THE LIMITS OF LIBERALIZATION
REGULATORY COOPERATION AND THE NEW TRANSATLANTIC AGENDA

Washington, D.C.
16 January 1997

American Institute for Contemporary German Studies
The Johns Hopkins University
Conference Report

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This AICGS Conference Report is made possible through grants from The German Marshall Fund of the United States and The Boeing Company. Additional copies are available at $5.00 each to cover postage and processing from the American Institute for Contemporary German Studies, Suite 420, 1400 16th Street, N.W., Washington, D.C. 20036-2217. Telephone 202/332-9312, Fax 202/265-9531, E-mail: aicgsdoc@jhunix.hcf.jhu.edu, Web: http://www.jhu.edu/~aicgsdoc/
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FOREWORD

In providing a synthesis of the discussion and compilation of statements made by ten representatives of government agencies, business, public interest groups, and policy analysis organizations, this report vividly reflects the scope, complexity, poignancy and insights generated at the January 16, 1997 Washington conference, “Regulatory Cooperation between the United States and the European Union.” That event was an innovative blend of the research and public affairs dimensions of AICGS and involved three primary areas of AICGS engagement: transatlantic relations, comparative public policy and the workings of the European Union (EU) as a multilevel system of governance.

Institutional partnership with the European Community Studies Association (ECSA-USA) permitted an unusually fruitful combination of resources. At the request of the ECSA transatlantic project committee I headed, David Vogel, Professor of Business and Public Policy at the University of California School of Business in Berkeley, agreed to produce a manuscript on the compelling issues raised by the existence of parallel and sometimes clashing regulatory regimes. ECSA is publishing Vogel’s monograph.

Over sixty participants convened to discuss transatlantic regulatory cooperation in a highly structured format, using both Professor Vogel’s manuscript and the statements reproduced here as points of departure. Vogel addressed three domains of regulatory practice (pharmaceuticals, food and the environment) sharing a distinctive “social” orientation that affect trade and investment flows. Specifically, he considered nine cases of complaints brought by the U.S. against the EU and vice-versa. Cases involving U.S. complaints included the ban on growth hormones for...
beef, import ban for fur from animals caught by leg-hold traps, and the EU eco-labeling regime. EU complaint cases included the CAFE standard for U.S. car imports, U.S. approval procedures for introducing new drugs to market, and the U.S. embargo on tuna caught with nets that coincidentally killed dolphins. In the interest of providing a broader framework for discussion, in addition to involving policymakers and interested parties representing “social regulation,” experts from three additional areas in which the “economic” dimension predominates—financial services, telecommunications and competition policy—were also invited to participate.

Anticipating the discussion to be generated in four round tables, conferees were invited at the outset to ponder the similarities and differences in regulatory practices and articulate how these might affect strategies for transatlantic cooperation both within and between the “social” and “economic” categories. Their mandate extended beyond this to consider a wider issue: in light of the emergent patterns of regulatory practice and cooperative experience, just how far can and should transatlantic market integration go? What sort of policy instruments and strategies might be developed to reconcile tensions arising from the desire to advance trade and investment when the legitimate exercise of power by duly constituted public authorities creates barriers? These questions were not answered during the conference, but they informed the discussion and provided an agenda for future efforts.

As background for what follows, a few lines outlining Vogel’s main points are in order. First, the “big story” in U.S.-EU economic relations continues to be the large and increasing levels of market integration: Vogel’s cases affect a very small portion of trade. Second, none of the conflicts in question are driven primarily by protectionist sentiment or
designs, but rather are artefacts of broad similarities in preferences on both sides of the Atlantic with respect to the definition of welfare and the levels of protection to be achieved. Standing behind the disputes are highly specific preferences that emerge from the democratic process, reflecting the campaigns and concerns of public interest groups (NGOs), legal traditions, institutional peculiarities, and policy styles. In short, at the core of Vogel’s analysis is a paradox involving disputes arising among trade and investment partners whose interaction and policy similarity is greater than between the partners of almost any other pairing in the global economy. This paradox leads to a third observation: there is no evidence of declining standards, i.e., “regulatory arbitrage” leading to a “race to the bottom” at work in the transatlantic relationship—quite the contrary. Finally, in light of the relatively small stakes involved, a fourth finding concerns the reasons behind the pattern of testiness in U.S.-EU encounters on these issues. It may be that the very size of the overall U.S.-EU market creates a sense of vulnerability on both sides, fear that a concession could lead to a “slippery slope” with cumulatively declining regulatory effectiveness, or that wariness about the demonstration effect that any U.S.-EU accord might produce for ongoing negotiations with third parties. Indeed, Vogel warns against transatlantic myopia, a preoccupation with increasing access to each other’s markets that carries with it a characteristic pathology: presenting the EU with a Hobson’s choice between greater EU integration versus greater transatlantic cooperation. He concludes that the more enduring issue confronting the U.S. and EU is achieving agreement on a joint strategy for advancing regulatory cooperation at the global level, where in contrast to U.S. and EU, differences prevail in the values to be defended and the levels of protection to be afforded.
Lively and frank discussion demonstrated both the immediate and longer-range benefits of the conference. Stakeholders could gain insight into the motivations, strategies, and limitations of their counterparts. Policy science gained a privileged look at this interactive process parallel to comments directed specifically to the Vogel manuscript.

We were fortunate in being able to associate Professor Maria Green Cowles with this project in the role of rapporteur. An AICGS Fellow in 1994-1995 and current board member of ECSA, her own analyses of business strategy with respect to the EU policymaking nexus are increasingly in demand.

We would like to express our gratitude to The German Marshall Fund of the United States and The Boeing Company for their support of this publication.

Carl Lankowski  
Research Director  
June 1997
THE LIMITS OF LIBERALIZATION:
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NEW TRANSATLANTIC AGENDA
A Conference Report

Maria Green Cowles

I. INTRODUCTION

In recent years, the status of regulatory cooperation between the European Union (EU) and the United States has become increasingly important in overall U.S.-EU relations. The two polities account for more than one-third of world trade and approximately fifty percent of the global gross domestic product (GDP). As David Vogel points out, the pattern of U.S.-EU regulatory relations has significant implications not only for the western hemisphere, but for the entire global economy. Both the United States and EU are regulatory models that serve as standards for the rest of the world. Consequently, virtually all trade disputes between the U.S. and EU affect other countries as well. Every bilateral dispute has the potential to become a multilateral dispute.¹

On January 16, 1997, the European Community Studies Association (ECSA) and the American Institute for Contemporary German Studies (AICGS) sponsored a conference to explore the status of U.S.-EU regulatory relations. As a point of departure, David Vogel, Professor of Business and Public Policy at the Haas School of Business, University of California-Berkeley, presented a paper on U.S.-EU Regulatory Cooperation.² Presentations and discussion followed by officials from numerous government agencies and departments, business leaders, non-governmental organization representatives, think-tank officials and academics, all involved in transatlantic regulatory matters.

The purpose of this report is to provide a summary of the various themes that emerged from the conference proceedings. More
specifically, the report highlights the factors driving regulatory cooperation, the difficulties in achieving regulatory agreement, and the prescriptions that exist for future U.S.-EU regulatory cooperation.

II. FACTORS DRIVING U.S.-EU REGULATORY COOPERATION

The salience of U.S.-EU regulatory cooperation has grown considerably in the past decade. The end of the Cold War and concerns that the two transatlantic partners were “drifting apart” provided political fodder for improving the U.S.-EU relationship. Renewed economic cooperation became a focal point for strengthening the transatlantic partnership. Both the U.S. government and the European Union conducted studies to determine the feasibility of creating a “Transatlantic Free Trade Area” or a “Transatlantic Economic Space.” The signing of the New Transatlantic Agenda (NTA) and “Action Plan” in late 1995 promoted expanding economic ties and regulatory cooperation between the two sides. The creation of the Transatlantic Business Dialogue (TABD) advocated exchanges between leading public and private actors from both sides of the Atlantic with a view to eliminating barriers to trade and investment.

While these political concerns undoubtedly played a role in promoting the transatlantic relationship, other factors were also important in explaining the renewed focus on the U.S.-EU regulatory cooperation.

Trade Liberalization and Business Concerns

One set of factors accounting for the growing emphasis on U.S.-EU regulatory cooperation concerned trade liberalization and increasing demands on industry in the global economy. As David Vogel points out,
the broad thrust of trade liberalization drives interest in regulatory policy. As trade became more liberalized through successive GATT rounds, regional arrangements and bilateral agreements, its impact on domestic markets became increasingly evident. The new trading arrangements created different advantages and disadvantages for domestic companies and thus produced both winners in losers as a result of international regulatory negotiations. It also gave foreign producers a vehicle for intervening in domestic policy. Indeed, evidence suggests that domestic producers have not gained over their foreign competition. U.S.-EU regulatory cooperation did not result in overall gains for domestic producers. Consequently, there has been increased scrutiny of regulatory policy between major trading partners. Given the extensive transatlantic trade—U.S.-EU bilateral trade flow is second only to that of U.S.-Canada trade—interest in the transatlantic regulatory cooperation has risen significantly.

While trade liberalization raises awareness of regulatory issues, business concerns often prompt this liberalization in the first place. As Charles Ludolph, Director of EU and Regulatory Affairs in the International Trade Administration for the U.S. Department of Commerce argues, transatlantic regulatory cooperation is increasingly important for large U.S. firms who rely on global sourcing and imports in the face of mounting cost pressures and international competition. According to Ludolph, global sourcing has accelerated tremendously in the past six years as multinational firms, for example, manufacture a product in the Far East, assemble the good in Europe and sell them in the United States. Large firms are demanding that regulatory policies be adjusted to address global sourcing. Ted Austell, Executive Director of Government Relations-International for Tenneco and codirector of the Transatlantic Business Dialogue Secretariat concurs. According to
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Austell, large firms—unwilling to wait for serious regulatory rows to emerge—are now attempting to set the regulatory agenda and encourage proactive government activity on a number of regulatory issues.

Of course, this regulatory agenda is pushed forward by business groups that are less protectionist and/or by U.S.-EU firms that dominate the world market in certain industries such as the pharmaceutical and chemical industries. As Vogel points out, if all firms wanted U.S.-EU regulatory cooperation, there would not be any trade problems. The fact remains that not every business is willing to open up its domestic market share to international competition. Moreover, not every NGO believes that business concerns regarding trade liberalization and global sourcing are the key regulatory priorities to pursue. Thus, these NGO groups have also renewed their interest in U.S.-EU regulatory cooperation to ensure that their concerns are addressed as well.

Improvement in Regulatory Effectiveness

The growing experience of government regulators as a result of the changing international trade agenda has also contributed to U.S.-EU regulatory cooperation according to Vogel. As government regulators meet in transatlantic forums, they have developed greater awareness of one another’s regulatory models and have learned to place greater confidence in each others data and test procedures. The effectiveness of the FDA, for example, is improved by the extent to which it can use foreign test data. Thus, regulators themselves are driving international cooperation.

At the same time, producers drive the regulators. As Ludolph attests, “the idea that a regulator can be indifferent to global sourcing is impossible.” Producers have impressed on regulators the need to be more global in their outlook. Similarly, they have emphasized the need
for regulators to reduce the “temporal burden” on manufacturers. In an era of rapid technological change, producers must bring their products to the market in a timely manner. However, outdated lengthy regulatory procedures can prevent manufacturers from gaining a competitive edge.

Linda Horton, Director for International Policy for the U.S. Food and Drug Administration (FDA), agrees that companies have influenced regulators response and effectiveness in a number of ways. First, companies play an important role in identifying regulatory problems to the regulators. Second, because agencies like the FDA cannot afford to send inspectors around the world to cover all regulatory issues, companies become a key source of information on the status of foreign regulatory activities and enforcement. Finally, large firms put pressure on agencies to find alternative solutions to regulatory problems. For example, the December 1996 Chicago meeting of the Transatlantic Business Dialogue was designed to bring European and American chief executive officers together to meet directly with U.S. and EU regulators. As Horton recalls, industry leaders asked FDA officials why they were “quibbling” over certain matters relating to the pharmaceutical industry. The companies’ advice to the FDA was simple: “Get on with it.”

