. The fifteen members of the Article 29 working group (of national data privacy authorities) came and met with BBB OnLine to see how self-regulation works within the U.S. setting. This, combined with the FTC’s commitment to expeditiously pursue complaints referred to it by European authorities, helped seal the Safe Harbor deal.
202 European authorities have limited staff and resources and cannot possibly monitor all company practices throughout the world, much less in Europe. This point was stressed by Gary Laden of BBBOnLine, telephone interview, June 6, 2001.
other jurisdictions. The Safe Harbor Principles are an example of an instrument for reconciling these regulatory concerns with the goals of liberalized trade. They represent a form of compromise that recognizes different institutional approaches and social values, yet nonetheless sets baseline rules where domestic values are affected by trade.\textsuperscript{203} To make them work, however, will require sustained, cross-border cooperation. These new experiments in governance are a much preferred way to proceed than through litigation before a supranational court, such as the WTO’s Dispute Settlement Body. New institutional development requires creative problem-solving and political will. The Safe Harbor Principles point to what—potentially—can be accomplished.

VI. Conclusions: The Prospects and Limits of U.S.-EC Bilateral Regulatory Cooperation through Mutual Recognition Agreements: Moving Toward an EC System?

A. Reasons for Enhanced Bilateral Regulatory Cooperation. Despite the significant difficulties of implementing the various U.S.-EC bilateral agreements, they also have created frameworks for interaction among regulatory officials who are responsible for protecting the health and safety of residents in an array of areas. Even if these transatlantic regulatory interactions result in tensions, blockages and obstacles, the concerned regulatory authorities also become more educated about each other’s systems and are simultaneously initiating and pursuing various informal parallel programs which receive less attention than the conflicts, but may be more important in the long-term. Sustained regulatory encounters promoted by the various bilateral agreements ultimately are much more important than abstract undertakings to engage in regulatory cooperation.\textsuperscript{204}

This regulatory interaction, at least potentially, can lead to more protective social regulation \textit{and} greater trade facilitation, both to consumers’ benefit. First, regulatory exchange can spur improved social regulation, as authorities compare experiences and learn from each other’s best practices. In a world characterized by rapid technological change under conditions of uncertainty, more sustained regulatory exchange can enhance informed decision-making.\textsuperscript{205} FDA and member state regulatory officials, for example, meet to study their different evaluations of

\textsuperscript{203} For a review of the deliberations that took place between U.S. and EC officials that eventually led to the safe harbor principles, see Henry Farrell, \textit{Constructing the International Foundations of E-Commerce–The EU-U.S. Safe Harbor Agreement} (forthcoming in International Organization, manuscript on file with author) Farrell cites a Commission representative as stating, “[T]he discussions that eventually led to the Safe Harbor agreement were an enormous learning experience for both sides... initially, we both took stances that were rather simplistic, because we didn’t know any better.” \textit{Id.}, at 27. Farrell applies a constructivist approach to mutual learning among public and private actors on both sides of the Atlantic that made the agreement possible.

\textsuperscript{204} Such abstract undertakings are reflected in the NTA, the TEP and their action plans. In 2002, the United States and EC finally agreed to U.S.-EU Guidelines/Principles on Cooperation and Transparency in Establishing Technical Resources, after almost four years of negotiation. See Gary Yerkey, \textit{U.S., EU Agree on New Guidelines to Improve Cooperation on Regulatory Policy}, 19 Int’l Trade Rep. (BNA) 696 (April 18, 2002). This agreement could have practical impacts to the extent that it is actually applied. For example, the United States and EU have agreed to implement the guidelines “starting with pilot projects involving automotive safety and dietary supplements.” See Gary Yerkey, \textit{U.S., EU to Begin Implementing New Guidelines on Regulatory Cooperation}, 19 Int’l Trade Rep (BNA) 1088 (June 20, 2002).

