S. HRG. 108–330

U.S.–EU COOPERATION ON REGULATORY AFFAIRS

HEARING

BEFORE THE

SUBCOMMITTEE ON EUROPEAN AFFAIRS

OF THE

COMMITTEE ON FOREIGN RELATIONS
UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

OCTOBER 16, 2003

Printed for the use of the Committee on Foreign Relations

Available via the World Wide Web: http://www.access.gpo.gov/congress/senate

U.S. GOVERNMENT PRINTING OFFICE

91–958 PDF WASHINGTON : 2004

For sale by the Superintendent of Documents, U.S. Government Printing Office
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U.S.–EU COOPERATION ON REGULATORY AFFAIRS

THURSDAY, OCTOBER 16, 2003

U.S. SENATE,
COMMITTEE ON FOREIGN RELATIONS,
SUBCOMMITTEE ON EUROPEAN AFFAIRS,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:28 p.m., in room SD–419, Dirksen Senate Office Building, Hon. George Allen, presiding.

Present: Senator Allen.

OPENING STATEMENT OF HON. GEORGE ALLEN, U.S. SENATOR FROM VIRGINIA

Senator ALLEN. I call this hearing of the Subcommittee on European Affairs to order. I want to thank all of our witnesses for appearing before the committee this afternoon.

We are here today, ladies and gentlemen, to explore the importance of cooperation between the United States and the European Union on regulatory affairs, and the impact that this has and will continue to have on transatlantic trade and investment.

The flow of transatlantic trade and investments between the United States and the European Union is the largest clearly in the world, amounting to approximately $1 billion every day. The European Union and the United States together account for about 37 percent of the value of global trade in goods. When you look at global trade in services, 45 percent of the global trade in services are between the European Union and the United States. Now, this is unique not only because of its size and complexity but because it's a relationship that truly benefits both sides immensely. There are tens of thousands or American and European citizens that go to work every day to businesses which are a result of our bilateral trade and this investment relationship.

Having served as Governor of Virginia going on trade missions, I am well aware of the tremendous numbers of jobs in just the Commonwealth of Virginia that are from companies from Great Britain, Germany, France, Italy, Denmark, Sweden, The Netherlands, Austria and other European countries, and I know the number of American businesses that go over to Europe and have a presence in those various countries as well.

The key element in making sure that this relationship stays positive and hopefully growing is regulatory cooperation, making an effort to work with or consult with each other prior to new regulations becoming effective or going into law. Both the United States

and the European economies are very dynamic, they are fast moving, and changes that are enacted in either regulatory regime or system without prior participation and consultation could result in lost commerce and jobs.

Though the markets are more intertwined than ever before, we nonetheless have disputes. I need not hammer on each and every one of them, but they are from within the areas from everything in agriculture, genetically modified foods to how we raise our cattle to a variety of other issues. All of this makes it important that we do consult with one another.

I do think a positive step was taken in June of this year at the U.S.–EU summit where the United States and Europe agreed to start to increase cooperation on new regulatory issues and look for ways to coordinate rulemaking between the U.S. and the EU agencies. Not all of our government agencies have bilateral mechanisms for consultation on these regulatory issues, but there are numerous bilateral private sector groups promoting cooperation, and while our agencies, the government agencies, are working to coordinate regulatory policymaking, it has been my view that in some cases the corporate sector on both sides has led the way.

Take for example the automobile industry. Both United States and European auto makers have been successful in selling their vehicles around the world and in each others markets, because they consider regulatory consultation a necessity for their own survival, their market share and for their growth. For the auto industry, international regulatory consultation is not an afterthought, it is a priority, and now that we are seeing the European Union grow from 15 to 25 countries, this cooperation is going to be more important than ever.

There is no question this is going to open up new opportunities for people in central Europe, what some would call eastern Europe. For the central European countries it's just going to be greater opportunity for us to have our goods and services there as well as theirs getting into our market, or will it constrict it. So the cooperation with the current 15 is important, but in fact it's even going to be more important in the future, if history is any lesson.

Now, there are certain regulatory policies that seem to evade consensus, and continue to cost both valuable man-hours and revenue to companies in both the United States and Europe.

Probably one of the most recognized and discussed are the environmental standards the United States and the United Nations have signed for products going to market. While it's important to note that the directive has yet to be formally released, many U.S. and European chemical industries have expressed grave concern with the proposed EU chemical directive. And there are U.S. companies who do business there, and I will not mention the companies so they get dragged into it, but there is the strong presence of a German company in the Commonwealth of Virginia who is involved in the chemical business, and they see the concerns.

So it's not just one side or the other of the Atlantic, it has an impact on both sides. And depending on the final version, this directive could have a massive adverse ramification both leading to the loss of jobs and revenue.

I have other things I will put in the record, but the point is, we have had impressive cooperation in recent years, but, it's very obvious, I like to be positive and optimistic, but let's be also forthright and realize we have some challenges as we go forward to streamline trade and investment regulations and opportunities across the Atlantic.

As the European Union countries and that Union grows, they are going to play an even more prominent role in these issues. I strongly advise our government officials to be involved. That's one of the reasons I wanted to have this hearing. And I certainly wanted to say to our friends, truly, our friends and allies, people who share our love of freedom and great enterprise to recognize that it is beneficial for the people of both the United States and the European Union to have the opportunities of prosperity, to goods and services, and to a better quality of life that comes from cooperation and working together.

With that, I want to thank all our witnesses for being here, and I will introduce the first panel and each panel as the individuals come forth.

The subcommittee has invited representatives from U.S. Government agencies and private sector representatives to discuss their perspectives on U.S.–EU regulatory cooperation and to offer their insights and suggestions for methods of increasing cooperation in the future so that we can have more investment, more trade, and the bottom line is more jobs for people in both the EU and the U.S.

On the first panel, from the United States Department of Commerce, we're pleased to have Deputy Secretary for Europe, Eric Stewart with us. Thank you for being with us. The Department of Commerce is on the front line in helping to promote direct trade flows between Europe and America, and will provide unique insights on how regulatory cooperation might facilitate trade in a number of markets.

Charles Ries is the Principal Deputy Assistant Secretary for European and Eurasian Affairs. He can give us a historical perspective on the past U.S.–EU efforts toward cooperation, providing examples of recent successful collaborations. The resolution of the dispute concerning the import of Spanish clementines into the U.S. market might provide insight into how similar disputes might be approached in the future.

With that, I will also put a personal note. The rest of the family likes those Spanish clementines. I prefer navel oranges from California or Florida, and Ruby Red grapefruits from Texas, but in my family, children like those clementines, so they were happy by your good work, on a personal note.

Mr. Ries, we will hear from you first.

STATEMENT OF CHARLES RIES, PRINCIPAL DEPUTY ASSISTANT SECRETARY, BUREAU OF EUROPEAN AND EURASIAN AFFAIRS, U.S. DEPARTMENT OF STATE

Mr. RIES. Thank you, Mr. Chairman. I welcome this opportunity to appear before you today to describe the trends in regulatory cooperation between the U.S. and the European Union, and we appreciate very much your interest in this important topic.

Mr. Chairman, I'm pleased to report that the U.S. Government and the EU are making real progress in making our regulatory approaches more compatible. This progress should especially encourage us when we consider the challenges.

Discussions in the regulatory field often involve multiple agencies on both sides of the Atlantic, each with their own responsibilities and mandates. To complicate matters further, the U.S. and EU approach the drafting and implementation of regulations in different ways, reflecting our dissimilar government structures and administrative traditions.

Aware of these philosophical and structural differences, the U.S. and EU leaders have established a number of mechanisms for addressing regulatory issues. The new Transatlantic Agenda of 1995 established a framework of regular contact and a commitment to common action. It recognized that regulatory issues in particular need to be dealt with early. The new Transatlantic Agenda also recognized the importance of industry and nongovernmental organization involvement.

The 1998 Transatlantic Economic Partnership resulted in guidelines on regulatory cooperation and transparency that further encouraged both sides to exchange expertise, information and ideas. Most recently, as you mentioned, U.S. and EU leaders agreed upon a positive economic agenda at the last summit, comprising regulatory cooperation projects in five areas and an informal dialog on financial markets.

In line with these policy declarations, U.S. and EU regulators have launched a number of informal and innovative initiatives. Just last month, for example, the FDA and its European counterpart, the European Agency for the Evaluation of Medicinal Products, agreed to share nonpublic information in the area of pharmaceuticals. Our National Highway Traffic Safety Administration and its European counterpart recently agreed to a similar information exchange arrangement.

Regulators reached these arrangements without creating any kind of new international legal obligations. But while these arrangements are informal in nature, they help ensure that regulators operate from the same facts and are likely to foster common regulatory approaches.

Mr. Chairman, let me focus this afternoon on just two current issues in the U.S. regulatory arena, given our shortness of time, the food safety provisions of the U.S. Bioterrorism Act and the EU so-called REACH chemical directive that you mentioned in your opening comment.

The European Union, along with our other key trading partners, has had a key interest in the establishment of the new FDA food safety requirements designed to reduce the risk of bioterrorism. Twice during the public comment period, the European Commission submitted extensive comments on behalf of the EU regarding potential effects of the proposed new regulations. We welcomed this input. As published last week, the FDA's interim final regulations were modified to make them less burdensome on trade, in part in response to the comments received from the EU and our other trading partners. In this case, U.S.–EU cooperation resulted in a better outcome for both sides.

For its part, the European Commission presently is considering new legislation that would impose extensive testing and approval requirements on tens of thousands of chemicals produced in or traded with the EU. The U.S. was one of many interested parties that viewed the so-called new REACH chemicals regulation package as overly costly, bureaucratic and burdensome, and ultimately unworkable, as you mentioned.

In response to the concerns expressed by many, including us, over the lack of transparency during the policy development phase, the Commission recently posted the draft chemicals regulation on the Internet and accepted public comment for an 8-week period. More than 6,400 organizations and individuals submitted comments.

As a result, we understand the Commission is preparing a more limited proposal that we hope will reflect the concerns we and others expressed. We hope that this public comment process is the beginning of a trend. We would like to see this greater spirit of transparency and inclusiveness structurally built in to the EU regulatory framework so that each new regulation also benefits from meaningful stakeholder input.

As we work more and more with the EU on regulatory issues such as these, we discover ways in which we could promote regulatory cooperation and minimize regulatory-based trade disturbances. Let me suggest a few elements of our strategy.

First, we believe in patient engagement and sustained public diplomacy. We work best when we engage the EU on multiple levels. In this spirit, our embassies' economic, commercial and public diplomacy officers work hard to explain our point of view to all interested parties in the EU and in Europe as a whole. Frequent working-level discussions between U.S. and EU regulators play an important part.

Second, we have discovered that multilateral approaches sometimes can be used to resolve regulatory issues. For example, OECD regulatory reform reviews and WTO committee meetings provide the U.S. with additional fora in which to work with the EU and other interested parties on regulatory issues. The International Civil Aviation Organization (ICAO) played a similar role a couple of years ago in finding a way to resolve our concerns about the EU's hush kit regulations.

Third, public-private coordination enhances our chances of success. The support of business, consumer and environmental groups benefits us in government tremendously. Our transatlantic business and consumer dialogues play an important role in this as well.

The final key to our success rests on the principle of timely intervention. When we act proactively rather than reactively we have a much better chance of ending up with a positive outcome.

Our action plan, therefore, includes the following: We are continuing to press the EU for more meaningful transparency and stakeholder access. We are promoting informal information exchanges and dialogs. We are encouraging interested parties on both sides of the Atlantic to meet regularly just to discuss the hot issues. And finally, we are enhancing interagency cooperation among U.S. Government agencies that work on U.S. regulatory issues.

A colleague of mine likes to say about the transatlantic partnership, "what defines us makes headlines; what unites us makes progress." The U.S. and the EU don't receive enough credit for our collaborative effort at regulatory cooperation.

We both recognize that if we reach agreement on these important issues, everyone wins. If we don't, everyone loses.

A more prosperous world community, therefore, hinges on the continued success of our partnership.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Ries follows:]

PREPARED STATEMENT OF CHARLES P. RIES

Thank you, Mr. Chairman. I welcome this opportunity to discuss with the subcommittee cooperation between the U.S. and the EU on regulatory affairs. I'm sure we all appreciate the relevance and impact of this issue on the competitiveness of our businesses that operate globally, and on the safety of the products that we use here at home. We at the State Department appreciate your attention to this ever-pressing issue.

We in the U.S. government, along with our colleagues in the EU, have made great progress in reconciling our regulatory approaches. We too often overlook the progress that we've made when we focus our attention on the issues that still divide us. Certainly, we must be realistic in our appraisal of the transatlantic regulatory environment, and we must press the EU for more openness, flexibility, and progress on the issues of contention between us. However, we should also appreciate how much our common resolve has achieved.

Our continuing progress on regulatory convergence promises significant benefits not only to the U.S. and EU economies, but to the world economy as well. We know that more closely aligned regulatory systems benefit both of our economies, by facilitating trade and ensuring robust protection of health, environment, and safety. In addition, however, since U.S.–EU regulatory cooperation sets the standard for the rest of the world, the more regulatory convergence we achieve, the more we facilitate trade among all nations. Clearly, this issue affects trade on a much larger scale than many would believe.

THE CHALLENGE OF COOPERATION

All this having been said, the U.S. and the EU follow different regulatory approaches, and we must also acknowledge how plainly difficult and elusive regulatory convergence can be. Negotiations between the U.S. and the EU often involve multiple agencies on both sides, each with their own responsibilities and mandates. To complicate matters further, the U.S. and the EU approach the drafting and implementation of regulation in differing ways, reflecting our different governmental structures and administrative traditions.

The EU generally relies on a more "prescriptive" approach to regulation, by which its regulators inform industry exactly how it can conform to rules. Additionally, EU regulators often base regulations on their controversial "precautionary principle," an approach we believe can improperly overlook relevant scientific evidence and can take risk-avoidance efforts to an extreme.

We in the U.S. depend on a more "outcome-driven" approach, by which our regulators specify certain performance requirements while granting industry considerable latitude in how to achieve them. As much as possible, our decisions are "science-based" and are the products of sound risk analysis.

In addition, U.S. and EU regulations must pass through different review processes. The EU more frequently requires endorsement at the political level by ministers for regulatory decisions, while we rely on independent regulators and regulatory agencies removed from the political process. Our system, based on public notice and comment, provides a transparent process open to stakeholder participation.

We obviously believe that our regulatory approach works better in the long run because it tends to product more flexible outcomes based on more appropriate risk management analyses. These outcomes, in turn, are better able to adjust and adapt to changing technologies and levels of knowledge. Our different frameworks for drafting, approving, and implementing regulation, can create structural obstacles in our efforts to promote regulatory cooperation. On occasion, it can also lead to trade friction and differing approaches in multilateral negotiations.

THE HISTORICAL BASIS FOR COOPERATION

In the context of these differences in approach and structure, U.S. and EU leaders have established a number of mechanisms for addressing regulatory issues. The New Transatlantic Agenda of 1995 established a procedure for governments and industry to deal with regulatory issues before they became hot-button issues. Among its many achievements, the NTA set up several dialogues between constituencies on both sides of the Atlantic. Two of these, the Transatlantic Consumer Dialogue (TACD) and the Transatlantic Business Dialogue (TABD), have actively proposed areas for regulatory cooperation. These Dialogues can help develop a common recommendation by their constituents and then press both the Commission and U.S. authorities to take those recommendations on board.

The U.S. and the EU have launched a number of initiatives related to regulatory cooperation. For example, we have reached a number of Mutual Recognition Agreements, or MRAs, under which U.S. exporters of designated products can conduct testing in the U.S. according to EU requirements, and the reciprocal being true for EU exporters. The 1998 Transatlantic Economic Partnership (TEP) produced "Guidelines on Regulatory Cooperation and Transparency," which further encouraged both sides to exchange expertise, information, and ideas on alternative approaches to regulation. Most recently, at the 2002 U.S.–EU summit, U.S. and EU leaders introduced the Positive Economic Agenda (PEA), which launched regulatory cooperation projects in five areas (cosmetics, auto safety, nutritional labeling, food additives, and metrology) and endorsed an informal dialogue on financial markets, led by Treasury with the participation of U.S. financial regulators, which builds on long-standing channels of cooperation and communication. Pursuing these arrangements has contributed to a formal, regulatory structure for us to identify and address potential regulatory challenges at an early stage.

INNOVATIVE, INFORMAL APPROACHES

Out of these formal approaches, U.S. and EU regulators have launched a number of informal initiatives to strengthen transatlantic cooperation. We see these informal arrangements as promising examples of innovation in the spirit of the transatlantic partnership.

Just last month, for instance, the FDA and the EMEA, the European Agency for the Evaluation of Medicinal Products, agreed to share non-public (business confidential) information in the area of pharmaceuticals. In this enhanced spirit of partnership, both sides will share documentation on proposed regulations, position papers, and safety and test results. The potential benefit to consumers, producers, and regulators is significant.

In another example of transatlantic cooperation, our National Highway Traffic Safety Administration (NHTSA) and Europe's Directorate General for Enterprise have reached a cooperative arrangement in the field of motor vehicle safety. This June, the two agencies agreed to hold annual meetings, share and discuss R&D plans, conduct joint analyses, and exchange other forms of information. This arrangement, like the one on pharmaceutical information exchange, rests on the simple principle that more information leads to better regulation.

While both of these arrangements were created in the spirit of the NTA and the TEP Guidelines on Regulatory Cooperation and Transparency, neither emerged directly from, nor resulted in, a new binding agreement. In fact, regulators on both sides reached these arrangements without "creating any kind of international legal obligations on the part of the U.S., the European Commission, or the European Community."[1] While these arrangements are therefore informal in nature, they enhance regulatory cooperation between the parties involved to an unprecedented degree. As U.S. and EU officials exchange information, ideas, and opinions, they build trust and confidence, and, as a result, make more informed and coordinated decisions. In promoting trust, transparency, and more informed regulation, these arrangements demonstrate the effectiveness and desirability of working-level discussions between the U.S. and the EU.

We can also avert regulatory problems before they occur when we consult cooperatively in areas in which the EU is currently expanding and building its regulatory scope. An example of this can be seen in the creation of the new EU aviation safety agency, EASA (European Aviation Safety Agency). The FAA worked closely with its EU counterparts as the proposal for EASA made its way through the European leg-

[1] "Exchange of letters between the United States of American and the European Commission relating to regulatory co-operation in the field of motor vehicle safety," from Paul Weissenberg, Director of DG Enterprise F, to Mr. Jeffrey W. Runge , MD, Administrator of the National Highway Traffic Safety Administration, June 13 2003.

islative process. FAA officials continue to work closely with the Commission to provide a smooth transition from bilateral agreements with member states to a comprehensive U.S. agreement with the EU as a whole for those areas now under EASA oversight, which will ensure uninterrupted transatlantic safety oversight of air-related products and services.

We encourage U.S. and EU regulators to seek cooperative arrangements along informal lines on other issues. All of these informal arrangements received a significant boost thanks to a recent opinion by the Advocate General of the European Court of Justice defending the constitutionality of TEP guidelines and effectively encouraging the United States and the European Commission to consult each other on proposed EU regulations before they receive the European Council's formal approval.

RECENT AND CURRENT MAJOR ISSUES

I will now turn my discussion to recent and current "major issues" in the U.S.–EU regulatory arena. I will discuss the evolution of the U.S. ban on the import of Spanish clementines, the EU's e-commerce VAT tax, our recent bio-terror food safety initiative, and the proposed EU Chemicals Directive known as "REACH." I chose these four examples not only because of their recent prominence, but also because they show how consensus can be reached over even the most contentious of issues.

Spanish Clementines

The dispute arose when the U.S. banned imports of Spanish clementines due to phytosanitary concerns. Domestic citrus growers applauded the decision, citing worries about the possible spread of the Mediterranean fruit fly to the U.S. through contaminated shipments of clementines. On the other hand, the Spanish government protested on behalf of the Spanish growers who lost all access to our market.