The Development of the Single Market Program

European regulatory cooperation is not a novel development. Indeed, it can be traced to the early years of European integration in the postwar period. Keith Feith, senior environmental scientist in the U.S. Environmental Protection Agency (EPA), points out that the reconstruction of Europe after World War II depended heavily upon the free movement of products and materials across state borders. In the early 1950s, working groups were created in the UN Economic Commission for Europe (UN ECE) to address differing vehicle weight
restrictions and safety regulations. The agreements resulting from UN ECE working groups have been a source of both cooperation and conflict between the United States and EU ever since.

The EU’s Single Market program, however, added an entire new dynamic to the U.S.-EU regulatory relations. In the first place, the dramatic increase in EU regulations in the post-1985 period has raised concerns for U.S. exporters. The U.S. Department of Commerce, for example, has estimated that “EU legislation covering regulated products will eventually be applicable to fifty percent of U.S. exports to Europe.” Equally important is the nature of these newly created EU standards and regulations. As Vogel reveals, “the EU is at the cutting edge of creating a market to reduce regulations without compromising health, safety and environmental standards.” Indeed, Brussels has been pressured to adopt stricter standards. Consequently, while the average EU standard may be as stringent or less stringent than a U.S. standard, the strictest EU standard is often higher than U.S. standards. This drives increased U.S. interest in U.S.-EU regulatory cooperation as Americans are concerned that the higher EU standards make it more difficult to enter the European market. One result of U.S.-EU regulatory cooperation has not been a regulatory race to the bottom—i.e., the lowering of standards. Rather, one increasingly finds a race to the top.

The outcome is often led to less than harmonious relations between the U.S. and EU in regulatory matters. Indeed, as Vogel points out, oftentimes “the U.S. is asking the EU to trade off EU integration for U.S.-EU transatlantic relations.”

The development of the single market program in the European Union is also significant in that it parallels the developments in transatlantic and international regulatory initiatives. Oftentimes, the European Union served as the laboratory for issues such as “mutual
recognition” and “proportionality” that are later adopted at the international level. To understand the new concepts and dynamics of bilateral or multilateral trade negotiations, therefore, one need look no further than the bargaining among EU institutions and fifteen member states within the EU itself.

**Weak Multilateral Institutions**

The growing interest in U.S.-EU regulatory relations is also related to the general U.S. belief—largely shared by the Commerce Department and business officials—that multilateral institutions are still too weak to achieve significant results. Ludolph maintains that the World Trade Organization (WTO) Standards Code is not developed to the point to where one could adequately ascertain the activities and compliance of countries as diverse as China and Germany. Moreover, there are no obligations of any regulatory authorities to accept the results of bodies such as the WTO or the International Standards Organization (ISO).

There are also problems with other multilateral organizations such as the UN Economic Commission on Europe, the International Conference on Harmonization, ICAO, and the International Maritime Organization. Many multilateral institutions do not provide adequate transparency of their activities and/or do not allow private industry and NGOs to participate in the proceedings. There is not a “robust forum” in which public and private voices can be heard. Not everyone agrees with this assessment of multilateral institutions. As discussed below, many NGOs believe they are given greater access to multilateral bodies and, to date, have been largely excluded from U.S.-EU bilateral negotiations.

Yet another reason for the salience of U.S.-EU regulatory cooperation is the existence of what Ludolph calls “a certain comfort level” between the two polities. While there are considerable cultural
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and ideological differences between the U.S. and EU, as discussed below, these differences pale when compared to differences between the United States and, say, the Pacific Rim countries. There is a certain commonality in political institutions, traditions, language and cultural norms that facilitate cooperation between the two sides.

Yet, as Vogel points out,

Paradoxically, it is precisely because the EU and the U.S. are so politically and culturally similar that trade disputes between them are so common and intense: both are democratic, relatively open societies in which numerous NGOs enjoy substantial political access and influence. The result is a highly fluid and constantly expanding regulatory agenda which has made the achievement of coordination a moving target.  

III. CONFLICT IN U.S.-EU RELATIONS

To understand U.S.-EU regulatory conflicts, one can begin by looking no further than the regulatory disputes that exist within both the U.S. and EU. After all, the reality of competing interests of domestic groups in an pluralistic system often leads to regulatory conflict within society. Thus, in the United States as in Europe, differences persist between producers, trade negotiators, regulators and environmental groups. As evidenced by the AICGS-ECSA conference discussion, one area of growing regulatory conflict involves Process Production Methods (PPM) -- the means by which a product is produced.

Bob Heinen, Director for International Trade and Investment for the E.I. DuPont de Nemours Company, asserts that from industry’s perspective, “how one makes things is at the core of a firm’s competitive advantage.” There is no single way to make a product. Requiring
companies to restrict their production processes risks hurting innovation and technological advances in significant ways. Heinen maintains, therefore, that “the production process itself should be irrelevant in terms of international regulation.” U.S. trade representatives, who often are most interested in the economic gains achieved in negotiations, tend to agree.

Regulators, however, disagree. According to Kenneth Feith of the EPA, “the process is important to regulators,” and Horton points out that in pharmaceutical matters, for example, the FDA regards PPM as a valid means to determine the appropriate amount of a drug’s active ingredient. Similarly, regulation of PPM are necessary to ensure that seafood is processed correctly and stored at proper temperatures. From the regulator’s perspective, therefore, PPM are critical to ensure health and safety standards.

Environmental groups have also been strong proponents of PPM regulation. Frank Loy, Chairman of the Board of the League of Conservation Voters, maintains that PPM can be an important means to safeguard the economy by restricting different products or procedures in the production process. Environmental groups argue that their positions carry significant legitimacy in that they are often supported by American public opinion.

Decisions regarding the role of PPM in U.S. domestic regulatory policy, therefore, in often controversial in and of itself. Indeed, similar disputes between producers, regulatory, environmental groups and member states exist within the EU as well. Elevating PPM debates to U.S.-EU regulatory negotiations can lead to greater conflict when coupled with competing cultural differences and constitutional concerns, institutional problems, lack of regulatory interdependence and trust, diverse economic sectors, as well as disagreements over the use of
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bilateral or multilateral forums. The fact that many of these factors are intricately intertwined makes the promotion of transatlantic cooperation all the more difficult.

**Competing Cultural Differences and Constitutional Requirements**

Many of the key U.S.-EU regulatory disputes revolve around cultural differences. In the case of PPM, for example, problems often arise because environmental, consumer and labor groups as well as public opinion on both sides of the Atlantic differ in their regulatory priorities. The case of animal leg traps is one such example. Because Europeans tend to raise animals in “harvesting farms,” they view the U.S. policy of trapping animals in the wild as inhumane. Similarly, whereas American interest groups have not raised strong objections to beef hormones and genetically altered agricultural products, the same cannot be said of European groups. The issue of eco-labeling—one of the most contentious PPM cases—is perhaps most difficult because different groups have different priorities in terms of how to produce products in an environmentally friendly way. Thus, as Vogel argues, most of the big “headline disputes” between the United States and European Union involve cases driven not by producers, but by NGOs and public opinion.

The situation is exacerbated by cultural norms embodied in constitutional requirements and negotiating procedures. In the United States, it is generally argued that producer interests and market efficiency hold greater sway in government negotiations than do environmental or labor concerns. Indeed, the government-mandated private sector advisory committee system consists primarily of industry groups—notably the Industry Policy Advisory Committee (IPAC) and the Industry Sector Advisory Committees (ISACs). Environmental
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advisory groups were only recently added under the Clinton administration.

The situation is quite different in the European Union, however, where there is what Shalini Venturelli, associate professor at The American University, calls a “constitutional mandate” enshrined in documents such as the Maastricht Treaty in which certain environmental, social, and cultural issues are incorporated in EU law. These same constitutional issues are even stronger in the member states. Consequently, EU negotiators must carefully examine the relationship between industry, environmental and social issues in transatlantic regulatory policy. As Leon Hurwitz, Professor at Cleveland State University notes, the EU negotiators’ situation is all the more complex because they must also address the cultural differences of fifteen different member states.

These constitutional differences result in differing negotiation styles between U.S. and EU negotiators. Ralph Ives, Deputy Assistant U.S. Trade Representative for Europe and the Middle East, points out these different negotiation styles over the Mutual Recognition Agreements (MRA). The U.S. government prefers to negotiate MRA on a sector-by-sector basis, thus promoting the maximum advantage possible to producers in various sectors whether it be medical devices or pharmaceuticals. The Commerce Department and U.S. Trade Representative have promoted MRA in terms of the benefits that both sides can achieve, i.e., the millions of dollars that manufacturers can save by avoiding duplicative testing and certification procedures.

The European Commission, however, prefers to combine all sectors under a “framework” or “umbrella agreement.” This approach is viewed as too cumbersome to U.S. government negotiators because it brings together different sectors that are regulated by different regulatory
agencies. The Commission, however, finds it easier to address competing societal interests because the umbrella agreement allows EU negotiators to assess the overall gains and losses of different societal groups in the MRA process. As described by Ives, this “balanced benefits” approach also enables the Commission to take into account the various member states’ interest in the MRA negotiations.

Cultural and constitutional differences are delicate matters in U.S.-EU negotiations. Negotiators and societal interests often are concerned with what Vogel calls the “slippery slope” argument: if they accede to the demands of one government on one issue, they will be called upon to “give in” on other issues. The tendency is for each side to resolutely stand by its own positions without any willingness to compromise. Indeed, some societal groups call for the respect of domestic legislation unless one can demonstrate that the legislation was designed to gain a trade advantage. For example, Loy argues that U.S.-EU negotiators should not challenge domestic environmental laws in principle unless these laws were formulated to discriminate against foreign trade. He warns that the legitimacy of bilateral and multilateral trade agreements comes from the support of domestic groups and public opinion. Failure to take into account legitimate domestic cultural concerns could ultimately hurt international regulatory regimes.

Cultural differences also prove difficult in defining basic underlying concepts in U.S.-EU trade negotiations. Charles Stark, head of the Antitrust Divisions’ Foreign Commerce Section of the U.S. Department of Justice, points out that while U.S. and EU antitrust laws share strong roots of commonality—the U.S. influenced German antitrust law which was, in turn, the seed for antitrust legislation in the Treaty of Rome—important cultural differences remain. The primary U.S. objective in antitrust law is consumer welfare. In the EU, antitrust policy is used not
merely for consumer welfare, but also to achieve further integration of the common market. Thus, while the roots are similar, the rules and application of the policy are quite different.

Similarly, William Garrison, Director for the International Communications studies Program at the Center for Strategic and International Studies (CSIS), notes that legal rights are often defined in culturally-specific ways. Negotiating U.S.-EU telecommunications regulations is complicated by the fact that European telecommunications firms were staterun utilities that guaranteed specific rights and benefits to citizens. Coming to a U.S.-EU agreement on basic definitions of legal rights is difficult. Having participated in a U.S.-European data protection discussions, one participant noted that unless the different sides can find a dialogue on “concepts” and “procedures,” U.S. and European negotiations simply talk past one another. Garrison summarizes the situation more succinctly: “Cultural differences are a first class headache.”

**Institutional Transparency, Voting Rules and Competence**

Complicating U.S.-EU regulatory policy are institutional problems such as transparency, voting rules and competence. Each of these institutional problems is important because it plays an important role in who controls the negotiating process.

Trade negotiators, regulators and NGOs alike find that the transparency of the regulatory process is one of the more difficult issues in U.S.-EU regulatory cooperation. Individually, each system is fairly transparent. In the U.S., the Administrative Procedures Act by Congress ensures that any person or group can comment on ongoing regulatory activities. Within the EU, the Brussels policymaking procedures and standards-setting bodies also enable different parties to provide input
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into the process. The transparency problems, however, often arise in other bilateral and multilateral bodies that have not allowed input by NGOs in the proceedings. Fran Irwin, fellow at the World Resources Institute, notes that NGOs were not allowed to participate publicly in the UN ECE or ISO. Similarly, until recently, little effort was made by the Transatlantic Business Dialogue to involve NGOs in regulatory discussions. Lack of transparency often means lack of domestic political support for the U.S.-European negotiations at hand.