\textsuperscript{205} See e.g., Karl-Heinz Ladeur, Towards a Legal Concept of the Network in European Standard-Setting, in EU Committees: Social Regulation, Law and Politics (Christian Joerges and Ellen Vos, eds: 2001), 151, 152,160 (maintaining, under a broad concept of networks involving public and private actors, “the network concept could serve as a frame of reference for the linkage of different decision-makers…and different types of contributions…which are to be tied together within a better-structured process of decision-making under conditions of complexity.”).
new products and the reasons why one authority may grant and the other withhold approval. They complement their reviews of market approvals with new joint alert and safeguard systems to more rapidly notify each other of risks that they encounter, and better coordinate procedures to address them.\textsuperscript{[206]} Through these information exchanges, regulatory officials learn to build on each other’s separate experiences, avoiding duplicative efforts so that they can target resources for other challenges.\textsuperscript{[207]}

Second, in some cases, regulatory exchange can lead to harmonized standards and procedures, which can help facilitate and spur further regulatory cooperation because officials more easily understand each other’s systems and activities. Moreover, these harmonized standards and procedures can facilitate trade and competition by reducing production costs, since firms no longer need different product lines and product evaluation controls for multiple jurisdictions.\textsuperscript{[208]} For example, increased interaction between the FDA and European regulators could facilitate transatlantic and international harmonization through the Global Harmonization Task Force.\textsuperscript{[209]} These harmonization efforts reciprocally could facilitate implementation of the medical devices MRA by easing the FDA’s review of European products and procedures.\textsuperscript{[210]} Individuals, in turn, could have more rapid access to new products and greater product choice at lower prices. Although harmonization is not an end in itself,\textsuperscript{[211]} harmonization in the transatlantic

\begin{itemize}
  \item \textsuperscript{[206]} Interview with official in DG Enterprise, June 15, 2001, Brussels.
  \item \textsuperscript{[207]} Majone, for example, notes “the important role of the [EC]… in complementing the regulatory capacities of the member states. See Geiandomenico Majone, \textit{The Rise of the Regulatory State}, 17 West European Politics 77, 85 (1994). Similarly, Wessels notes that “a major dynamic for European integration [leads] not to a transfer of loyalty by national officials to a new centre but to a cooperation of officials into a new system of shared government” resulting in a “positive sum game.” Wofgang Wessels, \textit{Administrative Interaction}, in \textit{The Dynamics of European Inegration}, William Wallace, ed: 1990), 229, 230.
  \item \textsuperscript{[208]} For example, EC pharmaceutical manufacturers exporting to the United States currently are inspected for GMP compliance by both member state and FDA officials. Similarly, U.S. pharmaceutical manufacturers exporting to the EC must have each batch/lot of their products tested and certified by an EC importer in accordance with specifications and controls set forth in EC directives. The EC importer also must be a licensed pharmaceutical manufacturer subject to GMP reviews by the member state authority. For certain new products, European member state authorities sometimes conduct inspections at manufacturers’ facilities within the United States. Interview with Commission official from DG Enterprise, June 18, 2001, Brussels. For U.S. manufacturers, the MRA would eliminate the additional costs of these importer batch/lot tests, certifications and inspections. Again, reducing redundant product inspections permits products to get to market faster at a lower price. The key issue, of course, will be whether such products, on balance, pose more of a risk to consumers because of reduced regulatory oversight or offer greater health benefits on account of their more rapid availability.
  \item \textsuperscript{[209]} The Global Harmonization Task Force has created four study groups that respectively cover regulatory systems, post-market vigilance, quality systems and auditing. To give one example the Global Harmonization Task Force has adopted an “Essential Principles of Safety and Performance of Medical Devices on a Global Basis” See Chai, Medical Device Regulation, supra note. , at 78. A Commission official confirms that this document is based on EC “essential requirements” set forth in the 1993 EC medical devices directive. Interview with Commission official in DG Enterprise, June 16, 2001.
  \item \textsuperscript{[210]} This goal is specifically envisioned by the annex, which confirms the parties’ intention to continue to participate in the Global Harmonization Task Force and to review whether the Task Force’s work is “applicable to the [MRA’s] implementation” (article 18).
  \item \textsuperscript{[211]} Regulatory diversity, of course, can reflect differences in constituent values, environmental conditions and other contexts. In addition, harmonization can be problematic where it reduces experimentation in a complex world of rapidly changing technology. See \textit{discussion in} David Leebron, \textit{Lying Down with Procrustes: An Analysis of Harmonization Claims}, in \textit{1 FAIR TRADE AND HARMONIZATION: ECONOMIC ANALYSIS} 41 (Jagdish Bhagwati & Robert Hudec eds., 1996); Daniel Esty in \textit{REGULATORY COMPETITION AND ECONOMIC INTEGRATION} (Daniel C. Esty & Damien Geradin eds., 2000); and Daniel Esty, \textit{Revitalizing Environmental Federalism}, 95 MICH. L. REV. 595 (1996), and Ladeur, supra note…, at 167.
\end{itemize}
context could involve less of a traditional vertical hierarchical order of command, than a horizontal one based on coordinated monitoring and supervision by transatlantic regulatory networks involving public and private actors.\footnote{For a discussion in the EC context, see John Vervaele, Shared Governance and Enforcement of European Law: From a Comitology to a Multi-level Agency Structure, in Joerges and Vos, EU Committees, supra note…, at 129, 144.}