Fortunately, we were able to reach a solution. By October of 2002, we were able to agree with Spain on a new inspection and quarantine regime to decrease the likelihood of contaminated shipments of clementines from reaching U.S. soil and accordingly we were able to lift most of the earlier import restrictions. We at State helped resolve the issue by working closely with all parties involved: the USDA, the lead regulatory agency on the issue; the OMB, the rule making body; the Spanish Government; the European Commission; and domestic U.S. citrus growers.

E-Commerce VAT/Internet Taxation

On July 1st of this year, the EU began requiring non-EU companies to collect VAT taxes on digitally downloadable retail products sold over the Internet to European customers. The new EU directive raises potential national treatment concerns on our end, since it could require U.S. companies to collect VAT taxes at differing rates than their EU-based competitors in some cases. It could also impose comparatively higher administrative costs on U.S. businesses. We also felt that the EU passed the new rules prematurely and differing implementation at member state level created uncertainty and confusion for U.S. businesses. Unfortunately, to date the EU has not been able to re-open the difficult internal compromise that produced this VAT tax regime. However, some large firms, including AOL, have successfully adapted to the new tax by strategic relocations of their European headquarters. It is more uncertain how the tax will impact small U.S. enterprises.

Bioterrorism/Food Safety Regulations

Food safety is a top priority of the U.S. government, and the events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Just last week, the Food and Drug Administration announced interim final regulations for two provisions of the Bioterrorism Act.

The European Union, along with other key trading partners, has had a keen interest in the development of these bioterrorism regulations. Twice during the public comment period, the EC submitted extensive comments regarding the potential effects of our proposed regulations on US-EU trade. We welcomed this input.

As published, the interim final regulations have been significantly modified to make them less burdensome on trade, in part in response to comments received from the EU and our other trading partners.

We are pleased with this example of constructive cooperation in the development of our regulations, and are hopeful we will be able to contribute in a similar vein to the development of EC regulations that have an effect on our trade relationship.

Chemicals Directive (REACH)

I'll now move on to discuss a current hot-button issue: the proposed REACH chemical directive that would overhaul EU chemical regulations. I'm going to dwell

on this topic a little longer than the others because although we feel that much progress still remains to be made, we are encouraged by the Commission's recent openness on this issue.

Earlier this year, the Commission unveiled its first draft proposal that, to put it plainly, was riddled with problems. First of all, it was grounded on their problematic "precautionary principle" instead of science-based risk assessment. As such, it effectively shifted the burden of proof for industry to unworkable levels. Just as importantly, it would have required testing all new and existing chemicals, even those that have been in everyday use for decades, and it would have imposed these testing requirements even on downstream users of chemicals. We were one of many interested parties that viewed the new regulations package as overly costly, burdensome, and bureaucratic—and ultimately unworkable. REACH has been controversial on both sides of the Atlantic, as the EU chemicals industry and the leaders of the UK, France, and Germany have cited similar concerns with the package.

In response to criticism over the lack of transparency in development of the policy, the Commission broke new ground by posting the draft chemicals regulation on the Internet and accepting public comment for an eight-week period this summer. This move marked the Commission's first use of a public comment period for proposed regulation. When all was said and done, more than 6,400 organizations and individuals had submitted comments to the Commission. In response, the Commission is preparing a more limited proposal that we hope will reflect the concerns that we and others expressed.

We hope that the Commission's public comment process on REACH signals the beginning of a trend. We believe that the Commission should ask for stakeholder input on all cases, not just in ones as highly visible as this one. We would like to see this greater spirit of transparency and inclusiveness structurally built-in to the EU regulatory framework, so that each new regulation also benefits from meaningful stakeholder input. Finally, while the continued use of the comment period would represent a significant step forward, the Commission should also consider other measures aimed at increased transparency so that the regulatory process can become more inclusive and less obscure.

HOW ARE NEGOTIATORS INCORPORATING LESSONS LEARNED?

The more we work with our European counterparts, the more we both learn how to improve our cooperation. Over the years, we've discovered a number of ways in which we in the U.S. can promote regulatory cooperation and minimize regulatory-based trade disturbances:

The first key is a strategy of patient engagement.

U.S. regulatory agencies have found that persistent, regular technical exchanges and dialogues at the working level with their counterparts in the Commission build rapport and resolve differences more effectively than high-profile diplomatic, political, or commercial efforts. In these working level talks, regulators compare their plans for future regulatory activities, allowing them to share criteria and methodologies at the inception stage.

However, we should not restrict our engagement to the Commission alone. We should also continue to engage the EU on multiple levels, including the members of the Council, the European Parliament, and member state regulators.

One key to success in this area turns on the important role played by our Embassies' economic officers. They are our representatives on the ground, providing a source of early warning on possible regulatory conflicts, while working hard to spread the U.S. point-of-view to all interested parties in Europe. All too often their hard work is overlooked.

A second strategy for success relies on the effectiveness of our public diplomacy.

Public diplomacy officers at our European embassies play a critical role in explaining the U.S. regulatory system and policy to EU opinion leaders and the public. At the U.S. Mission to the EU, for example, the public affairs office initiated a "Dialog on Better Regulation" between U.S. and EU policy makers and shapers. Four major conferences have already taken place in this ongoing series of two-day events that bring together high-level representatives from government and academia to engage in a candid dialog on regulatory issues.

We need to do more to publicize instances when we cooperate on initiatives so that Europeans and Americans alike can appreciate the strength of the transatlantic partnership. The resulting goodwill will help mitigate the tension that surfaces on both sides over issues of regulatory dispute.

Along a similar vein, more resources need to be devoted to shaping European public opinion on key issues. Not surprisingly, EU officials often cite public opinion as

the basis for their policies, so the support of the Europeans themselves often proves crucial to the success of our diplomacy.

I've already talked about how the U.S. can work within EU institutions by engaging all of its relevant institutions—the Commission, the Council, the Parliament, the Presidency, and the member states themselves.

In the member states, we should continue to capitalize on the strength of our bilateral relationships by contacting the relevant institutions.

In addition, we can often benefit from greater ties with the European private sector. For instance, the U.S. government and the European chemicals lobby found that they had much common ground with respect to the REACH chemicals directive.

We've also discovered that multilateral approaches sometimes can be used to resolve regulatory issues. Outside the EU, international standard-setting organizations, OECD regulatory reform reviews, and WTO Committee meetings provide the U.S. with additional fora in which to work with the EU and other parties on regulatory issues, and to urge greater transparency and accountability in the EU regulatory process. We also capitalize on multilateral negotiations, including environmental negotiations, to build international coalitions to support our approach to regulation and risk management.

Finally, we can benefit from the support of the scientific and NGO communities as well as watchdog groups to promote a more science-based regulatory approach.

A fourth key to success is the effectiveness of public/private coordination. The more the U.S. government and U.S. businesses work together, the more they both achieve in their relations with overseas regulators. Put simply, disunity dilutes and undermines the message that we're trying to convey to regulators overseas.

Our final key to success rests on the principle of timely intervention.

Through experience we've discovered that once the EU settles on a position, it will usually try to hold to that position, in part due to the complicated structure of EU process and politics.

Consequently, we should be prepared to act proactively rather than react, since the earlier we intervene in the drafting process, the better chance we have of ending up with a positive outcome. As seen in some earlier examples, the more time regulators on both sides of the Atlantic spend together, the increased likelihood that they will pre-empt regulatory outcomes that require costly and time consuming efforts to correct. We should think creatively about how to foster greater and more frequent exchanges among our regulators.

CONCLUDING REMARKS

To sum up, I've isolated a few goals essential for the future of U.S.–EU regulatory cooperation:

- We should continue to press for more meaningful transparency in and access to the EU regulatory process.
- We should work to ensure that American interests are able to make comments early enough in the EU process to be meaningful, and we should continue to ensure that Europeans have comparable access to our system.
- We should promote informal information exchanges and dialogues between the U.S. and EU regulators as a way to minimize unnecessary regulatory divergences.
- Along with our EU colleagues, we should continue to work in the spirit of the New Transatlantic Agenda to develop strategies that help forestall regulatory discrepancies before they happen or resolve regulatory disputes once they emerge.
- We should encourage interested parties on both sides of the Atlantic to regularly meet and discuss "hot" issues. (In particular, we should take greater advantage of DVC videoconference technology that allows for more frequent bilateral meetings without the expense and hassle of travel. The State Department would happily host such exchanges.)
- We also support a more active role for Congress in the process. We recommend continued and enhanced support for the Transatlantic Legislators' Dialogue (TLD) so that American and European legislators participate in the dialogue on regulatory policy issues. We note the recent positive video conference between Congressmen Mica and Congressman DeFazio with their colleagues in the European Parliament on conflicts between EU Privacy regulations and our need for access to airline passenger name record data to combat terrorism.
- Last, U.S. agencies should continue to work with each other to share information and advise on U.S.–EU regulatory issues.

As a colleague of mine likes to say about the transatlantic partnership, "what divides us makes headlines, what unites us makes progress." The U.S. and the EU don't receive enough credit for their collaborative efforts at regulatory cooperation. We both realize that if we can't reach agreement on these important issues, everyone loses, whether in the U.S., the EU, or elsewhere in the world. A more prosperous world community hinges on the continued progress of our partnership.

Thank you, Mr. Chairman. I welcome any questions that you and the members of the subcommittee may have for me.

Senator ALLEN. Thank you, Mr. Ries. Mr. Stewart.

STATEMENT OF ERIC STEWART, DEPUTY ASSISTANT SECRETARY FOR EUROPE, U.S. DEPARTMENT OF COMMERCE

Mr. STEWART. Thank you, Mr. Chairman. I do appreciate the opportunity to be here today and quite frankly, the timing of this is very good. We have been pending a lot of time at the Department of Commerce as well as the Department of State and our friends at the USGR working on these obviously very important regulatory issues. Because quite frankly, as you indicated in your opening statement, the requests are coming from industry. It's not the government sitting around saying gee, we ought to do this, it's industry who continues to tell us this is the right thing to do and this is what's most important to us. So your calling of this hearing is obviously very very timely.

I was in actually Brussels last week having varied discussion with my counterparts in Brussels, and actually as early as this morning sat with our 25, the 25 econ officers from the various embassies met here in Washington. We all sat in one room, which actually was quite daunting when you think about all these varying countries sitting in one room and trying to, let alone come up with a regulation they can agree on, but obviously a lot of other larger issues as well.

I will say, I also share your cautious optimism with dealing with Europe. When you really think about the amount of trade, as you indicated earlier, it's quite mind boggling, but what we try to keep in mind as well is where in the organization, or what is the organization working on with its views. What we try to keep in mind is that the numbers vary.

Somewhere between 85 and 95 percent of all trade between Europe and the United States is dispute free, and that doesn't count chemicals, because we don't know where that one is going to shake out. But it is a staggering number of the amount of trade that actually is quite positive.

And you alluded to the company here in Virginia, the German company. And when you think about the number of employees that are working for U.S. companies that are in Europe, somewhere in the neighborhood of 6 million, and the number of employees here, obviously many constituents of your, here in the United States working for European companies, somewhere in the neighborhood of 4 million. So really, obviously our economies are so integrated.

And what we do continue to hear from businesses this year is not terrorists, which is an issue that we continue to run into in a lot of other countries. It's the average tariff is somewhere between 1.8 and 2 percent between Europe and the United States. So really what the issue does come down to, as we hear time and time again, is regulatory affairs and standards. So obviously, our joint goals in

working together is to eliminate this anywhere from 5 to 15 percent friction between our two entities. And I use the word friction, but I don't use it lightly because 5 to 10 percent is obviously billions of dollars and is not a rounding error.

As Mr. Ries pointed out in his testimony, there really is a difference in philosophy in dealing with regulatory affairs, and this is one of the major hurdles that we continue to try to fight through with the European Union. In a sense they almost have a top down way of going about regulatory affairs and I think, although we still have a lot of issues and concerns with the chemical REACH legislation itself, that was a very good example of the European Union taking more of a bottom up, if you will, approach. An 8-week period of hearing comment, 6,400, as Mr. Ries pointed out, 6,400 comments that came in during that period. And quite frankly, when I was in Brussels last week meeting with one of my counterparts discussing this issue, he indicated to me anywhere between 50 and 100 of those 6,500 comments that were received actually were used and actually made a difference in the legislation and it was actually implemented, which is a good sign. I mean, it's a good start and that's what we're hoping to continue to encourage with the European Union's overall, you know, Lisbon strategy, if you will.

So in a sense, although we have a lot of difficulties and concerns with the legislation, clearly with the amount of jobs and amount of regulations that it will create, the process itself was a step in the right direction.

One of the other, I think, very large points that you pointed out in your opening testimony as well is the issue of accession and whether or not this is going to have a positive effect or negative effect, and obviously time will tell.

One of the discussions we had this morning with the econ officers was the fact quite frankly that, you know, it has been difficult up until this point for 15 of the countries to agree on a lot of these regulations. Now you're going to have a very different mix of 10 who in a lot of countries, quite frankly, may not have a lot of resources, they may not have a lot of the infrastructure for handling this amount of new legislation, new directives, new laws that they will quite frankly have to adopt even to become a member of the European Union. This is something we're going to have to continue, obviously, to work closely with them on and provide assistance and guidance to them, as to even helping them point out all the things that they are adopting by becoming members of the European Union.

Mr. Ries highlighted a few of the successes that we've had and I'd like to mention a few as well through the TABD process, the Transatlantic Business Dialogue, that obviously has been supported by both sides and is now, as you indicated also, being supported very much by industry. A few areas that we have been able to establish agreements, which are very positive in the sense of working together, telephone, electromagnetic capability, recreational craft, and my understanding is very soon to be medical devices as well.

These are good steps forward.

Obviously, there are still industries that are still in need. One of the industries that we're working on and hoping to have an agree-

ment here in the near future is information and communication technology, ICT. It's one of the major focuses that we have now turned to because it is obviously such a large industry and it will help us to continue to bring our regulatory relationship even closer.

There are a few things, and I will try to wrap up quickly as I know you're tight for time, a few things that we want to work on and that I have been discussing with my counterparts at the European Union and Department of Commerce, and USGR as a whole is really obviously to continue to eliminate barriers, that's the bottom line. But one of the other things that we have been discussing and were hoping to adopt slowly because there are some differences in how we go about it, is the idea of early notification, the idea of trying to talk before a regulation or directive is introduced and just automatically put into place. And quite frankly, a dialog is going to have to be on a very technical level and a very low level, but obviously our hopes are to increase that further to a higher level.

The other interesting opportunity that we continue to discuss with our counterparts is the idea of third country cooperation, because there are some areas where quite frankly, and I realize this is focused on European Union, but there are some areas that we can work together with the European Union in other markets as well to continue to work on some of the regulatory affairs that we agree on and ensure those are being adopted in third countries. I recognize that this hearing is on European Union affairs, but I wanted to point out one of the positives that we continue to have discussions with them.

All these things that we continue to talk about obviously in our minds dovetail very nicely into what Secretary Evans has proposed, which is an initiative on reducing standards and focusing on regulatory affairs, and this is not only going to be some of the things we discussed but continuing, as I mentioned earlier, to reach out to the business community, because quite frankly, the business community tells us what our priorities should be on these issues in dealing with the European Union in a lot of cases as it relates to economics and commerce, and we will continue to do that.

We have also created a liaison within the U.S. department of Commerce to focus on standards and regulatory issues, which he will be solely focused with working not only with the Department of Commerce employees but also with our counterparts at State, overseas, and our three compliance liaisons that are now in overseas embassies as well.

With that said, I will wrap up. But just to say, to continue to say that the EU regulatory cooperation is not just a good idea in our mind, we see it as imperative. We've heard from the business community, we've heard them loud. We've heard our friends from across the street here in Congress and recognize that this is a mutual goal not only of the U.S. Government executive branch but the industry and Congress as well.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Stewart follows:]

PREPARED STATEMENT OF ERIC STEWART

I. INTRODUCTION

Mr. Chairman, Ranking Member Biden and members of the Committee, thank you for inviting me here today. I am honored to appear before the Senate Foreign Relations Committee Subcommittee on European Affairs to discuss U.S.–EU Cooperation in Regulatory Affairs. This is a topic that has and will continue to occupy much of the time and energy of my staff. In fact, just last week I was in Brussels discussing this issue with my European Commission counterparts, and I am pleased to have the opportunity to share with you and your colleagues our perspective.

II. THE U.S.–EU RELATIONSHIP AND ITS IMPORTANCE

The significance of U.S.–EU regulatory cooperation should be viewed against the strength and potential of the overall Transatlantic relationship. I think that no one here disputes the importance of the U.S.–EU ties. From the economic perspective, the U.S.–EU relationship is vital. A few statistics make this obvious.

The European Union and the United States enjoy the world's largest economic relationship. Two-way U.S.–EU trade is over $500 billion annually, and the U.S. and EU are the largest investors in each other's markets.[1] Of the $5.2 trillion in foreign assets owned by U.S. companies, nearly 60 percent of these assets are in Europe. Similarly, nearly three-quarters of all foreign direct investment to the U.S. comes from EU investors. The importance of U.S.–EU foreign direct investment on the labor market is clear: U.S.-owned affiliates in Europe employ 6 million European workers, and over 4 million Americans get their paychecks from European companies. These economic figures are not just numbers on balance sheets. They account for the livelihoods of many Americans, including, I am sure, many of your constituents.[2]

III. OPPORTUNITIES THROUGH GREATER COOPERATION

I believe it is vital that we embrace the U.S.–EU economic relationship as one that will continue to bring greater foreign direct investment, more transatlantic trade in goods and services, and consequently more and better jobs for Americans. We have made considerable progress in reducing the trade burdens on consumers in both the EU and the United States. Significant trade liberalization has already occurred: U.S. exports to the EU face an average trade-weighted tariff of scarcely more than 2 percent while EU exporters face an even lower tariff here—just 1.8 percent.

In order to deepen and strengthen the U.S.–EU economic relationship we must work to eliminate the "system friction" that our different regulatory regimes can cause. Foreign regulations can be daunting to outsiders and their mere existence can be a deterrent to trade—especially to small- and medium-sized businesses. On the other hand, greater regulatory cooperation and mutual recognition policies insure trade flows continue to grow as non-tariff barriers are minimized.

Several ambitious initiatives for regulatory cooperation and deregulation in services are already underway. The Administration and the European Commission kicked off negotiations for an "open skies" agreement at the beginning of this month, a project that could increase transatlantic travel by up to 11 million passengers a year, accruing benefits of about $5.2 billion to passengers through lower fares and increased travel.[3]

IV. WHY REGULATION IS A NECESSARY PART OF BUSINESS

Before I share with you existing and future Department of Commerce activities in regulatory cooperation, I would like to comment on the role regulations play in international trade.

The purpose of many regulations is to protect consumers and the environment, but the broader impact on society, such as innovation and progress must be taken into account. Eighty percent of global trade in manufacturing and merchandise is regulated, sometimes at multiple levels, and a growing body of EU regulation covers fifty percent of U.S. exports. EU regulations are often arcane, difficult for foreign and domestic firms to comply with, and the process by which they are developed

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[1] U.S. Department of State, Office of the Spokesman. "Fact Sheet: United States—European Union Relations" June 25, 2003, Washington, D.C.

[2] Quinlan, Joseph. "Drifting Apart or Growing Together? The Primacy of the Transatlantic Economy" Washington, D.C.: Center for Transatlantic Relations, 2003.

[3] Reitzes, James and Dorothy Robyn. "An Analysis of the Economic Effects of an EU–U.S. Open Aviation Area" The Brattle Group, 2003.

opaque. The standards mandated by EU regulations can also create market access problems, as they are often drafted with little or no outside input. As a result, non-European firms seeking to export to Europe may have to do extensive testing or even redesign their products. This can be particularly burdensome for small business trying to access new export markets. Unfortunately, international regulatory cooperation is challenging because most regulators are focused on domestic priorities, which can impede competition.

