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**Mutual Recognition  
and Standard-Setting:  
Public and Private Strategies for  
Regulating Transatlantic Markets**  
Michelle Egan

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## INTRODUCTION

Transatlantic trade diplomacy is changing rapidly. The institutionalization of bilateral summits between the United States and the European Union to discuss trade and investment issues illustrates the growing importance of the non-security dimension of transatlantic relations.<sup>1</sup> Over the past three decades, the European Union, as distinct from its constituent member states, has become more important for the United States, in terms of partnership in the management of global security and international political economy. Underpinning the importance of the economic relationship is the pattern and size of foreign direct investment and trade. The U.S. and EU share the largest two-way relationship in investment and trade in the world.<sup>2</sup> In fact, the relationship is relatively “balanced” which is unusual for the United States as it has become a substantial net importer of foreign direct investment from Europe, and has therefore become less exceptional.

While these trade figures are an important indicator of economic relations, there has been a growing sentiment that further steps should be taken towards an ever more ambitious goal of a “new transatlantic marketplace” or other arrangement for market access and liberalization. Given global networks, production practices and flexible organizational structures that involve many European-American business consortia and alliances, the degree to which business demands can be categorized as distinctly European or American generates new pressures for redefining market rules in ways other than national or territorial structures.<sup>3</sup> The calls for enhanced transatlantic economic cooperation through the New Transatlantic Agenda and Transatlantic Economic Partnership has been seized upon as an opportunity to define priorities, shape agendas and exercise leadership in finding regulatory solutions to the increased number of issues facing the global trading system.<sup>4</sup> The agenda reflected a concern among many advocates of a free trade area

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<sup>1</sup> For a recent discussion of the security dimension in transatlantic relations, see the Report of the Independent Task Force sponsored by the Council on Foreign Relations, New York, 1999

<sup>2</sup> In 1997, EU exports in goods and services to the U.S. were \$219 billion, with U.S. exports to the EU of \$232 billion. As of 1997, EU cumulative FDI in the U.S. was \$381.9 billion, accounting for 56 percent of total FDI in the U.S., while cumulative U.S. FDI in the EU was comparable at \$369 billion.

<sup>3</sup> The term value-chain networks is therefore more appropriate to describe this wide gamut of relationships and their impact on market integration.

<sup>4</sup> European Commission (1998) *The New Transatlantic Marketplace* COM (125) final 11 March; Resolution on Transatlantic Economic Partnership, European Parliament, A-4 0387/98, Rapporteur, Erica Mann; Transatlantic Economic Partnership Action Plan, 4 November 1998.

that the U.S. and U.S. were drifting apart in the post-Cold War era.<sup>5</sup> The New Transatlantic Agenda proposed a number of areas of cooperation, many of which were not economic,<sup>6</sup> and only later in the European Commission's proposal for a New Transatlantic Marketplace in March 1998 did the focus shift to a broad liberalization agenda of removing regulatory barriers to trade in goods, creating a free trade area in services and removing barriers to procurement, intellectual property and investment. Vetoed in April 1998 by French concerns over the possibilities that "exporting the single market program" would undermine multilateral trade liberalization and expand transatlantic negotiations into sensitive areas of services and audiovisual, the Commission returned with another proposal in September 1998 for a Draft Action Plan for a Transatlantic Economic Partnership.<sup>7</sup> Shorn of its ambitious agenda, and much more tepid in terms of its overall goals, the transatlantic marketplace was thus focused primarily on regulatory cooperation.

Although recent high profile trade disputes over genetically modified organisms, safe harbors, airplane hushkits, data privacy, metric measurements, and mobile phone standards (Pelkmans, forthcoming; *Journal of Commerce* 1997; Egan 1998; Calingaert, 2000; U.S. Mission 1999) seem the most visible components of the relationship, and point to a frequent, often rancorous relationship, in fact, a great deal of effort is made to foster cooperation. Both U.S. and EU trade officials have listed a number of reasons for trying to mitigate the effects of regulatory fragmentation and provide a new impetus and commitment to transatlantic economic relations. Firstly, the efforts to construct a transatlantic marketplace generally promote both political as well as economic goals. European fears that the United States may distance itself from Europe in the absence of a collective challenge and increased concern that the United States had shifted its focus "south" through the hemispheric free trade area (FTAA) proposal and "west" to East Asia through the Asia-Pacific Economic Cooperation (APEC) led to calls for a free trade area for the Atlantic.<sup>8</sup> Secondly, there is a need to avoid commercial disputes. Since the American extra-territorial application of certain laws has contributed to the complexity of the business climate, and economic rule-making is increasingly subject to overlapping jurisdictions, cooperation is seen

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<sup>5</sup> Brian Hindley, "New Institutions for Transatlantic Trade" *International Affairs*, Vol 75 no 45-60, 1998.

<sup>6</sup> These included joint actions on terrorism, crime and drugs, promotion of democracy and human rights.

<sup>7</sup> The May U.S.-EU Summit in London had agreed upon the Transatlantic Economic Partnership.

<sup>8</sup> Jacques Pelkmans, "Atlantic Economic Cooperation: The Limits of Plurilateralism" July 1998, Horst Siebert, "TAFTA: Fuelling Trade Discrimination or Global Liberalization?" AICGS Economics Working Paper # 19, March 1996; Policy Forum: Transatlantic Free Trade, *Washington Quarterly*, Vol 19 no 2, 1996.

as a means of fostering political dialogue to avoid confrontation and disagreements over the application of laws rather than constant resort to international arbitration.<sup>9</sup> Thirdly, although progress towards multilateral trade liberalization has depended heavily on the U.S. and EU in promoting regulatory solutions, their leadership role is made more difficult by the expansion of membership and the various coalitions that have either challenged or divided Atlantic hegemony in the negotiating process as evidenced by the recent ministerial in Seattle.<sup>10</sup> Fourthly, business on both sides of the Atlantic has promoted the importance of trade and business facilitation as well as the removal of barriers to trade. “Private sector leaders and other advocacy groups have been consistently out in front of governments in more recent years in pressing for more open trade.”<sup>11</sup> Business leaders have drawn attention to the economic costs of divergent industrial standards, procurement, investment rules, and competition policy in their discussions with government officials. Their argument is that competitiveness is hampered by excessive regulation and that the differences between the U.S. and EU regulatory system need to be addressed. Since business is increasingly transnational, as evidenced by the growing number of transatlantic mergers, acquisitions, alliances, and joint ventures, the business-government relationship is now much more varied, often territorially ambiguous and mobile, requiring governments to respond to the changing business conditions. They have done so by focusing on these “behind-the-border” issues that affect market access and corporate strategies, and one clearly sees that most of the issues specified concern regulation.

Without some degree of regulatory harmonization, exporting firms still face the costs of adapting their goods and services to meet the myriad of standards, regulations and conformity assessment procedures (Egan, forthcoming a: Chapter 3).<sup>12</sup> Both sides recognize that complete regulatory convergence is neither possible nor desirable, and that market access is typically limited

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<sup>9</sup> The Senior Level Group of U.S. and EU officials that meets quarterly as well as a host of working groups have promoted damage control efforts through bilateral means such as the suspension of the Helms-Burton Act and Libya Sanctions Act that escalated after the Total Oil investment decision.

<sup>10</sup> The recent WTO leadership dispute is a good indication of the decreased dominance of the EU and U.S. Resistance to the inclusion of environment and labor standards in the next round as evidenced by the failure of the Seattle Ministerial to reach agreement, and new coalitions that have emerged on agricultural liberalization and the information technology agreement highlight the importance of the Cairns group and APEC group as crucial players in the process.

<sup>11</sup> Ernst Preeg, “Policy Forum: Transatlantic Free Trade, *Washington Quarterly* op cit p. 110.

<sup>12</sup> Conformity assessment is the set of procedures by which products and processes are evaluated and determined to conform to particular standards or regulations.

by different approaches to regulation in the U.S. and EU rather than the existence of regulation *per se*.<sup>13</sup> Nonetheless, domestic regulatory policies, once treated as a sovereign preserve, are now subject to intense scrutiny, and reflect the increasing impact of “behind the border” issues on transatlantic trade. This means that the potential for trade disputes exists over a much wider range of issues than previously, and involves a wider number of domestic interests and constituencies who have a keen stake in the trade negotiations.