Voting rules also cause considerable problems in negotiations involving the U.S. and EU countries. Wendy Moore, an Economic Officer with the U.S. State Department, points out that in the ISO, the European Union member states each have a vote in the organization—yet often vote as a bloc. It is not in the U.S. interest to negotiate on a one-on-one basis with the EU on some matters, and to negotiate against a 15-to-1 bloc in another. Moore maintains whoever controls the voting process has more leeway vis-à-vis its domestic constituency. It is not surprising, therefore, that the United States has tended to favor domestic standards when faced with what it finds to be unfair voting rules.

U.S.-EU negotiations are also complicated by the fact that the European Commission does not have the competence to negotiate on all regulatory matters. Consequently, U.S. negotiators are not certain whether they can approach the Commission or the member states on certain issues. Peter Cowhey, Senior Counselor for Economic and Competition Policy at the International Bureau of the Federal Communications Commission, notes that the question of European Commission competence is an important one in terms of negotiation dynamics. When the European Commission has competence, member states are not in the negotiating room. At the same time, industry and other groups—that traditionally channel their interests on international
negotiations through their national governments—must now focus their energies on the European Commission.

Sometimes, U.S.-EU negotiations may enhance the European Commission’s role. For example, the European Commission did not have competence for the wireless communications market. Cowhey notes that with U.S. prompting, the European Commission was gradually—and quite happily—pushed into the negotiations. Vogel argues that the extent to which the EU gains regulatory competence is important. As suggested above, the U.S. tends to prefer negotiating with the EU alone, and not with fifteen different member states. In Vogel’s view, the EU’s growing regulatory competence will facilitate U.S.-EU negotiations, a countervailing trend to the integration/transatlantic relation trade-off mentioned previously.

The multi-level nature of the European Union is troublesome for U.S. negotiators. Harry Freeman of the Freeman Company notes that the European Commission recently intervened in a U.S.-UK antitrust agreement, arguing that it had primary competence in the matter. Indeed, disagreements over competence and subsidiarity mean that intra-EU differences will likely continue in the foreseeable future.

Lack of Regulatory Interdependence and Trust

Along with cultural differences, different regulatory procedures and the lack of trust by the two sides are among the most important sources of conflict in U.S.-EU regulatory relations. Feith (EPA) points out that Congress has not sought to create “regulatory interdependence” between the U.S. and other governments. Thus, as Horton (FDA) notes, agencies are first and foremost domestic bodies. A similar statement could be made in the European Union. The result is often a clash of regulatory
models—and a lack of trust among U.S. and EU negotiators, regulators, and interest groups.

For regulators, the issue of trust is of paramount importance. According to Horton, due to increasing demands on regulators at a time when resources are limited, FDA regulators are increasingly interested in knowing more about the conditions and regulations in the countries that are sending products to the U.S. They want transparency in order to see that regulatory systems are in place in foreign countries and that exports meet U.S. standards. Regulators want to be certain that inspection procedures are properly adhered to and that enforcement is carried out. U.S.-EU regulatory cooperation is important in that it allows U.S. regulators to meet domestic requirements like safe public health, safe roads, safe medicines. For cooperation to be achieved, however, each side must trust the procedures of the other. Finding that trust has proven to be a difficult task.

Interestingly, in U.S.-EU regulatory negotiations, the lack of trust is found within the United States and Europe as well. Trade negotiators, regulators and interest groups all have different interests at hand. As Ives (USTR) pointed out,

... The [U.S.] regulators want to act autonomously. Their key interest is in the integrity of the imported product. [U.S.] Trade agencies ... are trying to conclude agreements that enhance market access and trade. We do not want to interfere in any way with the regulatory agencies’ authority or procedures. But, the trade agencies and the regulatory agencies almost speak different languages—the regulators in scientific terms, the trade agencies in economic.
Bringing these forces together has proven to be very difficult and very challenging.

**Diverse Economic Sectors**

Yet another difficulty involved in U.S.-EU relations is what Vogel describes as the “enormous diversity of cooperation mechanisms around different sectors.” There is no single regulatory formula or procedure that can be applied to all economic sectors. Regulating medical devices, for example, is very different from regulating cars.

The situation is further complicated by the unique nature of certain sectors. Bradley Belt, Director of Capital Markets and Domestic Policy Issues at CSIS, notes that financial services deal largely with intangibles, especially information—and not the goods and labor traditionally provided in other sectors. Traditional geographic and political boundaries are much less relevant. Indeed, regulators are constrained in that financial interests can literally move their businesses to more accommodating regulatory regimes overnight. Moreover, the rapid change in financial markets also makes it difficult for regulators to have direct oversight of these markets.

Indeed, U.S.-EU regulators have fairly limited say over financial markets. Belt points out that in financial services, U.S.-EU regulatory cooperation is minimal due to the fractured regulatory framework in the U.S. (regulatory bodies tend to be independent from the government) and different regulatory models (German versus UK) in Europe. The little U.S.-EU interaction that does take place involves market access issues.

In the case of telecommunications, Garrison reveals that there is simply a lack of multilateral organizations in which the U.S. and EU can coordinate laws for economic commerce and services on the internet. The WTO, the WIPO, and the Organization for Economic Cooperation...
and Development (OECD) all cover bits and pieces of this aspect of telecommunications services. The challenge is quite simply for U.S. and EU negotiators to find suitable negotiating forums.

**Bilateral versus Multilateral Forums**

Indeed, the choice of negotiating forums is a also point of contention in U.S.-EU regulatory cooperation. As suggested by Ludolph’s comments above, the U.S. finds many multilateral organizations to be too weak to develop comprehensive agreements. U.S. Commerce and USTR officials as well as business groups tend to prefer negotiating in a bilateral format first, and then moving the agenda to a multilateral arena such as the WTO. Some NGOs charge that the U.S. promotes this route because business groups can promote cost savings and efficiency more readily in bilateral negotiations than in multilateral institutions where environmental, labor and other concerns may be given a greater voice.

The European Union has also expressed uneasiness with the U.S. determination to focus on bilateral agreements first. The EU’s emphasis on constitutional rights—the need to consider business, environmental, labor and cultural concerns in a comprehensive manner—suggests that the EU is comfortable with the multilateral level. The fact that the European Union itself involves negotiations among the fifteen member states means that the EU is familiar with the multilateral format. There is also the general belief among many EU negotiators that other countries should be involved in important trade negotiations.

Addressing the issue of bilateral versus multilateral negotiations remains a point of contention in U.S.-EU regulatory cooperation. Whether or not the two partners can agree on this issue remains an open question.
IV. PRESCRIPTIONS FOR THE FUTURE

While conflict abounds in the U.S.-EU regulatory relationship, so too do opportunities for greater cooperation in the future. One of the goals of the AICGS-ECSA conference was to provide a prescriptive statement of the transatlantic regulatory partnership. What can be done to improve U.S.-EU cooperation? What advice can be given to policymakers?

To begin, one can argue that transatlantic cooperation is not possible in all areas of U.S.-EU regulatory policymaking. Cultural and constitutional differences are often deeply ingrained and therefore the ability to alleviate these differences will likely be at a minimum slow and incomplete. At the same time, there is the opinion that transatlantic cooperation may not even be desirable in certain situations. Loy of the League of Conservation Voters argues that certain environmental domestic laws simply should not be challenged if they are not intended to discriminate against foreign traders.

At the same time, conference participants suggested a number of ways that do exist to improve transatlantic regulatory cooperation. These public policy prescriptions are identified below.

Learning Best Practices

Wolfgang Reinicke (Brookings Institution) suggests that one means to improve transatlantic cooperation is for the U.S. and EU to learn from each other’s experiences. Clearly, the United States can learn from the success of the EU’s Single Market program. At the same time, as the EU reforms its food safety regime in the wake of the mad cow disease scandal, perhaps the EU should take a closer look at the U.S. system. At a minimum, Reinicke argues that both sides of the Atlantic in their own domestic reform efforts should look toward other side with a view to making their systems more compatible. Working to create regulatory
interdependence upfront would undoubtedly facilitate closer transatlantic cooperation.

In the business world, this process is known as adopting best practices. It is in each side’s interest to learn what procedures, what institutional arrangements, what legal guidelines allow for the best means of creating regulatory policy.

**Building Confidence**

Conference participants generally agreed that the most important means to improve regulatory cooperation is for the U.S. and the EU to build confidence in each other. Sitting down with one’s counterparts to discuss cultural differences, institutional difficulties, and complex procedures may be time-consuming, yet participants found it to be critical to the success of their regulatory activities. Indeed, building confidence enables the two sides to learn from one another. Regulators, government lawyers, business groups, and trade negotiators at the AICGS-ECSA conference all mentioned a number of confidence-building examples that promoted cooperation in regulatory policymaking.

Horton points out that since 1989, the FDA has conducted formal bilateral meetings with the EU’s Directorate-General III (the EU’s industry directorate) on an annual basis. The two sides share information on a very wide range of subjects. They benefit in obtaining firsthand knowledge of ongoing events in the U.S. and Europe, and in developing professional relationships and contacts with their counterparts. U.S. and EU officials “compare notes on policy directions that we are taking and always find that we bring home new ideas with us.”

Feith (EPA) raises similar examples of face-to-face discussions on environmental issues. The transformation of the UN ECE Working Party 29 on automobiles from a European to a global forum finally occurred
after the Department of Transportation and the EPA sent a number of officials to simply sit down, exchange ideas, and work out differences with their EU counterparts.

The U.S.-EU business community has also focused on confidence building within the Transatlantic Business Dialogue. The first year and a half of the organization was largely spent giving U.S. and European companies the opportunity to meet and discuss trade barriers and institutional arrangements, and to feel at ease with one another in the business partnership. As Austell (Tenneco/TABD Secretariate) points out, the companies have also created opportunities to meet directly with U.S. and EU regulators and to propose possible solutions to regulatory barriers. Current TABD efforts include reaching out to the NGO community. TABD seeks to foster trust not only between the U.S. and EU, but within each polity. After all, before U.S. and EU trade negotiators can see eye-to-eye, the USTR, the regulatory agencies and the interest groups must also support the regulatory initiative.

Austell notes that to date, there has been little evidence of confidence-building measures among U.S.-EU NGOs. The Transatlantic Labor Dialogue announced by EU and EU government officials never appeared to get off the ground. Financial restrictions as well as the diverse nature of these groups may impede transatlantic meetings and dialogue. Policymakers may wish to explore what role, if any, the U.S. and EU can play in facilitating transatlantic meetings between NGOs.

In addition to face-to-face discussions, there are a number of procedures that also can promote confidence building. Stark (U.S. Department of Justice) points to the 1991 U.S.-EU Antitrust Cooperation Agreement as one such example. Under the agreement, the two sides agreed to notify one another of upcoming antitrust proceedings, to consult and try to coordinate actions before formal decisions are made.
As Stark points out, the U.S.-EU agreement “reflected a recognition on both sides that enforcement cooperation between them, and a mechanism for avoiding or minimizing potential differences, would be enormously important in the future.”

Ives (USTR) notes that negotiators have created “transition periods” during which the two sides can gradually adapt to Mutual Recognition Agreements. During these testing period, the two sides seek to “work out the bugs and, most importantly, to change attitudes from distrust to cooperation.” The development of transition periods in other regulatory policy areas could foster similar trust.

In short, confidence building allows the U.S. and EU to trust in and learn from one another, and to bridge the cultural, institutional, and constitutional differences that once seemed insurmountable. At the same time, building trust signals the building of legitimacy for the transatlantic regulatory initiatives.

**Promoting Participation and Transparency**

Yet another means to build confidence and legitimacy is to ensure that regulatory procedures are transparent and open and that all groups can participate in regulatory discussions. As highlighted above, the lack of transparency is an important problem in U.S.-EU regulatory relations. The U.S. has complained that it makes little sense for regulators to promote functional equivalency or to harmonize standards if there are no adequate means to ensure that all sides are complying with and enforcing these measures. Efforts to promote transparency must be made at the national as well as at the European level.

At the same time, groups such as NGOs must be given a voice in bilateral U.S.-EU regulatory policy matters. As Irwin notes, one reason for NGO support of multilateral solutions is due to the fact that NGOs
have largely been excluded from bilateral negotiations. Moreover, there is little incentive for transatlantic NGO cooperation when the groups have not been given adequate participation. While adding additional voices to regulatory negotiations may delay and/or complicate the process, fuller participation of all parties will undoubtedly lend further legitimacy and cooperation—at both the domestic and transatlantic levels—to U.S.-EU regulatory activities.