Regulators on both sides of the Atlantic believe not only that they are "doing the right thing" but also in the right way. This often means unique and complicated levels of regulation and accountability. As we all are aware, in the United States businesses must often deal with federal regulators as well as in some cases as many as fifty state regulators. In Europe, the European Community regulations are enforced and often duplicated by fifteen—soon to be twenty-five—Member State regulators. A maze of accountability, a web of constituencies, and complications with enforcement result. The EU itself recognizes this and has made moves under its "Lisbon Strategy" to identify better and reduced regulation with the aim of a more competitive Europe. And the U.S. Government has encouraged this process by submitting comments on the Commission's Better Regulations Package in July 2003.

With particular institutions come particular cultures, and regulatory culture influences how regulations are made and implemented. The European Commission often invokes the so-called "precautionary principle" in drafting regulation. The "precautionary principle" permits the banning of products in the absence of any evidence of harm to human health or the environment. This is the guiding principle behind the recent EU chemicals proposals.

The cost of this approach to regulation can be staggering: the EU chemicals proposal could be read to cover all chemical-containing products, such that most U.S. manufactured exports to the EU ($143 billion in 2002) could potentially be affected.

Finally, regulation in Europe is often used as a broader political tool. Harmonization of member state regulations and standards was identified as the key to the formation of a European single internal market in the 1980s. The effort required a broad coalition of business and political interests to make it successful. Development of this single internal market fueled more ambitious projects for economic and political unity. Evidence of these spill-over effects is apparent in today's headlines, not least of which is the nascent European constitution.

V. EXISTING TOOLS

With this perspective on standards and regulations, I would like to outline some of the existing cooperation projects where my office and the Department of Commerce play a leading role.

Since its inception in 1995, the Transatlantic Business Dialogue (TABD) has been one of our most effective tools for increasing transatlantic regulatory cooperation. The Commerce Department has played a critical role in facilitating TABD's efforts, but I emphasize that the business community, not the government, has taken the initiative. This approach has been enormously successful.

TABD is focusing on lowering transaction costs and minimizing friction between U.S. and EU governments in order to maintain and increase competitiveness of businesses on both sides of the Atlantic. U.S. and EU CEOs participating in TABD have consistently cited what they regard as unnecessary divergence of U.S. and EU regulatory regimes as hampering transatlantic economic growth. For several years, TABD has remained committed to convergence of regulations in areas ranging from dietary supplements, to environmental emissions, to accounting standards. This successful forum is expected to continue to focus on convergence of regulations, as well as on removal of unnecessary barriers created by certain standards, testing and certification requirements.

Commerce will continue to work closely with TABD to foster U.S.–EU cooperation on regulatory and standards issues. I recently met with my European Commission counterparts in Directorate General Enterprise and we all agreed that continuing TABD efforts is crucial.

In the mid-to-late 1990's TABD also provided the momentum that kept the U.S.–EU Mutual Recognition Agreement (MRA) negotiations moving toward a successful conclusion. As a result, today we have three operational MRA annexes facilitating trade and reducing testing and certification costs in the areas of telecommunications equipment, electromagnetic compatibility (EMC) and recreational craft. It is expected that the medical device annex will be operational soon. If all goes as planned, the reach of the U.S.–EU MRA will be expanded this fall. The goal is to conclude an MRA with the European Free Trade Area (EFTA) States who are members of the European Economic Area (i.e., Norway, Iceland, and Liechtenstein). This will be

a parallel MRA to the existing U.S.–EU MRA and will be restricted to those sectoral annexes that are operational (i.e., telecom, EMC, and recreational craft).

TABD is also credited with breaking the impasse in negotiations on the U.S.-EC Guidelines on Regulatory Cooperation and Transparency over language on transparency. TABD recommended text on transparency that allowed us to conclude the Guidelines. Since that time, the U.S. and EC have launched a number of regulatory cooperation projects based on the Guidelines, specifically in the areas of auto safety, cosmetics, food additives, nutritional labeling, and metrology.

For cooperative projects on metrology, the Commerce Department's National Institute for Standards and Technology (NIST) is spearheading U.S. government activities. In a joint declaration signed in 1999, the U.S. and EC agreed in principle to proceed with cooperation in the field of metrology. U.S. and EC technical experts met in the U.K. in August 2003 and at this time are working to identify projects that are technically feasible and of clear benefit to both sides. The overarching goal stated in the Joint Declaration is to support and further mutual recognition of test reports, calibration and measurement certificates provided for regulatory and market place compliance purposes, to improve regulatory efficiencies and facilitate trade. Projects will be geared to reduce unnecessary duplicative measurements, tests and calibration requirements and improve regulator confidence in measurements, tests and calibrations performed by qualified laboratories in the U.S. and the EU.

VI. FUTURE INITIATIVES

These examples of existing efforts I have described are laudable and I appreciate the countless hours that have already been devoted to them. But if we are to embrace a U.S.–EU economic relationship that is ambitious and dynamic, our regulatory cooperation must similarly be ambitious and dynamic. Existing efforts must expand while new strategies are initiated. Let us not forget that entrepreneurs and scientists here and in Europe continue their work. Every year since 1994 the U.S. has spent more on R&D as a percentage of GDP than ever before. European companies spend six-times more on research and development than Asian companies. This means productivity and innovation but also new products, new applications and of course new standards and regulations.

I would like to assure the committee that we are building on existing initiatives and breaking new ground in other areas of cooperation. For example, Commerce officials are exploring a new cooperative project that would complement the U.S.–EU Guidelines on Regulatory Cooperation and Transparency I just described. Through transatlantic dialogue on proposed information and communications technology (ICT) regulations and related standards, the proposed project would act as an "early warning" system for U.S. companies in the ICT field. The dialogue will focus on ICT-related issues that fall within the Department's scope and authority.

The proposed project has two primary objectives. The immediate objective would be the creation of a mechanism, specifically related to the ICT field, to address longstanding U.S. industry concerns regarding lack of transparency, access, and accountability in EU regulatory and standards development process. Initiating regular exchanges of information on government-developed regulations is a first step toward allaying industry concerns. The dialogue will provide the necessary information regarding EU regulatory and standards development processes at a sufficiently early stage to permit industry to respond effectively. The second, long-term objective is to facilitate direct U.S. industry access to such EU decision-making processes.

Within my own unit, I have urged my staff in the Office of European Union and Regional Affairs to expand efforts to address EU regulatory and standards policies. We have developed and are implementing a far reaching Standards and Regulations Strategy geared to reduce or eliminate market access barriers to U.S. exports due to EU standards and regulatory policies: (1) in the EU, (2) in third countries, and (3) in international and multilateral fora. Under the Strategy, work plans have been launched to resolve the most pressing issues through outreach to U.S. and EU industry, to government officials in the EU, the Member States, third countries, and to standards organizations at all levels. The foundation of each work plan involves close collaboration intra- and interagency to ensure coordinated action within U.S. government and with outside stakeholders. This Strategy complements Secretary Evans' Standards Initiative and the Bush Administration's Manufacturing Agenda, both announced in March 2003, and dovetails with the TABD's new focus on standards and regulations.

At the highest level of the Department, Secretary Evans announced a Standards Initiative earlier this year, based on eight-points. Standards are key, because they

often can be included in regulation, creating divergent regimes and potential trade frictions. Let me discuss each point in turn.

First, we are developing a Global Standards Activity Assessment to inventory current standards-related programs and activities. NIST is already surveying all Commerce agencies, and plans to request input from other Federal agencies, from industry, standards development organizations, and advisory committees. At the end of the process, the Secretary will be presented with internal report on the results of the activity assessment, with recommendations for going forward.

The second and third points relate to development of enhanced training: an in-depth training program for our standards attaches based overseas to strengthen their expertise, and a standards training program for Commercial Service Officers in overseas posts so that they have a sufficient understanding of the impact of standards and regulations on international trade.

Fourth, we will develop a Best Practices database so that Commerce officials can address the challenges industry faces more effectively.

Fifth, NIST will continue and expand distribution of its free "Export Alert!" web-based service that provides subscribers with automatic electronic notification of proposed technical regulations in global markets.

Sixth, we have established a dialogue on standards within the President's Export Council. ITA and NIST representatives briefed the PEC's Subcommittee on Technology and Competitiveness on the Department's Initiative earlier this month and got a very positive response from subcommittee members.

Seventh, we are in the process of hosting roundtables with specific industry sectors to gain a better understanding of industry's concerns and priorities regarding standards. Additional roundtables will be held for standards-setting organizations and on compliance and testing methods. Information from these roundtables will also be fed into the activity assessment noted above.

Eighth, the International Trade Administration has established a new standards liaison position and recently brought on board an expert to fill this position.

I am confident with the many tools available for addressing standards and regulatory issues with the EU, we will enhance the ability of U.S. companies to export to and compete in the European marketplace. As I indicated earlier in my testimony, the Bush Administration is committed to continued close cooperation with the business community and EU officials. We believe that open dialogue is one of the most effective ways to avoid disputes, promote cooperation and lower business costs for U.S. and European companies.

VII: CONCLUSION

Today's U.S.–EU economic relationship has not been built on convenient choices and simple solutions, but on hard work, critical analysis and energetic cooperation. For this relationship to continue to prosper, similar energy, creativity and dedication must be given to regulatory cooperation. U.S.–EU regulatory cooperation is not just a good idea, it is imperative. The Bush Administration is positive that regulatory cooperation is the linchpin of a prosperous future economic relationship. My staff and I are working to make successful regulatory cooperation a reality.

Senator ALLEN. Thank you, Mr. Assistant Secretary. Both secretaries have delivered good testimony. I know you have summarized your testimony, and with your permission I would like to enter it into the record as written.

Mr. Ries, both of you can comment on this. Some of the questions I already had you addressed on the chemical issues and accession countries and so forth. Mr. Ries, you mentioned in yours a concern on the VAT taxes, and I only say this in passing. The VAT taxes and the imposition of the VAT taxes for large companies is probably not a big problem; they're getting into whichever country has the lowest VAT tax and sell that way; it's just good economics and makes sense. I would just note for both of you all, if it gets into assisting small and medium-sized companies, they will generally need more assistance whether from Commerce or from State. And again, I know this from my experience as Governor and working with trade commissions and so forth, the consulate and embassies, a lot of those folks can be helpful. The VAT tax will harm the

smaller companies. And I have read your statements that it's uncertain how the tax will impact small U.S. enterprise.

When others that are not going to be able to put a physical presence in Europe want to sell on line, they are going to have to figure out a lot of things and be subject to some kind of confusion in their approaches. So I would ask you, No. 1, to continue to monitor that. I know that I will, and I would hope that the Europeans would put some practicality to that.

The question ultimately, though, is how do you all see, and I think I will give this to Assistant Secretary Stewart for comments, where do you see in your secretariat your assistance to medium-size or small companies who often do not have the resources to devote to studying and overcoming regulatory barriers? Just as both of you all alluded to, the difficulties of the 10 countries generally in southeastern and central Europe coming in, and the ability to comply with all these regulations which are costly, how do you see your offices assisting those smaller businesses with trying to keep up to speed and somehow overcome some of those barriers?

Mr. STEWART. Mr. Chairman, it's obviously a very good question and it's something we continue to focus on. The Secretary himself continues to go out and have round tables throughout the country, the under secretary and on down the line, we continue to reach out to the business community and quite frankly the small business community, because we do recognize that they don't have lobbyists, they don't have a lot of resources to be flying into Brussels and discussing these issues. And quite frankly, that's one of the things that we continue to focus on is our outreach.

But at the same time, you know, with technology today with the Internet, the chemicals legislation is a good example of where a small business does have opportunity to be able to make comment. Now granted, it's over the Internet and it's not a one-on-one discussion which is obviously what you would prefer, but at the same time it gives that company in Richmond the ability to comment and make suggestions on a piece of legislation that might be going to the European Union.

And one of the things, and that all sounds well and good, but one of the things that's also important and that we put on our shoulders is to get the message out to the small businesses that this even exists, that there is even a potential issue or potential piece of legislation that might affect them. So we, again, have been using the Internet and the web to try to get those messages out.

We have two different web sites. One is the TCC, which is an on-line sort of subscription, if you will, to technical barriers to trade and notification on issues that might be coming up. And Export Alert is another one that is being run out of the Department of Commerce as well, to allow small businesses to be notified so they don't have to try to continue to keep up with it themselves.

Senator ALLEN. That's great. Thank you.

One final question to you, Mr. Ries. We've seen in the past the problem with the GE, General Electric-Honeywell case and what happened there as far as that proposed merger. In the current situation with Microsoft where there has been a comity so to speak, using that legal term, do you see the State Department working with our Department of Justice and the European Commission to

ensure that we avert a repeat of the General Electric-Honeywell case as a result of the European Commission's proposed remedies for Microsoft?

Mr. RIES. Well, Mr. Chairman, thank you very much. We have been working on competition policy with the EU for a number of years, since my days in Brussels working for Ambassador Eizenstat, who will follow me today. He and I worked very hard to foster a dialog between our antitrust authorities and then DG-IV, now DG Competition, which of all of the many EU common competencies or common powers, competition policy is the strongest, really. The Commission has sole jurisdiction to determine whether or not activities or mergers affect competition within the European Union, and even outside of the European Union, if they have an impact on trade within the European Union.

What we have done is we tried in a number of different ways to get the FTC and Justice Department antitrust people in close regular touch on the current issues, cases, findings of law, findings of policy, and economic analysis. For the most part we succeeded very very well. There really, you can remember the handful of cases very clearly where there has been divergencies. Honeywell is one; Boeing-McDonnell is another one, but there are hundreds of cases which operate where the antitrust review on both sides of the Atlantic comes up with largely compatible approaches. Again, that's been our goal.

I think on the Microsoft case I really can't speak to the dialog in specifics of the case because it is privileged between the Justice Department case attorneys and the Commission case attorneys. But I think I can accurately say that the dialog has been deep and continuing throughout the course of the case in which our side has endeavored to reach common evaluations of these very complex questions of the impact of software sales practices on the markets. As you know, Mr. Chairman, very well, the key task in any competition policy case is the definition of the market and that is something that we have to engage very much with the European Union. We very much hope that the Microsoft case in its final disposition resembles the hundreds of very successful cases in which success is defined by a compatible approach on both sides of the Atlantic.

Senator ALLEN. Fair enough, thank you, Mr. Ries. I want to thank both of you gentlemen. You may get questions from me or other members for the record. Thank you both for your leadership, for your efforts, and also your vigor on this important subject. Thank you, gentlemen.

Mr. RIES. Thank you, Mr. Chairman.

Mr. STEWART. Thank you, Mr. Chairman.

Senator ALLEN. Next we will call our second panel, one witness.

The European Commission, I will say to those listening and in the room, has been gracious enough to accept our invitation to participate in this hearing. We appreciate the cooperation of the European Commission in providing this presentation to the subcommittee, and we welcome Monsieur Gérard Depayre, Deputy Head of the Delegation, for his voluntary appearance here today.

Bien venue, and we would be happy to hear a summary and/or any remarks you would want to make on the subject.

Please understand that your testimony, full testimony if you wanted to summarize it, will be included in the record.

STATEMENT OF GERARD DEPAYRE, DEPUTY HEAD OF DELEGATION, EUROPEAN COMMISSION TO THE UNITED STATES, WASHINGTON, D.C.

Mr. DEPAYRE. Thank you, Mr. Chairman. I am Gérard Depayre, Deputy Head of the Delegation of the European Commission in Washington, and I'm presenting a statement on behalf of the European Commission.

At the outset, let me say that the Commission values the opportunity offered by this hearing to present its view on U.S.–EU regulatory affairs and in particular on our cooperation in this area.

Your interest in EU–U.S. regulatory cooperation is helpful in furthering our mutual efforts to deepen the Transatlantic Economic Partnership and in promoting regulatory convergence.

A recent study published by Joseph Quinlan of the Johns Hopkins University, which you referred to in your introductory statement, illustrates the importance of making headway in the transatlantic economic agenda. It demonstrates the high degree of interdependence of our two economies. Such intertwining makes it even more necessary to engage in further liberalization, leading to reduction of costs for business on both sides of the Atlantic.

Despite, or perhaps as a result of, this interdependence, it has become apparent in the last few years that the most significant barriers to trade between the EU and the U.S. are no longer the visible barriers such as tariffs. It is now the hidden technical barriers which add cost and frustration to the conduct of business.

Promoting further liberalization thus implies that we resolve problems resulting from differences in existing regulations, and that we avoid new problems which would arise from diverging regulatory developments, i.e., future regulations.

How can that be achieved? A solution to both these problems can only be reached through the dialog and close cooperation between regulators. The ideal result should be to arrive at harmonized regulations. Failing this, efforts should be made to ensure maximum convergence of regulations to both sides of the Atlantic, which makes possible the mutual recognition of equivalence of regulations.

Resolving problems arising out of differences in existing regulations is often very difficult due to the natural resistance of regulators to accept amendments to the products, to their products. A solution which requires a clear realization by both sides of the unnecessary burden imposed to business by two sets of conflicting regulations could in certain cases be found in movement by two regulators to a greater convergence, and thus create the basis for mutual recognition. Another alternatives is the reduction of differences and conflicts in the implementation of legislation, whenever such legislation leaves adequate flexibility to the regulator.

Preventing problems arising out of new regulations implies that a dialog between regulators takes place at the earliest stage possible in the process of establishing regulations. Early preventive dialog between regulators, but also involving scientists, consumer groups, politicians and businessmen, is fundamental. Timely dialog

allows us to foresee problems, to reach agreement on their nature and scope, and either to develop common approaches to dealing with them or failing that, to settle on the approaches that are as compatible with one another as possible.

This implies in turn, Mr. Chairman, transparency and the possibility for stakeholders, including governments, to make their views known before final decisions are made, and that such views are duly taken into consideration by regulators.

While many countries subscribe to the principles of transparency, such as public access to official documents and public consultation, the way these principles are implemented differs widely.

For our part, the European Commission has taken a number of important steps in recent years to ensure transparency.

Its recent White Paper on European Governance of 2001 calls for more effective and transparent consultation of civil society and interested parties, as well as for am improved dialog with governmental and non-governmental actors, including third countries.

This new approach combines two essential elements: A set of minimum standards for consultation aimed at increasing the transparency for stakeholders and for the public at large. A new regulatory impact assessment system requiring the Commission to take economic, social and environmental effects into account when making regulatory proposals.

Let me now turn to regulatory cooperation in EU–U.S. relations, but before I turn into the details of our cooperation, I would like to recall the differences in our legislative and regulatory systems, to which Mr. Ries alluded earlier. These are the results of different administrative cultures and historical development on both sides of the Atlantic. Any comparison between our system should also take this into account.

First, the term regulation relates to different concepts on both sides of the Atlantic. While in the U.S. it designates secondary-type legislation adopted by regulatory agencies based on primary legislation passed by Congress, in the EU it refers to community-wide legislation, legally binding in member states, the nature of which could be either primary or secondary.

Regarding the decisionmaking process, technical regulations are adopted in the EU by the legislative branch, either the Council of Ministers but more frequently the Council and the European Parliament upon a proposal made by the Commission. Since legislation has to be preceded by a Commission proposal it is necessarily subject to prior consultation and transparency requirements, those I referred to earlier.

This is different from the situation where Congress initiates and passes legislation mandating the subsequent adoption of regulations. This may at times create transatlantic conflicts, as you know. The Bioterrorism Act and the Sarbanes-Oxley legislation are relevant examples in this respect, not to mention the Byrd amendment.