What makes the issue more difficult is that many domestic regulations are not protectionist in intent. They represent legitimate public policy differences in terms of market and administrative culture, risk assessment and societal goals. Hence, reconciling trade and regulatory objectives necessitates new instruments and strategies to coordinate markets. At the core of this effort is a range of public and private strategies that seek to promote international acceptance of a particular norm or rule in the regional or transatlantic marketplace. The European Union has been at the forefront of promoting such regulatory cooperation through policies of mutual recognition and standardization, and has consciously sought to use this strategy in other bilateral, regional and global negotiations. The degree to which these trading principles may be exportable to the wider trading community, given substantial differences in regulatory and business practices, is an important issue for the transatlantic relationship, especially since it assumes that respective regulatory authorities will accept, in whole or part, the regulatory authorization from another territory, in terms of standards or mutual recognition of testing and certification practices. Hence, the benefits come at a high cost for public authorities who have to contend with the consequences of transferring regulatory sovereignty to other public authorities or private bodies over which they have little control.<sup>14</sup>

This paper analyzes developments at both regional and transatlantic levels, highlighting the emergence of mutual recognition and standardization as important innovative trade tools. While often dismissed as bureaucratic and technical procedures, they are the building blocks of market governance at both the regional and transatlantic level. Unlike traditional measures of non-discrimination and national treatment, the U.S. and EU in their efforts to address the trade-impeding effects of these barriers through some form of regulatory cooperation, are confronted

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<sup>13</sup> See Commission of the European Communities, Directorate-General for External Economic Affairs (DGI) Background Paper on Regulatory Convergence, November 1991.

<sup>14</sup> Nicolaidis and Egan (Forthcoming); Nicolaidis (1998).

with a fundamental trade off between loss of regulatory sovereignty and autonomy over rules and opportunities for wealth creation and improved market access (see Brittan 1999).

Though coordination this has meant relinquishing some degree of regulatory sovereignty and jurisdictional control over national markets, the emergence of successful international coordination, built on mutual interests, depends on regulatory legitimacy and credible commitments (Majone 1999). Agreement on mutual recognition or standardization is not sufficient to achieve market liberalization, since it requires the pursuit of energetic, sustained intervention, and the power of enforcement to realize gains. Although collective action problems are endemic to international politics, assessing developments in removing barriers to trade involves looking at the multitude of cooperative negotiating networks linking the different agencies and sectors that have emerged at the regional and transatlantic level, and the implementation and effectiveness of such negotiated agreements. The resulting bargaining between states and between firms to generate collective goods can best be seen as a coordination problem, and the ability to resolve them depends on monitoring and enforcement of agreements, deliberation and information (see Nicolaidis and Egan, forthcoming; Hall and Soskice, forthcoming).

And this in turn suggests that the success or failure of collective action very much depends on the institutional context in which it takes place. As we shall see, the structures of governance that are emerging to tackle regulatory barriers are based on modes of decision-making and institutional arrangements combining both state and non-state actors. In the European case, governments have harnessed private sector resources to further public policy goals, and the expansion of indirect governance has created a regulatory system that blends the public and private spheres (Grobosky 1995; Ayres and Braithwaite 1992; Egan, forthcoming b). The European Union has chosen to delegate or devolve certain public functions upon private interests (Egan 1998). This form of cooperative governance has enabled organized interests to play an important role in the formulation and implementation of policy, albeit within an institutional framework that is underwritten by public authorities.<sup>15</sup> Thus even where decision-making has been

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<sup>15</sup> To avoid conceptual confusion, the term public authorities and/or governments is used in the European Union context rather than state given that the EU does not perform all functions usually attributed to a nation-state.

devolved to private standards institutions, public authorities still retain crucial rights to create and shape markets.

In the transatlantic case, governments have used their own agencies to negotiate regulatory agreements, and have delegated regulatory responsibility and oversight functions to other governments. State actors participate in policy networks, where power is dispersed across agencies, and this kind of negotiated system provides for collective problem-solving and new transnational relationships. This form of cooperative governance involves the horizontal dispersion of authority,<sup>16</sup> and organized interests play a more conventional lobbying role in the formulation and implementation of policy. While it is important to distinguish the different negotiating dynamics, institutional make-up and outcomes at the regional and transatlantic level, it is important not to overemphasize the agenda setting and problem solving capacity of private interests (cf. Cowles 1999). Though active through the Transatlantic Business Dialogue, Transatlantic Small Business Initiative, Federal Advisory Committees, and various trade associations, the level of cooperation and dialogue between Commission units and American agencies is equally impressive.<sup>17</sup> Though not commanding a high political profile—like the business dialogue—high ambitions would produce unrealistic goals given the domestic and legal constraints on both sides of the Atlantic.

The American administration faces political and public opinion that is deeply divided over trade issues. This environment was created in part by the bruising battles over NAFTA and the GATT Uruguay Round, which highlighted fears over losing sovereign regulatory control, and the absence of fast track authority makes the U.S. a laggard in trade diplomacy. In Europe, a similar inward-focus prevails. Politicians and publics are focusing on national problems including economic growth, high unemployment, dismantling the welfare state and dealing with the long term consequences of aging, pensions and social security. The European Union faces a parallel

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<sup>16</sup> The loss of operational power in regulating domestic markets (internal sovereignty) is offset by the growth of external sovereignty in monitoring and regulating products and services for export to foreign markets.

<sup>17</sup> A pilot program of bilateral regulatory cooperation was proposed in 1994 covering a number of sectors such as mobile satellite communications, which was subsequently abandoned after agencies on the American side expressed concerns about loss of autonomy, and the need to take trade considerations into account in determining their overall regulatory objectives.

situation to the United States where it has seen its own trade negotiating authority reduced.<sup>18</sup> As a result of the European Court of Justice's decision, multilateral leadership will be difficult as trade competencies for services and intellectual property issues are now "mixed competencies" requiring the member states and European Union to cooperate closely during negotiations.<sup>19</sup> Thus, the U.S. and EU may find more success in strengthening transatlantic relations through "a dull and unambitious agenda" of regulatory cooperation, given the political sensitivities of certain sectors and the lack of alternative potentially attractive options at the moment.<sup>20</sup>

Even then, in the course of engaging in negotiations for standards and mutual recognition, many factors such as coalition-building, structural capacities for reform, and institutional asymmetries may affect organized cooperation among competitors. Governments at both regional and transnational level have sought to alter the terms and conditions under which regulatory cooperation takes place in order to mitigate the problems of conflict and deadlock. By studying negotiations and reforms in two contexts, the paper illuminates the interaction between international pressures and domestic politics since different levels simultaneously affect one another, and what happens at one level of negotiation resonates at other levels (Putnam 1988). To examine this interaction in more detail, we must focus not only on the negotiations involved in regulatory cooperation but also the implementation of such agreements, since it is only then that we can show the gaps between goals and outcomes. While the ultimate goal of benefiting their economies through improved cooperation is pursued by both sides, success depends on creating the right framework conditions for trade by tackling the trade-impeding effects created by differences between EU and U.S. regulatory systems. Though two avenues of international cooperation—trade liberalization and regulatory coordination—have traditionally been associated with separate institutions, separate agencies within national governments, what has changed is that the association between trade and regulation has forced European and American policy makers to reappraise the link between these two realms of cooperation.

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<sup>18</sup> Agreements in these areas must be ratified by all member states—not just by the European Council as in the case for pure trade in goods agreements—thereby providing increased opportunities for domestic divisions and/or opposition to thwart any negotiated agreement.

<sup>19</sup> European Court of Justice Opinion (1/94) and Article 113 Amsterdam treaty.

<sup>20</sup> Cf Ellen Frost's proposal for NATEC (North Atlantic Economic Community), see Ellen Frost, *Transatlantic Trade: A Strategic Agenda* (Washington DC: IIE, 1998).