Third, in an age of limited government resources for the oversight of rapidly changing, expanding and interacting economies, regulators also can save costs through enhanced cooperation with foreign regulatory officials and decentralizing product certification systems. The FDA simply does not have the resources to adequately conduct all testing itself, especially where testing involves significant foreign travel.\footnote{FDA officials also note that by freeing the FDA from having to conduct tests in Europe, FDA can allocate more resources to products produced elsewhere, such as “surgical gloves produced in Malaysia.” Telephone interview with FDA official, June 8, 2001.} By permitting an “over-extended and under-resourced” FDA\footnote{Merrill, Challenges of Mutual Recognition, supra note, at 744 (further noting “that resources have not kept pace with workload”). For example, the value of EC pharmaceuticals and medical devices imported into the United States nearly doubled in just three years between 1994 and 1997, resulting in only one FDA inspection for every $60 million of imports. Sharon Smith Holston, An Overview of International Cooperation, 52 FOOD & DRUG L.J. 197, 198 (1997). Ms. Holston was FDA Deputy Commissioner for External Affairs.} to outsource testing and evaluation of medical devices to private bodies, the FDA can reallocate its resources to areas of higher concern, while retaining high product and process standards and post-market surveillance controls. In particular, FDA officials are more concerned by medical devices produced in jurisdictions other than Europe, so that the transatlantic MRA could free up resources for it to address these other areas. Similarly, FDA officials admit that they are already unable to conduct annual pharmaceutical GMP reviews of foreign manufacturers as they would prefer, and thus the MRA could ensure more consistent oversight of foreign manufacturers’ practices.\footnote{Telephone interviews with two FDA officials, respectively on June 7, 2001 and June 8, 2001.}

Fourth, from the perspective of democratic legitimacy, in an increasingly interdependent transatlantic economy in which choices in one jurisdiction can have significant impacts on constituents in others, regulatory decisions are more informed– and more inclusive– when made in the context of sustained regulatory exchange. A central normative goal of transgovernmental regulatory cooperative efforts is to create frameworks that conduce national regulators to reflexively take into account the impact of their actions on affected, but otherwise unrepresented, foreign constituents, while remaining deferential to disparate national values and priorities.

**B. Limits to Transatlantic Regulatory Coordination.** Irrespective of the potential benefits to firms and regulators, and irrespective of political pressure for regulatory adaptation, transatlantic regulatory cooperation remains by no means a foregone conclusion. While the New Transatlantic Agenda and Transatlantic Economic Partnership create various frameworks for regulatory coordination, significant obstacles remain, whether on account of institutional asymmetries, market contexts, differences in culture and values, or concerns over legitimacy. The challenges of implementing the 1997 Mutual Recognition Agreement and 2000 Safe Harbor Principles so demonstrate. Where existing regulatory structures, cultures and standards mesh, then regulatory coordination becomes easier. Both the FCC and the FTC have dual missions focused on assuring consumer protection and open competition, so that they have been relatively more open to cooperating with trade authorities under the 1997 MRA and 2000 Safe Harbor...
Principles. However, where regulatory agencies, such as the FDA and OSHA, experiment for the first time with delegating functions to private testing bodies, and, even more importantly, where these agencies are wary of new EC-like approaches, building and retaining the requisite trust and confidence requires considerable time and resources. Institutional learning curves are steep. Where the issues involve differences in complex regulatory systems, such as those covered by the 1997 medical device annex, independent agency interests more likely prevail because political pressure from the executive and legislative branches is difficult to sustain.\(^{216}\)