When it comes to the involvement of stakeholders in the preparation of the regulations, in the EU we do not have the exact equivalent to your Administrative Procedures Act which imposes largely standardized formal consultation requirements on U.S. regulatory agencies. What we have instead are practices developed by the

Commission's different directorates general on the basis of the White Paper on European Governance which I referred to earlier. While these practices are not as formal as those of the APA, they are always at least as effective in terms of dialog between authorities and third parties. Indeed, having very formalized procedures is not always a guarantee for the parties that their position will be taken into consideration. Here implementation of the Bioterrorism Act by the FDA is a good case in point.

That being said, let me now turn to the EU–U.S. regulatory dialog. Based on our 1998 Transatlantic Economic Partnership Action Plan, the European Commission and the U.S. government developed in 2002 the so-called Guidelines for Regulatory Cooperation and Transparency, offering political commitment for a dialog between EU and the U.S. regulators.

This framework is already up and running in a number of areas. In particular, ideas and recommendations stemming from civil society, such as the Transatlantic Business and Consumer Dialogues, have received attention. Four initial pilot project to implement the guidelines were agreed in November 2002. In addition, two new areas have been agreed recently, cooperation on standards in information and communication technology sector, and pharmaceuticals.

It is clear, Mr. Chairman, that these first results, still modest in relation to the tasks ahead of us, need to be expanded. We are now discussing ways to make regulatory cooperation a more sustainable process. This could be done by various means, including the exchange of annual work programs, organizing dialogs horizontally and/or in specific areas, and enabling exchanges of regulators.

It is important to note that our bilateral regulation cooperation goes far beyond the areas covered by the guidelines, which only apply to trade in the industrial goods.

Our cooperation now extends to a number of sectors and in the first place to financial services, the liberation of which could bring enormous benefits to both our economies. In that context, we are tackling both regulatory obstacles such as the impossibility for EU stock exchanges to place trading screens in the U.S., and more recent problems resulting from the Sarbanes-Oxley Act. In dealing with these issues, we have instituted a dialog with U.S. regulators which has already yielded some positive results.

We have an intensive dialog on transport security, notably on the Container Security Initiative and the Passenger Name Record. We hope this dialog will result in the resolution of problems arising out of the conflicting requirements of our respective laws and regulations in this field. While we share the underlying security concern of the U.S. in this area, a balance has to be found between these concerns and the effects of such initiatives on trade or the protection of personal data mandated by EU law.

We have, finally, initiated a dialog with the FDA on the implementation of the Bioterrorism Act and have submitted our comments on the proposed regulations. However, we have so far not seen any active engagement by the FDA in our dialog.

In the chemical sector to which you referred earlier, during the ongoing process of formulating its proposals for a new chemical policy, the European Commission has held early consultations on two consecutive texts, which were open to all stakeholders from Europe

and the rest of the world. When finally adopting its proposals, the European Commission will take into full consideration and respond to the thousands of comments received.

Finally, Mr. Chairman, I would not want to end this testimony without mentioning the transatlantic legislators' dialogue, which has an important role to play in regulatory cooperation. Thank you, Mr. Chairman.

Senator ALLEN. Thank you, merci beau coup for your testimony. You addressed so many of the issues and many that our representative from State, our Assistant Secretary from State and Commerce addressed. And it is important, I think, that when regulations, your laws, you use the term laws and we use the term regulations, are being formulated, that we have the earliest consultation, understanding, forecasting, give us the opportunity with the transparency that you talk about to have this consideration of the economic impacts, the trade impacts and clearly the people of the countries, of the European Union and the people in the United States care about our people and care about their safety, their health, and also their opportunities for prosperity.

So I thank you so much for coming and sharing your views and sentiments, and it appears to me that if everyone continues to work consistently in their actions as we have stated here in writing, as well as by words, the future can continue to be very prosperous and productive among people who really treasure values of human rights, dignity, as well as common concepts of free markets and free enterprise. Thank you so very much.

Now I would like to call up our third panel.

From the private sector, we're pleased to have the Honorable Stuart Eizenstat, co-chair of the European-American Business Council. Mr. Eizenstat is uniquely qualified to speak from both perspectives, as he has served as U.S. Ambassador to the European Union and Deputy U.S. Treasury Secretary We look forward to hearing Ambassador Eizenstat's testimony on what both sides need to do to facilitate greater cooperation.

Representing the voice of the business community is Gary Litman, who has appeared at other times before us, the Vice President of the International Affairs Division of the U.S. Chamber of Commerce. Mr. Litman will talk about problem areas in our present day cooperative relationship and ways U.S. Government agencies might improve the situation.

And we have Mr. Farmer. Mr. Farmer is the General Counsel for the Bankers' Association for Finance and Trade, and an affiliate of the American Banker's Association. We hope to hear insights on cooperation in the area of financial services.

Ambassador Eizenstat, go ahead.

STATEMENT OF HON. STUART EIZENSTAT, CO-CHAIR, EUROPEAN-AMERICAN BUSINESS COUNCIL, WASHINGTON, D.C.

Ambassador EIZENSTAT. Mr. Chairman, thank you for these hearings, and I hope they serve as a stimulus to reduce U.S.–EU trade and investment barriers. Let me say at the outset that my firm represents a number of American and European companies with interests in these issues. And even as co-chair of the European-Amer-

ican Business Council, my testimony nevertheless represents my personal views.

I would like to begin by noting that notwithstanding the headlines about difficulties on steel, GMOs, bananas and others, we have a balanced, productive and successful relationship on the great bulk of our trade, but still far to go. We need a longer term broader vision of our transatlantic relationship, which frankly, I have not heard from our previous witnesses, and to set our sights on a more ambitious goal. That ambitious goal should be, Mr. Chairman, a barrier-free economic relationship between the U.S. and the EU by the end of this decade. We should put all of our energies into achieving this goal.

We need to do so not only through active engagement by the governments on both sides of the Atlantic, but a reinvigorated transatlantic business relationship. I helped create the Transatlantic Business Dialogue in 1994, but the TABD has not played the central role it should in recent years, but now with Doug Daft from Coca-Cola and Niall Fitzgerald from Unilever as new co-chairs, along with the commitment by Secretary Evans to reinvigorate, I hope that TABD will help stimulate the achievement of this barrier-free transatlantic economic space.

I would like to highlight up front what I consider to be a crucial factor in achieving this goal. That is advancing the principle of mutual recognition. Because both the U.S. and EU share high health, safety and other technical standards, and because regulators on both sides of the Atlantic generally have confidence in each other, the U.S.–EU should, in my view, focus heavily on expanding recognition of each others' regulatory processes. Broadening this mutual recognition will lower costs for businesses on both sides of the Atlantic, streamline product development and enhance productivity. Enhanced mutual recognition could serve as a key step toward realizing the goal I'm suggesting of a barrier-free transatlantic economic space.

Quite frankly, the progress that we've made going back to 1998 in having MRAs covering multiple sectors, telecommunications, information technology, pharmaceuticals, and medical devices, has stalled in recent years. Indeed, while serving in the Clinton administration I saw some of the obstacles facing progress, namely that regulatory agencies cover domestic and not an international focus. I saw this particularly with FDA in the pharmaceutical sector.

Encouraging greater confidence in regulatory systems across borders, together with a renewed momentum for MRAs by expanding their reach into as many sectors as possible, would significantly contribute to U.S.–EU cooperation in regulatory matters.

But let me say very frankly, I have been around this, I have been in the White House with President Carter, President Johnson, with the Clinton administration for 8 years, and this will not happen if regulators are left to their own. It will not happen. There is not a sufficient dialog, their focus is domestic. It takes White House direction to get them to engage in regular sustained dialog with their transatlantic counterparts to achieve a level of confidence in each other's regulatory processes that in turn will promote mutual recognition.

In the area of financial markets, there are some good recent examples. Understanding that a transatlantic capital market can't function efficiently without a genuinely cooperative regulatory approach, the U.S. and EU have undertaken productive discussions on at least two key issues for financial markets; resolving the application of Sarbanes-Oxley to European companies and harmonizing U.S. and European accounting rules. These are only the first steps toward the ultimate goal, a barrier-free financial market.

I applaud the initiative of the International Accounting Standards Board and the Financial Accounting Standards Board to facilitate a convergence between the U.S. GAAP and EU IAS accounting standards. Under the leadership of EU Commissioner Frits Bolkestein and Paul Volker, progress is being made in which each side would recognize the adequacy of the other's accounting standards, the concept of equivalence as Mr. Bolkestein has called it.

Even where mutual recognition of regulatory standards may not be achievable, Mr. Chairman, cooperation is nevertheless advanced by pursuing workable solutions, such as the current talks seeking to clarify the application of Sarbanes-Oxley rules to European companies, requiring European auditors to register with U.S. authorities. Here again, Mr. Bolkestein is working effectively to find a solution, this time with William McDonough. A reasonable deference to European inspections of European auditors will clear the way for an agreement.

Just as MRAs can serve as a positive model for improving cooperation, there are unhelpful examples. The worst of them at this point would be the chemicals directive you have been good enough to highlight. This is a timely example of regulation in the wrong direction.

Senator ALLEN. Mr. Ambassador, I'm sorry, I just got a message. If I don't get there, I'm going to miss it.

Ambassador Eizenstat: I understand.

Senator ALLEN. Thank you very much, gentlemen. There will be two votes. I will be voting at the end of the first vote and right at the beginning of the second. I will be right back. This hearing is in recess for, I would say about 10 to 15 minutes. Thank you, Mr. Ambassador.

[Whereupon, the hearing recessed from 3:27 to 3:45 p.m.]

Senator ALLEN. I thank our panelists and everyone here for your indulgence and patience. My thanks to you, Ambassador Eizenstat, for your understanding. We will resume the hearing now, and Ambassador Eizenstat, if you would like, please continue with your statement.

Ambassador EIZENSTAT. Thank you, Mr. Chairman. Before I go to talk about some unfortunate deviations from what may be progress in this area, let me clarify one thing. When we talk about mutual recognition agreements, which again, we did to a considerable extent in 1998 and 1999, which I mentioned, they need to be reinvigorated. What that means is that the U.S. would recognize the competence of a European country to certify that a particular product had met U.S. standards.

What we ultimately want to go—and that's good, but we want to go to a broader standard and that's what Bolkestein is trying to do

now in getting a convergence between European IAS accounting standards and our GAAP accounting standards, so that while they may not be identical, they are sufficiently converged and close that each side recognizes that the other's regulation is sufficient to protect its interests even though it's not identical.

Now one particularly timely example of a regulatory step in the wrong direction, Mr. Chairman, is the current EU proposal for regulation of chemicals which we know as REACH, which you were good enough to mention. It requires manufacturers and importers of chemicals or products containing chemicals to register their products with the newly established European Chemicals Agency, and to provide information on hazard, exposure and risk for 30,000 new and existing substances that are produced and imported in yearly quantities exceeding one metric ton.

Candidly, it represents exactly the kind of top-down, non-risk based regulatory approach that impedes progress on achieving a barrier-free marketplace. In particular, the EU should streamline the authorization process, which will be dominated by individual member states who could regulate similar chemicals in different ways, causing massive confusion and cost. One method for streamlining the process is through a more risk-based approach. Similarly, there should be more comprehensive exemptions for substances which pose low health and environmental risks.

There was a welcome public comment period. It elicited 6,400 comments around the world, from Japan to the United States, and that has led to some changes. But, permit me to say that the September draft continues to have many of the basic flaws of the earlier draft that impose heavy costs.

Just as I was in Brussels this week, just their own estimate is $7.5 billion, that's their own estimate, or 7.5 billion euros of new costs. And that is theirs, I'm sure that's the lowest estimate one will find. It represents a retreat from risk-based scientifically oriented regulation and is a significant step in the wrong direction.

Trade barriers. Both the U.S. and the EU impose numerous barriers to the free flow of transatlantic trade, the most obvious being one that affects your state as well as many others and that is the moratorium which has now lasted 4.5 years on genetically modified products. Farmers in the United States are losing several hundred million dollars a years in sales. I was able to get as Ambassador to the first product, a product called ROUNDUP READY soybeans. We have barely gotten another one since. The EU moratorium is devoid of any scientific basis. It's based on fear of the public. It violates WTO standards, and I applaud Bob Zoelick for initiating a WTO dispute resolution process.

On the other hand, we are hardly blameless. We have adopted measures that are also questionable and restrict European trade, in particular the unilateral imposition of tariffs on steel, which were based more on good politics than good policy. These we rejected in the last year of the Clinton administration. Perhaps because we rejected them, I am sitting here as a private witness and not as a public witness.

They should be terminated at the earliest possible moment.

Senator ALLEN. You're a good witness. Go ahead.

Ambassador EIZENSTAT. Likewise, the "Fly America" requirement imposed on U.S. Government travel limits travel options for hard-pressed senior U.S. officials and is increasingly dubious in an era of transatlantic airline alliances and international code-sharing.

We also should work to eliminate investment barriers that limit investment by U.S. companies in Europe and European companies in the United States. For example, we limit foreign investment in areas like airlines and in the broadcast sector, restrictions which are antiquated in an increasingly integrated transatlantic marketplace. And likewise, the "Buy America" provisions in the House version of the fiscal 2004 DOD Authorization Bill undermines efforts to remove remaining barriers and prevents the Pentagon from getting the greatest flexibility to purchase the best products at the lowest cost.

Closer U.S.–EU antitrust cooperation is also essential to achieve this goal of a barrier free market to reduce and eliminate, if possible, the uncertainty and inefficiency that occurs from different results are on merger, acquisition and competition cases. You were good enough to mention, Mr. Chairman in your opening remarks, the divergence in the GE-Honeywell case. Likewise, in the Boeing-McDonnell Douglas case and when I was in government, the merger was ultimately approved by the EU after the U.S. had approved it but it was substantially different and in more onerous terms, causing transatlantic tensions. Sensitivity to U.S. competition authorities in these instances would have been warranted and would have avoided harm to our efforts to advance transatlantic competition relations.

Similar sensitivity should be exercised by EU competition authorities, as you were suggesting in your question in their investigation of Microsoft, particularly when proposing the very remedy, the unbundling of Microsoft's Media Player software in its Windows operating system that U.S. authorities considered and rejected. The same approach proposed by the EU was rejected by the District Court judge approving the Justice Department settlement in rejecting the approach of the minority states, now only one. The EU seems to be following that approach and when rejecting that approach, Judge Kollar-Kotelly stated that unbundling would cause clear and certain harm to the entire personal computer ecosystems. The EU's proposed remedies create significant inefficiencies and could threaten growth in the information technology sector because it would require Microsoft to ship one product to the EU and another to the rest of the world. I am aware of only one instance where the U.S. has disapproved of a merger approved by the EU.

The 1991 EU–U.S. antitrust agreement is based, as you suggested, on the principle of comity in antitrust investigations, and dictates that one party to avoid conflicts with the other will recognize the other's important interests.

Similar positive cooperation can occur with the establishment of the U.S. antitrust working groups. Progress has been made already on mergers, but progress needs to be made on other areas of the competition laws so that we aim for convergence of views on key substantive issues.

Just think, Mr. Chairman, of two U.S. companies wanting to merge, or Microsoft wanting to do business in a particular market.

The prospect of having different outcomes in an integrated market is really a very difficult and uncertain situation which is not good.

Let me conclude by saying there are many examples where we can create this barrier-free transatlantic marketplace. An excellent one is the EU–U.S. open skies initiative, given the recent legal competence of the European Commission to negotiate Europe-wide agreements. So by building on productive efforts like harmonizing competition and accounting standards, expanding the reach of MRAs and ultimately moving toward equivalency, while dealing with counterproductive efforts like the REACH proposal and Buy America provisions, we can make a major step toward creating a barrier-free transatlantic relationship.

I can't begin to tell you how much, and I'm serious, I appreciate your hearings, because no one is going to pay any attention to this, and your hearings will help stimulate everybody to action. And may I suggest, as Bill Roth, when he was chairman of the Senate Finance Committee, that if you yourself, if I may be so bold as to suggest this, will remain engaged with the Commission and with your counterparts in the European parliament to push these kinds of issues, you can play a major role yourself in creating this goal of a barrier-free transatlantic marketplace. Thank you very much.

[The prepared statement of Ambassador Eizenstat follows:]

PREPARED STATEMENT OF STUART E. EIZENSTAT

Thank you Mr. Chairman for the opportunity to appear before the Committee today on the important issue of U.S.–EU regulatory cooperation. I hope that your hearings will serve as a stimulus to help reduce U.S. and EU trade and investment barriers. During my service in the Clinton Administration, I devoted considerable effort to advancing U.S.–EU trade relations, and I continue to take a keen interest in expanding cooperation between these two trading partners, who together account for nearly 40% of world trade.

In the Clinton Administration, I served as U.S. Ambassador to the European Union, Under Secretary of Commerce for International Trade, Under Secretary of State for Economic, Business, and Agricultural Affairs, and Deputy Treasury Secretary. In the spirit of full disclosure, I would first like to inform the Committee that my law firm, Covington & Burling, represents a number of American and European companies with significant interests in U.S.–EU regulatory issues. A number of the firm's clients are very satisfied with the regulatory environment; a number of other clients are less than satisfied or have company-specific problems on either side of the Atlantic. I also serve as Co-Chair of the European-American Business Council (EABC) along with former EU Ambassador Hugo Paemen. But this testimony represents my personal view.

As this hearing concerns U.S.–EU cooperation, I would like to begin by noting that current U.S.–EU trade relations—perceptions notwithstanding—are, on balance, quite productive and successful, and have been fundamentally sound for decades. Indeed, some $3 trillion of trade and investment between the United States and European Union occurs annually, the great majority of which is unimpeded. Millions of workers on both sides of the Atlantic owe their jobs to affiliates of U.S. and EU companies. The U.S. enjoys freer trade relations with the European Union than with most of its other trading partners. A strong, vibrant and productive economic relationship with the European Union is in the United States' national interest. Similarly, the United States is the largest market for Europe; strong economic relations with the United States is in Europe's interest as well. Most of the public attention and press coverage of the EU–U.S. relationship focuses on the most contentious, high-profile issues including steel, bananas, and GMOs. Nevertheless, we must not lose sight of the overall healthy trade relationship across the Atlantic.

We are still far from where we should be. We need a longer-term, broader vision for our transatlantic relationship and to set our sights on a more ambitious goal. That overarching goal should be a barrier-free economic relationship between the U.S. and EU by the end of the decade. Already on the trade side, tariffs are gen-

erally low, averaging around 3–4%. We should put our energy into eliminating regulatory and investment barriers.

In achieving this goal, we not only need more active engagement of the U.S. and EU, we need a reinvigorated transatlantic business relationship. I was pleased to play a major role in creating, along with the late Ron Brown, the Transatlantic Business Dialogue (TABD) in 1994. Its purpose was to create business/government cooperation across the Atlantic. However, in recent years, the TABD has not played the essential role it should, because governments on both sides of the Atlantic have not given it the attention it deserves. We now have an opportunity to change that picture. Douglas Daft, Chairman and CEO of Coca-Cola, and Niall Fitzgerald, Chairman and CEO of Unilever, have agreed to serve as new Co-Chairs. In addition, Secretary Donald Evans has committed to a major effort to assure that TABD recommendations are given serious consideration. The European-American Business Council is being reinvigorated, and along with TABD, can play a major role in helping to achieve the goal of a barrier-free transatlantic economic space.

MRAs: Mutual Recognition as a Way to Achieve a Barrier-Free Transatlantic Economic Relationship

I would like to highlight up front what I consider to be a crucial factor for improving U.S.–EU regulatory cooperation: advancing the principle of mutual recognition. Because both the U.S. and EU share high health, safety and other technical standards, and because regulators on both sides of the Atlantic generally have confidence in their counterparts across the Atlantic, the U.S. and the EU should, in my view, focus heavily on expanding recognition of each others' regulatory processes. Broadening mutual recognition between the U.S. and EU will lower costs for U.S. and European companies, streamline product development and enhance productivity on both sides of the Atlantic. Enhanced mutual recognition could serve as a key step toward realizing what in my view should be the ultimate goal for U.S.–EU bilateral trade: a barrier-free transatlantic economic space.