The paper is structured as follows: Section 1 examines European negotiations on mutual recognition and standardization; Section 2 focuses on transatlantic negotiations on mutual recognition and standardization; Section 3 examines the governance issues involved and evaluates the feasibility and effectiveness of these new trade strategies; and Section 4 assesses the implications in terms of accountability and legitimacy of emerging models of trade liberalization.

## **1. SETTING THE AGENDA: EUROPEAN RULE-MAKING AND DELEGATED GOVERNANCE**

Although European governments have been concerned with the need to address so-called technical barriers to trade, including disparities between national standards and regulations as well as national conformity assessment procedures, the starting point for assessing the development of regulatory reform in the European Union is the failure of traditional harmonization policies. While governments were under pressure to pursue greater harmonization of their regulatory systems, this method proved cumbersome and difficult to achieve significant results. Agreement was constantly behind the development of national regulations so that by the time agreement was reached, the legislation was often technologically obsolete and out of date (see Vogel 1997; Dashwood 1983; Schreiber 1991).

The European Union adopted a series of reforms beginning in the mid-1980s and continuing into the 1990s to improve efforts to address regulatory barriers to trade. This resulted in a more flexible attempt to harmonize policies through delegation to public and private authorities (see below). Regulatory compatibility was to be achieved through harmonization of technical standards and regulations together with the mutual acceptance of products regardless of applicable standards (*Cassis de Dijon* principle). With standards and regulations to be mutually recognized and/or partially harmonized through new flexible strategies that moved away from the old harmonization approach, the EU used its treaty principles and compliance mechanisms to foster the internal market.

Though the completion of the European single market was based on the expectation that “equivalence” between national standards ought to be a sufficient pre-condition for free movement of goods and services, this necessitated a great deal of prior harmonization to ensure

the “equivalence, acceptance or compatibility” of regulatory systems.<sup>21</sup> To achieve this goal, the European Union innovatively reorganized the responsibilities and role assignments of the various economic and institutional actors involved in managing regulatory policy (Previdi 1997: 225). The European Union delegated responsibility for standards and conformity assessment coordination to the private sector under the “new approach” and the “global approach” respectively.<sup>22</sup>

The “new approach” provided a template for removing national restrictions on the free movement of goods. Its main purpose was to ensure that only those regulations that were “essential” or “genuinely necessary” to protect health, provide consumers with adequate information, ensure fair trading and provide for necessary public controls would fall under EU harmonization legislation. Although the European Union did not forsake all regulatory responsibility since it spelled out the “essential requirements” for product safety under the new approach, it gave considerable leeway to private bodies to develop specific standards that satisfied these requirements. Because standards were voluntary, those firms that choose to meet the regulatory requirements without referring to European standards could choose to have their products tested and certified by independent auditors.

Anxious to make use of private sector resources, the EU proposed new approach directives across a wide range of services and products.<sup>23</sup> This was not unusual in the sense that national governments support and utilize standards set by private or quasi-private standard-setting bodies (Voelzkow 1996). As a result the two main organizations, Comité Européen de Normalisation (CEN) and the Comité Européen de Normalisation Electrotechnique (CENELEC) began coordinating standards activity among their membership, which comprises the national standards bodies of the EU and EFTA. Currently, CEN has nineteen full members, affiliate members mainly from Central and Eastern Europe,<sup>24</sup> and associate members representing broad European interests including European Trade Union Federation (ETUC) for health and safety issues, European Construction Industry Federation (FIEC), European Computer Manufacturers Association (ECMA), European Chemical Industry (CEFIC) and European Association for

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<sup>21</sup> Mutual recognition and standardization/harmonization are in fact complementary. For a longer discussion of this, see Nicolaidis and Egan (Forthcoming).

<sup>22</sup> These two steps applied specifically to product standards and conformity assessment.

<sup>23</sup> There are no fixed numbers of new approach directives as evidenced by the continuing expansion of standardization programs to meet new requests in areas such as public transport, foodstuffs, biotechnology and utilities.

Cooperation of Consumer representation in Standardisation (ANEC). CENELEC also has eighteen full members, seven affiliate members from central and eastern European states and formal cooperative arrangements with seventeen European industry associations.

Although much has been written about the process through which the market generates product and service standards (Farrell and Saloner 1988), as well as the role of government regulations in the area of health, safety and environmental standards (see Vogel 1985; Vogel 1997), less attention has been given to the “negotiated rule-making” that takes place among private or quasi-private governance regimes. Actual negotiations take place in technical committees that draw on the expertise of members of the national standards bodies. This includes trade associations, individual firms, consumer and labor groups, as well as regulatory agencies. Standard-setting uses a formal rule-making process, combining the use of expert committees with a plenary approval process that is structured to ensure that national or functional delegations can weigh in on the negotiated agreement. Although the standards bodies operate formally by consensus, this masks the actual negotiations that tend to be dominated by a few producer interests willing to put time and resources into the committee negotiations. With over twenty new approach directives, CEN and CENELEC coordinate the activities of over 25,000 participants in more than 2,000 technical committees at the European level.<sup>25</sup> Although firms involved in the process can make informed choices about future alliance strategies, and minimize their own risks of choosing an inappropriate technology, the overall effectiveness of the single market depended on the ability of those involved in standard-setting to reach some form of agreement.

But even when standards or regulations have been mutually recognized and/or partially harmonized, exporters must often continue to comply with certification requirements imposed by conformity assessment bodies that force importers to undergo redundant testing and certification procedures. Conscious that its efforts in the area of standardization would be undermined by the lack of a complementary policy in conformity assessment, the European Union adopted the “global approach” to remove any inconsistencies between national testing and certification systems by insisting that national testing and certification bodies operate according to common criteria or

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<sup>24</sup> CEN affiliates include Bulgaria, Cyprus, Lithuania, Romania, Slovenia, and Turkey.

<sup>25</sup> Simple pressure vessels, toys, construction products, electromagnetic compatibility, machinery, personal protective equipment, weighing instruments, medical devices, gas appliances, explosive products,

standards. Under the global approach, if third party assessment (independent verification) of conformity to European regulations (i.e., laws) was required, product approval could only be granted by bodies notified to the European Commission as technically competent by member states. Hence, the global approach allowed member states to maintain regulatory oversight over testing and certification activities, as only “notified bodies” located in each member state could legitimately perform such functions. This form of coordinated accreditation and verification by member states meant that the global approach provides for mutual recognition of conformity assessment across Europe. To provide a framework for cooperation through mutual recognition agreements between these notified bodies, and other public and private agencies involved in conformity assessment, the European Union created the European Organization for Testing and Certification. The European Organization for Testing and Certification serves as an umbrella framework for mutual recognition of conformity assessment organizations within Europe, providing common standard of accreditation and certification for both public and private testing and certification bodies. Confidence in the comparability of conformity assessment systems would go a long way in different sectors towards market openness and access.

## **2. EXPORTING TRADE RULES AND PRINCIPLES: TRANSATLANTIC NEGOTIATIONS**

In the transatlantic context negotiators were able to borrow ideas exported from the single market program. This has proved important in sustaining the transatlantic relationship. The United States and the European Union began cooperating over a package of mutual recognition agreements (MRAs) in the early 1990s to promote trade liberalization. When the first round of agreements was concluded in 1997, these agreements on mutual equivalence or compatibility between their respective regulatory systems were based on the oft quoted principle “approved once, accepted anywhere.” Yet the agreements themselves were limited to mutual recognition of conformity assessment, and clearly more limited than the mutual recognition concept inherent in the single market program (see also Pelkmans 1999). Yet the focus on often complex, and politically unexciting “deliverables” such as mutual recognition agreements to promote regulatory

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telecommunications terminal equipment, boilers, recreational craft, lifts. Proposals include precious metals, cable installations, noise emission.

cooperation is crucial since the prospects for broader transatlantic economic cooperation have been soured by long-standing disputes that are seemingly difficult to resolve (see Peterson, forthcoming; Brittan 1999).