As noted above, transatlantic mutual recognition agreements potentially could save costs for regulatory agencies. However, it remains unclear whether governments actually will save costs while ensuring consumer safety, at least in the short term. Cross-border regulatory interaction is not free, and thus the net benefits for regulators of the MRA remains an open question. Regulators on both sides of the Atlantic have had to dedicate considerable resources to implement the MRA, especially during the transition period.\(^{217}\) Just to start, the effort entails considerable up-front negotiation costs and the costs of regulators learning and becoming comfortable with each other’s systems.\(^{218}\) The FDA estimated that it already had expended over $10 million dollars by June 2001 to implement the annex.\(^{219}\) EC officials have been even further behind schedule, citing a lack of resources. By mid-2001, they had yet to conduct any joint tests or training of U.S. certification bodies’ for the testing of medical devices.\(^{220}\) Similarly, the FDA maintains that it does not have the resources to verify the equivalence of all fifteen member states’ systems for implementation of the pharmaceutical GMP annex.\(^{221}\)

\(^{216}\) Comment of Ambassador David Aaron, formerly head of the international trade division of the U.S. Department of Commerce, at a conference at the European University Institute, Fiesole, Italy, July 6, 2001.

\(^{217}\) Some regulators believe that these transition costs will be more than recouped, although others remain skeptical. In addition, the MRA’s impact on public safety remains an open question, as its implementation remains at an early stage. However, there has been no evidence of a threat to public health on account of the EC’s single market program, which arguably should also be the case with the transatlantic MRA. Nonetheless, considerable resources have been expended to implement the EC single market program. The United States has been unwilling to dedicate such resources to the MRA.

\(^{218}\) Negotiation of both the 2000 Safe Harbor Principles and 1997 Mutual Recognition Agreement required considerable personnel time and government expense. The 1997 MRA magnifies these costs, since both parties retain separate standards and procedures and thus must train each other’s regulators and testing bodies in these standards and procedures. In the case of member state authorities and certification bodies from non-English speaking countries, especially from southern Europe, language issues create additional obstacles. For example, to implement the medical device annex, FDA has trained foreign private bodies in its methods, conducted joint inspections, and assessed detailed dossiers. A number of the European applicants submitted documents in a foreign language, which FDA returned for translation. Even after translation (at the Commission’s expense), some applications were drafted in a broken English, again complicating FDA’s task. Telephone interview with FDA official, June 7, 2001.

\(^{219}\) See Steffenson, The EU-US Mutual Recognition Agreements, supra note..., at 22; See e.g. TACD Bruce Farquhar and Alex Donahue, Briefing Paper on Mutual Recognition Agreements 20 (September 2000) (on file with author) (citing U.S. General Accounting Office reports).

\(^{220}\) The EC training and approval process will involve a working group of member state regulatory officials and representatives of DG Enterprise. Interview with Commission official from DG Enterprise, June 15, 2001.

\(^{221}\) However, EC officials are unclear if the FDA is “merely playing games” with its assertions about resource constraints. EC officials point out that the EC has also signed an MRA on pharmaceutical GMPs with Canada, and Canada has completed evaluation of all fifteen member state regulatory systems within a shorter transition period. The EC has signed MRAs concerning pharmaceutical GMPs with Australia, New Zealand, Canada, Switzerland and Japan. Unlike the MRA with the United States, under these MRAs, the inspection reports are usually included by the manufacturer with its batch/lot certificate. Thus, the system will work in a more fluid manner, without direct exchanges of inspection reports between regulatory officials in most cases, although regulatory officials will retain the power to make such requests. Interview with Commission official, June 18, 2001, Brussels.
C. Moving Toward an EC Model? Overall, transatlantic institutional adaptation has been slow (and often creeping), but where it has occurred, it has been rather unidirectional, and will likely continue to be so.222 Simply stated, the United States has made most of the changes. The United States has done so through adoption of international standards that mirror EC ones, through delegation of testing and certification responsibilities to private laboratories (reflecting the EC’s “global approach”), and through coordination and oversight of these laboratories under a new U.S. national program analogous to those operating in the EC for over a decade.223 Because the United States lacked a coordinated system of accredited testing and certification laboratories, European officials were concerned about the ability of U.S. regulators to guarantee the competence and quality of U.S. conformity assessment bodies. In response, the U.S. National Institute of Standards and Technology, a division of the Department of Commerce, created a new U.S. program named the National Voluntary Conformity Assessment Program. Taking from the EC model, the U.S. program aims to coordinate and oversee U.S. conformity assessment bodies, and thereby provide greater confidence to regulatory officials, whether domestic or foreign.224