Encouraging EU Competence

As suggested above, it is in the interest of both the U.S. and the EU to encourage the extension of competence of the European Commission in regulatory issues. EU competence allows for transatlantic negotiations to be conducted on a one-on-one basis rather than in a 15-to-1 multilateral forum. Similarly, it encourages EU interest groups to organize on a European level in Brussels rather than through fifteen disparate national channels.

Reinicke suggests that the U.S. continue to explore ways to improve EU regulatory competence so that it becomes less dependent on the member states’ opinions. At same time, he encourages U.S. officials to simplify their own regulatory process so that fights and competition among various bureaucracies can be minimized. In short, streamlining the negotiation process on both sides of the Atlantic can improve the chances for cooperative activity at the transnational level.

Promoting Multilateral Solutions

Vogel argues that despite protestations to the contrary, the U.S. and EU should seek multilateral agreements instead of focusing on bilateral negotiations. According to Vogel, multilateral agreements have helped reduce U.S.-EU tensions. By paying more attention to their common
agreements vis-à-vis the rest of the world, they can spend less time on their differences vis-à-vis each other.\textsuperscript{10}

Vogel maintains that the transatlantic experience serves as an important model for integrating Japan and other countries in multilateral regulatory decision-making. Yet, as Reinicke points out, not all developing countries are actually interested in pursuing the regulatory measures addressed in U.S.-EU negotiations. Indeed, the current North-South debate over trade, environment and labor standards suggests that these countries may be reticent to do so. Reinicke contends that one way to promote bilateral cooperation as well as multilateral cooperation is for the U.S. and EU to discuss possible inducements they can offer to developing countries to agree to the formation of global regulatory regimes.

V. CONCLUSION

The U.S. and the EU are important rivals and partners in the emerging global economy. The purpose of this AICGS-ECSA conference was to examine the regulatory cooperation of this formidable economic powers. It is interesting to note that the conference participants spent little time discussing how much regulatory integration was desirable or achievable. Instead, much attention was focused on the inevitability of this transatlantic partnership—for better or worse. The challenge remains for policymakers to learn from this relationship and to prescribe innovative approaches to ensure that a cooperative partnership endures both across the Atlantic and in the world.
Regulatory Cooperation and the New Transatlantic Agenda

ENDNOTES


2  The European Community Studies Association commissioned Professor Vogel to write the monograph. Professor Vogel presented his paper to this Washington, DC, conference on January 16th. He gave a similar presentation in Brussels a month later to a group of EU government, industry and think-tank officials. Based on input from these two conferences, Vogel presented the final version of his paper to the ECSA Biennial Conference in Seattle, on May 30, 1997. ECSA will publish Professor Vogel’s final monograph in early 1998.


4  Vogel, p. 12.

5  Vogel, p. 13.

6  IPAC and the ISACs are jointly managed by the Departments of Commerce, Agriculture, Labor and the Environmental Protection Agency.


8  See Cowles.

9  Charles S. Stark, “International Antitrust Cooperation,” in Marked, Konkurrans Og Politikk (8 April 1997) pp 259-270

10  Vogel, pp. 64-65.

11  Naomi Kawin, FDA Associate Director, International Policy, was principal author of this paper.
The Limits of Liberalization
STATEMENTS OF CONFERENCE PARTICIPANTS

Ambassador Ralph Ives
Office of the United States Trade Representative

THE ABCs OF MRAs

Introduction

What I plan to do today is to describe some of the pressures of trying to conclude mutual recognition agreements -- some of the forces that work with you and the many that push against. While my case study is the U.S.-EU MRA negotiations, many of the same pressures prevail in any negotiation and I believe would occur in MRA negotiations with other partners. Let’s begin our ABCs.

“A” is for “Absolutism”

As in, “its my way or no way.” Now, this pressure occurs in the initial stages of almost every negotiation. My side has worked hard on its position, we know what is right; the other guy is just wrong. We’ll teach him.

This pressure manifests itself in ways that are common to all negotiations with the EU and in other ways that appear unique to MRA discussions.

I was interested in David Vogel’s assessment that the United States and the EU are “politically and culturally similar.” Since this is a relative term, I guess I can agree. But, the differences when diving into something like MRAs tend to emerge much more readily than the similarities. In this “A” of the ABCs, the differences seem to stand out more than our wish to cooperate and find common ground. How else can one explain why agreement still eludes us after over three years and eight negotiating sessions?
To try to explain, let’s begin “absolutism” with the definition of MRA. You might think coming to an agreement on a definition of what we are negotiating would be easy. Not so.

MRAs are foreseen as a means of facilitating trade by streamlining the procedures used by manufacturers to demonstrate the conformity of their product (or processes) to foreign market requirements. An MRA allows covered products or processes to be assessed for conformity in the domestic market to the standards and technical regulations of the exporting partner. An MRA with the EU would allow qualifying U.S. organizations to test and/or certify product in the United States to EU requirements, while qualifying EU bodies would be able to test and certify product in Europe to U.S. requirements.

We do not try to change standards. We try to work with each other’s.

Being pragmatic Americans, U.S. negotiators have taken the position that mutual recognition can entail any part of the conformity assessment process that U.S. and EU negotiators can work out. If both sides can agree to “certify,” fine. If all we can work out is reducing costs by eliminating duplicate inspections, then that’s at least a start in the right direction.

The EU has a more principled approach and defines “full” mutual recognition to be that in all areas both sides should reach “equivalence” in their standards or regulations and then “market access” should be assured by a one-step conformity assessment procedure with no further regulatory procedure in the import market. This definition no doubt comes from the EU member states’ internal experiences, including the ECJ case discussed in Dr. Vogel’s paper.

This “full” MRA can possibly work out in some sectors but in other sectors runs into the difficult Mr. Vogel described—i.e., their legal inability to enter into binding commitments for such “full” mutual
recognition. So, despite our many years of negotiating, we are still hung up on this definition.

Moving on to other “absolutisms, we can see that differences are not just between the U.S. and EU negotiators. Differences exist between the cultures in trade agencies and regulatory agencies. Differences exist between tasks the various regulatory agencies have been assigned by law and the way these regulatory agencies approach their assignments.

A successful MRA negotiation requires regulatory authorities to cooperate with trade officials. The regulators want to act autonomously. Their key interest is in the integrity of the imported product. Trade agencies are trying to conclude agreements that enhance market access and trade. We do not want to interfere in any way with the regulatory agencies’ authority or procedures. But, the trade agencies and the regulatory agencies almost speak different languages—the regulators in scientific terms, the trade agencies in economic terms.

Bringing these forces together has proven to be very difficult and very challenging.

Let me pull out one example in the MRA negotiations with the EU. The U.S. position at the start of these negotiations was that we would like to conclude agreements sector-by-sector. We would conclude an agreement in say, electrical safety covering some products, such as telecommunications. As agreements were concluded in other sectors, we would implement them.

The EU approach is to combine all sectors under a “framework” or “umbrella” agreement. They want a “joint committee,” composed of representatives for the two parties—the EU Commission and the USG—to make decisions affecting the operation of the agreement.

The problem with this umbrella approach is it is trying to bring together many different sectors and regulatory agencies, which use a
variety of procedures for determining conformity assessment. The other problem is that the regulatory authorities are concerned that trade agencies are sitting on a committee, which in theory can make decisions affecting their regulatory authority. In practice, of course, USTR cannot make decisions about how a regulatory agency operates, but the perception remains. So, something as seemingly innocent as a committee to bring disparate sectors together can create tremendous difficulties.

We are trying to overcome these concerns in drafting the framework agreement. For example, if either party can effectively block decisions, the regulatory agencies should receive some comfort in seeing that the joint committee cannot even pretend to make decisions about their operation.

When one dives into the absolutism of each sector, additional difficulties emerge. Let’s look at the status of negotiations in the two sectors in which there appears to be the greatest differences between the U.S. and EU—pharmaceuticals and medical devices.

U.S. and EU differences in the pharmaceuticals section of the MRA reflect a wide, long and deep philosophical and legal divide. FDA must approve all drugs and inspect all manufacturers—foreign and domestic—that supply the U.S. market. FDA officials claim that they can allow some other countries to prepare certain types of inspection reports but that FDA cannot delegate ultimate authority to approve such reports or to inspect manufacturing facilities.

The EU decided that the only way it could form a single market in drugs was to declare that all member State’s regulatory authorities were equal for approving, inspecting and enforcing EU directives for pharmaceutical production. Dr. Vogel’s paper describes the two procedures for obtaining product approval in the EU. Now that all
member states adopted this system, the EU does not want to accept less from an MRA partner. The EU wants the FDA to accept all member states’ regulatory authorities inspection reports as being reliable, with the FDA being allowed to review such reports for transparency and to inspect manufacturing facilities in only very specific circumstances.

To make progress on this issue we need to see if we can go beyond the “absolutism” of these two positions. Obviously, preserving the health and safety of Americans will remain FDA’s dominant preoccupation; as a consumer, I wouldn’t want it to be any other way.

U.S. and EU differences in the medical devices area of the MRA are also very wide, reflecting the substantial differences in the two partners’ approval processes. FDA approves medical devices sold in the United States. The FDA proposes allowing EU third party private companies to conduct some inspections, subject to FDA final approval. This proposal should reduce the cost of duplicative inspections.

In the EU, private companies (third-party certifying bodies) can certify that EU manufacturers are meeting EU standards for most medical devices. The EU maintains that its testing companies should be allowed to certify that low and medium risk devices meet FDA standards.

Are these “absolute” positions here to stay? Is there any way to bridge this gap?

Why is it necessary to conclude agreements in all areas—in an “all-or-nothing” approach? To try to answer this, let’s go on to B, as in ...
MRAs save manufacturers the expense of shipping products to have conformity assessment performed in the foreign market, and reduce associated uncertainties and delays. MRAs can also save regulatory agency resources by enhancing regulators’ confidence in products imported from MRA partners and reducing the need to test and inspect those foreign products. An MRA with the EU would allow qualifying U.S. organizations to test and certify product in the United States to EU requirements, while qualifying EU bodies would be able to test and certify product in Europe to U.S. requirements.

The Commerce Department has estimates of the millions of dollars that can be saved if MRAs are concluded.

You would think the “B”—benefits—would work in favor of concluding MRAs. And, to a large extent it does.

But, the EU has injected another “B” word—balance. In an effort to bring as many member States on board for MRAs as possible, the EU Commission insists that the initial package must be “balanced” in trade terms. I assume this means that two-way trade in the sectors covered must be roughly the same. But, I believe it also means that the MRAs must reflect various member States’ interests.

So, while the U.S. has taken the view that there are benefits for both parties from each sector for which we conclude an MRA, the EU believes in a “balanced” benefits approach.

This need for balance has also extended to the EU’s proposal for rules of origin. In essence, the EU maintains that the way to ensure balance is to require that products covered by the MRA be limited to those originating in the territories of the two parties.

While this proposal might seem reasonable on the surface, the U.S. side believes it has severe problems. First, it seems inconsistent with globalization—allowing manufacturers to source from wherever they
want. Second, we do not understand the need to impose an additional requirement on an agreement that is trying to reduce government requirements. Third, we are concerned that rules of origin requirements can change and create uncertainty.

Less you begin to believe all is lost, let me quickly go on to the “C” in my ABCs—as in...

“C” is for Change

Can we change the attitudes between trade agencies and regulatory agencies? Can we improve the trust between the U.S. and EU needed to make progress on mutual recognition in sensitive areas?

Here again, Dr. Vogel’s paper provides some solid indications that there are reasons to believe we can. He points to several areas in which U.S. and EU authorities are cooperating, including the sensitive areas under negotiation in the MRAs.

But, this change will take time. Building trust takes time.

This is the main reason that in all of the sectors there are “transition periods” during which no mutual recognition occurs. Instead, each party’s system undergoes a testing period to work out the bugs and, most importantly, to change attitudes from distrust to cooperation. I believe, from my brief exposure to this issue that this change can and will occur.