The Europeans have been able to bring mutual recognition from its technical aspects and make it an exportable principle of economic integration that applies to external as well as internal trade (Nicolaidis 1998). Concerned that the image of “fortress Europe” hung over their efforts to improve market access and trade liberalization, the European Union was anxious to play down such concerns by assuring trading partners of their commitment to openness and transparency. Because the issue of standard-setting was at the top of the transatlantic agenda due to vociferous complaints from American business about the lack of influence in shaping European standards, there were repeated efforts to gain influence and access to the deliberations. Rebuffed in their efforts to gain a seat at the table in European standard-setting,<sup>26</sup> attention turned towards alternative avenues of influence. American exporters had a major incentive to push for negotiations over the conditions of market access into the EU since the completion of the single market had altered the conditions in some sectors and countries (Nicolaidis 1998; *Wall Street Journal* 1996).<sup>27</sup>

Though the EU had persuaded the European standards bodies to engage in dialogue with their American counterpart, the American National Standards Institute, the end result was simply an exchange of information regarding on-going projects. Though American firms could express opinions during the European negotiations, there was some skepticism about the extent to which this actually played any role in influencing the final outcome. Anxious to allay fears since the European Union had not clearly considered the external dimension of its single market program, the principle of non discrimination and market access were clearly stated with regard to mutual recognition and standards. To reassure trading partners, the European Union externalized the principle of mutual recognition, stating that “any product, which is introduced on the Community territory, as long as it satisfies the legislation of the importing member country, and is admitted on

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<sup>26</sup> This was proposed in 1989 by then Commerce Secretary Mosbacher.

<sup>27</sup> See Dormont Testimony to the House Committee Technology Subcommittee, June 4-5, 1998; Sergia Mazza, ANSI President, Testimony Before House Subcommittee on Technology, Environment and Aviation, 101 Congress, 22 September 1994.

its markets, will be entitled, as a matter of principle, to the benefits of free circulation in the Community” (European Commission 1988: 3).

The major trade problem stemmed from the testing and certification provisions that had emerged under the global approach. To promote regulatory convergence and mutual recognition, the European Union had pushed for common standards for testing, certification and accreditation. To ensure functional equivalence, the European Union had delegated responsibility to oversee compliance with these goals onto member states that were essentially asked to “police the single market.” Because only notified bodies recognized by member states could be located in Europe, American companies would have to use testing and certification companies in Europe to enable them to meet the legal requirements for market access. Since this placed American firms at a competitive disadvantage, many testing and certification laboratories/companies sought bilateral agreements with their European counterparts so that the work could be subcontracted out to testing and certification bodies in the United States. Because this was cumbersome and also no guarantee that American companies would not be subject to further scrutiny, pressure was placed on the EU to engage in discussions on mutual recognition. Since the EU wanted to ensure regulatory equivalence and could only do so within the context of the Community framework, such a policy could only work in external trade negotiations if there was a similar commitment to “equivalence” or “acceptability” with single market regulations by the counterpart’s regulatory system (see Clarke 1996). If U.S. bodies were to be granted the status of notified bodies, the U.S. government would need to become involved in guaranteeing the competence of its conformity assessment bodies and thus provide formal assurances to its partner that U.S. bodies could meet “essential requirements” and certify to EU standards.

The resulting negotiations over mutual recognition agreements between the Department of Commerce (with assistance from USTR) and the Directorate-General I (External Relations, with assistance from DGIII, Internal Market) focused on equivalence of testing and certification of products not the underlying standards themselves. The European Union assumed that testing and certification was to be done on the basis of European standards, and as a result, foreign governments needed to have mechanisms in place to accredit testing and certification agencies/companies so that they would be the equivalent of European “notified bodies.” Without such mechanisms, there would be no basis for mutual trust and credibility in the operation and

equivalence of another trading partner. The European Union used this as a means of exercising leverage on their American counterparts, and pushed hard to ensure that there was reciprocal access. Constant complaints that the lack of a standardized system in the United States with numerous federal agencies including Food and Drug Administration, Federal Communications Commission and Department of Defense and private companies engaged in conformity assessment meant that European companies encountered far more obstacles in accessing American markets than their American counterparts in accessing European markets (Nicolas 1996). American companies view their market driven system as more appropriate, and there is a growing sense in the business community that the increasing use of standards by the EU as a competitive weapon has not elicited a sustained and effective response by government negotiators (see Office of Technology Assessment 1992; National Research Council 1995; Line 1998).

Bolstered by vocal support and strong lobbying from the Transatlantic Business Dialogue, which strongly articulated the importance of mutual recognition agreements, negotiators on both sides began preliminary discussions on what sectors should be the focus of initial discussions.<sup>28</sup> Though initially eleven sectors were proposed, this was finally whittled down to six sectors, namely pharmaceuticals, medical devices, electromagnetic compatibility, electrical safety, telecommunication equipment and recreational crafts. Business estimated that the costs of heterogeneous standards and duplicative regulatory burdens were high: approximately half of the \$110 billion of American exports to the EU required some form of EU certification (Stern 1998). The Transatlantic Business Dialogue focused on the issue through the Committee on Standards and Regulatory Reform. Business on both sides of the Atlantic used this forum to provide constant recommendations on the importance of the mutual recognition agreements, and continued to make further recommendations on a sector-by-sector basis. The small and medium sector dialogue, TASBI, has also articulated its own priorities in this area, supporting the expansion of mutual recognition agreements to include environmental technology requirements since they are likely to be the main beneficiaries of reduced regulatory obligations (Struhs, Heymans and Warner 1999).

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<sup>28</sup> Interviews with European Commission officials suggested that in terms of their relationship with TABD, they “look at recommendation to see if useful-but the EU does not always agree -and is not bound to act upon them or force us to.” Interview November 1999; interview September 1998.

Yet the negotiations revealed sharp institutional differences between the two regulatory regimes that were not easily glossed over. While Europe has promoted widespread cooperation between the public and private sector in standard setting, as well as conformity assessment, the EU continues to set broad regulatory guidelines and even delegated bodies are designated or approved by governments. The relationship is much different in the United States where there is no system of coordination of private certification like the European Organization of Testing and Certification. Though many companies in the United States favored self-certification and third party assessment being performed by the private sector, they faced strong resistance from federal regulatory agencies. As Nicolaidis (1998) points out, European negotiators were unable to appreciate the extent of regulatory autonomy prevailing in the U.S. Because mutual recognition agreements involved the transfer of regulatory authority albeit limited to conformity assessment, several federal agencies were unwilling to place their regulatory procedures into a trade agreement and allow foreign regulators to determine domestic safety issues. But American regulatory agencies found themselves under pressure to concede some autonomy to reach a deal. The negotiations proceeded differently across sectors with relative ease in recreational craft given regulatory symmetry and with relative difficulty in pharmaceuticals given regulatory asymmetry. What became clear was that the American negotiators sought to conclude agreements sector by sector whereas the Europeans advocated an overall agreement that reflected the classic “package deal” with gains and losses in opening up different areas to mutual market access.

The Commerce Department was handicapped in the negotiations by the opposition of several regulatory agencies to any reduction in their oversight role. With pressure from transatlantic business, which wished for tangible results and did not wish the discussions to break down, trade negotiators sought to accommodate federal regulatory agencies concerns. During the fall of 1996 the negotiations reached a dramatic and publicized stalemate over pharmaceuticals, with expectation that no agreement would be reached on the entire package of MRAs due to disagreement over pharmaceuticals. Disagreement centered over the definition over Good Manufacturing Practice (GMP), and as a result there were slightly different interpretations between the U.S. and EU that caused a “hang up” in the negotiations.<sup>29</sup> Opposition from the Food and Drug Administration diminished, not due to any shift on the part of regulators in the

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<sup>29</sup> Interview, European Commission, September 1998.

negotiations, but due to domestic pressures for organizational reform of what was considered an overly cautious and bureaucratic agency.<sup>30</sup> Congressional pressures, notably on-going Republican efforts to reform the agency resulted in the FDA Modernization Act, which was less draconian than originally envisaged (*Financial Times*, 21 December 1997). From the EU perspective, the reforms meshed well with the mutual recognition agreements since there were renewed legislative efforts to delegate approval of some medical devices to third-party private certifiers. Encouraged by such developments, European negotiators found the FDA more willing to concede to their demands as the increasing constraints on their resources could be offset by delegating foreign inspections to counterparts in Europe. Final disagreements were resolved when negotiators agreed to confidence-building measures and exchange of inspectors to cope with potential friction from regulatory differences in testing and certification practices. This had been the result of hard bargaining from American regulatory agencies (notably the FDA) concerned about the regulatory capabilities of new members in any subsequent enlargement of the EU. Joint committees were to be set up to deal with problems and discuss any market access problems.