Unlike their U.S. counterparts, EC regulatory authorities have operated for over a decade under a dual mission of ensuring public safety, on the one hand, and ensuring free movement of goods within the EC’s single market, on the other. They consequently are more experienced in managing the coordination of distinct national regulatory systems than their U.S. counterparts.225 The EC experience thus offers a model to be considered and adapted for the transatlantic context, although U.S. and EC regulators avoid formally acknowledging this on account of U.S. political sensitivities. Although Europe certainly has learned and borrowed from U.S. experiences with regulation, as in the fields of competition, consumer and environmental law, more recent transatlantic regulatory change has tended to adopt important aspects of an EC model. This tendency is opposite of that assessed by leading commentators on economic integration, such as Giandomenico Majone.226

Yet, regardless of the EC model’s appropriateness for transatlantic governance, the EC exercises significant market leverage in determining transatlantic standards and regulatory structures required to implement mutual recognition policies due to the size of its single market,

---

222 There is, however, some move on the EC side to create independent regulatory authorities, such as the European Medical Evaluation Agency and the new European Food Safety Authority, although these agencies will typically not have independent regulatory authority, at least to anywhere near the extent of their U.S. counterparts. EC political bodies have delegated relatively limited powers to them. See e.g. Renaud Dehousse, Regulation by networks in the European Community: the role of European agencies, 4 J. OF EUROPEAN PUBLIC POLICY 246, 258 (1997) (“powers delegated to agencies are extremely limited”); Pollack and Shaffer, Food Safety and GMOs in the Transatlantic Relationship, in TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY, supra note..., at 159-160 (concerning new European food authority).

223 See EGAN, CONSTRUCTING A EUROPEAN MARKET, supra note..., at 255.

224 Similarly, the European Commission helped forge a “European Organization for Testing and Certification” (EOTC) in 1990 in order to “(1) coordinate testing and certification practices to prevent firms from having to undergo multiple market entry and approval requirements, and (2) develop a common European framework to encourage mutual confidence and trust in member countries regulatory and self-regulatory testing and certification practices.” See e.g. EGAN, CONSTRUCTING A EUROPEAN MARKET, supra note..., at 152.

225 Although the United States is a federalist system under which states may retain separate regulatory regimes unless preempted by federal legislation, the areas covered by the 1997 Mutual Recognition Agreement largely have been federalized, with federal regulatory agencies overseeing federal regulations, a much different approach than the multi-level coordinative ones used in the EC.

which is already larger than that of the United States. This market leverage will only increase as
the EC potentially expands its borders to encompass up to thirteen additional nations within the
next decade. Firms that desire access to the large EC market can pressure their national officials
to adapt their national system to accommodate a reciprocal trading arrangement. As the EC
enters into mutual recognition agreements with other OECD countries, such as Australia,
Canada, Japan, New Zealand and Switzerland, and as these countries adapt their systems to
interact with EC governance structures, the pressure on the United States to adapt its own
regulatory structures could augment. The same process occurs as the EC negotiates with other
countries regarding the adequacy of their data privacy protection laws, and as these countries
adapt by enacting new legislation affecting the export of data to the United States. Consciously
or unconsciously, the EC is exporting its systems globally. The 1997 Mutual Recognition
Agreement and the 2000 Safe Harbor Principles so attest. In pooling their sovereignty at the EC
level, European member states collectively exercise much more leverage in transatlantic and
international negotiations over common regulatory standards and procedures.

D. Legitimacy: Ensuring Public Health and Safety while Retaining Open Markets: The
Need for Political Will and Resources to Build Transatlantic Regulatory Trust and Confidence.
Assessing the legitimacy of enhanced bilateral regulatory cooperation raises questions of both
substance (outputs) and procedure (inputs). From a substantive perspective, bilateral cooperation
cannot be accomplished on the cheap or it could result in deregulatory measures with little
oversight. This result would lead to challenges that the system benefits only producer, and not
consumer interests, and thus that regulatory outcomes are substantively illegitimate. From a
procedural perspective, citizens justifiably fear that they will have less control and access to
international negotiations that result in regulatory decision-making made outside of their own
borders, raising issues of procedural legitimacy.227

A number of consumer advocates, such as Public Citizen, distrust new transatlantic
mutual recognition arrangements.228 They are concerned about both procedures and substantive
outcomes. The transatlantic push for regulatory coordination and reform arguably has led to
increased delegation of traditional public services to private testing bodies. U.S. consumer
advocates, in particular, distrust the adoption of the EC’s decentralized approach based on