In conclusion, the ABCs of MRAs involve moving from “absolutism,” using the “benefits” as the lever to get to “change.”
We at FDA see the 1990s as the beginning of an era of greater cooperation among food and drug health authorities around the world, including those of the European Union (EU), with corresponding impacts on health and trade. Consequently, we were delighted to have the opportunity to comment on Professor Vogel’s draft paper.

There are many reasons why FDA views regulatory cooperation with the EU and others as so important at this time. We view regulatory cooperation with other countries and with the EU as a means of achieving our own regulatory objectives.

FDA’s world has changed a lot in the last two decades, and we now need to be much more internationally involved than ever before. As Dr. Vogel’s paper mentions, new international trade agreements demand our attention, and international standards have taken on new importance.

But of equal significance to us is the fact that imports into the U.S. of FDA-regulated products, especially foods, have increased tremendously. And FDA’s resources to monitor imports have not kept pace with this deluge of shipments. The great growth in imports in relation to our resources to inspect them has led FDA to become increasingly interested in knowing more about the conditions and regulations in the countries sending us these products. We want to see regulatory systems in place in foreign countries that assure that their exports meet our standards.

Thus, we see international regulatory cooperation as a means of helping us achieve our core mission—domestic public health.
What are the means we can use to cooperate with other countries? Three means of cooperation that are very important to us relative to the EU are bilateral information exchange meetings, equivalence, and harmonization.

**Bilateral Information Meetings**

FDA has been conducting bilateral meetings with the EU’s Directorate-General III, or DG-III, since the late 1980s. Directorate General III is the part of the European Commission that deals with industrial products, including drugs, medical devices, and processed foods. Representatives of other DGs also participate in these meetings. The meetings are generally held annually, and the seventh such meeting will coincidentally take place in late January in Brussels.

At these meetings, FDA and the European Commission share information on a very wide range of subjects of mutual interest. We find that there is great benefit in getting firsthand knowledge about what is happening in Europe and in developing the professional relationships and contacts with our European partners. We compare notes on policy directions that we are taking and always find that we bring home new ideas.

The minutes of the six bilateral meetings that we have held with the EU show the broad range of subjects discussed.

**Equivalence**

The second form of cooperation that I would like to discuss is our work with the EU towards regulatory equivalence. Equivalence can be said to exist when two (or more) regulatory systems are different, but achieve the same level of health protection. In other words, the two countries may use different means to achieve the same level of protection
against a health risk. The WHO agreements that became effective last year encourage countries to work towards equivalence on food safety issues, and as I will explain in a minute, we are doing that with the EU. We are also actively working towards equivalence in certain other areas related to drugs and devices, as part of overall mutual recognition agreement (MRA) negotiations. As you know, part of FDA’s mission is to ensure the healthfulness of products imported into the U.S., but FDA does not have the resources to inspect many food firms abroad. We therefore want to be able to rely on the results of foreign regulatory agencies’ inspections of their own firms for our own decision-making purposes. If we know that a foreign regulatory system’s regulations are as good as ours, and if we know that the inspection and enforcement system is as good as ours, we can be assured that the products they ship to the U.S. generally attain our level of health protection. Furthermore, if we know which of the foreign country’s firms are not in “good standing” with the foreign regulatory agency, we could look at those firms’ imports more closely when they come to our borders, to be sure that they meet our standards.

FDA is currently negotiating three equivalence-type agreements with the EU. One agreement covers products that the EU calls “veterinary products,” that is, products—mainly foods—derived from animals such as meat, poultry, seafood, dairy, etc. We are also involved in pharmaceuticals negotiations, which are mentioned in Dr. Vogel’s paper, and in negotiations in the medical devices area. President Clinton and President Santer have pledged their support for the successful completion of all these agreements.

With respect to the veterinary discussions with the EU, USDA and USTR are participating in these discussions, as well as FDA, since the agreements cover meat and poultry, which are principally regulated by
USDA, and since there is a strong trade angle to these discussions as well as a public health angle.

The proposed veterinary agreement would establish what we are calling a “framework” for working towards equivalence on the various products covered by the agreement. The agreement would lay out a consultation process that the U.S. and the EU would follow in working towards equivalence, and it sets up various information exchange mechanisms, as well. The consultation process is very important, since equivalence is such a new concept that there could be many different ways of defining it and many ways of determining whether two systems are indeed equivalent.

Each FDA determination of equivalence will address both the equivalence of the foreign country’s standards and the equivalence of the foreign country’s inspection system (including its compliance activities). In addition, FDA will reach determinations of equivalence for only those product areas where the foreign standards and enforcement system assure the same (or a higher) level of health protection as does the U.S. regulatory system. FDA will not revise its own standards downward in order to achieve equivalence. Furthermore, we intend to go through notice and comment rulemaking on each equivalence determination that we reach. In other words, before declaring the seafood regulatory systems of the EU countries to be equivalent to that of the U.S., we will seek public comment on the basis for our equivalence determination. This is required of FDA by the legislation implementing the Uruguay Round agreements establishing the World Trade Organization.

We had hoped to have a veterinary agreement signed by the end of 1996. Unfortunately, that didn’t happen, and now we and the EU are working towards trying to complete the agreement by April of this year.
The Limits of Liberalization

Moving on to pharmaceuticals and medical devices, I’ve just returned from a negotiating session in Brussels, where we made a lot of progress. A further negotiation will occur the last week of January in Washington.

Harmonization

The third form of cooperation with the EU that FDA is engaged in is harmonization. Harmonization is said to exist when two (or more) countries have a common set of requirements in place. Sometimes a country must revise an existing standard to achieve harmonization, and sometimes harmonization can be achieved prospectively. Our most successful harmonization effort to date has been in the pharmaceuticals area, that is, the International Conference on Harmonization (ICH) initiative that is discussed in Dr. Vogel’s paper.

Specific Comments on Dr. Vogel’s Paper

Currently, the focus of the paper is on the trade reasons for regulatory cooperation. In discussing health and safety issues, I strongly recommend that the public health impetus for regulatory cooperation be discussed and that some of FDA’s examples be included in the paper.

Also, I would stress that regulatory agencies can commit themselves to change and implement that commitment. In addition, agencies such as FDA can bind themselves if they follow notice and comment processes, e.g., on equivalence. Other countries have their administrative processes, too. This is well understood by regulatory agencies and poses no significant barrier to cooperation activities. FDA has even issued regulations to help facilitate sharing of predecisional and confidential commercial documents with other countries.
In sum, we at FDA have seen how cooperation can help achieve public health objectives.
First of all, David Vogel deserves praise for his concise and accurate
descriptions of several cases of importance, and for the analysis he
brought to bear. Vogel is right when he says that while in important ways
the EU and the U.S. are similar societies, the very openness of those
societies will produce differing regulatory schemes and recurring,
perhaps constant conflict. What should we do about that?

The first step to lessen the conflict would be to make the regulatory
process more transparent. This means letting the other side of the
Atlantic know what’s proposed, what evidence is adduced to support the
proposal, and also letting the other side participate in the process. That
will help, but only some.

The most serious conflicts have arisen, and will continue to arise,
when the parties, relying on the trade rules governing the EU-U.S.
relationship, seek to knock down a domestic piece of legislation designed
to improve the environment. These rules ought to enjoy a significant
presumption of validity. Of course such a presumption could be rebutted
if it is shown that the intent was to gain a trade advantage, or that there is
no reasonable scientific basis for the rule. But the presumption should be
in support of the rule.

For example, the CAFE rules for automobile fleets had a clear
environmental rationale and were clearly not written in a discriminatory
manner. The fact that they hit European auto exporters especially hard
because they exported mostly larger cars may be tough luck for them --
but the CAFE regulations should not have been knocked down on that
ground. The beef hormone rules may be an example running the other
way. The U.S. may argue that the Europeans have no basis for
discriminating against been that is fed hormones—but why is this not a valid European decision, unless you can show some nefarious intent? It will not be good for the future of the trading system if we are inadequately sensitive to differing ways to address domestic environmental and health desires.

The tuna/dolphin case in another example where the proponents of a restriction-free trading system do themselves little good by trying to knock down a piece of domestic law that is designed to address an environmental goal of the U.S. There was no evidence that this was a hidden protective provision. Quite the contrary. This proposal clearly did not originate with a U.S. fishing industry.

A useful contrast can be made with the WHO case involving Venezuela’s complaint against the U.S. over the EPA’s regulations on reformulated gasoline. Even though the regulations were initially put forward as a way of promoting cleaner air, the evidence was strong that the way the regulations were formulated was unnecessarily discriminatory, that the failure to change them after complaints were lodged was for domestic protection reasons, and that you could get the same results with a much fairer regulation.

In some ways, the big problem for Europe and the U.S. in the trade field will not be the disputes between them, but rather the difficulty of defending a liberal trade regime that seems to benefit both economies against a concerted attack from organized labor, the environmental community, and (in the U.S.) the Buchanan wing of the electorate. Some of that opposition is ideological, isolationist, and, in the case of part of the environmental community, suspicious of economic growth because of the perceived harm it does to environmental values. These opponents cannot easily be converted.
The Limits of Liberalization

But there are others in the environmental (and, I believe, labor) camps that do not have any ideological problem with increased trade that leads to growth. But they absolutely see the need to balance the increased efficiency that comes with such a regime with environmental values and interests. They really believe that the globalization of trade can bring potential harm as well as benefits. The environmental community is quite split on its basic attitude toward the benefits of globalization.

If the trade communities in Europe and the U.S. don’t want to be faced with a solid opposition of the environmental community, they must pay attention to these more practical, less ideological branches of the environmental communities. That means two things: be careful about knocking down domestic laws, adopted for environmental and similar domestic (but not protectionist) purposes, and begin to work on a WHO agenda of unsolved issues.

Specifically, the EU and the U.S. might promptly begin work on these trade and environment issues that bedevil the WHO and other trade forums -- and if not resolved can damage the WHO seriously:

• finding a way to assure that multilateral environmental agreements (MEA) are protected from attack as being in violations of the countries’ GATT obligations. This involves finding criteria that distinguish those MEA that deserve protection from others (the criteria might relate to the way the MEA were negotiated; the number and character of parties; the care with which they addressed the substantive issues, etc.)

• finding a way to protect labeling regimes adopted in various countries that are designed to help consumers distinguish between environmentally benign and environmentally harmful products. This is a
very tough assignment, but necessary because appealing to informed consumers is a less intrusive approach to environmental progress than command and control regulations.

- harmonizing practices and environmental assessment criteria of EU and U.S. export credit, insurance and guarantee agencies.

Beginning serious discussions about how the WHO ought to think about the problem of identical goods (which the GATT requires to be treated identically) which however are produced in very different ways - for example in one case produced in an environmentally good way and in another in an environmentally bad way. This is called in trade the PPM issue (production and process methods). It is very difficult to articulate a regulation regime that will deal with this fairly. But the PPM issue is at the heart on most of the tough trade disputes to date (tuna/dolphin; shrimp/turtle; steel leghold traps; fine paper) and we ought to begin the tough slog of trying to come up with some rules.
Professor David Vogel’s paper “Regulatory Cooperation Between the European Union and the United States” has highlighted several of the more prominent trade issues that have arisen from divergent national regulations and policies between trading partners. I don’t wish to elaborate further on those since I believe Professor Vogel’s treatise has presented a thorough review.

Instead, I would like to briefly address what professor Vogel refers to as “regulatory interdependency” in the context of environmental rules, followed by an insider’s view of a real-world negotiation of an international agreement that is intended to address potential trade barriers resulting from divergent motor vehicle safety and environmental regulations. As many of you know, regulatory agencies in the U.S. generally undertake the business of rulemaking in response to a Congressional mandate(s) that sets forth very specific social or national objectives and/or goals. Frequently, the mandate will specify a time frame to meet specific objectives and/or quantify the intended national benefit, i.e., the Clean Air Act. The Process that the regulatory agency must follow in the development of a regulation is spelled out by Congress in the Administrative Procedures Act and also frequently in the specific agency mandate.

While this process is intended to assure “transparent” rulemaking that gives consideration to views and information from all interested parties (regardless of national origin or geographic location), there is presently no mandate for the U.S. Environmental Protection Agency to align or harmonize its regulations with other governments; the concept of international “regulatory interdependency” is not codified in any U.S. environmental statute. To my knowledge, regulatory interdependency
between the U.S. and other governments has not been a significant or influential factor in EPA’s domestic rulemaking to date.