Although mutual recognition agreements have been lauded as an important trade liberalization strategy that can be replicated in other sectors, the implementation stage, which is likely to take eighteen months to three years, will provide a better guide to the impact of regulatory cooperation. The various stakeholders involved in the negotiations have now turned to implementation issues, which has produced on-going dialogue about the expertise and equivalence of notified bodies. Although there have been some concerns about the effects of any regulatory changes upon equivalence, market surveillance is likely to come from business as much as from government regulators. Thus far, complaints from American medical associations about possible changes in European regulations in medical devices have generated substantial dialogue, pressure and exchange. Whether this will activate an “early warning system” remains to be seen.

This has not deterred new efforts since agreement was reached in the biotechnology sector with the signing of a Veterinary Equivalence Agreement to facilitate trade.<sup>31</sup> This proceeded much more easily than other sectors, in part due to the willingness of both sides to adjust their internal rules to accommodate the horizontal transfer of competencies.<sup>32</sup> Further negotiations on mutual

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<sup>30</sup> Interview, European Commission, September 1998.

<sup>31</sup> Senior Level group Meeting Memo, December 1999.

<sup>32</sup> No Paper presented to EU, June 1999.

recognition agreements are envisaged in marine safety equipment, road safety, elevators and cosmetics, with each side pushing for inclusion of certain sectors rather than others. By December 1999, agreement was reached on opening negotiations on an MRA on marine safety equipment and on the first services MRAs on insurance, architecture and engineering services.<sup>33</sup> There was some initial disagreement over the inclusion of services. The U.S. reluctance to negotiate on services based on concerns that the federal government cannot negotiate for the states or regulatory professions has not, however, prevented it from proposing mutual recognition of legal services which are also state regulated.

While both sides view regulatory cooperation on insurance as promising, they are focusing their attention on different issues so that any agreement is likely to be protracted. No progress has been made on tackling regulatory differences in government procurement and intellectual property rights. Again, the EU is expecting that the U.S. will change its regulatory procedures to align themselves with European practices. Calls for better market access in public procurement by the EU (itself interesting given the recent European summit to liberalize procurement by 2003 in a sector that has experienced problems in the single market program), necessitates the inclusion of states and local governments in any agreement, something which the U.S. has fiercely resisted. Likewise, efforts to persuade the U.S. to adjust its regulatory practices in intellectual property have made little headway. This has produced some fears that the “hostage syndrome,” where unrelated sectors have been held hostage as governments negotiate umbrella agreements, would undermine any further cooperation.

### **3. EFFECTIVENESS AND EFFICIENCY: ASSESSING THE NEW REGULATORY REGIMES**

The changes instituted in the EU offer the best laboratory for assessing whether the new governance framework can generate the necessary collective goods to reconcile the twin objectives of regulation and free trade. Both mutual recognition and standardization, two distinct but related processes, were more difficult to implement than originally expected. More than a decade after the single market program was initiated, there are still restrictions on the free

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<sup>33</sup> Senior Level Group Report, December 1999.

movement of goods and services (Egan, forthcoming a).<sup>34</sup> As the liberalization process encountered the complexities of dealing with different regulatory regimes, the new strategy was powerfully conditioned by the interests and institutions affected by regulatory reform.

### **Regional Implementation**

The shortcomings of the new regulatory policy drew attention to the slow pace of standardization.<sup>35</sup> When the ambitious goals and timetables for common European standards were not being met, the European Commission sought to intervene in an effort to improve the design, structure and operation of European standard-setting. In soliciting opinions about its strategy, the Commission Green Paper on the *Development of European Standards*, subtitled *Action for Faster Technological Integration in Europe*, sparked a major debate among the business community. The reform proposals laid out some of the concerns that would repeatedly reappear on the Commission's agenda. Criticism focused on the effectiveness, transparency and accountability of European standardization (European Commission 1989). Anxious to raise the profile of European standards-setting, the Commission argued that both public and private sectors needed to pay more attention to the strategic significance of standardization, pushing for some bold changes to increase the speed and delivery of negotiations on European standards needed for the single market. The Commission's proposals elicited a mixed reaction. Many firms and trade associations opposed any radical overhaul of the existing process, fearing the increased burden that would be imposed on them. Unconvinced by the Commission's proposals, the national and European standards bodies argued that the problem was due in part to the politically imposed guidelines that failed to acknowledge the difficulties faced in negotiating technically complex agreements.

In the follow-up report in 1992,<sup>36</sup> the Commission was forced to acknowledge that some of the delays and problems that had emerged were partly their responsibility. The European Commission could not simply issue regulatory guidelines and expect that agreements would be resolved quickly, given its own experience for many years under the old harmonization process. In the ensuing negotiations within standards committees, the heterogeneity of economic interests

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<sup>34</sup> See also COM 1999 299; Egan, forthcoming a; COM 1999 10.

<sup>35</sup> For a detailed analysis, see Egan, forthcoming a.

<sup>36</sup> The results of the debate were summarized in the Communication from the Commission on Standardization in the European Economy, 16 December 1991, OJ C 96, 15/4/91.

often made agreement difficult. Because the negotiations included a range of multinationals, small and medium enterprises, as well as trade unions, consumer groups and other organized interests, those involved had to strike a balance to achieve some kind of consensus. Given the rules and norms within standardization, it was impossible to circumvent and exclude dissenters. This meant that agreements reached were the result of long drawn out negotiations, and took on average about five to ten years for each standard requested under the single market new approach directives.<sup>37</sup>

The shortcomings of standardization did not go unacknowledged. As soon as the Commission threatened to take control of the standards process, the European standards bodies responded by introducing a series of internal reforms. In particular, the European standards bodies sought to dismiss criticism that they were too rigid to respond to technological changes and suffered from lack of effective coordination between the three different bodies involved in standard-setting. The reforms introduced more effective coordination, shorter lead times for standards development, and agreement to make increased use of qualified majority voting. Under the old regime, the consensus rules had allowed disaffected interests to simply oppose any agreement without putting forward any alternative proposals. The shift in decision rules forced those involved in negotiations to lobby and mobilize support for or against suggested standards. This required participants in standardization to become more engaged in the process since they could not longer rely on the default condition of the status quo (see Scharpf 1985).

While the failure to generate a single coordination equilibrium in some areas is a problem in Europe, the result may lead to market problems. The governance process may produce no agreement, leading to multiple standards and limiting economies of scale as evidenced by the cases of color television and electrical standards in Europe (Crane 1979).<sup>38</sup> The lack of coordination may retard innovation and the market may split into several, poorly supported standards or orphaned standards where companies are locked into their investments and unable to shift to new technologies and options (as in the cases of Betamax, high definition television and

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<sup>37</sup> Although ETSI has since 1993 reduced the average development time from forty-five to twenty-eight months and CENELEC has also reduced its development time to between twenty-four to forty-eight months, CEN at present requires on average 75 months, and this is a substantial improvement from the average of 135 months in 1991.

telepoint). Because standards wars are expensive, those involved in standardization in Europe have tried to reduce negative effects of competition, and engage in early pre-standardization agreements to reduce risks. This is especially the case in high tech standards where the crucial element in such a rapidly changing technological environment is speed, and total returns for industry are maximized by agreeing to a common standard ahead of market entry.<sup>39</sup> However, standards committees operate on a much longer time-frame than market needs, and negotiations inevitably move slowly compared to market solutions in rapidly changing sectors and industries. Where participants are under pressure to reach some form of agreement, consensus may be achieved without full commitment.