One of the key early benefits of the creation of the TABD was the development of mutual recognition agreements, or MRAs. The basic concept behind MRAs was the simple proposition that products could be tested once and considered to have been tested in both markets. MRAs generally allow procedures for product assessment—such as testing, inspection, and certification—to be performed in the United States and Europe that recognize each other's standards. MRAs operate through confidence in each side's regulatory capabilities and reliance on each side's inspections and the exchange of inspection reports.

In 1998, the U.S. and EU completed MRAs covering multiple sectors, including telecommunications and information technology equipment, pharmaceuticals, and medical devices. These markedly reduce business costs of duplicative tests and inspections. Although the emergence of MRAs in the late 1990's raised hopes of an advancing trend, momentum has since stalled. Indeed, while serving in the Clinton Administration, I observed first hand some of the obstacles facing cooperative efforts such as MRAs operating within regulatory systems that are overwhelmingly domestic in focus. In the pharmaceutical sector, for example, the FDA was consistently suspicious of the capability of some EU Member States to oversee high pharmaceutical standards in laboratories. A related obstacle on the European side is the EU's inclination to regulate at the European level, only to leave enforcement to Member States, which often results in different levels of enforcement and different treatment of European and U.S. companies.

Encouraging greater confidence in regulatory systems across borders, together with a renewed momentum for MRAs by expanding their reach into as many sectors as possible, would significantly contribute to U.S.–EU cooperation in regulatory matters.

But this will never happen if matters are left solely to individual regulatory agencies, which have a domestic, rather than international, focus. Agencies need strong White House direction to engage in regular sustained dialogue with their transatlantic counterparts in order to achieve a level of confidence in each other's regulatory processes. This, in turn, will help promote mutual recognition.

The business community, through TABD and EABC, needs to be proactive in suggesting to governments on both sides of the Atlantic ways to achieve greater mutual recognition. There is a recent example, in the area of financial markets, of ways in which mutual recognition can be used to make progress.

Understanding that a transatlantic capital market cannot function efficiently without a genuinely cooperative regulatory approach, the U.S. and EU have undertaken productive discussions on at least two key issues for financial markets: resolving the application of Sarbanes-Oxley to European companies and harmonizing U.S. and European accounting rules. But these are only first steps to what should be our

ultimate goal—a barrier-free financial market, which would encourage robust competition between European and U.S. exhanges.

I applaud the initiative of the International Accounting Standards Board (IASB) and the Financial Accounting Standards Board (FASB) to facilitate a convergence process between U.S. GAAP and EU IAS accounting standards—such efforts will help to eliminate barriers such as the EU requirement that all companies listing on a European exchange adopt IAS standards by 2005. Similar application of mutual recognition could also help to resolve the current unhelpful stance of the SEC in placing "trading screens" on the U.S. market for foreign companies; given that European standards are comparable to U.S. regulation of the financial markets, a targeted accommodation by the U.S. in this instance would help to support transatlantic market access without harm to investors. Under the leadership of EU Commissioner Frits Bolkestein and Paul Volker, former Chairman of the Federal Reserve, a great deal of progress is being made. In effect, each side would recognize the adequacy of the other's accounting standards, the concept of "equivalence" as Commissioner Bolkestein calls it.

Moreover, even where mutual recognition of regulatory standards may not be achievable, cooperation is nevertheless advanced by pursuing workable solutions, such as current talks seeking to clarify the application of Sarbanes-Oxley rules to European companies, requiring European auditors to register with U.S. authorities. The EU sees the application of Sarbanes-Oxley to European firms as extraterritorial, while the US sees the law as a legitimate post-Enron effort to assure the adequacy of audits of companies that choose to list themselves on a U.S exchange. Here again, EU Commissioner Bolkestein is working effectively to find a solution, this time with William McDonough, Chairman of the Public Company Accounting Oversight Board (PCAOB), and William Donaldson, Chairman of the SEC. Reasonable deference to European inspections of European auditors could clear the way for an agreement. Creatively, Mr. McDonough has suggested a joint registration, in which firms would register both with their national authorities, and with the PCAOB, and there would be joint U.S.–EU inspection of auditors outside the U.S.

Just as MRAs can serve as a positive model for improving regulatory cooperation between the United States and European Union, we also have available, unfortunately, numerous unhelpful examples.

A Step in the Wrong Direction: The EU Chemicals Directive

One particularly timely example of a regulatory step in the wrong direction is the current EU proposal for regulation of the chemical industry, known as REACH or Registration, Evaluation, and Authorization of Chemicals. The REACH proposal requires manufacturers and importers of chemicals, or products containing chemicals, to register their products with the newly-established European Chemicals Agency and to provide information on hazard, exposure and risk for 30,000 new and existing substances that are produced or imported in yearly quantities exceeding one metric ton. Evaluation requires regulators to assess risks for 5,000 substances that are produced or imported in yearly quantities exceeding 100 tons, and also for substances in lower quantities if they are "of concern." Authorization applies to substances of "very high concern," for which specific permission would be required for certain uses. In addition, "downstream" users would be required to carry out additional testing if the exposure or use of a covered product exceeds that foreseen by the manufacturer. The European Commission appears likely to adopt its proposed regulation at the end of October 2003.

Candidly, the current REACH proposal represents exactly the kind of top-heavy, non-risk based regulatory approach that only impedes progress on EU–U.S. cooperation in regulatory matters. In particular, the EU should streamline the authorization process, which will be dominated by EU Member States who could regulate similar substances in different ways, to ensure that the system is practical and efficient, while still protecting public health and the environment. One method for streamlining the process is through a more risk-based approach that would expand the regulatory focus beyond intrinsic hazardous properties to include the potential for exposure to the environment. Similarly, more comprehensive exemptions should be made available for substances whose chemical structures or uses pose low health and environmental risks.

The public comment period for the REACH proposal was welcome, something not often seen with EU regulation. It elicited over 6,000 comments worldwide, most negative. These comments have led to some changes in the revised draft, like the temporary exception of polymers. However, the revised September draft continues to have some of the basic flaws of the earlier draft and imposes heavy costs on the chemical industry and downstream users. The REACH proposal represents a retreat

from risk-based scientifically-oriented regulation and thus is a significant step in the wrong direction for US-EU cooperation in regulatory matters.

Trade Barriers

Both the U.S. and EU impose numerous barriers to the free flow of transatlantic trade. The EU's longstanding moratorium on approval of Genetically Modified Organisms or GMOs in food products has cost U.S. farmers hundreds of millions of dollars in lost sales annually in the EU. When I was U.S. Ambassador to the European Union, I was involved in helping obtain EU approval for GMO products like ROUNDUP READY soybeans. But unrealistic fears of GMO products by the European public has blocked approvals for several years of other safe GMO products. The EU moratorium is devoid of any scientific basis and, in my opinion, violates WTO requirements. I applaud the initiative of Bob Zoellick, the United States Trade Representative, to initiate the WTO dispute resolution process against the EU.

But the U.S. is hardly blameless. We have adopted measures that are also questionable and restrict European trade. The unilateral imposition of tariffs on steel products from Europe and other nations seems to have been based more on good politics than good policy. We rejected tariffs in the last year of the Clinton Administration. A WTO panel has found they violate WTO rules. A recent U.S. government study has found that while these tariffs have helped the steel industry, they have damaged a far broader group of steel users, including the U.S. auto industry. They should be terminated at the earliest possible moment.

Likewise, the "Fly America" requirement imposed on U.S. government travel limits travel options for hard-pressed senior U.S. officials, and is increasingly dubious in an area of transatlantic airline alliances and international code-sharing. In addition, both sides maintain restrictions on the ability of professionals to practice in each others jurisdictions.Investment barriers

We should also work to eliminate investment barriers that limit investment by U.S. companies in Europe and European companies in the U.S. We limit foreign investment in areas like airlines and in the broadcast sector. These restrictions are generally antiquated in an increasingly integrated transatlantic market. Likewise, the "Buy America" provisions included in the House version of the Fiscal Year 2004 Department of Defense Authorization Bill undermine current efforts to remove remaining barriers and prevent the Pentagon from having the greatest flexibility to purchase the best product at the lowest prices.

There are obviously legitimate international security concerns with foreign investment in general and European investment in particular in certain limited instances. The Exon-Florio Act and the CFIUS process reflect these concerns. But Exon-Florio has been used to block foreign investment only in a few instances. However, we must make certain that Exon-Florio is not used inappropriately. My recent experience is that a few U.S. agencies would like to bar all foreign investment in "critical infrastructure," even presumably from companies in allied European countries. This would be a serious mistake and must be avoided. September 11 should not be used as an excuse to impose new barriers on European investment.

At the same time, we must work hard in a post-9/11 environment to balance national security interests with maintaining open U.S.–EU commerce. This presents a challenge to new areas. First, the U.S. is requiring extensive passenger reservation data, which conflicts with EU data protection laws. Hopefully, the EU can provide a derogation from these laws if it gets reassurance form the U.S. about the scope of the data required, limits on the time it would be stored, and use only for the war against terrorism.

The second conflict is with the U.S. demand for inspection of containers at the ports of EU Member States. The U.S. has signed a number of bilateral container agreements with individual Member States without recognizing that the European Commission has legal competence in this area. The 1997 U.S.–EU Customs Cooperation Agreement could be expanded to address container security issues.

Closer Antitrust Cooperation

The U.S. and EU should strive to achieve the same results in major merger/acquisition and competition cases in order to avoid the uncertainty and inefficiency to business occasioned by differing results. Our marketplaces are similar, and our antitrust outcomes should reflect these similarities. One setback for U.S.–EU cooperation in regulatory matters arose from the EU decision to block the merger of General Electric and Honeywell approved by a U.S. antitrust authority, using a "bundling" concept that could make it difficult for companies to offer a range of products. In the Boeing-McDonnell Douglas case, the merger was approved by both competition authorities, but with substantially different terms required by the EU, causing transatlantic tension. Sensitivity to U.S. competition authorities in this instance—

where the investigation focused on two U.S. companies—would have been warranted and would have avoided harm to U.S.–EU efforts to advance transatlantic competition relations. Similar sensitivity should be exercised by EU competition authorities in their investigation of Microsoft, particularly when proposing the very remedy—the unbundling of Microsoft's Media Player software and its Windows operating system—that U.S. authorities had considered and rejected. The same approach proposed by the EU was rejected by Judge Kollar-Kotelly, the District Court Judge who approved the settlement. In rejecting the approach of the minority of states whom the EU seems to be following, Judge Kollar-Kotelly stated that "unbundling" would cause "clear and certain harm to the entire personal computer ecosystem." The EU's proposed remedies create significant inefficiencies and could threaten growth in the Information Technology sector because it would require Microsoft to ship one product to the EU and another to the rest of the world. I am aware of only one instance where the U.S. has disapproved of a merger approved by the EU, namely the Air Liquide/BOC/Air Products merger.

Greater sensitivity in both instances would have found support in the 1991 U.S.–EU Agreement concerning application of competition laws. The 1991 Agreement affirmed longstanding principles of "comity" in antitrust investigations. At its core, this doctrine dictates that one party, in order to avoid conflict with the other, will recognize the important interests of the other party in exercising its jurisdiction, particularly when the substantive issues under review predominantly impact one party. Similarly positive for cooperation efforts was the establishment of a U.S.–EU antitrust working group comprising representatives from the U.S. Federal Trade Commission, the Department of Justice, and the European Commission. Progress has been made on mergers, as in the successful Solvay/Montedison-Ausimont transaction, in which divestitures were required on both sides of the Atlantic. Indeed, multiple mergers illustrate successful instances of U.S.–EU cooperation, including Imetal/English China Clays, Exxon/Mobil, and Halliburten/Dressor. But progress should be made in other areas of competition law that could further advance U.S.–EU cooperation in competition matters. US and EU competition authorities should aim to reach a convergence of views on key substantive issues (such as the bundling of complementary products and services) as well as procedures (such as the timing of the merger review process).

Conclusion

There are other areas where we can help create a barrier-free transatlantic marketplace. One example would be a U.S.–EU open skies initiative, given the recent legal competence of the European Commission to negotiate Europe-wide agreements. A liberalized transatlantic aviation marketplace is a worthy goal. By continuing to build on productive efforts—such as harmonizing competition and accounting standards, and expanding the reach of MRAs, while dealing with counterproductive efforts, such as the REACH proposal and Buy America provisions, we can further stimulate the already productive U.S.–EU relationship and take a major step toward creating a barrier-free transatlantic space.

Congress has a strong role to play in these areas. For example, former Senate Finance Committee Chairman Bill Roth was deeply involved in these issues. I applaud your initiative, Chairman Allen, and hope you will remain engaged with the European Commission and your counterparts in the European Parliament in working toward a barrier-free transatlantic market.

Senator ALLEN. Thank you, Ambassador Eizenstat, for your studied and cogent remarks. And we'll hear from the other panelists, and I will have some questions. But again, thank you, Ambassador Eizenstat, for your testimony.

Now we'd like to hear, and let me make sure we have the order here. Mr. Litman is next on our list. Mr. Litman, will you please proceed.

STATEMENT OF GARY LITMAN, VICE PRESIDENT EUROPE AND EURASIA, U.S. CHAMBER OF COMMERCE, WASHINGTON, D.C.

Mr. LITMAN. Thank you, Mr. Chairman. Thank you for having me back. I would like to request that my written statement is made part of the record.

Senator ALLEN. So ordered.

Mr. LITMAN. Thank you. I would like to echo in my remarks most of what Ambassador Eizenstat said and just make a few additional points.

Obviously, the U.S.–EU cooperation is critically important for members of the U.S. Chamber of Commerce and the business community both in the U.S. and the European Union.

Without regulatory cooperation, this market will suffer.

Regulatory cooperation between the U.S. and EU is also essential for continuous functioning of all multilateral and international bodies and for the global economy as a whole.

It does take place, regulatory cooperation exists in many forms, as outlined by government witnesses. It also takes place through associations like ours, within companies.

Sometimes regulators are unaware of the way we are interacting and actually supplying them with ideas and input that has been negotiated between companies and industries in the transatlantic marketplace. There is no shortage of interaction. The challenge for all of us is to have the political will to get the rulemakers and legislators on both sides to recognize that their actions immediately affect one integrated transatlantic market—enormous, integrated and very dynamic.

In economic terms, meaningful domestic regulations are increasingly hard to find. The fact that this market exists is testimony to regulatory cooperation. Our concern and the reason this hearing is so important is that past performance is no guarantee of future returns. We want this integration to continue. Our integration between companies, between businesses and industries, seems to have outstripped the duality of two regulatory systems to function with minimum friction.

I think it is instructive to look at the recent agenda of the European Council of Ministers in charge of business. Here are the points discussed: political agreement on regulating measuring instruments; regulation of drugs; regulation of detergents and political agreement; consultation on tourism; consumer protection and consumer credit. Each item affects numerous Americans interests. Each is potentially a huge boost to the economic growth in the U.S. and Europe or the source of friction. The question is whether there is a will in Washington and Brussels to take this into account in arriving at political agreement.

None of these discussions were developed through a process even remotely similar to the Administrative Procedure Act in the United States and that's all right. What matters to us is that we have a joint transmission mechanism between the two systems and it better be a low friction one, because as the automobile dispute and bananas and others have shown, technical debates become political traps.

I want to make one point from the point of view of our membership. We have no fear of European regulations. We frequently feel for Europe when it lurches into regulations.

The much-discussed chemicals policy is a good example of regulatory adventures that take our breath away. We have had similar impulses post-9/11 and we have discussed them a lot with our European partners. The main point for us is that cooperation does not require imposing regulatory models on each other.

Each model reflects the democratic choice of the policies on the respective side of the Atlantic, and we need to look beyond the political assessment procedures.

A better strategy may be creating specific funded mandates to enable our agencies to consider the impact on transatlantic actors and companies in each other's jurisdiction. It is important to be at each other's hearings or stakeholder consultations. It's even more important to be heard at these hearings, and that is the method of political will and done by legislators such as yourself.

We would also recommend that in seeking areas for regulatory cooperation, both sides would focus on policy areas where the rules are not being written or that the technologies involved have a two-way cutting edge. The hydrogen fuel initiative may be an example. The business community would also welcome an initiative to develop common guidelines for risk assessment of new technologies and materials.

We suggest that the key missing element in bilateral regulatory relations is willingness by Members of Congress and members of the European Parliament to ask hard questions of regulatory authorities about why they fail to accommodate shared transatlantic economic interests in dealing with regulations. That is the test from the business point of view. There will be many instances of failing to agree.

It is also important to make sure that U.S.–EU discussions of each other's rulemaking and legislative activities are conducted outside the World Trade Organization dispute settlement mechanism. Our relations with Europe are different than other nations and than anybody else in the world. We can take our coordination much further. Such hearings on regulatory cooperation are hard to imagine with any other region in the world, and we should recognize that.

Otherwise, we risk politicizing every discussion of standards and practices. Rather, we may want to consider setting up a number of panels that do not report to the World Trade Organization, which is ultimately about terrorism.

In effect, what we're advocating is beginning serious work on a bilateral agreement on the principles of rule making, common information exchange, and impact assessment.

One last point. The European Union is constantly changing, which is a challenge for all of us and it is very difficult to expect leadership in this matter from Brussels.

They are revising their own constitutional treaty, they are revising their checks and balances. They are setting up numerous new agencies, from cyber security to health to military procurement, and many others. Therefore, it is up to us, the United States, to offer leadership and to invite the Europeans to discuss the need for this agreement.

Let me make one more point, maybe by way of example. Even when regulators do a great job coordinating what they are doing, it doesn't mean that success is assured. A recent example is the discussions between the EPA and their counterpart in Europe on emission standards for diesel engines. Regulators used every consultation mechanism available, they discussed like standards for engine manufacturers both in the U.S. and Europe, produced very

much alike agreements on standards for emissions, and the Commission introduced it to the Parliament. And the problem is, they decided to amend it, giving no thought to the preceding process of regulatory cooperation. And now everybody is stuck with a political decision in the European Parliament. As far as we can tell, as far as our members tell us, it was not an issue of competing with an American company, it was done out of ignorance or out of inability to take into account the good work product of regulators.

The bottom line in all these discussions is that without supervision the agencies will not find it possible to cooperate. They need to have a mandate, they need to have funds and they need to have supervision and leadership, both from the White House and from the legislative bodies. Thank you, Mr. Chairman.

[The prepared statement of Mr. Litman follows:]

PREPARED STATEMENT OF GARY LITMAN

INTRODUCTION

I am Gary Litman, Vice President for Europe and Eurasia of the United States Chamber of Commerce. The U.S. Chamber is the world's largest business federation, representing more than three million businesses and professional organizations of every size, sector and region in the country. Tens of thousands of our member companies derive much of their business from trade with European partners, obtain their capital from European creditors and investors, and build their competitive edge on the basis of European supplies and human capital. Throughout the last decade, Europe accounted for half of total global earnings of U.S. companies, as measured by U.S. affiliate income.[1] The Chamber welcomes this opportunity to present its views on U.S. regulatory relations with the European Union [EU].

The fact that we discuss regulatory cooperation rather than tariffs and quotas reflects the depth of the Transatlantic market and its integral nature. With the possible exception of Canada, no other economic partnership affords companies opportunities to operate so efficiently, almost seamlessly in two distinct jurisdictions. An ever-improving U.S.–EU regulatory cooperation is important for business in order to preserve the enormous gains of the transatlantic market and prevent any frictions between the two systems from spiraling out of control.