Clearly, barriers can and have evolved as the result of the intersection of international trade objectives with national policies and goals concerning human safety, health and welfare. The automotive sector (vehicles and engines) constitutes the largest global trade activity in both product volume and revenues. Divergent national regulations regarding vehicle safety and/or environmental performance can and have had a significant impact on the free flow of international commerce in these products.

The need to align or harmonize vehicle regulations became evident in Europe following World War II. The reconstruction of Europe depended heavily upon the free movement of products and materials across state borders. The major obstacles at that time were differing vehicle weight restrictions. From this problem was born the Inland Transportation Committee of the Economic Commission for Europe. In 1955 the Working Party on the Construction of Vehicles (WP-29) was formed to address emerging divergent road vehicle safety regulations. In 1958, WP-29 adopted an Agreement Concerning the Adoption of Uniform Conditions of Approval and Reciprocal Recognition of Approval for Motor Vehicle Equipment and Parts; subsequently referred to as the “58 Agreement” Some twenty-eight European Countries have become signatories to this agreement, including fourteen of the fifteen EU member states.

The United States and Canada, who are the only non-European members of the ECE, are not signatories to the “58 Agreement” because of significant differences between the U.S. and European regulatory systems. Regulations developed by WP-29 have, in large part, been
clones of directives issued or proposed by the EU or primarily tailored to meet the safety and environmental objectives of the EU.

Approximately four years ago, WP-29 formally recognized the need to reach beyond Europe and seek to harmonize future vehicle safety and environmental regulations. To this end they adopted revisions to the “58 Agreement” that would permit somewhat greater flexibility in the development and adoption of regulations. The U.S. presented a proposal that would transform WP-29 from a regional to a global forum. As such, it would be the only globally international forum in which government representatives work toward the development of harmonized environmental and safety standards and regulations for vehicles and engines.

The European Commission supported the global concept but opposed the U.S.-proposed revisions to the “58 Agreement.” The basis for the EC opposition was not articulated with respect to the first U.S. proposal. The regulations were technically and politically complex. High levels of misinformation and distrust had to be overcome. Two revised U.S. proposals over two years, and literally several thousand person hours of formal and informal discussions with both members and non-members of the EU, have resulted in the development and formal submission to WP-29 of a “multinational” proposal for a separate “global” agreement that would exist in parallel with the existing “58 Agreement.”

If this global agreement is established within the ECE/WP-29, then the U.S. will become a signatory and we will trust that most nations throughout the world will ultimately become signatories. Through this agreement, we (EPA and DOT/NHTSA) believe that trade problems associated with divergent safety or environmental regulations can be resolved on a case by case basis.
Recognizing that the EU, U.S. and Japan are the principle producers of automotive products, regulations and/or trade policy’s that are mutually agreed to by these three parties become, *de facto*, global in recognition.
First, I would like to thank ECSA and AICGS for inviting me here to be included in these talks. As many of you know, Tenneco recently took the reins from Ford Motor Company to chair the U.S. side of the Transatlantic Business Dialogue (TABD). Therefore this discussion today has provided some useful feedstock as we are currently in the process of shaping the TABD agenda for 1997 with our counterparts at Philips in Europe.

From a business perspective, I would like to make a few comments about the TABD’s approach towards regulatory cooperation. In a word it is front-loaded, rather than a reaction to regulatory trade disputes. The concept behind the TABD is to take a proactive position that will lead to enlightened regulatory policy and will ultimately reduce the costs of doing business in both the U.S. and the EU. We do this by seeking and articulating a united transatlantic business consensus.

Some Background on TABD

When the late Secretary Ron Brown proposed a CEO-led business-to-business transatlantic dialogue two years ago to complement the already existing U.S.-EU government dialogue, nobody knew exactly what would come of it. To determine the preliminary agenda for the business dialogue, the U.S. Administration and the European Commission surveyed American and European companies in the spring of 1995 to determine the issues of greatest concern to industry involved in transatlantic commerce. These issues formed the working groups for the first CEO-level TABD conference which was held in Seville, Spain, in November 1995.
By far, the number one priority for business was the convergence of standards and regulatory policy, and mutual recognition of testing and certification. In fact, forty percent of the U.S. respondents identified these issues as their priority objective. The question is not whether private industry ought to be regulated, but rather, how to do so most effectively without placing additional burdens on industry. I should also make clear that my use of the term “industry” is not just the multilateral corporations, but also small and medium sized businesses who want to gain access to these markets. After all, additional burdens to industry are inevitably passed onto the consumer. Some products are kept out of the marketplace. In these cases, nobody wins. The business leaders involved in the TABD strongly believe that these costs can be eliminated without compromising the legitimate oversight of governments in the areas of safety, health and the environment.

Dana Mead, Tenneco’s Chairman, served as the U.S. chair of the Standards, Certification and Regulatory Policy Working Group at the Seville Conference. The first recommendation resulting from that conference was the formation of the Transatlantic Advisory Committee on Standards and Regulatory Policy (TACS). Throughout 1996, the TACS worked, on a sectoral basis, to identify areas where companies believed the U.S. and the EU could work together toward convergence and/or mutual recognition.

The primary goal of the TACS is to promote a regulatory model based on the principle “approved once, accepted everywhere in the transatlantic marketplace.”

With that in mind, one of the issues that the participants of the TABD have been keenly interested in is the rapid conclusion of the MRA negotiations. Leading up to the TABD conference held in Chicago in November, the negotiations looked to be in jeopardy due to difficulties in
the pharmaceutical, medical devices, and other sectors. At the TABD conference in November, there was an agreement, in principle, to conclude these talks by the end of January 1997. At the U.S.-EU Summit in December, President Clinton, President Santer and Irish Prime Minister Bruton, praised the breakthrough in Chicago and recommitted the governments to the January deadline. The TABD now has a constituency of CEOs that will be watching as talks resume next week to make sure the governments deliver on their commitment. If the January deadline passes with no agreement, there will be some serious explaining to all who are involved in it, especially the CEOs.

The TABD launched regulatory convergence discussions in many sectors. I recommend to you the body of literature that the TABD has produced over the past year-and-a-half. In many sectors, it is the first form of formal declaration of intent on the part of industry regarding regulatory cooperation, at least, from a united European-American business community.

Last April, for example, the U.S. and the EU automotive industries met in Washington under the auspice of TABD. The goal of the conference was to build consensus between manufacturers and government regulators on both sides of the Atlantic regarding how international automotive regulatory harmonization can be achieved, particularly in the areas of vehicle safety and environmental regulations.

The TACS will continue through 1997 and the process will remain an open one. There may be additional sector-specific sessions like the automotive one to push similar issues forward. Any sector is welcome at the table where it has identified a counterpart on the other side of the Atlantic and where it has a clear agenda towards regulatory harmonization and mutual recognition. Furthermore, it is important to know that the TABD is not looking to find the cheapest way to do
business. When we work toward the goal of regulatory harmonization, we are certainly NOT aiming for the lowest common denominator, or a “race to the bottom.” Professor Vogel’s reference that this has not occurred is encouraging regarding the longer-term benefits. We welcome the input of environmental, consumer, labor, and other groups in making our recommendations to the government.

I’ll close with that. Again, thank you for including me in these discussions. The timing of this seminar could not have been more appropriate as we shape our agenda for the coming year. I believe TABD presents us with an opportunity to cooperate in regulatory policymaking with the EU in a productive and positive way. I hope that others in this room will look for ways to get involved in the process.
The Limits of Liberalization

Charles Stark
Chief, Foreign Commerce Section
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U.S.-EU ANTITRUST COOPERATION

The First Generation of Antitrust Agreements

The United States’ early start in antitrust enforcement, including its international aspects, carries with it many advantages, including deeply rooted domestic support for antitrust principles and a great reservoir of experience. A byproduct, however, was that early American efforts to prosecute foreign cartels that encompassed the U.S. market occasionally met with opposition in countries that were not yet as fully hostile to cartels as is widespread today.

Some of the United States’ earliest antitrust disputes arose with Canada, which motivated the U.S. and Canada to develop effective informal arrangements for notification and consultation in international antitrust matters. (More recently, as is described below, the U.S. and Canada have been in the forefront of successful antitrust enforcement cooperation.) These arrangements in turn influenced successive versions of the OECD’s recommendation on antitrust cooperation. The United States is a party to four formal bilateral antitrust cooperation agreements, the earliest of which was signed with the Federal Republic of Germany in 1976. Later agreements involved Australia (1982), Canada (1984, superseded by a new agreement in 1995), and the Commission of the European Communities (1991).

Although the importance of U.S.-EC antitrust cooperation is self-evident, three developments in Europe made the need for an agreement seem especially compelling at the time negotiations began in 1990. First, the European Court of Justice in the woodpulp case had recently
confirmed the application of Community antitrust law to offshore conduct. By bringing the U.S. and EC approaches to jurisdiction closely into line, the decision broadened opportunities for enforcement cooperation and lessened the chance of disputes over jurisdictional principles. At the same time, it served as a reminder of the need for amicable ways to deal with any differences that might arise from overlapping jurisdiction.

It was also a period of intense and visible expansion of Community-level regulation under the “1992” program, aimed at the completion of the common market. From an American perspective, the “1992” campaign spotlighted the importance in the economic landscape of EC antitrust enforcement, even though it did not involve extension of the Commission’s antitrust powers.

Third, the Council had just adopted the new Merger Regulation. The Commission and the U.S. antitrust authorities expected they would regularly be examining the same mergers under their respective laws and believed they would need, at the least, a regular channel of communication for those cases.

The U.S.-EC agreement was widely viewed as the state-of-the-art in antitrust cooperation, and in many ways it was. It called for cooperative and coordinated enforcement by the world’s two most influential antitrust regimes. It included “positive comity” provisions calling for each party to weigh the impact of anti-competitive conduct on the other party as a reason in favor of challenging conduct that would otherwise violate the enforcing party’s antitrust laws. Its other comity provisions included more detail than earlier agreements on factors that are relevant in considering one another’s interests when making enforcement decisions.
The immediate impact of the U.S.-EC agreement was a marked increase in communication between the American antitrust authorities and the European Commission. These communications included formal notifications, regular consultations, informal contacts among the heads of the agencies, and a regular flow of phone calls and faxes between agency staffs. In fact, all of these things could legally have occurred before the agreement, and to some extent they did. But the agreement spurred the agencies to seek opportunities for cooperation in a proactive way that had not occurred before.

New Generation Agreements: Obtaining and Sharing Investigative Information

The U.S.-EC agreement shared a significant limitation with all the other “first generation” agreements: it did not change or override provisions in either party’s law designed to protect the confidentiality of investigative information. Consequently, if the U.S. Department of Justice and the EC’s DG-IV were investigating the same international cartel, they could not share the most important fruits of their respective investigations—typically obtained through the grand jury process in the United States and through “dawn raids” by the Commission. These confidentiality provisions in national laws serve important purposes, but they had also become an impediment to the kind of cross-border cooperation required in the late twentieth century global economy. A further limitation was the absence in these agreements of a satisfactory mechanism to deal with the increasingly frequent need for foreign-located evidence in the hands of firms or individuals.

These considerations led to the introduction and enactment of the International Antitrust Enforcement Assistance Act of 1994. The Act follows the basic outline of earlier legislation that authorized U.S.
securities regulators to cooperate with their foreign counterparts. It allows the U.S. antitrust authorities to enter into agreements with foreign antitrust authorities to (1) exchange information with one another when disclosure would otherwise be prohibited by confidentiality laws, and (2) use their investigative powers at the request of a foreign authority to obtain evidence from private parties in their respective territories.

U.S. antitrust authorities have stated that they would welcome such an agreement with the EU, and a 1995 experts group appointed by Commissioners Brittan and Van Miert recommended that the EU enter into such agreements with the United States and other key EU trading partners. To date, however, only one such agreement has been announced. On April 17, the Department of Justice and the Federal Trade Commission said they had sent a proposed agreement with the Australian government to the Federal Register for publication and a 45-day period of public comment. Australia already had legislation in place that provides Australian authorities with powers comparable to those given to U.S. authorities by the IAEAA.