Coordinating technologies and reconciling various strategic interests involved has not always been smooth sailing within the European standards bodies (Egan, forthcoming a). Though concerns such as trade protectionism and industrial development have guided European regulatory intervention, the coordination problems inherent in standard-setting were not anticipated. Expecting that the process would move quickly once agreement was reached at the political level under the new approach, the priority shifted towards establishing a critical mass of standards as quickly as possible to maintain the momentum of the single market. Under such constant pressure from the European Commission, and then the European Parliament, the standards bodies have continually sought to build credibility by proving that the existing system could address problems effectively.

Rapid increases in the number of approved European standards lent support to their claim that they were able to meet expectations. The continued stream of internal memorandums and working papers by the European Commission acknowledged that standards bodies have to a certain extent adapted to the challenges in the European technological and regulatory environment in the last ten years, but cautioned that there is nonetheless room for improvement (European Commission 1995: 4) Although the Commission continued to advocate the need for increased efficiency and transparency (European Commission 1998), their proposals seemed contradictory.

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<sup>38</sup> In color television, three incompatible systems (PAL, SECAM and NTSC) emerged at same time and no-one system could dominate and create a bandwagon effect. See Farrell and Saloner (1988) for theoretical analysis of the bandwagon effects of standardization.

<sup>39</sup> This is the model approach of ETSI, the European Telecommunications Standards Institute that seeks to establish common proprietary standards that spreads the use among competitors, reduces costs of duplication and stranding, and defends intellectual property rights of those involved.

While advocating the need to speed up the process through a more systematic use of qualified majority voting to overcome entrenched interests and introducing shorter implementation periods, this seemed at odds with increased efforts to open up existing practices to more representation from small companies, employees, consumer and environmental associations. Collective action necessitates smaller groups of participants while greater interest heterogeneity is likely to make consensus or agreement more difficult (Genschel and Plumper 1998).

As the Commission had no qualms about focusing on the needs of the wider standards community, the fear among national standards bodies that they would be the losers in the process forced them to collectively resist any further changes. Anxious that the Commission wanted to shift power from territorial representation to functional representation, the national standards bodies—particularly in Britain, France and Germany—sought to prevent any further reforms that would undermine their position. For years, they had benefited financially from the development of national standards, and the shift in focus to the regional level threatened to undermine their economic and political position in shaping domestic regulatory guidelines. While the European standards bodies found that some member states were particularly receptive to a possible merger among the major two European standards institutions, other member states—such as Denmark—favored the creation of a new standards institute. No decisions have been made at the time of writing, although the European standards bodies were put on notice that their work was increasingly being monitored as renewed political commitment to the single market focused on ironing out remaining problems.<sup>40</sup>

Yet these discussions do not tell us all of the problem. Member states continued to adopt national regulations, oftentimes undermining community efforts to promote liberalization. Despite legal provisions to inform and notify the Commission of draft regulations to prevent the occurrence of new trade barriers,<sup>41</sup> along with efforts to cut back on Community level regulation (“Better Lawmaking Report”),<sup>42</sup> member states continue to introduce national regulations for products and services. Because the level of national regulations far exceeds, in volume and complexity, the measures adopted at the community level, there are continued concerns that this

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<sup>40</sup> Interview, European Commission, May 1998.

<sup>41</sup> For detailed statistical analysis, see Report from the Commission on the Operation of Directive 83/189/EC in 1992, 1993 and 1994 COM (96) 286 Final. Directive 83/189 has now become directive 98/34.

<sup>42</sup> Better Law Making 1998- A Shared Responsibility COM (1998) 715 final.

undermines the principle of mutual recognition.<sup>43</sup> Political attention has thus increasingly turned towards the application of mutual recognition in the single market.<sup>44</sup> The Commission recognized that problems existed for products, and even more so for services, with economic operators complaining that obstacles were the result of a misunderstanding or misapplication of mutual recognition by member states. Many national authorities failed to accept mutual equivalence, especially cases involving novel or complex products or those involving considerations of health and safety or consumer protection.<sup>45</sup> Business complains most frequently about problems in foodstuffs, electrical products, construction and chemicals sectors.

As part of its initial response to increased problems in implementing the single market, the Commission drafted an Action Plan in April 1997.<sup>46</sup> Designed to make the single market more effective, the plan focused on policing the single market to ensure that common rules for industrial and consumer products were respected, and mutual recognition was applied properly. Though there was much publicity given to the creation of a Single Market Scoreboard to spotlight the performance of member states in implementing single market legislation into national law, other initiatives such as the business test panel (BEST)<sup>47</sup> and simpler legislation for the single market (SLIM) were crucial in drawing attention to existing regulations. Two new-approach directives for construction products and electromagnetic compatibility were found to be good candidates for legislative simplification. Standards for these two areas had fallen behind schedule, in part due to the difficulties of integrating broad framework legislation with the hundreds of new standards needed to put the legislation into practice. This may also ease trade tensions with the United States, as pressure to simplify emission standards (electromagnetic issues) has been a top priority among government negotiators who have raised the issue a number of times in senior level group meetings.

Credible monitoring of the standards process has improved its functioning. Though similar efforts have been made to improve the functioning of mutual recognition, unlike standardization

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<sup>43</sup> There are no reliable statistics on the extent of the problem since some manufactures simply comply with additional national regulations of the country of export, others forgo market access, so that only those that officially register a compliant at the national or European level receive attention.

<sup>44</sup> The Internal Market Council in 1998 brought this issue to the attention of member states, and was asked to submit a Communication to the Parliament and Council on the problems to be resolved.

<sup>45</sup> Single Market Scoreboard, October 1998.

<sup>46</sup> Single Market: Commission Agrees Outline of Action Plan, IP/97/365 April 30, 1997.

<sup>47</sup> COM (98) 550 30/9/98.

where the problem rests principally with private sector coordination and collective action, the operation of mutual recognition depends on the willingness of public authorities to assume regulatory equivalence. Because of different regulatory traditions, there is an inherent conflict between policy styles of “market oriented” and “state oriented” systems of governance (see Hall and Soskice, forthcoming). Though designed to avoid creation of detailed rules at the Community level, there are problems in the application of mutual recognition in practice.<sup>48</sup> Complaints by firms in food, engineering, and automobile sectors that they still face administrative and bureaucratic delays in marketing products, are matched by a growing number of complaints in the service sector from business communications, construction and security services industries. The difficulties experienced in the financial sector have rarely been notified to the European level. There has been a great deal of problems associated with exemptions provided under “general interest” to prevent the marketing of financial services even though mutual recognition should operate under terms that provide member state of origin the right to approve and regulate transactions without any further requirements imposed upon (i.e., home country control).<sup>49</sup>

Though committed to increased monitoring of the situation, the Commission has set up sectoral round tables, training schemes, and specific initiatives to foster transnational networks and information, notably in the aviation and telecommunications sectors, to avoid conflicts over regulation in future. The notification mechanisms (Directive 98/34, previously 83/189) to gauge national initiatives to regulate products and services have taken on increased importance in ensuring that further obstacles are not created by new regulations and standards, and that the principle of mutual recognition is actually guaranteed in practice. Improving mutual recognition will be further aided by the insistence of the Court of Justice that member states have an obligation to include mutual recognition clauses in national legislation.<sup>50</sup> This formalizes the legal commitment towards mutual acceptance of regulation, ensuring it will receive better attention among public authorities in member states.

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<sup>48</sup> COM 1999 299 final.

<sup>49</sup> see COM 99 232 final.

<sup>50</sup> Case C 184-96 Commission vs France.