In analyzing regulatory cooperation between U.S. and Europe, we proceed from the fact that the European Single market is of vital importance to American business. The EU is here to stay and grow and we welcome it. Next year will mark yet another transformation of the EU with the accession of ten new member states, a new Constitution, elections of a new and more powerful Parliament and a new college of Commissioners. Through this evolution, the EU will remain based on a social model and legal regime that are different from the United States and reflect the European democratic choice. We have no intention to advocate the importation of the European regulatory practice in the U.S. Nor do we wish our problems on our European partners. The business community is not advocating the creation of supranational regulators for the Transatlantic market. Our goal is to rid this market of duplicative or incompatible rules. Our ambition is to preserve the flexibility afforded by two highly sophisticated regulators without always having to fight off the next crisis in relationships over a specific product, standard, or procedure. In our view, this goal can only be achieved through political will and engagement by legislatures on both sides. It is up to the U.S. Congress and its counterparts in Europe to both compel and enable regulators to cooperate.

The next twelve months will see the reform of most European institutions. Please note in this regard a submission from the American Chamber to the European Union, AmCham EU, which represents many of European firms of American parentage, attached. This is the best time to show our commitment to regulatory cooperation so that in shaping their institutions, European have confidence that we mean business in regulatory cooperation.

[1] Joseph P. Quinlan, Drifting Apart or Growing Together? The Primacy of the Transatlantic Economy, Center for Transatlantic Relations, Washington, 2003.

U.S.–EU ECONOMIC PARTNERSHIP IS ESSENTIAL FOR GLOBAL GROWTH

As we mentioned in our previous testimony before this subcommittee, June 24, 2003, the U.S. commercial relationship with the European Union is unlike any other we have in size, complexity and degree of integration. Our extraordinary level of trade is only the tip of the iceberg of our commercial relations. Over 20% of U.S. exports in goods go to the European Union and Enforcean customers consume over 40% of American services. Although we export more to Europe, and Europe exports more to the U.S. than we each do anywhere else in the world, trade accounts for less than 20% of transatlantic commerce. U.S.–EUrope commercial relations are much more about investments and direct job creation in each other's markets than it is about trade. Consequently much of this trade is between parent companies and their affiliates.

Our immense level of investments in each other's markets validates that our commercial relationship is balanced, mature and very similar in structure.[2] Therefore, we do not lose jobs to Europe; instead we create jobs in each other's markets. Last year about one in twelve factory workers in the U.S. was employed by one of 4,000 European-owned businesses.[3] We have become responsible for each other's growth and prosperity.

It is therefore important to nurture the transatlantic economy and find all possible means to further develop it. European economists estimate that dismantling the remaining tariff and non-tariff barriers between U.S. and Europe would add about one percent to European GDP, accruing in perpetuity, or somewhere between 40 and 50 billion USD. Other studies suggested that the gains for the U.S. economy would be about 0.5% of U.S. GDP.[4] Expansion of the transatlantic marketplace would directly and immediately benefit millions of Americans and Europeans.

Beyond the Atlantic, U.S. and Europe economic partnership generates worldwide growth as the principal engine of economic development in the world. Conversely, a dysfunctional or underdeveloped U.S.–EU relationship would have far-reaching negative consequences beyond the Atlantic shores. The economies of the Middle East, Africa, Central and South America depend on a well functioning and growing U.S.–EUrope commercial relationship to develop their own economies. The multilateral consequences of this essential bilateral relationship are important to keep in mind.

Future Regulatory Cooperation Rests on an Honest Assessment of Past Efforts

Prior attempts by the U.S. and the EU to patch their differences and sign mutual recognition agreements have to some limited extent helped the transatlantic economy grow, but are far from being satisfactory. They focused on recognition of conformity assessment bodies in each other's jurisdiction and on guidelines for exchange of information between technocrats and enforcement agencies, for example, in antitrust and competition matters. The record of implementation of various regulatory cooperation agreements shows that cooperation only works when there is political will on both sides of the Atlantic. In other words, the role of Congress and European legislatures is critical to the success of any agreement on regulatory cooperation.

Political backing is essential in preventing regulatory divergence because domestic lawmakers and regulators generally do not take into consideration the impact of the rules they propose on foreign companies.[5] Domestic regulations often clash with the demands of international trade and investment, and foreign companies typically do not have a voice in domestic and regulatory processes. Non-cooperation on regulatory and legislative matters results in direct costs to companies and consumers, with the creation of duplicate and non-compatible rules on both sides of the Atlantic.

Frameworks for U.S.–EU cooperation exist, notably with the 1997 U.S.-EC Mutual Recognition Agreement [MRA] and its six "sectoral" annexes. However, these cooperation attempts appear to have yielded limited gains. Our members indicate two factors for the limited success of the MRAs: (1) the independence of the regu-

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[2] Gary Clyde Hufbauer, Institute for International Economics and Frederic Neuman, Johns Hopkins School for Advanced International Studies, Paper presented at a conference titled "Transatlantic Perspectives on the U.S. and European Economies: Convergence, Conflict and Cooperation", Kennedy School of Government, Harvard University, April 11–12, 2002.

[3] Hylke Vandenbussche *et al.*, "Enhancing Economic Cooperation between the EU and the Americas," Centre for Economic Policy Research, London 2002.

[4] USITC, "The Economic Effects of Significant U.S. Import Restraints," Publication 3201, May 1999.

[5] Gregory Shaffer, *Reconciling Trade and Regulatory Goals: The Prospect and Limits of New Approaches to Transatlantic Governance Through Mutual Recognition and Safe Harbor Agreements,* The Parker School of Foreign and Comparative Law, Columbia University, Columbia Journal of European Law, Fall, 2002.

latory agencies involved and (2) the lack of committed resources for transatlantic regulatory collaboration. We should also add the fluid nature of European institutions that are in the midst of a major reform due to enlargement and constitutional changes. We urge Congress to review the short history that led to the signing of the 1997 MRA and assess the limited successes and failures of this agreement. There is no need to reinvent the wheel, especially if the wheels we recreate will lead us in the same unsatisfactory direction.

We suggest Congress should review the roles played by: (1) the Federal Communication Commission [FCC] in the implementation of the 1997 MRA Telecommunications and Electromagnetic Compatibility annexes; (2) the Occupational Safety and Health Administration [OSHA], a division of the Department of Labor, in the implementation of the 1997 MRA Electrical Safety annex; and (3) the Food and Drug Administration [FDA] Medical Device and Pharmaceutical Good Manufacturing Practices annexes. Clearly where the U.S. Trade Representative [USTR] office was ahead of its time with compelling reasons to negotiate swift and ambitious agreements with the European Commission, U.S. regulatory agencies found the practicalities of cooperation much more questionable, and the resources unavailable.

BASED ON PAST EXPERIENCE, WHAT CAN WE REASONABLY EXPECT AND WANT?

The major problems for U.S. business are not found at the borders. They are not related to tariffs and quotas, which play a relatively minor role in U.S.–EU relations. Since American companies see themselves very much as part of the European economy and vice versa, it is the EU and Member State domestic regulations and public policies which concern us most of all. Internal regulations and practices directly affect U.S. economic interests at least as much as they crimp the business of European companies in the same jurisdictions.

As the EU is devising new and much strengthened regulatory agencies and centers of regulatory power, it is remarkable how little strategic coordination exists between most of the relevant U.S. and EU agencies. Among the many new agencies in Europe currently at different stages of development are the European Food Safety Agency, Cyber Security Agency, European Environment Agency, and Office of Harmonization in the Internal Market, the Joint Research Centre, the European Chemicals Agency and probably an intergovernmental defense procurement agency.

Having certainty that regulators on the transatlantic marketplace coordinate their regulatory activities in a transparent, strategic and efficient way would advance American business interests. Nothing could be more damaging to business than ad hoc regulatory forays in the new Europe driven by political expediency, the absence of regulatory benchmarks and a lack of understanding of how transatlantic business will be impacted.

It would be particularly valuable to build strong linkages during the process of establishing new regulatory bodies in Europe. The Transatlantic Economic Partnership [TEP] initiative, launched at the U.S.–EU Summit of May 1998 was to promote a more positive trade agenda. Among other lofty goals, TEP Action Plan should have improved the "dialogue" between U.S. and EU regulators. In the process, TEP proposed in April 2002 non-binding U.S.–EU guidelines on Regulatory Cooperation, which so far seem to have produced limited results and are in need of being energized. Priority agencies that need to develop better lateral coordination with emerging European counterparts include:

1. National Institute of Standards and Technology (NIST);
2. Food and Drug Administration (FDA);
3. Federal Communications Commission (FCC);
4. Environment Protection Agency (EPA);
5. Securities and Exchange Commission (SEC);
6. Department of Homeland Security (DHS);
7. International Trade Commission (ITC);
8. Federal Trade Commission (FTC);
9. Department of Energy (DOE);
10. Department of Transportation (DOT & FAA).

A vigorous and systematic dialogue between U.S. and European regulators similar to that in effect on anti-trust matters, thanks to the fairly successful Application of Competition Laws Agreement of 1990, would allow us to better understand the impact of European regulations and avoid the surprise in Brussels when a new draft proposal suddenly becomes another bone of contention with the United States. We need to look beyond conformity assessment. A better strategy may be a process of

sharing regulatory initiatives between agencies with a specific funded mandate to consider the impact on transatlantic actors and companies in each other's jurisdiction. It is important to be able to appear at each other's hearings or stakeholder consultations. There are some good examples of openness to this notion, including the recent Internet consultation on the European Chemicals Policy Directive. Attached is the U.S. Chamber's submission to the EU Commission and a set of comments from one of our members with broad interest in the matter. We were pleased to have the opportunity to comment. We would be even more encouraged if any of our comments were taken into consideration in the amended text to be released later this month. The proof will be in the pudding.

At the same time, we need to develop mechanisms that would guarantee consideration to each other's views that is commensurate to the important stake we have in the continuing growth of the Transatlantic market. We would also support recommendations by the Atlantic Council to encourage the U.S. Congress and the European Parliament to compare "best practices" in regulatory policy and rule-making, and to focus on policy areas where the rules have not yet been written or the technologies involved are truly transformative (e.g. the hydrogen fuel initiative).[6] The business community would also welcome an initiative to develop common guidelines for risk assessment of new technologies and materials.

No amount of regulatory cooperation will be sufficient without supervision by the legislative bodies. A recent example is provided by the Diesel engine emissions regulations in Europe. In this case the U.S. Environmental Protection Agency and European Commission have each proposed comprehensive new emissions standards for off-road diesel engines ranging from 50HP to 750HP. The respective regulations would impose a range of emissions limits for specific pollutants and implementation dates. The two regulators consulted at an early stage in European rule-making process. As a result, the Commission's Directive (COM (2002) 765) is aligned with EPA's proposed rules. Where discrepancies exist, such as between emissions levels, power categories, and implementation dates, the Commission has intended that a 2007 Technical Review, called for in its proposals, would further align the standards. Thus, the regulators have succeeded in coordinating sophisticated technical matters. Nevertheless, the European Parliament is now considering amendments that would put the Commission Directive further out of alignment with the EPA proposed rule. If passed, the amendments would require the use of different engine technologies between the U.S. and EU, resulting in two different engine and machinery product lines. Each machinery line would be more expensive because of the lower volume of production over which to recover fixed costs. European machines will be more expensive to produce and purchase and would be more expensive to operate. Environmental gains will be minimized as well, as the increased cost of new equipment will inhibit farmers and other equipment owners from converting from older, non-compliant equipment. A better understanding of the integrated nature of the marketplace by European legislators in this case would save millions to companies and consumers.

We hope that a strategic regulatory dialogue will soon lead to negotiations and strong mutual commitments between the U.S. and the enlarged European Union. In fact, the Chamber believes that it is time to start discussing with the European Union a way to negotiate a bilateral trade, regulatory cooperation and investment enhancement agreement, similar to the agreement currently under consideration between Canada and the EU, that would recognize the unique and highly integrated nature of our common business with Europe and establish clear ways of resolving regulatory differences. The transatlantic business community does not want the two regulating juggernauts to impede the exciting business opportunities that constantly emerge in our extraordinary shared marketplace.

This concludes my testimony.

Senator ALLEN. Thank you, Mr. Litman. You raised some good points, and I want to followup with you in questioning.

Now we would like to hear from Mr. Farmer.

[6] The Atlantic Council Bulletin Vol. XIV, No. 2, "Managing Risk Together: U.S.–EU Regulatory Cooperation," June 2003.

STATEMENT OF THOMAS L. FARMER, GENERAL COUNSEL, AMERICAN BANKERS ASSOCIATION, WASHINGTON, D.C.

Mr. FARMER. Mr. Chairman, as the last witness I will try to keep my remarks very very brief and ask that my short written remarks be entered into the record.

Senator ALLEN. So ordered.

Mr. FARMER. And I will not repeat any of the things I said there.

Let me commend you briefly for the inclusion of financial services in this discussion. Financial services have a very large and very unique role in national trade and it's not a good idea to treat them separately from the rest of the trade venture.

My written testimony was limited to process and to the exclusion of substance, mainly because the issues of substance are extremely technical and complex and not well discussed in a single hearing of this kind. But that doesn't imply that there are not major financial services regulatory issues that still need resolution.

I would especially point to the EU Data Protection Directive which has been discussed between the U.S. and the EU over a long period of time and no progress has been made as far as we can tell.

I did not intend to talk about convergence. However, Stu Eizenstat has made a very very good case for the idea of regulatory convergence and in the area of financial services that seems to us to be the way to go. He mentioned accounting standards, which is certainly an area where convergence appears to be yielding results. There are indications that Commissioner Bolkestein and Will McDonough are getting closer and closer to a joint way of dealing with accounting issues of various kinds, with Paul Volker as well, and in the financial services sector that could do a great deal. Our feeling is that the EU Data Protection Directive as far as financial services is a primary candidate for an approach of convergence.

Let me briefly summarize a few points I did make in the written statement, which is that in the financial services sector the cooperative mechanisms on regulation between the EU and U.S. are very far advanced. They have been in the last few years formalized to the point that both governments refer to these regular discussions as the U.S.–EU financial markets dialog and under that framework there are regular meetings at the cabinet levels between Commissioner Bolkestein and the Secretary of Treasury. There are meetings at the level of under secretaries and assistant secretaries, and an agenda which includes, of course, active participation by the SEC and the Federal Reserve Board, who have the actual power to make the regulatory adjustments. And that process has been going well and the industry is very much supportive of it.

However, we do see a few areas for improvement of that mechanism and that is that it really lacks transparency. Now, the negotiators or the discussants on both sides feel that the informality and fluidity of the process requires microtransparency. However, it seems to us that the timely input from industry is difficult when industry doesn't have a good idea as to what the agenda is or is going to be. This is especially true in looking ahead at developments, market developments that are not yet on the agenda, in an area like capital improvements where new instruments appear very quickly, and having the industry expertise of making forecasts

as to what may happen might well be useful, and we would think that consultancy, even an informal one, might help.

The other area that I join both of my colleagues here in urging more participation is in the area of the Congress and the European Parliament talking to each other and learning each other's regulatory philosophy. The European Parliament is expanding its powers very rapidly and will have a very major impact, and I think prevention of the sort of situation Mr. Litman talked about is very important, and it may be that a timely and regular contact at the congressional level rather than just ad hoc visits, which are useful, but might be improved upon.

So that, those are the main areas in which we think this process could be improved, but I want to say that the EU–U.S. financial markets dialog is a very good model and very promising. Thank you, Mr. Chairman.

[The prepared statement of Mr. Farmer follows:]

PREPARED STATEMENT OF THOMAS L. FARMER

Chairman Allen and Members of the Committee:

Good Afternoon, I am Thomas L. Farmer, General Counsel of the Bankers' Association for Finance and Trade (BAFT) an affiliate of the American Bankers Association (ABA). My testimony is on behalf of both BAFT and ABA.

First, I want to commend the Committee for holding hearings at this time on this subject. At a time when transatlantic political collaboration is strained, good economic relations become even more crucial. U.S.–EU regulatory cooperation is a central element in the transatlantic economic relationship, which merits special attention. Second, I would like to thank the Committee for inviting BAFT to testify about the financial services aspect of that relationship. I want focus my comments on a few aspects, which are unique to the financial markets.

In many respects, the transatlantic capital market is already an integrated market. There are numerous examples of U.S. and European firms competing actively and successfully in one another's markets. There is considerable data, which indicates that progressive steps to integrate these markets have served to lower the cost of capital both in Europe and the U.S.—thus benefiting economic growth on both continents. Furthermore, the financial service industry is a highly regulated industry on both sides of the Atlantic and thus highly sensitive to regulatory conflicts which may prevent effective cross-border activities by either U.S. or European firms. Finally, the regulatory framework for financial services has, in recent years, undergone far-reaching changes both in the U.S. and Europe. In the U.S., the regulatory landscape was dramatically altered by enactment of the Gramm Leach Bliley Act in 1999 and the Sarbanes-Oxley Act in 2002. Meanwhile, the European capital market is being restructured even more extensively and more rapidly than the U.S. market. U.S. firms and regulators are especially alert to detect and to hopefully prevent potential conflicts in regulatory architecture, which could hinder the competitiveness of U.S. firms in the European market.

In the development of a single European financial market, it is important to recognize that the integration of the capital markets has lagged behind the integration of other European markets. When the EU finally adopted its Financial Services Action Plan (FSAP) in 1999, efforts to create an integrated European capital market began to make significant headway. The self-imposed objective of the FSAP to develop a single integrated EU capital market by 2005 indicates the determination of the Commission and the member states to move forward expeditiously with this complex project. The plan envisages 43 separate legislative and non-legislative measures in banking, securities and insurance. Within the 2005 overall deadline, there are benchmarks for the completion of individual measures. Somewhat surprisingly, the EU has managed to keep pace with this ambitious timetable and has promulgated various parts of the FSAP much more rapidly than is normal for EU legislation and rule making.

The U.S. banking industry considers the FSAP highly beneficial for the European, U.S. and global economies and supports its objectives. At the same time there is the realization that "all politics is local" and that the primarily the FSAP is designed to address domestic European requirements. We were, nevertheless, pleased to see

that in a formal report released in June 2003, the European Commission emphasized the transatlantic and global impact of its policymaking on financial markets and urged that this aspect of its work receive special attention in the development of the next phase of policy. The cross-border impacts of the FSAP were well defined by the Commission report:

> Financial services are increasingly delivered on a global scale. The regulation and supervision of financial markets can no longer ignore the reality that measures taken by any country or group of countries may have consequences on business undertaken outside that jurisdiction. Measures intended for a purely domestic context may unintentionally require compliance by market operators in other jurisdictions with only a marginal or indirect presence in that jurisdiction.
>
> Bilateral regulatory dialogues on financial services may provide a means for managing regulatory spill-over that may occur in highly inter-dependent financial markets; especially with the EU's major commercial partner, the U.S.. We need to cooperate through a continuous and informal dialogue on how to enhance transatlantic integration of financial markets and how to deal with global financial issues.

As a potential victim of the "spill over" effect that concerns the Commission, the banking industry welcomes the Commission's call for regulatory dialogue with the U.S. on integration of financial markets and global financial issues.

Fortunately, there already exists a broad and sophisticated transatlantic dialogue on financial markets, which deserves the attention of your Committee. This transatlantic dialogue functions on several levels—i.e. among governments and regulators, among private sector financial firms and trade associations and among European Parliamentarians and Members of Congress. Furthermore, the governmental regulatory dialogue on financial services has been active and important for many years. Until recently, however, it was conducted largely as bilateral exchanges between Central Bank Governors and regulators in the U.S. and counterparts in EU member states. More recently, the EU Commission has become the principal partner of the U.S. in this dialogue on regulatory issues.