**New Generation Agreements: Positive Comity**

The U.S. and EC antitrust authorities recently disclosed that they are negotiating a new agreement to elaborate on the “positive comity” provisions of their 1991 antitrust agreement—in fact, the Commission published the draft text on their World Wide Web site. “Positive comity,” it will be recalled, is a term that was coined to describe a provision in the 1991 agreement that allows one party to ask the other to enforce its antitrust laws to deal with conduct that adversely affects both parties. This mechanism is likeliest to be useful for conduct that occurs in the requested party’s territory and can most effectively be investigated and remedied by that party.
The Limits of Liberalization

The proposed agreement would go beyond the 1991 agreement’s “positive comity” provision. Notably, it would create a presumption that a party — referred to in the draft published by the EC as the “affected party” — would defer or suspend its own investigation of conduct that affects and appears to violate both parties’ antitrust laws, in certain circumstances. The territorial party, for its part, would have to be prepared and able to investigate and remedy the conduct effectively, in a way that alleviates the adverse impact on the affected party’s interests. In addition, the territorial party would agree, within the framework of its own laws, to consult on an ongoing basis with the affected party on the progress of the investigation, on remedies, and to seek to reach a conclusion within six months or within another agreed-on time period.
As a preliminary to discussing potential regulatory harmonization between the U.S. and the EU in the telecommunications industry, I would briefly note the industry’s historic structure and the change in that structure inherent in trade in telecommunications services. Telecommunications services have traditionally been provided through carriers licensed as monopolies or through state-owned administrations or ministries. While this industry structure has been justified on the basis of economic characteristics that seemed to preclude competitive provisions, telecommunications has also presented very real national security and defense concerns—concerns used energetically by incumbent carriers to preserve monopoly industry structure. As technology has advanced, particularly in the last twenty years, the economic characteristics that support a monopoly structure have been substantially overcome and the technological options for addressing legitimate security and defense issues have expanded. Thus, the historic incubi to multiple parties entering this industry have largely dissolved.

However, the controlling position in national markets of the dominant incumbent carriers is only just beginning to dissolve. Adoption of a trade regime governing telecommunications services could prove the keystone to widespread restructuring in favor of competitive provision. Trade liberalization both depends upon and will compel the opening of national markets to competition in order that non-national service providers be able to obtain a route to market that is not controlled or adversely manipulated by incumbent carriers.

Supporting this trade-related imperative is the growing acceptance around the world that telecommunications and information infrastruc-
ture and services are now critical to economic growth and development. No developing economy can hope for sustainable growth without communications networks adequate to provide at least reasonably widespread access to global information services. Inherent in this consensus is a significant change in public policy orientation away from traditional concerns over provision of widespread voice service to recognition of the growing importance of data and information services and the need to provide expanded access to those services.

When one looks at the U.S. and EU markets with their relatively mature communications infrastructures—mind you, I say “relative” because both markets are susceptible to substantial impacts from new satellite and wireless systems that are only just now coming “on-line”—and the determined moves by policy makers in both markets toward full competition, the near-term harmonization of the fundamental rules of doing business as well as greater transparency of process appears the essential requirement to the creation of a “common market” between these trading partners. Regulations must be better coordinated if a transatlantic market for this industry is to attain real meaning.

At present, two basic and differing approaches to the regulation of this industry can be found in Europe—one more compatible with the U.S. model than the other. In the U.S., our model has been quasi-judicial, multi-member commissions at the federal and, generally, at the state levels—that use public proceedings and generate publicly accessible evidence, data and records. This model appears to have been chosen, at least in structure, by France and Germany this year. In the UK, Netherlands, and other EU member states, however, we find the single regulator model—usually designated as Director General or Minister—with sole regulatory authority over critically important issues, as often utilizing or even required to utilize less-than-transparent fact finding
procedures and not generating a public record of information submitted or of reasons employed in a given regulatory rulemaking.

This difference wants analysis and adjustment. Without more compatible and transparent regulatory processes in all constituent markets, harmonization of regulatory rules between the U.S. and the EU may not, at the end of the day, mean very much. A competitor, particularly one that is foreign-based, will most likely be disadvantaged in any system where data, representations, arguments, and evidence considered by the regulator are not purposely made available to review, comment or rebuttal.

I would like to turn now to what regulatory issue areas must be “harmonized” if a transatlantic market is to be created for this industry. Certainly foreign ownership restrictions are the critical and threshold non-tariff barriers that must come down. We can be encouraged by the pressure that the industry itself is bringing in the form of Cable & Wireless’s presence in the U.S. market, the licensing of U.S. carriers for both domestic and international services in the UK, the expanding market share of cable operators—many U.S.-owned—in the local service market in the UK, the decision of the German Parliament to eliminate statutory restrictions on foreign ownership of telecommunications networks, and the investments of BT in MCI and of FT and DT in Sprint. These, however, are episodic and are insufficient, in themselves, to create a harmonized marketplace.

More closely harmonized economic regulation may be required, particularly regarding interconnection pricing. Achieving this is complicated by the jurisdictional authorities of the member states in the EU and the fifty states in the U.S. Our best hope for accomplishing this harmonization relatively cleanly may lie in the WHO trade regime. Many are pessimistic as to the chances for the current negotiations in
Geneva. However, I believe that, even if these talks fail to reach agreement, the FCC has put in motion an “end game” for the national monopolies. With restructuring and opening to competition the NAFTA countries (at least partially), the EU member states, Japan and in several countries in Latin America, the question comes down to what will the governments of the developing economies of other regions do when the subsidies flowing from international traffic to their monopoly carriers are progressively cut off?

The U.S., along with the U K, is the primary paymaster of this subsidy system. The FCC has given notice, in its recently announced plan for bench marking international accounting rates, that the subsidy system is going to soon be scaled back. Consequently, countries without competitive structures face an inevitable end of the “golden goose.” The FCC is positioned to provide the “big stick” that will support a competitive trade regime or to apply progressive leverage to countries that refuse opening their markets to competitive provision.

What other issues must be addressed besides industry structure and regulatory transparency? In view of the growing importance of the INTERNET and electronic commerce, we must establish common rules governing commercial transactions and financial settlements over electronic information networks. We must have common treatment of intellectual property and content—an area that has been perennially nettlesome for our two markets. In this regard, some very fundamental issues arise—protection of copyrighted data, application of “first sale” doctrines to the distribution of electronic information, rights of reproduction and sale over electronic transmissions, harmonized currency transactions, common accounting standards, and agreed protocols providing security for commercial and financial transactional data. Without harmonization of these issues, global information
Regulatory Cooperation and the New Transatlantic Agenda

interaction will not progress beyond exchange of relatively neutral and economically unimportant data and information services.
First, well designed and balanced regulations is a good thing. Ample evidence shows that well regulated markets fare better than poorly regulated or unregulated markets. Regulation is needed because markets sometimes fail. In the financial services context, market failures relate to what economists would call information asymmetry and externality problems.

Second, regulatory cooperation is a good thing.

Third, regulatory harmonization or convergence is probably a good thing. Qualified, because many economists would argue that regulatory competition is a good thing.

Starting from these premises, I would offer a few general observations about financial services regulations as they relate to U.S.-EU relations.

1. Financial markets are unique and distinct from the model as outlined by Professor Vogel. By and large dealing with intangibles, especially information—not goods and labor, financial markets are characterized by 1s and 0s coursing through fiber optic cables and bouncing off satellites. Traditional geographic and political boundaries are much less relevant.

2. Currently, there is very little formal regulatory cooperation/interaction between the EU and U.S. This results in part from a fractured regulatory framework in the U.S. and traditionally different regulatory models (Germany vs. UK) in Europe. To the extent that there is interaction, it is primarily in the context of market access issues - as
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embodied by the EU financial services directive and U.S. legislation such as Fair Trade in Financial Services.

3. Formal cross-border regulatory cooperation and harmonization occurs through organizations such as the Basle Committee, IOSCO, by virtue of bilateral informative sharing agreements. These are helpful but increasingly anachronistic, because they are based on outmoded firm classifications. In addition, perhaps the most important regulatory cooperation is informal - Greenspan picking up the phone to call George or Tietmayer or other central bank heads.

4. The Vast majority of financial market interaction between the U.S. and the EU is virtually unregulated—Forex markets (interestingly enough, very little attention has been paid in the U.S. to the potential impact of monetary union and a single currency)—and relatively limited regulation of U.S. Treasury and Eurobond markets.

5. Financial markets are much more sensitive to regulatory costs—financial service providers can, virtually overnight, move their business to a more accommodating regulatory regime—practice of regulatory arbitrage.

6. Moreover, given the pace of change in financial markets, regulators will be increasingly constrained in their ability to effectively oversee markets. They lack the resources, technical skills, and decision-making cycles.

Given the above, is there anything to be gained by enhanced regulatory cooperation in the financial services sector between the U.S. and EU? Indeed —

- increased cooperation between the U.S. and the EU in the financial services sector would be especially helpful in the development of
common prudential standards to help lessen systemic risk (e.g., payments systems linkages).

- it would be helpful in dealing with fraud and enforcement of laws and provide adequate standards for protection of retail markets.

- it would also be helpful to ensure unfettered access to each other’s markets, but also to present a united front in opening up third markets.
Two research and policy domains are of particular relevance when discussing U.S.-EU regulatory cooperation and conflict; both have emerged again and again in today’s discussions and are covered in David Vogel’s paper. The first, what I would call the macro policy domain, relates to the U.S. and the EU as partners and rivals in an emerging global economy. How important is cooperation? What can be done to avoid conflict? The second, the micro policy domain focuses on the detailed comparative analysis of regulatory policy in a variety of functional areas in Europe and the U.S. Obviously the two are difficult to separate. While the data shows that most of the economic dynamism in the world economy currently exists outside the transatlantic relationship, the transatlantic economy remains the most deeply integrated region and thus provides an excellent laboratory to gain experience from closer regulatory cooperation that may well become very important as other parts of the world economy join this core global economic space.

As David’s excellent paper focuses for the most part on the micro dimension, let me begin with that. It seems to me that most of what we heard here today addresses the continuing number of considerable differences across the Atlantic regarding regulatory activity. We have heard about the two broad approaches used in regulating economic activity relying either on market based incentives or government regulation. We also discussed the many instruments such as banning, harmonization, functional equivalence, standards, mutual recognition agreements, and others that each partner has on occasion used, or proposed when tackling a regulatory issue.

I fully agree with the explanations given in David’s paper as to why these differences persist. At the same time, and assuming that this paper
is directed largely at policymakers, I feel that it is necessary to make some recommendations on how to adjust our respective approaches to these questions so that further progress can be made on transatlantic public policy issues. After all, it is precisely because of the fact that the two sides have moved from shallow to deep integration that non-tariff barriers to trade have come to dominate the bilateral policy agenda exposing the constitutional, legal, institutional differences and idiosyncrasies that exist in our respective social, economic and political environments. As David correctly points out, given their level of affluence and economic development and degree of interest group participation in politics (especially by NGOs), there is little disagreement on the basic importance of many of the regulatory issues. Rather it is the procedural variations that create the problems. For example, what explains the different use of environmental regulatory policies reflected in Corporate Average Fuel Economy (CAFE) standards versus gasoline taxes? Are there any ways of reconciling these variations in process? Can we learn from the EU experience itself? How could we improve institutional compatibility? At a minimum shouldn’t policymakers on both sides of the Atlantic in their own domestic reform efforts look toward the other side of the Atlantic with a view to make the systems more compatible? For example, should the EU as it reforms its own food safety regime in the wake of the BSE scandal take a close look at the U.S. system? How can we improve EU regulatory competence so that it becomes less dependent on the member states’ opinions? How can the regulatory process in the U.S. be simplified and streamlined so that turf fights and competition among the various bureaucracies can be minimized improving the chances for resolution at the transatlantic level?
In addition to trying to achieve greater procedural compatibility in the context of the existing structures and institutions which undoubtedly will be difficult, the two sides may also agree that the time has come to change the transatlantic policy making process itself. Here the Transatlantic Business Dialogue (TABD) which was inaugurated in the summer of 1995 deserves greater attention in David’s paper; both for what it is and for what it is not. Regarding the former, there are good reasons to believe that the TABD has helped to eliminate a variety of bureaucratic and institutional rigidities, and thus was able to move forward the Transatlantic Agenda agreed to at the US-EU summit in Madrid. Regarding the latter, questions must be raised about the absence of other interest groups in this debate. Governments on both sides should be encouraged to promote their participation in this debate. Finally, what is the contribution of the transatlantic scientific/epistemic community in this process? Often scientific opinions are used in support of a particular position that subsequently leads to transatlantic conflict. Cooperative projects in the field of science and technology prior to actual policy debates may help to eliminate friction and thus help policy resolution.