## **Transatlantic Implementation**

The shortcomings of transatlantic regulatory coordination have yet to garner as much attention. The lack of institutional symmetry between the U.S. and EU has an important effect on the relative feasibility of implementing agreements on common standards. Such divergent patterns, reflecting differences in the relationship between business and government, makes it difficult for private sector actors to cooperate with each other. Complaints that the European Union is using standards as a quasi-industrial policy has caused conflict with the United States market driven approach to standards.<sup>51</sup>

Throughout Europe, the national standards bodies are peak associations that are officially recognized by the state or public authorities. This is replicated at the European level where the EU is able to elicit adequate cooperation from business through centralized standards bodies. Compared to European standards-setting, American standard-setting is more fragmented and decentralized. The greater reliance on market mechanisms has resulted in over four hundred trade and industry associations, scientific and technical societies setting private standards. These operate at both federal and state level, enjoying relative autonomy in the sense that they have greater opportunities to set industry-wide standards in their sector. Although the American standards system does have a central coordinating body, namely the American National Standards Institute, its role is more limited than its European counterparts. The American National Standards Institute does not set standards itself, and its membership does not include all standards bodies. Many other prominent standards organization such as the American Society for Testing and Materials (ASTM), and International Institute of Engineers (IIE) prefer to act independently because they have come to question the role of the American National Standards Institute in articulating their specific needs and interests. Although many of these standards organizations have sought to maintain their independence, the fragmentation of the standards system has been a crucial factor in the EU's refusal to cooperate on standardization (Nicolas 1996). These organizational features go a long way towards explaining the systemic difficulties in promoting transatlantic standards coordination. We can thus understand the reluctance to engage in

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<sup>51</sup> See the comments of David Aron, U.S. Under-Secretary of Commerce and Ray Kammer, Director of NIST at the NIST/ANSI Conference, "Towards a National Standards Strategy To Meet Global Needs," September 1998.

transatlantic coordination of standards due to the asymmetry in institutional structure between the European and American systems.

Yet public authorities managed to overcome such institutional asymmetries to agree on mutual recognition agreements. Although the negotiations revealed different strategies (package deal versus sectoral deal), in the course of such agreements, public authorities also learnt from their counterparts about institutional adaptation. The European Union, with its experience in coordinating mutual recognition of conformity assessment, has instituted oversight and control mechanisms (so-called notified bodies) to ensure that public authorities were able to make regulatory equivalence enforceable and feasible. As a consequence, the European Union wanted the same guarantees that American public authorities would verify regulatory equivalence from the many public and private organizations engaged in conformity assessment. The absence of government recognition in the United States proved to be a stumbling block that forced institutional adjustment by the American system to bring it closer to that of the EU.<sup>52</sup> After careful consideration and much concern about the anti-trust implications of such a move, the Department of Commerce requested that the National Institute of Standards and Technology create the National Voluntary Conformity Assessment Program (NVCASE) to accredit conformity assessment bodies in the U.S. This is an important point because notwithstanding the power of business in pushing for such agreements, governments often have great difficulty in shifting their regulatory strategy. With the accreditation system in place, further cooperation could take place between the United States and EU. The relative feasibility of implementing mutual recognition agreements will have an important effect, in the long run, on patterns of regulatory cooperation and adjustment paths within regulatory agencies.

In the transatlantic context, the problem is how to secure mutual trust and credibility across regulatory systems, since the agreements did not provide for formal monitoring and sanctioning mechanisms to ensure compliance. Since mutual recognition agreements are to be extended further in both products and services (such as insurance professions), the extent to which regulatory acceptance is actually working without any additional constraints and

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<sup>52</sup> The United States advertised its proposed reforms in the Federal register. The proposed system NVCASE provided for government accreditation of various public and private institutions providing conformity assessment. This would satisfy European concerns of equivalence and essentially create a similar system of “notified bodies” that existed within the European market.

impediments being imposed upon business will be the true test of transatlantic regulatory cooperation. Given the experience in the EU single market program, transatlantic negotiations need to focus on mechanisms to enforce compliance. In this regard, the early warning systems,<sup>53</sup> exchanges of information as well as building mutual trust and credibility are crucial.<sup>54</sup> This can minimize conflict when there are legitimate or entrenched differences in regulatory standards, and public authorities need to assess the conditions necessary for mutual recognition or regulatory equivalence. Over time this can enhance the transatlantic commitment to trade liberalization, and ensure that the absence of a legal framework does not preclude the U.S. and EU from institutionalizing closer cooperation among public authorities. Given that this bilateral model of trade liberalization has been emulated in other bilateral settings, as well as regionally within APEC, ASEAN, NAFTA, MERCOSUR and the FTAA,<sup>55</sup> its successful implementation will reverberate beyond the transatlantic marketplace.

### **Exporting Strategies, Transatlantic Relations and the International Context**

Though the bilateral negotiations are slow and laborious work,<sup>56</sup> the tensions involved in regulatory cooperation have increasingly spilled over onto the international arena. The signatories of the Uruguay Round called for the bilateral or multilateral negotiation of MRAs both in the agreement on Technical Barriers to Trade (TBT) and in the General Agreement on Trade in Services (GATS), as well as the use of international standards and good manufacturing practices where possible to prevent technical barriers to trade arising from domestic regulatory requirements. The United States and European Union have pushed for international standards across a range of issues from bribery to pharmaceuticals in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals (ICH), WHO Codex Alimentarius, United Nations Economic Commission for Europe (UNECE), Organization for Economic Cooperation and Development (OECD), and International Standards Organization

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<sup>53</sup> There are currently eight designated early warning issues, two of which have been recently resolved—metric measurements and safe harbours, See TABD Newsletter, Brussels.

<sup>54</sup> Interview, NIST September 1998; Senior Level Group Meeting Memo.

<sup>55</sup> For a recent overview of this trend, see Nicolaidis (1996): Appendix 1 for summary of existing agreements or negotiations.

<sup>56</sup> It was assumed that the U.S.-EU agreements would be the most difficult. However it has taken four years for MRAs to be concluded between EU and New Zealand-Australia due to subnational constraints that saw German Länder and Australian states hesitant to accept mutual assurance in conformity assessment.

(ISO), to promote market accessibility and reach consensus on health safety and environmental principles—that is not simply a lowest common denominator approach that would merely serve to justify weak national regulatory practices and deter many states from replacing their own more stringent domestic regulatory standards with international ones.

While both sides agree in principle, there have been strikingly different perceptions about the role of international standardization in the United States and European Union. This has resulted in sharp interchanges and deep criticisms of both sides from policymakers and business. The European Union has advocated increased use of international standardization, in part to deflect criticism from the United States that their own system lacks openness and transparency. This has proved to be quite contentious in the United States, where there has been an apparent reluctance to play a major role in international standardization due to the perceived bias as being Europe-dominated, either because of the organization of voting rights, or because of close links between international and European standards bodies. This view is not without merit since the European standards bodies make use of memorandums of understanding between the two bodies to accelerate voting on European standards at the international level under the Vienna and Lugano Agreements. Although the national standards bodies in Europe have a collective vote that is much stronger than the singular vote of the United States, the European Union has criticized the United States standards system for being unable to deliver effective domestic application of international standards into the domestic regulatory system. While the European Union has consistently transferred standards work to the international level, ostensibly to avoid duplication of work, the overall effect has been to increase the perception among American business that international standardization is not as responsive to their interests (see House Committee Hearings, Technology Subcommittee 1998; National Resource Council 1995). As one senior trade association official noted, “the EU is a master at trying to develop standards and then work through international standards organizations to get adoption of those standards as international ones in order to give a distinct comparative advantage to the EU manufacturer.”<sup>57</sup>

The problem is compounded by concerns that European standards bodies have far more resources and funding that enables them to engage in trade promotion and outreach activities in

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<sup>57</sup> Time Bennett, Senior Vice President, American Electronics Association, quoted in “U.S.: EU uses standards as trade weapon” *Journal of Commerce*, 2 November 1998.

developing nations. American companies have complained that their own system is the only one that receives no direct government support.<sup>58</sup> Efforts to establish standards infrastructures and promote the adoption of European standards have given European companies a market edge in Asia, Africa and Latin America (Office of Technology Assessment 1992). This lack of sustained attention and assistance to international standardization in the United States has pushed many companies into participating in consortia to push their standards at the international level. Because this has resulted in some spectacular failures (such as open systems interchange (OSI), Java), American companies have become increasingly hostile to the formal standards development process (Tate, forthcoming). Pushing for alternative forums for standardization, the United States has found itself increasingly at odds with Europe over the direction of international standardization. Many American companies with proprietary technologies (such as Microsoft) refuse to engage in international standardization, and the common perception that international standards through ISO/IEC are responsive to European needs, and only at times responsive to American industrial needs, has transferred trade friction from the purely transatlantic context to the broader international arena (see ASTM 1998; *Journal of Commerce* 1999).<sup>59</sup> But the disputes reflect divergent philosophies. The U.S. preference for standards set by the market after competition between competing technologies, and the European preference for standards through institutionalized industry cooperation and industrial planning, is indicative of the difficulties that transatlantic cooperation will continuously face in cooperating over standardization.