Even more importantly the U.S.–EU regulatory dialogue has become, in recent years, significantly deepened and institutionalized to the point that both governments now refer to this process of consultation officially as the "U.S.–EU Financial Market Dialogue." The U.S. Secretary of the Treasury and the EU Commissioner responsible for the Internal Market and Taxation lead the Dialogue on the Cabinet level. At the working level, senior officials of the Treasury, the Federal Reserve and the SEC coordinate U.S. participation. On the European side, the participants consist of the Director of the Internal Market and his staff. At present, the Dialogue appears informal and open ended and additional issues are put on the agenda as required. Consultations in this framework have become more frequent so that currently formal dialogue meetings, at one level or another, occur four or five times a year.

Consultations on regulatory issues have also intensified among U.S. and European banks. For some years, the President of the ABA has met twice yearly with the heads of the national banking associations of the OECD member countries and the European Banking Federation. Progressively these consultations have focused on U.S.–EU regulatory issues to the point where recently the group has issued joint statements on important regulatory concerns. Additionally, BAFT's European Advisory Council was, in part, established to start a facilitate a discussion of transatlantic regulatory concerns encounter by both our European member bankers and the BAFT Board of Directors, who are practicing bankers, in their day work experience. Then jointly advocate agreed solutions to the respective governmental bodies in both the U.S. and the EU. To a limited extent the transatlantic dialogue on financial services has also included discussions between the U.S. Congress and the European Parliament. However, these contacts have been essentially limited to a few members of the House of Representatives and members of the European Parliament's Economic Monetary Affairs Committee. The European Commission continues to encourage expansion of these parliamentary contacts but so far discussions in this forum are not very substantive or regular.

In conclusion I want to say that while the transatlantic dialogue on regulation of financial services is going well, it could be strengthened. Although the U.S.–EU Financial Market Dialogue is still in its early stages, it has already influenced awareness regarding the regulatory philosophy prevailing on the other side. Additionally, the governmental dialogue appears to have brought about a certain level of regulatory convergence, which the financial services industry certainly welcomes. It must, however, be noted that the agenda and the thrust of the consultation has lit-

tle transparency. The governmental participants appear to feel that this is necessary to preserve informality and fluidity in these talks. Nevertheless, this lack of transparency makes it difficult for the private sector to make a contribution to these talks. Both parties to the Dialogue have indicated a desire to consider issues or possible areas of conflict, which have not yet become the subject of legislation—whether in draft or enacted. Such anticipatory discussions are particularly useful in avoiding regulatory conflicts, which impact the private sector. But it is precisely in this area where the private sector, with its sophisticated knowledge of business trends, can make a uniquely useful contribution. A process of informal but structured consultations with the private sector might be a way for governments to access private sector knowledge without encumbering the governmental consultations. As for strengthening the dialogue between Congress and the European Parliament it is our view that familiarity with each others regulatory architecture and philosophy might well contribute to avoidance of conflicting legislation not only with respect to financial services.

Senator ALLEN. Thank you, Mr. Farmer.

I'm going to make some observations here and ask some questions and maybe followup on some of your comments. All three of you all and others have mentioned the importance of having dialog with the parliamentarians, the European legislative branch with our Federal legislative branch, and you make a good point. Mr. Farmer stated a prime example of them, and rather than ad hoc efforts. I have found in my discussions, and there haven't been many, but the few I have had with leaders from Europe is that you can talk things out, you can discuss them and say why do you do this this way. I mean, you can be forthright, you have to be diplomatic, but you really can just discuss things, haggle them out and get their perspective instead of reading about it, and everybody gets a more particular understanding of the other's point of view.

So I think, Mr. Farmer, Ambassador Eizenstat and Mr. Litman, and others have made that comment and that's probably something that we can do out of the Foreign Relations Committee and would be a natural for be to start that, as the chairman of the European Affairs Subcommittee. It would seem to me that we would all benefit from that, and we will discuss things of common interest as well as some of the areas that have been discussed today. I thank you all for that idea, which I think is an important one.

Ambassador EIZENSTAT. May I just comment on that one second?

Senator ALLEN. Sure.

Ambassador EIZENSTAT. First of all, particularly under the new constitution which is going to be passed by the end of this year, the European Parliament has become a real power, it has real powers, it has increasing budget powers, it has real legislative powers over the Commission's recommendations, so it's a real body, it's a real legislative body, which one would not say was the case 10 years ago.

Second, with the exception of some members like Former Chairman Ben Gilman when he was chairman of the Foreign Relations Committee on the House side and now Jim Kolbe and a few others, the only sustained dialog that occurs is on the House side with a few members. It doesn't include Ways and Means, it doesn't include a broad swath of Foreign Relations, and it has never included the Senate. The Senate has a dialog with NATO over in the Atlantic Council but not with the EU.

So if you could initiate this, it would really have a dramatic effect, because when something like the chemical directive goes to the Parliament as it probably will by the end of October, the Par-

liament is going to have to decide whether to try to improve it by amending it. Without having any contact between our Congress and their Parliament, they don't hear what they need to hear, so I think it's a tremendous idea and if you did that, I think it would be extremely well received by the European Parliament. And you could combine your visits by also meeting with the commissioners, the executive arm of the EU.

Senator ALLEN. Thank you, and we will try to do that. I think that's where we have to refer to, Mr. Litman, their efforts to amend it and improve it, and it would strike me as they pass their laws, they call them laws, we call them regulations, but you would think that they would take into account what the economic impact of these regulations are. You take for example, not just with the chemical matter but the other, which Mr. Litman brought up on the diesel standards.

On the diesel standards it strikes me as common sense that you're going to have the same standards for the diesel engines, just for the quantity, the mass production, instead of having a diesel engine, low polluting diesel engine for Europe and a different one for the United States, as many diesel engine are manufactured by Mercedes, Volkswagen or whomever, they make good diesel engines, as well as Volvo, General Motors, Ford and so forth, it would just seem to me so logical for them so say well, how is this going to help you, how will this make our diesel engine, European manufactured diesel engines exportable and usable in the United States when it is such a big big market.

Europe is a big market for us, the U.S. is a big market for them, and it's hard for me to believe that they wouldn't take that into consideration or that in the body of the Commission's findings they did not bring up that harmonization or the symmetry of similar standards so that it would fit into the U.S. market. Are those considerations not taken into consideration by the European Union's Parliament when acting on these? Do they not hear from those who actually manufacture diesel engines that this is going to increase the cost if they have to manufacture two diesel engines as opposed to one that meets improved air quality standards for people in both countries?

Mr. LITMAN. Mr. Chairman, in this particular case actually, the European Commission did its homework and proposed setting up a standard that is fully aligned with the EPA proposal. The problem is that the argument that we have negotiated this with Americans does not sound like a compelling argument to many members of the European Parliament.

Senator ALLEN. Well, that's understandable. They respect their sovereignty. Of course, they've given up some of their sovereignty by creating the European Union.

Nonetheless, they have the right, clearly, to control their own destiny. And I could imagine the same in this country, that because the Europeans want to do it this way, that probably wouldn't be all that compelling an argument for us.

What would be a compelling argument, I'll speak only for myself, would be the fact that if we do have this symmetry in this regulation or this rule or this law, or this standard, this means that some company in Ohio, or Kentucky or Virginia, or Georgia, they will be

able to manufacture that engine and that engine could also be sold in all 25 countries of the European Union, to me that makes sense, it's just logical.

Was that not made as an argument that if we have this, these engines made in Bavaria or Bonn, or wherever it may be, could be sold into the United States?

Mr. LITMAN. My answer is yes, the argument has been made and what happens in Europe is the European Parliament is not as material an institution and well adapted to accepting input as the U.S. Congress or national legislations within Europe.

What frequently happens is, because they frequently act in a rush result without a lot of staff work, the members of the European Parliament tend to play to particular constituents that are far removed from the economic realities of the country that elected them. And we have to work both with the members of the European Parliament and with member states so that ultimately at some point we can make that point and when I say we, it's American and European businesses together.

So we go to the governments of Germany and France and Holland and Britain, and make the same point. When the issue comes up from the Parliament back to the heads of state on the council, we will be able to have another chance to make the case for economic growth of one transatlantic market.

But instances of operating in a vacuum within the European Parliament still exist and it's one of the reasons we want them to come here as frequently as they can, and we want to go visit with them as frequently as we can. It's a new institution, they are still feeling about for themselves, frankly, and it will get enormous new powers a year from now.

This is a critical moment to engage them. They hear from industry, they hear from various radical environmental groups.

It's difficult for them to discriminate to do the analysis since they don't have the mechanisms for that. And they don't have the processes of hearings like you do.

So you are absolutely right. The case has been made but at the same time, nothing can take the place of direct legislative comment like you offered to me, what do you mean by this. That would take it a long way.

Senator ALLEN. Well, you know, some of the conflicting and the arguments of different groups and individuals who have strongly held beliefs, that's the vibrancy of representative democracies, and there are times when I wonder why the heck we pass some regulations that don't take into account the impact on a small business or on jobs, or the competitiveness of a state or for that matter our country. It's best that we try to understand in each country, and in Europe that they do have different points of view and people think differently, even within countries obviously.

These are free countries where people think freely. Some of the demonstrations they have are really something, on the Champs d'Elysee and elsewhere when it comes to the agricultural interest.

Let me go through some other points here. Ambassador Eizenstat, you were right insofar as, in my observations on the White House being involved. And obviously right now we have so many key issues with the war on terrorism; trade and jobs obvi-

ously are very important. I know Secretary Snow personally well, and he is certainly making a great effort, as well as Secretary Evans. But in other cases that I won't get into, but in private conversations, it's interesting what President Bush has shared with me in some of the issues that he has been advancing, with Russia and poultry, for example. The President is concerned about poultry from Russia and that matters a great deal. Sometimes those countries really don't understand our standards of cleanliness and health. And it is important as best we can just listen to President Bush as he was advocating—and I don't want to breach any confidences, but I know that he has worked hard, I will say that, as far as U.S. poultry into Europe.

And suffice it to say, your point is well taken that sometimes even if you do have staff, not in my case, but sometimes staff doesn't give you the accurate information to make decisions, and so sometimes the leaders do need to talk face to face with one another on some of these trade issues.

You might say, oh wait a second, he said this, you get some questioning that you might not otherwise have.

The other issue that came up from Ambassador Eizenstat and Mr. Farmer had to do with accounting standards. And from some of the hearings we did have with a European member on the accounting standards, I thought they were clearer in understanding the issue of stock options than people in this country. I think generally accepted accounting principles ought to be generally accepted and there is no generally accepted way of accounting for the value of stock options, or the value of stock options, which may be a great deal or may be nothing. It just depends. And listening to the European leader at a bipartisan hearing, the European gentleman seemed to understand it better than ours.

And you listen to the comments here of 6,400 different e-mails, it wasn't on stock options, but on another issue, it strikes me in some cases that the European Commissioners listen more closely to reality and the real will of the people than some of our folks supporting the Federal accounting standards in this country. So we may be actually helped by the Europeans' more logical realistic approach on stock options than some of the hysteria and harmful ideas that seem to be being pushed forward in this country.

The other issue that I wanted to do bring up with you is, how do you see this stock option issue, if you feel comfortable, Mr. Ambassador or Mr. Farmer? I know this is a financial matter and is not exactly a banking issue, but where do you see this issue of stock options whether you attempt to expense them, how do you value them and so forth going forward in the European Union?

Mr. FARMER. I will pass on that.

Senator ALLEN. Mr. Ambassador, if you have any insight, we would welcome it.

Ambassador EIZENSTAT. Let me just address a couple of the questions you mentioned. First on the White House involvement, most of the agencies in our government are either formally or informally independent regulatory agencies, FCC, the FDA, and so one has to be careful about the degree to which you mandate that they do certain things because they are independent. But without the kind of White House direction that we try to provide to encourage them to

talk to their counterparts and to recognize the fact that they can accept the standards and certifications at least to our standards, they simply won't do it. So they need to be pressed, they need to be pushed. It's not a President's job to do it but it is his staff's job to do it, and they need to be encouraged to think transatlantically.

Second, with respect to accounting standards, I think that what Commissioner Bolkestein is working toward is not that they would be identical but that they would converge sufficiently so that we could each say that they are substantially equivalent and we would be willing to accept theirs and they would be willing to accept ours as a condition, for example, of going onto the exchange or being listed, or the adequacy of auditors.

Senator ALLEN. Would it not be the case though, Mr. Ambassador, that if they had standards, that should certainly be the case, but if we had standards that were more restrictive, for example on the issue of stock options, it could make those companies more attractive or less attractive?

Ambassador EIZENSTAT. That is true.

Senator ALLEN. And whether it's in Europe or for that matter Asia, it's not as if the whole focus is on Europe, but there is a great deal of growth in entrepreneurship in east Asia and we could lose investments.

Ambassador EIZENSTAT. This is clearly one of the areas where they will have to try to see if they can reach some understanding. I'm not able to say where they are going in Europe. I think in the United States there is a slow trend toward expensing but there is a broader recognition that it is very difficult to value options, and this is certainly an area where there ought to be convergence. I don't think we should have one area of the Atlantic where we are expensing them and one area that they are not, so I think there is a need for convergence there. But I think that with Paul Volker and Bolkestein, I think there is significant progress in trying to get their accounting standards and our GAAP standards to a line that we will be close to being able to say they are equivalent enough to recognize each other's standards.

Senator ALLEN. Mr. Farmer, let me ask you a question on the Fair Credit Reporting Act, which we must act upon and renew before we leave here in the House and Senate this year.

How do you see—you were mentioning some of the data protection and privacy type issues. How do you see the Fair Credit Reporting Act in this country, and I assume you want to make sure we get it passed, but how do you see that converging, or the symmetry there?

Mr. FARMER. It's a vital building block if it's renewed without major changes and with the Federal preemption, which appears to be in the works, that's very important. However, the discussions with the Europeans, the issue with the Europeans is whether or not—their law provides that data from European consumers may not be exported to countries that don't have a "adequate standard of privacy" and the Commission has the authority to say it's adequate.

Senator ALLEN. Do they consider our law——

Mr. FARMER. Not adequate, and this debate has been going on for some time. And even before the FCRA became close to expiring,

they were still saying it's not adequate. The rationale as far as we can see, especially in financial services, is very difficult to understand. We do think this is a question of convergence, it's not identical to their privacy standards, but in the last 6 months or so these discussions have really been put on ice, because part of the European argument has been well, we don't even know whether FCRA is going to survive into 2004. So passing this Act should renew the ability to go back to the table to discuss the convergence.

And again, as Stu said, we're looking at standards which are very very similar, trying to accomplish the same thing but aren't identical, and our contention has been that the FCRA is essentially a counterpart to what the Europeans use.

Ambassador EIZENSTAT. I would say, Mr. Chairman, that what we did in the Clinton administration when David Aaron was Under Secretary of Commerce and took the lead in this negotiation, was to create a so-called safe harbor for data privacy so that the EU in the end said that our regulation was sufficient, it was not the same, but it was sufficient for them to create a safe harbor and not to apply their restrictions to us. That did not get extended into the financial services area but the concept was very similar to it.

Mr. FARMER. And that concept with some modification needs to be worked out and is a very important area. In general, though, this is not a financial services issue. The European thinking on privacy in many ways is different than ours and certainly also, some of the other areas such as security are contentious. So again, I think this is an area where informal discussions between Members of Congress and the European Parliament may help bridge a conceptual or cultural gap about what are we all trying to do with respect to privacy, what are appropriate limitations.

Ambassador EIZENSTAT. We also have this coming up on the war on terrorism because the U.S. is requiring detailed passenger list information and this puts the European airlines between that request and their own privacy laws. But here again, what Bolkestein is trying to work out, and is making some progress, is that if the U.S. will agree, A, that passenger lists will only be used on the war on terrorism, and B, that they will only be stored for a certain period of time and then they would be destroyed, and C, that scope would be more limited, than perhaps that can be provided as an exception.

Senator ALLEN. I'm certainly aware of security concerns affecting travel and tourism to this country, I'm not saying that everything is an economic bottom line, but security and safety are vital, and we've tried to do things in a way that do not have an exceeding, or can have an exceedingly adverse impact on our travel.

We'll finish off with one final question to Ambassador Eizenstat. We brought up the Microsoft case. During your time in the Clinton administration, you were discussing some of the matters you went through, and also the history on our side as far as starting and stopping the mergers. The point is, you have been involved in a number of competition disputes between the United States and the European Union, including most recently the McDonnell Douglas-Boeing merger. Do you see the Microsoft case as being different than those cases?

Ambassador EIZENSTAT. Those cases were merger cases, whereas this is a competition case, but the principle should be the same and that is, we should be trying to reach a convergence. The U.S. process with Microsoft took 5 years with two administrations. There was finally an agreement with the majority of states, nine states, later two, then one, ended up appealing. The basic concept that the judge accepted in the Justice Department decision with Internet browsers was that there did not have to be an unbundled separation of the browser from the basic software package, it did not have to be sold separately, and indeed it would be inefficient to do so.

Now in the third statement of objections with the Media Player, a very similar concept, is suggesting it has to be taken out. And this, I think leads to the kind of divergence which is very unhealthy and it would Microsoft to having to develop and distribute different versions of its Windows in the U.S. and in Europe. I don't know any other case where the remedies specifically rejected in the U.S. was able to be imposed as a requirement in the EU.

So in some respects this almost goes beyond some of the other merger cases, so it's a competition case and it sets up a very serious precedent.

Senator ALLEN. Thank you. I want to thank each of you,

Mr. Litman, Mr. Ambassador, Mr. Farmer, thank you for your patience, thank you for your testimony and your insight and your good suggestions, and we will follow through with them in this European Affairs Subcommittee. Thank you.

The subcommittee is adjourned.

[Whereupon, the hearing adjourned at 4:38 p.m.]

APPENDIX

STATEMENT SUBMITTED BY THE AMERICAN CHAMBER OF COMMERCE TO THE EUROPEAN UNION (AMCHAM EU)

EU–U.S. REGULATORY COOPERATION AND THE "BETTER REGULATION" INITIATIVE

Effective cooperation between America and Europe on regulatory affairs is crucial for American businesses operating in the EU. The mechanisms laid down in the 1998 EU–U.S. Guidelines on Regulatory Cooperation and Transparency, while positive, have not yet achieved their goal. Tensions on chemicals and on airline data, for example, are testament to this. We would like to see greater commitment from players on both sides of the Atlantic and in varied parts of government to build cooperation. In this context, it is important to be aware of the EU's evolving debate on regulatory processes. The EU institutions, led by the Commission, have undertaken a comprehensive look at current governance procedures and made concrete proposals for future reform. These will continue to be worked over the coming years. In this paper we give background to this debate and to the American ChaAmCham EU's involvement and positioning.

The EU Governance Debate and the "Better Regulation" Initiative

In 2001 the Commission issued a White Paper on Governance in Europe, leading to a wide debate between all stakeholders in the European regulatory environment. AmCham EU played an active part in this process, realizing that a more balanced, transparent and coherent regulatory process was critical for U.S. businesses seeking to engage in discussions on legislation that affected them. The outcome of this debate was the "Better Regulation" initiative.

The initiative consists of two packages of communications published in June and December of 2002 and addresses a number of objectives identified by the business community. In its recent position paper on the initiative AmCham EU expressed broad satisfaction with the work undertaken by the Commission. Both the objectives and the proposed action largely coincided with AmCham EU's consistent call for wiser regulation, basing the choice of policy instruments upon clear and transparent rules, systematic impact assessments, better coordination of community initiatives, objective justification for policy choices, adequate and timely consultation and better implementation and enforcement of existing legislation.

The challenge for business and other stakeholders now is to hold the European Commission to its promises. AmCham EU welcomes the Senate's commitment to regulatory cooperation and transparency in its cooperation with the EU. We hope that the Senate will work with us to achieve a full implementation of the "Better Regulation" Initiative.

AmCham EU saw six areas of the initiative as critically important.