Turning to the macro side, the paper understandably remains relatively brief. However, there are a host of important conceptual and policy issues that David correctly mentions, but deserve a lengthier treatment. First, the overall question as to what drives the need for regulatory cooperation. Clearly, globalization or the deep integration of parts of the world economy, reflected in corporate alliances, crossborder mergers and acquisitions, long-term supplier arrangements, and other corporate strategic adjustments drive this process. But have policymakers clearly understood the public policy implications of globalization and in particular how they differ from those that they confronted in response to rising economic interdependence? Second,
there is the question of enlargement of this regulatory policy space. Should Japan not be included in this process? Third, the paper argues that the transatlantic experience can serve as model for integrating developing countries. But questions must be asked whether developing countries are actually interested in such topics? Is there sufficient political support for such a process? The current North-South debate over trade and environment and trade and labor standards do not support such a position. It would therefore be important for the U.S. and the EU to think about possible inducements they can offer to developing countries to agree to the formation of global regulatory regimes in the areas discussed in David’s paper. Indeed in the domain of environmental regulation—considering the Montreal Protocol—we already can rely on such experience.
CONFERENCE AGENDA

Welcome
Carl Lankowski, American Institute for Contemporary German Studies
James A. Caporaso, European Community Studies Association

Paper Summary - “Regulatory Cooperation Between the European Union and the United States”
David Vogel, University of California - Berkeley

Roundtable - Social Regulation and Transatlantic Relations
Chair: Alberta Sbragia, Center for West European Studies, University of Pittsburgh
Food Safety/Ethical Drugs: Linda R. Horton, Food and Drug Administration
Environment: Frank Loy, League of Conservation Voters
Automobiles: Kenneth Feith, Environmental Protection Agency

Discussion

Luncheon Discussion - MRA Negotiations: A Report from the Field
Ralph Ives, Office of the United States Trade Representative

Roundtable - Economic Regulation and Transatlantic Relations
Chair: Leon Hurwitz, European Community Studies Association
Telecommunications: William Garrison, Center for Strategic and International Studies
Financial Services: Bradley Belt, Center for Strategic and International Studies
Antitrust: Charles S. Stark, Department of Justice

Discussion

Concluding Remarks: Sectoral Panel
Chair: Carl Lankowski, American Institute for Contemporary German Studies
United States Government: Charles Ludolph, Department of Commerce
Environmental NGO: Fran Irwin, World Resources Institute
Business: Theodore Austell, Tenneco/TABD
Policy Analyst: Wolfgang Reinicke, The Brookings Institution
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-Barnes, Richardson and Colburn

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Leon Hurwitz  
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Regulatory Cooperation and the New Transatlantic Agenda

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-League of Conservation Voters

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SUPPLEMENT

Frances Irwin
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David Vogel concludes that there is little evidence that either the European Union (EU) or the United States (U.S.) has deliberately used health, safety or environmental regulations as non-tariff barriers. He recommends that they shift their energy from ensuring access to each other’s markets to pursuing their common interests in fostering international regulatory cooperation in forums such as the World Trade Organization (WTO).

To do so, I suggest that the European Union and the United States need to recognize and incorporate three growing forces not stressed in Vogel’s paper. They are 1) the sustainability agenda; 2) the role of non-governmental organizations (NGOs) at all levels of decision-making—including global, and 3) the decreasing cost of instantaneous communication.

1. The sustainability agenda. The concept of sustainable development has been evolving over more than a decade and is beginning to be defined and put into practice. It is recognized in the Treaty of Maastricht which calls for “sustainable and non-inflationary growth respecting the environment” in the European Union. In reviewing the Treaty, some member countries are calling for a stronger statement. In the U.S., the President’s Council on Sustainable Development is taking the lead at the national level while some states and communities have their own initiatives.

At the global level, more than 150 countries agreed to the Rio Principles and Agenda 21 at the United Nations Conference on Environment and Development in 1992. These agreements build on the earlier Brundtland
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Commission report. The European Union and the United States need to take the crucial step of recognizing and addressing the intersections of the trade and sustainability agendas.

2. Transparency and NGO participants. Vogel’s paper notes the importance of NGOs in developing environmental, health and consumer regulations at the national level and suggests that transparency of decision-making is common to the EU and U.S. in comparison, for example, to Japan.

In fact, NGOs are playing an active role at all levels. Regional levels are increasingly important forums for NGOs at both the sub-national and continental scale. So is participation at the global level. Jessica Mathews documents the rise of the global civil society in the January/February 1997 issues of *Foreign Affairs* in an article called “Power Shift.” She says: “National governments are not simply losing autonomy in a globalizing economy. They are sharing powers—including political, social and security roles at the core of sovereignty—with businesses, with international organizations, and with a multitude of citizens groups, known as nongovernmental organizations.” She cites particularly the role NGOs played in developing the framework global climate accord.

While EU and U.S. negotiations are more transparent than those in some parts of the world, they have seldom involved NGOs directly. In contrast, NGOs are taking a major role in other international forums in which the European Union and the United States participate. Two of an increasing number of examples are development and implementation of guidance on Pollutant Release and Transfer Registers in the Organization for Economic Cooperation and Development (OECD) and preparation of a convention on citizen participation in the UN Economic Commission for Europe (ECE).

NGOs played an active role in a two-year process to develop the guidance
on what are known internationally as Pollutant Release and Transfer Registers. OECD picked up a recommendation in Agenda 21 that guidance on such public registers of emissions be developed. About thirty environmental and civic NGOs from a dozen countries participated with governments in five workshops. They took part in setting the agenda, providing background materials and participating on panels, drafting the conclusions, and commenting on drafts. The European Union hosted the first workshop in Brussels followed by Canada, Switzerland, Britain, and the Netherlands. The OECD environment ministers issued a Recommendation in 1996 calling on member governments to establish inventories and share the data reported. Regional conferences are being held with an international conference scheduled for 1998 in Japan.

A coalition of European environmental NGOs is at the negotiating table and playing an active role in drafting a convention on environmental decision making and access to information in a working group convened by the UN ECE. U.S. NGOs are working with them. The ECE’s members include not only all of Europe but Canada and the U.S. as well as the Central Asian Republics and Israel. The goal is to have a convention open for signature at the Fourth “Environment for Europe” Ministerial Conference in Denmark in July 1998.

In contrast to these examples, while the World Trade Organization has begun to make its documents public after action has been taken, the organization does not involve NGOs. As they work to increase regulatory cooperation in international organization—as well as in their own negotiations—the European Union and the United States need to involve a larger range of actors.

3. The Information Revolution. A significant driver of the growth of NGO networks is the rapidly decreasing cost of nearly instantaneous communication. As Mathews says: “The most powerful engine of change in the relative decline
of states and the rise of non-state actors is the computer and telecommunications revolution, whose deep political and social consequences have been almost completely ignored.” Government no longer has a monopoly on information.

This same force is also changing the nature of regulations themselves. Regulations governing pollution at environmental facilities are one example. The European Union has adopted an Eco-Management and Audit Scheme that lays out the framework of a performance-based system under which companies set goals, establishes a program to achieve them and tracks progress. Through a series of experimental projects, the United States is testing similar approaches that trade accountability through better information for more flexibility in achieving goals. The role of stakeholders is a key issue.

To advance regulatory cooperation effectively, the European Union and the United States will need to engage the sustainability agenda, involve NGOs directly, and recognize the implications of the information revolution for both the form regulations take and the process of developing them.
Regulatory Cooperation and the New Transatlantic Agenda

Charles M. Ludolph
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Thank you for inviting me today. I am pleased to have this opportunity to share perspectives on regulatory cooperation and the insights David Vogel has imparted in his paper prepared for this Project.

Regulatory cooperation with Europe has increased in its visibility as it is now an explicit part of the U.S.-EU New Transatlantic Agenda announced by President Clinton in the December 1995 Madrid Summit with the European Union. This NTA with its component dedicated to expanding the harmonizing of regulatory environments intends to support a new transatlantic marketplace which will benefit producers and consumers over the next years.

Regulatory cooperation is also visible in President Clinton’s National Export Strategy for 1995 through 1997 where at first U.S. regulators took unilateral action to reduce the regulation of exports and now aspires to promoting harmonized regulatory initiatives throughout the world.

This intensification of trade and commercial interest in the pace of regulatory cooperation comes from very natural roots.

World trade is growing rapidly and as markets open and they become more global and less nationalistic in orientation. National technical and regulatory positions reflect this. Regulation is now open to foreign influence and must be prepared to meet foreign interests. This is because imports mean more than ever in the U.S. market where imports are fifteen percent of GNP and because U.S. consumers source globally and can no longer afford to rely on products just from the national market.

Regulatory policy around the world is key for another reason. Tariffs are receding in importance as a barrier to trade. Over the last forty years we have reduced tariffs in industrial countries from fifty percent to three percent. But now standards and government’s technical requirements are becoming the
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most frequently cited issue in trade by business.

But even as the volume of trade is rapidly growing, the conditions for trade are fragmenting. More companies must pursue international trade. The U.S. domestic market grows at two-three percent per year while U.S. exports grow at ten-fifteen percent per year, which is identical to the growth on international trade worldwide. A few years ago, you could confidently design and market your product to U.S. regulations and standards not only for U.S. markets but the world.

Today a U.S. product design integrating U.S. safety and environment regulations is likely to get you no further than the U.S. border of Canada or Mexico. Today the world has fragmented into 100 technical requirements or more. U.S. business and the U.S. government now apply all our policy strength to trying to knit the world trading system back together again and regulatory cooperation could be a potent tool in this effort.

Another potent force is the relentless cost pressure that open world markets brings to bear on producers and regulators. Overall interest in quality and safety must be retained but it is no longer to be expected that high cost, unnecessary, or redundant approaches to safety can be supported as cost pressures continue and regulatory cooperation could well be a positive strategy to assure safety in an open and rapidly growing trading system.

Mr. Vogel’s paper is full valuable insights and I think has revealed principles that should be explored by the U.S. government in depth. The interesting thing that needs to be understood better, however, is that the “regulatory space” between the Europe Union and the United States is not where the major issues of safety and trade need to be addressed. More trade and more quality issues can be seen in Mexico, China and Indonesia than Germany and France and you would expect that policy making attention would be spent addressing these challenges. However, it is assumed that it is more difficult to achieve “regulatory cooperation” in these areas and it is also assumed that more progress can be
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made more easily with Europe because it is felt that the systems of regulatory protection are more equivalent.

Mr. Vogel’s examples provide many interesting insights—the most important of which is that the trend in U.S.-EU relations as reflected by the cases of disputes is that international trade or international competition leads to a strengthening of safety and environmental standards. If this is true, then understanding the underlying mechanism for this should be a key object of research. If this is true for the U.S. and Europe, is it also true for relations with countries that do not have a well developed safety system, like Brazil, but where trade is accelerating rapidly? I suggest that these examples and future research should examine more carefully the means by which regulators have sought to cooperate particularly in the establishment of equivalence and harmonization which seems to underlie the “meat inspection” case, “pharmaceuticals” and “fur skins.” This should be compared to cases where equivalence determination or harmonization efforts have been rejected such as in “hormones” and “tuna.”

The case Mr. Vogel makes that multilateral organizations hold the key to regulatory cooperation needs to be developed and supported. The WTO’s Agreement on Technical Barriers to Trade seems to me an inadequate basis for cooperation or dispute resolution since the agreement provides exceptions for regulations dealing with safety and health. Even existing international fora such as ISO, Codexes, and the International Conference for Harmonization (drugs) and the Global Harmonization Task Force (for medical devices) do not have obligatory procedures for adoption or dispute resolution. Most importantly, regulators in the United States and every other political entity have no mandate to recognize international rules that preempt nations’ laws and parliaments are under little pressure to account for these trends.