#### **4. ACCOUNTABILITY, LEGITIMACY AND GOVERNANCE**

Systems of regulatory cooperation have emerged at the regional and transatlantic level that rely on coordination among a variety of public and private institutions. In such circumstances, the governance systems that have emerged raise questions about the legitimacy and accountability of such efforts to shape market behavior. While standard-setting allows private actors to play a

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<sup>58</sup> This is a sensitive issue since many standards bodies want to keep government at arms length. However, the current financial crisis facing the American National Standards Institute indicates that it may have to solicit government funding to sustain their role in domestic and international standardization.

<sup>59</sup> Perhaps the best recent example is cellular telephone standards for third generation mobile telephony where European efforts to promote the GSM standard developed within the European Telecommunications Standards

central role in shaping commercial relations, in part because governments have delegated certain responsibilities to them, this system of private governance does raise questions about their legitimacy and accountability. While industry participants have stressed the importance of consensus and due process in their deliberations, there have been repeated concerns about the lack of transparency, representation and accountability surrounding the decision-making process (European Commission 1995). Though firms may cooperatively establish common rules for commercial interaction and set standards to reduce transaction costs and penetrate new markets, the outcome of such self-regulation may also be harmful by limiting competition and favoring narrow interests over public purposes (Haufler, no date). Concern about the dominance of industrial interests in standardization has led the Commission to alter the processes of representation by funding the participation of a number of public interest or advocacy groups such as the Consumer Committee for Standardization (ANEC) and the European Trade Union Federation (ETUC). However, “the balancing of interests is an inherently discretionary, ultimately political process” and although there have been attempts to address the representation bias in standardization, “it is difficult to see how non-elected officials could legitimately assume responsibility for adjusting the competing claims of various private interests” (Majone: 1999: 6). Although the Commission controls the power it delegates to private standard-setting bodies, through procedures of promulgation or oversight,<sup>60</sup> so that the standards agreed upon match regulatory expectations, it could be argued that the growth of technical committees in standardization, the opacity of the decision-making processes and their membership bias still represent an overall deficiency in delegated governance.

Although it could be argued that rule-making in the European context has no bearing on transatlantic relations, the emphasis on expertise and delegated governance has parallels in the transatlantic context. While Americans have long argued about the lack of transparency and access in European standard-setting for their own companies, and have unsuccessfully requested direct participation in the process to influence the final outcome (Egan 1996; Woolcock 1993),

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Institute (ETSI) and then within the International Telecommunications Union provoked a very public political row over standard-setting.

<sup>60</sup> Comitology committees do review agreed upon standards in order to ensure their compatibility with the framework legislation under the new approach (promulgation procedure).

similar concerns about legitimacy have arisen with regard to the transatlantic mutual recognition agreements.

The transatlantic system of regulatory cooperation allows regulatory agencies or directorates to accept functional equivalence, which may undermine current procedures and rights. Though there are often raised concerns about the legitimacy of the Commission bureaucracy, it is entrusted with negotiating external trade agreements on behalf of member states. By contrast, regulatory legitimation in the American context relies heavily on federal administrative procedures (Federal Advisory Committee Act, Administrative Procedures Act, Negotiated Rule-Making Act, and so forth) that allow for widespread input from interested parties through notice and comment. With regulatory agencies increasingly involved in trade negotiations, many interest groups fear not only the loss of regulatory sovereignty through its horizontal transfer to other jurisdictions under mutual recognition, but also the diminution of their influence over the negotiated outcome (see also Stern 1998). Agencies may have more discretion in international negotiations than in domestic policy-making given the various mechanisms of oversight that have evolved (see Stewart 1975), and may thus find themselves with more room to maneuver. As transatlantic relations increasingly shape the nexus between trade and regulatory issues, this raises questions about deliberative decision-making since it may be more difficult to challenge decisions agreed upon in the trade arena than in the regulatory arena.

## CONCLUSION

As this paper demonstrates, regulatory cooperation, a crucial component of market operations at the transatlantic or regional level, blurs the distinction between public and private, and generates new trade liberalization strategies that blur the boundaries between trade and regulatory cultures. As governments increasingly transfer elements of regulatory authority to other actors and institutions, the delegation of powers is meant to enhance the prospects of reaching agreement on trade liberalization. The attempts at collective action through standards coordination and mutual recognition have reshaped and reconfigured the traditional regulatory functions of states and/or public authorities. Although the effects of mutual recognition and standardization have restricted the freedom of national policy choices in the regulatory arena, it has resulted in a system of governance that has allowed governments to delegate certain functions and achieve regulatory compliance in different ways. What public authorities give away in terms of direct control, they may recover through using the resources and capacities of other public and private entities.

Although markets are constituted and their viability preserved by government regulation, the norms and rules that emerge are increasingly the result of **regulatory interdependence**. The type of governance mechanisms that have evolved at the regional and transatlantic level demonstrate the constellation of ideas, interests and institutions that shape trading relations. By studying regional integration strategies, it is evident that transatlantic negotiations have responded to increased pressures for market liberalization and reciprocal access, borrowing the idea of mutual recognition inherent in the single market program. The effects of policy borrowing on domestic institutions and interests deserves further attention, as the resulting governance arrangements may represent sequential adjustment or institutional adaptation—as illustrated by the American case. Whether goals and capabilities are in tandem can be an important factor in determining the successful “fit” between different regulatory regimes, and the degree to which regulatory interdependence can work in practice.

To garner credibility and trust, the strategies of trade liberalization have to be integrated into a legal framework that provides mechanisms and tools for compliance. In the European context, infringement procedures, and other selective incentives and controls have forced interests

involved in standardization to reach collective agreement. The “shadow of hierarchy” is ever present as the European Union has pushed those involved in standardization to meet contractual agreements and obligations for the single market. The organizational capabilities of standards setting institutions needs to match expectations, otherwise there is the possibility that regulatory activity devolved upon private interests may be revoked. Public evaluations of performance by the European Union has triggered intense pressure on the standards bodies to increase their efficiency and effectiveness. The same pressures have also been applied to member states to ensure the effective operation of mutual recognition in the single market. Serious trade problems still exist under mutual recognition in both goods and services, as mutual lack of confidence with regulatory equivalence across member states often results in constant interventions and restrictions that undermine free trade. While public comparisons of national performance may trigger peer pressure (as evidenced by the single market scoreboard and other measures), the “shadow of hierarchy” is ever present as the European Union can press for harmonization as an alternative mechanism when mutual recognition has failed and community intervention is warranted.

Although the application of mutual recognition has been much less successful in the single market than usually acknowledged, it has been exported to the transatlantic context. By contrast, standards-setting is deemed too difficult to harmonize at the transatlantic level given the historically different approaches that have emerged in Europe and United States. Although mutual recognition agreements have been successfully negotiated between the United States and European Union, these are much less ambitious than the trade principle underpinning the single market. By requiring a compliance program, the European Union has pushed the United States into monitoring private sector conduct as a condition of meeting their regulatory requirements. Although regulatory authorities on both sides of the Atlantic are coordinating strategies and practices so that they are mutually equivalent, to the extent that this is successful in practice depends on mutual trust and credibility. In the transatlantic context, the legal framework of infringement proceedings and legal obligations is absent, and regulatory compliance depends on voluntary procedures such as the exchange of information, early warning systems and transnational confidence building measures. It would seem, however, given the European experience, that insufficient attention in the transatlantic context has been focused on the implementation of such agreements. Just as the European Union has been forced to constantly

intervene to ensure the applicability of its free trade principles and liberalization strategies, the transatlantic relationship will need to create a genuine partnership to sustain the obligations inherent in mutual recognition agreements. Putting the new regulatory format into practice is still in its infancy as attention shifts from negotiation to implementation.

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