1. Communication on a reinforced culture of consultation and dialogue[1]

In this document the Commission seeks to establish general principles and minimum standards for consultation with all stakeholders—including governments and business—in all major new EU initiatives. The key elements in the document are:

- the assertion that that the guidelines, while not legally binding per se, will be de facto binding on *all departments* of the European Commission (Directorates-General);
- the obligation for all Directorates-General to report on progress implementing the consultation principles and minimum standards as part of an annual report on "Better law-making";

[1] COM (2002) 704.

- a call on interest groups to monitor the Commission's progress;
- the timeframe for comments. For the majority of proposals, this will be eight weeks. Feedback to comments received will be provided through the explanatory memoranda accompanying legislative proposals. In addition, the results of consultations undertaken in conjunction with the impact assessment process will be summarized in related reports.

While respecting the non-legally binding nature of principles and standards, AmCham EU recommended that their implementation be monitored, assessed and, where necessary, corrected on a continuous basis.

2. Communication on impact assessment[2]

This Communication proposes adopting a single approach for impact assessments, integrating current (but diverse) practices in the areas of environment policy, trade, business, etc. Detailed guidelines for implementation are under development. Impact assessments will be applied to all major initiatives and will help determine the appropriate policy instrument.

In response to this measure, AmCham EU called on the Commission to develop, in consultation with interested stakeholders, a clear methodology and process for impact assessment that will be applied uniformly. We also encouraged the development, by the Commission and interested stakeholders, of a set of common definitions of the policy options and alternative instruments available to legislators and the establishment of criteria for their application.

3. Communication on simplifying and improving the regulatory environment[3]

The Communication focuses on the three main parts of the legislation cycle: preparation and presentation of legislative proposals by the Commission; discussion of proposals by the European Parliament and the Council; and application of legislative acts by Member States. It identifies a number of areas for Commission action.

AmCham EU strongly supported the Commission's commitment to avail itself of opportunities to withdraw legislative proposals and create its own internal network for better regulation.

4. Communication on updating and simplifying the community acquis[4]

The acquis communautaire refers to the existing body of EU legislation. This Communication looks at:

- simplification, consolidation and codification of the acquis;
- reviewing the acquis' organization and presentation;
- ensuring transparency and effective monitoring at political and technical level;
- establishing an effective implementation strategy.

It also highlights the need for new legislative proposals to be developed in line with better regulation guidelines.

In response, AmCham EU called on the Commission, in the context of its efforts to consolidate and codify existing laws, to rethink legislative approaches where practicable and necessary, so that the simplification process supports the larger goal of better regulation.

5. Proposal to amend comitology procedures[5]

The comitology procedure is one of the more opaque aspects of EU policy-making, but basically refers to the method by which the Member States oversee the work of the Commission as it implements some technical aspects of EU legislation. The proposal would give a greater role to the European Parliament in this process, to better account for the European Parliament's extended role as legislator.

AmCham EU believes that the Commission's proposal to balance the powers of the Council and the European Parliament in the comitology process is indeed a necessary step.

6. Communication on the better monitoring of the application of Community law[6]

Law passed at the European level is directly binding, but its implementation requires the Member State governments to transpose it into national legislation. The differences between theory and practice present a consistent challenge for busi-

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[2] COM (2002) 276.
[3] COM (2002) 278.
[4] COM (2003) 71.
[5] COM (2002) 719.
[6] COM (2002) 725.

nesses operating in the EU environment. This communication seeks to improve this situation by encouraging those drafting legislation in the Commission to anticipate difficulties in transposition for Member States.

AmCham EU has consistently called for a coherent approach to implementing and enforcing EU law and therefore fully endorsed the objectives of this Communication. We recognized and supported the shift in focus that underlies this Communication.

Conclusion

AmCham EU would encourage the Senate to build a constructive transatlantic dialog on regulatory cooperation and to continue to underline the importance of the European Commission's work on better regulation. Successful dialog on regulatory cooperation can only bolster the initiatives undertaken by the Commission, leading to a more balanced, transparent and coherent regulatory process in the Europe. This will allow U.S. firms to grow and develop, bringing greater prosperity on both sides of the Atlantic.

STATEMENT SUBMITTED BY THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA

COMMENTS ON THE EU COMMISSION CONSULTATION DOCUMENT CONCERNING THE REGISTRATION, EVALUATION, AUTHORIZATION AND RESTRICTIONS OF CHEMICALS (REACH)

The Chamber of Commerce of the United States is the world's largest voluntary business federation, representing more than three million American businesses from every sector and region of the United States. Thousands of our member companies derive much of their business from commerce with the European Union and therefore have a major stake in a well-functioning and growing U.S.–EU marketplace.[1]

Therefore, the U.S. Chamber of Commerce greatly appreciates the opportunity to comment on the EU Commission's Consultation Document Concerning the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH) ["Chemicals directive proposal"] before it becomes law and seriously affects our member companies as well as the transatlantic commerce as a whole.

The U.S. Chamber of Commerce has three major concerns with the proposed Chemicals directive.

1. The regulation risks dampening the transatlantic economy;
2. The regulation advances questionable policies and goals without a realistic cost-benefit analysis;
3. The regulation has structural flaws that may result in unintended effects and inequitable treatment of American companies and products.

I. Economic Impact

Chemicals are a critical component of transatlantic trade in industrial and consumer products. Each year, the U.S. exports more than US$20 billion worth of chemicals to Europe and invests in the EU more than US$4 billion in the chemical and related sectors.[2] U.S.-owned affiliates and subsidiaries based in Europe research, develop, manufacture, and market within Europe and export outside the EU. U.S. exports of "downstream products" made with chemicals to the EU are well over US$400 billion annually. U.S. companies and consumers also purchase considerable amounts of chemicals and products made with chemicals from the EU. The U.S. imports from the EU more than US$40 billion worth of chemicals per year.

Given this scale of U.S.–EU commerce in chemicals and products derived from them, any major regulation affecting this trade will also have an effect on the overall transatlantic economy. In the proposed Chemicals directive, the EU Commission sets out to overhaul the rules of operation of a successful and well-functioning industry that has been at the forefront of innovation,[3] investments, employment, social and environmental welfare and economic growth. Therefore, the objectives of the Chemicals directive must be compelling to justify the considerable costs and risks the regulation will generate.

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[1] U.S. Chamber of Commerce Testimony before the U.S. Senate Foreign Relations Committee, Hearings on U.S. Relations with a Changing Europe: Differing Views on Technology Issues, June 24, 2003.

[2] U.S. Department of Commerce and American Chemistry Council (ACC).

[3] "About 90% of all industrial innovations can be traced to innovations from the chemical industry." European Chemical Industry Council (CEFIC).

Several credible studies have recently been conducted to assess the probable economic impact of the Chemicals directive proposal on key member states, including France and Germany.[4] According to these studies, national GDPs will be negatively affected, hundreds of thousands of jobs will be lost, and companies, especially small and medium size enterprises (SMEs) will suffer. Considering the level of integration and interdependence of U.S. and EU economies, the U.S. Chamber of Commerce is concerned that the U.S. economy will also be negatively impacted.

The U.S. Chamber of Commerce is also concerned that the Chemicals directive proposal will undermine European competitiveness at a time when member states are tackling difficult but vital socio-economical reforms and taking significant steps to reduce regulatory burdens.[5] A loss of economic momentum in Europe would go against the economic interests of American business.

II. Premises, Principles and Lofty Goals

The U.S. Chamber of Commerce is concerned that the Chemicals directive proposal overly emphasizes the dangers of chemicals per se over the risk of exposure to known hazardous chemicals. The directive does not adequately take into consideration sound scientific risk assessment methods and cost-benefit analysis to justify its regulatory reform proposal.

Companies are already well aware that certain chemicals that they produce or use are hazardous. U.S. and European companies already take precautionary measures, including extensive testing, to assess toxicity and exposure risks. It is not in any company's interest to underestimate the human and environmental risks posed by chemicals to its workers, customers, consumers or unrelated parties. U.S. and European governments have a proven record of regulating the industry and have in the process successfully assisted companies in the challenging task of protecting humans and the environment.

Chemical testing is an ongoing process that requires active collaboration between companies and governments. No amount of registration and authorization in itself generates scientific certainty. Results of one day could be contradicted by the observations of another day, and scientific research is always reassessing its findings. Thus, testing for all imaginable risks can be carried on practically *ad infinitum.* In this respect, companies and governments share the responsibility to constantly minimize risks to humans and the environment by reducing the exposure potential of the most hazardous chemicals. Other products should be allowed on the market if they comply with performance standards rather than be presumed harmful until proven otherwise. Therefore, testing should not be a condition for market access for most chemicals and for most products containing chemicals.

Extra-precautionary treatment of chemicals, as proposed in the Chemicals directive, can be justified in known cases of hazardous chemicals. On the other hand, it does not make sense to apply the same regulatory treatment to well-known and harmless chemicals. Applying a "one-size-fits-all" approach to all existing chemicals and all existing downstream products on a permanent basis would be costly and unnecessary.

In addition, regardless of the costs and of the implementation difficulties that the directive would entail, it is not certain that the directive could actually achieve its ambitious goals. What is known is that imposing blanket testing and certification requirements on most chemicals for all imaginable risks will impede innovation, stifle development and insert all sorts of bureaucratic intermediaries in the process of bringing goods to the market. It is questionable how this heavy burden on companies would in fact deliver the health and environmental benefits sought by the regulators. Another license filed with yet another regulatory body does not necessarily reduce any risks unless it guarantees that a science-based risk management process has been implemented.

The U.S. Chamber of Commerce is therefore urging the EU Commission to streamline the directive proposal to prevent the costly and unnecessary overhaul of a well-functioning industry and avoid the testing of thousands of well-known chemi-

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[4] "The Likely Impact of Future European Legislation in the Area of Chemical Substances," April 2003, Mercer Management Consulting study under the supervision of the UIC (Union des Industries Chimiques), the French Ministry of Ecology and Sustainable Development, and the French Ministry of the Economy, Finance and Industry. "Economic Impact of the EU Substances Policy," October 2002, Arthur D. Little GmbH study under the supervision of Bundesverband der Deutschen Industrie (BDI).

[5] *See* CEFIC News Release, June 27, 2003, reporting statements made by President Chirac, Chancellor Schroeder and Prime Minister Blair at the EU Council in Thessaloniki, Greece, June 19–20, 2003. *See also* comments made by CEFIC President Eggert Voscherau at CEFIC General Assembly, Hamburg, June 27, 2003.

cals.[6] The Chemicals directive proposal should instead target the most hazardous chemicals that pose known risks to humans and the environment. By setting priorities, the directive proposal would be more cost-effective.[7]

Crucially, the European Union should continue to encourage research into all aspects of chemical science and technology in order to develop insights into the hazards and risks associated with any products. As risks become known and understood, the business community will continue to embrace science-based risk management consistent with health and environmental goals. A sound scientific risk assessment basis for the Chemicals directive proposal would prevent unnecessary work, innovation delays and bureaucratic hassle.

III. Flaws and Unintended Consequences

The Chemicals directive proposal contains various structural flaws, which could result in unintended consequences that may unfairly harm non-EU companies. Below are some of the issues that most concern our members.

(a) *WTO Compliance:* The U.S. Chamber of Commerce is particularly concerned that some requirements of the directive at registration, testing and authorization levels could impede access to the EU market for non-EU companies and products, if not by design then in practice. Therefore, we urge the Commission to address the WTO compliance of the proposed directive and notify the WTO Secretariat of its proposed directive. Under no circumstances should the proposed directive establish technical barriers to trade and impediments to investments.[8]

(b) *Decentralized Authorities:* The U.S. Chamber of Commerce is also concerned by the two-tired administrative system that splits responsibilities between the central (EU level) authority and the Member States' national authorities, which will both administer the registration, evaluation and authorization of chemicals. With twenty-five national authorities and one central administration involved, all of them dealing with thousands of applications at once, the system will be prone to inefficiencies and distortions. Administrative bottlenecks and discrepancies will create frustrations and complaints that will be at best difficult to manage.

(c) *Transparent and Fair Review Process:* Any rejection of an application and any prohibition of a chemical must be subject to a fair and unbiased review and appeal process. Applicants, including non-EU companies, must be able to appeal any decisions at the national and EU levels based on sound scientific grounds. The U.S. Chamber of Commerce urges the Commission to ensure that a fair and science-based review system be implemented to avoid any appearance of discrimination against non-EU companies and products.

(d) *Substitution:* Substitution should not be an objective in itself.[9] Comparative scientific risk assessment studies, as well as comparative availability, affordability, functionality and socio-economic cost/benefits studies of existing and alternative chemicals must be undertaken before the EU imposes a substitution.

Market forces and international competition have encouraged innovation and substitution much more than regulation would achieve. Substitution with better products is a major factor of competitiveness. As long as companies are allowed to freely compete, innovations and substitutions will continue to occur for the benefit of consumers.

(e) *Responsibility Burden:* The proposed reversal of liability burden from public authorities to industry is creating legal uncertainties, which will notably alarm investors. Among these uncertainties, the imposed sharing of burden between chemical producers and downstream users could result in unnecessary disputes. Down-

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[6] According to a study conducted for the EU Commission "Business Impact Assessment of EU Chemicals Strategy" by the consulting firm Risk & Policy Analysts (RPA), May 2002, "testing alone comprises 88% of the total testing and registration costs." Thus, considerable savings could be achieved by avoiding the testing of already tested chemicals.

[7] The U.S. Chamber of Commerce respectfully suggests the EU Commission review cost-effective U.S. risk assessment policies. *See* for instance "Science and Judgment in Risk Assessment," Committee on Risk Assessment of Hazardous Air Pollutants, Board of on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council, the National Academies Press, 1994.

[8] The U.S. Chamber of Commerce urges the EU Commission to assess WTO compliance of its Chemicals directive proposal before disputes emerge. Several independent legal assessments have already suggested non-compliance after review of the EU "White Paper, Strategy for a Future Chemicals Policy." *See* for instance Crowell & Moring trade law analysis, November 7, 2002. *See also* American Chemistry Council letter to DG Trade Commissioner Pascal Lamy, April 16, 2002.

[9] *See* EU Committee of the American Chamber of Commerce in Belgium (AmCham EU) Position Paper on the Future EU Chemicals Policy, May 17, 2002.

stream users of chemicals may have differences with upstream users and/or producers based on their different knowledge and the scientific data (both evolving over time) they may have on the production and particular usage of certain chemicals. [10] Putting the regulatory burden on both the producers and users, while exonerating government's responsibilities to protect the public, could create grounds for costly and disruptive disputes, and eventually dampen innovation and private sector investments.

(f) *Uncertainties:* The Chemicals directive proposal will generate uncertainties as to whether certain chemicals will ultimately be authorized (i.e., reproduction of the pharmaceutical industry system). However, chemical companies and downstream users will not be able to recoup the cost of these uncertainties, because the market will not allow companies to price chemicals and related products at premium prices. This will result in reductions of investments, innovations and jobs.

(g) *Intellectual Property:* The Chemicals directive proposess a data-sharing requirement, which will put confidential commercial information at risk. The enormous amount of data that will have to be provided to regulatory authorities and the sharing arrangements between companies promoted by the directive for the sake of savings on testing costs and animal lives, are bound to compromise confidentiality. The U.S. Chamber of Commerce urges the EU Commission to ensure, in far stronger terms than currently suggested, that the data-sharing scheme will not compromise sensitive commercial information and give away trade secrets, and that no intellectual property rights will be violated. The rights of the data owners should receive a high level of protection.

(h) *Competition:* The data-sharing system could create situations of collusion or perceived collusion between competitors. It could notably favor non-competitive behaviors between EU companies against non-EU companies. The U.S. Chamber of Commerce urges the EU Commission to review all possible anti-competitive effects of the data-sharing scheme in order to prevent illegal anti-competitive behavior, notably against importers.

Any such anticompetitive practice would particularly hurt small and medium sized enterprises (SMEs), which lack the resources to fight against coalitions of large companies. SMEs would also have more difficulties and less means to acquire needed data sets, owned by larger and more powerful groups of companies, or otherwise meaningfully to participate in legitimate data sharing schemes.

(i) *Consumer Scare:* The Chemicals directive proposal risks creating consumer fears based on quasi-scientific information, which could cause unjustified consumer reactions against the purchase of certain products. This could lead to discrimination against some imported products.

(j) *Mutual Recognition:* The Chemicals directive proposal does not give sufficient consideration to the international ramifications of the regulatory overhaul it envisages. Specifically, there is clearly room for mutual recognition of testing facilities, data sets and results from non-EU countries, including the U.S. Some of these countries, including the U.S., have at least equal testing facilities and scientific assessment capabilities. U.S. companies have collected years of useful and valid data. Mutual recognition would save on cost, time and effort. In the case of the U.S. and the EU, mutual recognition would promote regulatory cooperation in the most important market of the world.

The U.S. Chamber of Commerce urges the EU Commission to consult and cooperate with relevant U.S. government and regulatory agencies and work together on mutual recognition guidelines and protocols. The U.S. Chamber of Commerce stands ready to assist this process in any way possible.

STATEMENT SUBMITTED FOR THE RECORD BY THE NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

Mr. Chairman, thank you for holding this hearing. NEMA would like to comment principally on the Electrical Safety Annex to the 1997 U.S.–EU Mutual Recognition Agreement, which was mentioned in the U.S. Chamber's remarks.

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[10] Downstream users have expressed serious concerns about their responsibility burden under the Chemicals directive proposal. *See* for instance AEA (formerly the American Electronics Association), EIA (Electronics Industries Alliance), ITI (Information Technology Industry Council), NEMA (National Electronic Manufacturers Association) and SIA (Semiconductor Industry Association) Position Paper on EU Chemicals, April 2002.

Based in Rosslyn, Virginia, the National Electrical Manufacturers Association is the largest trade association representing the interests of U.S. electrical industry manufacturers, whose worldwide annual sales of electrical products exceed $120 billion. Our more than 400 member companies manufacture products used in the generation, transmission, distribution, control, and use of electricity. These products, by and large unregulated, are used in utility, industrial, commercial, institutional and residential installations. The Association's Medical Products Division represents manufacturers of medical diagnostic imaging equipment including MRI, CT, x-ray, ultrasound, and nuclear products.

In NEMA's view, the use of government-to-government MRAs should be limited and considered only as an alternative for conformity assessment needs when applicable to federally regulated products such as medical devices. MRAs are not the answer to conformity assessment needs in non-regulated areas such as for most electrical equipment; if anything, they serve to encourage the creation of unnecessary product-related regulation. We strongly objected to the inclusion of the Electrical Safety Annex in the U.S.–EU MRA, and are pleased that Brussels has now moved to suspend it. We are also pleased that the U.S. has either excluded electrical products from its subsequently negotiated MRAs, or refused to sign on to any such accords that effect our unregulated products—most recently in the case of the U.S.-Singapore Free Trade Agreement.

Further, during the impasse over the Annex, we have supported OSHA in its insistence on retaining its authority over Nationally-Recognized Testing Laboratory (NRTL) accreditation. Particularly with the granting of status to a German Conformity Assessment Body (CAB) in 2001, OSHA has shown that the process has integrity, and European applicants will be given the same consideration as their U.S. counterparts.

NEMA applauds the Bush Administration and the European Union for their 2002 Guidelines Agreement on Regulatory Cooperation and Transparency. We ask that pilot projects adopted for implementation of the Guidelines include the current EU regulatory initiatives relating to Chemicals, Energy-using-Products (EuP) and the Restriction of Hazardous Substances (ROHS)—but, for the reasons elaborated above, we do not think that electrical safety would be appropriate. In any event, we strongly agree with the U.S. Chamber's call for meaningful U.S.–EU regulatory dialogue.

Thank you for your consideration of these remarks.

STATEMENT SUBMITTED FOR THE RECORD BY 3M CORPORATION

[The statement submitted by 3M exceeded the committee's policies on the length of prepared statements submitted for the record. A copy of the statement will be maintained in the committee's permanent records.]

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