Testimony of

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Subcommittee on European Affairs

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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 legislative 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

[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.

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.