227 The inadequacies of regulation at the purely domestic level have already been noted. Supra note [5]. However,
participation in democratic decision-making at the national level is of a much higher quality because of the closer
relation between the citizen and the state, the consequent reduced costs of organization and participation, and the
existence of a sense of a common identity and of communal cohesiveness— that is, of a demos (a people). This
Article does not address the design of procedural mechanisms to ensure adequate monitoring of, and input into,
transatlantic regulatory networks and decision-making processes. Nonetheless, the Article highlights the central
questions of identifying the appropriate balance between domestic and international decision-making processes, and
designing transnational decision-making processes to enhance and not undermine democratic participation,
oversight and control.

228 See e.g. U.S.-EU Mutual Recognition Agreement (MRA)- Congressional Hearing (visited March 10, 2002)
<http://www.publiccitizen.org/trade/harmonization/MRA/articles.cfm?ID=6156>. Mary Bottari, Peter Lurie &
(visited March 10, 2002) <http://www.publiccitizen.org/trade/harmonization/MRA/articles.cfm?ID=4302>. See also
Steffenson, Regulating the Transatlantic Marketplace, supra note..., at 22 (concerning reactions of the Transatlantic
Consumer Dialogue (TACD) and of the Transatlantic Environment Dialogue (TAED). The TACD and TAECD consist of non-governmental organizations from both sides of the Atlantic. See Francesca Bignami and Steven
Charnovitz, Transatlantic Civil Society Dialogues, in TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY,
255 (Pollack and Shaffer, eds. 2001).
manufacturer self-certifications and certifications by private laboratories. In part, this distrust could stem from the perception that, in the U.S. context, private actors lack the tradition of cooperating with regulatory authorities that exists in more corporatist, state-directed European systems. Substantively, however, there is no necessary link between private certification and increased risk to public health and safety, provided that these certification processes are based on high health and safety standards and are complemented by significant regulatory oversight and controls. Rather, as with the experience of the EC’s internal market and the transatlantic Safe Harbor program, standards can be raised. Analysts from varying political perspectives have noted the potential of new governance mechanisms based on private monitoring and information exchange. These mechanisms involve public-private collaborations that are ultimately backed by the authority of the state.

Building a transatlantic marketplace requires reconciliation of the twin goals of social protection and competition through open trade. These twin goals only can be reconciled through increased regulatory cooperation, which, in turn, will require sustained political will, institutional adaptation, and significant regulatory resources. EC member states have sustained such political will and dedicated such resources over decades in order to create the single market. And even so, they too have encountered significant setbacks and obstacles. While it is far too early to pre-judge the 1997 MRA, it nonetheless is fair to question whether the requisite political will exists on each side of the Atlantic to ensure that regulatory resources are made available.

Regulators engaged in this process must gain and sustain trust and confidence in each

---

229 See e.g. www.publiccitizen.org/trade/harmonization/MRA/articles.cfm?ID=4302.
230 See e.g. EGAN, CONSTRUCTING THE EUROPEAN MARKET, supra note..., at 131 (noting that, in the United States, “the public and private sector have remained much more distinct,” and the policy style is less “state-directed”); and Kagan, Regulatory Encounters, supra note..., at 3 (noting the much more “legalistic” and adversarial” regulatory style in the United States).
231 It is important to distinguish between deregulation of standards and deregulation of regulatory pre-market approvals. Arguably, the EC aims to raise substantive standards and decentralize procedural authorizations. Thus, a deregulation of product approvals does not necessarily mean that standards will be lowered. There is, in fact, little evidence that firms and private laboratories have conspired in any way to put public safety at risk in the EC, or that EC residents are subjected to more product safety risks than U.S. residents under more traditional U.S. approaches. See Michelle Egan and Dieter Wolf, Regulatory Oversight in Europe: The Case of Comitology, in Christian Joerges & Ellen Vos (eds.), EU COMMITTEES: SOCIAL REGULATION, LAW AND POLITICS 239, 253-254 (1999); and DAVID VOGEL, TRADING UP: CONSUMER AND ENVIRONMENTAL REGULATION IN A GLOBAL ECONOMY 50-55 (1995).
232 See e.g. Anne-Marie Slaughter, Agencies on the Loose? Holding Government Networks Accountable, in TRANSATLANTIC REGULATORY COOPERATION (George Bermann et al, eds.), supra note..., at 521-535 (providing proposals for enhancing the accountability and legitimacy of governance through transgovernmental networks); Jody Freeman, Collaborative Governance in the Administrative State, 45 UCLA Law Rev. 1, 30 (1997); and ARCHON FUNG, DARA O’ROURKE & CHARLES SABEL, CAN WE PUT AN END TO SWEATSHOPS? (2001).
233 The need for a back-up of state intervention is often referred to as the “shadow of hierarchy.” See e.g. MICHELLE EGAN, CONSTRUCTING A EUROPEAN MARKET: STANDARDS, REGULATION AND GOVERNANCE 130 (2001); and Michelle Egan, Mutual Recognition and Standard Setting, supra note..., at 205-206.
234 Vos, for example, in her study of European regulatory cooperation through the EC comitology process, notes that “in the years 1980 to 1989 annual Community expenditure on committees increased from approximately 3.8 million to 8 million ECU, whilst for 1998, this expenditure amounted to 19.5 million ECU.” Ellen Vos, EU Committees: the Evolution of Unforeseen Institutional Actors in European Product Regulation, in Joerges & Vos, European Committees, supra note, at 19, 20.
235 See EGAN, CONSTRUCTING A EUROPEAN MARKET, supra note 7 (“The task of market creation is extremely difficult given variations in the historical timing of regulatory development, in national institutional structures, and national legal traditions.”). For examples of various critiques of traditional EC governance mechanisms, see the articles in Special Issue on New Approach to Governance in Europe, 81:1 European Law J. 1-191 (March 2002).
other’s decisions, in particular in areas affecting public health and safety where they are asked to rely on testing, certifications and accreditations by foreign laboratories and officials. They will only trust each other if they are assured that their regulatory counterparts have the necessary capacity to ensure the social goals of a coordinated regulatory program. As Majone writes regarding the EC’s internal regulatory networks, “for a coordinated partnership… to operate effectively,… each participating organization must be able to perform the tasks assigned it, and there must be sufficient trust among the partners to keep the costs of transacting within acceptable limits.” Regulatory officials on both sides of the Atlantic complain that they simply do not have the resources to engage in the seminars, workshops, joint testing, inspections, and information exchange prescribed in the MRA, and necessary for its proper implementation. The Commission’s DG Enterprise confirms that it has yet to locate the resources to properly implement the medical devices MRA. The FDA asserts that the MRA annexes under its responsibility constitute “unfunded mandates,” because Congress has instructed the FDA to cooperate with trade officials in the negotiation and implementation of mutual recognition agreements, but has not provided it with the requisite resources. FDA officials are frustrated by what they view as “political pressure” from trade officials that “complicates our regulatory mission.”

This situation involves a curious reversal of arguments used by fiscal conservatives within the United States. Whereas it was the Congress of the “Gingrich Revolution” that decried “unfunded mandates” without cost-benefit analysis and the provision of adequate federal funding to state authorities to implement Congressional dictates, now consumer advocates and federal regulators decry unfunded mandates for cross-border regulatory coordination. Some consumer advocacy groups go even further, arguing that businesses, not taxpayers, should pay these costs. Regardless of how the necessary regulatory resources are obtained, the MRA’s proper implementation requires them. Without such resources, mutual recognition agreements could put consumer health and safety at greater risk. Given the United States’ traditionally more inward-looking approach, in particular, it is doubtful whether adequate resources will be dedicated to transatlantic regulatory collaboration. Thus, the prospects for effective new and global transatlantic economic governance mechanisms through the public sector are subject to significant constraints. As a result, the private sector likely will continue to take the lead in coordinating arrangements to meet disparate transatlantic regulatory requirements through private sector sub-contracting and other networking arrangements.

---

236 See Majone, Regulating Europe, supra note..., at 276. Majone further notes how “the principle of mutual recognition is extremely demanding in terms of mutual trust”). Id., at 279.
238 See Steffenson, Regulating the Transatlantic Marketplace, supra note..., at 22 (citing Transatlantic Consumer Dialogue, Principles of Harmonization, TACD Trade Document, issued February 2000). Some regulators agree, as demonstrated by OSHA’s initiation of fees for applications from testing laboratories. Yet, given the current market reaction to implementation of the 1997 Mutual Recognition Agreement, fee schemes, such as that imposed by OSHA, could further reduce the MRA’s prospects.