Statement presented by

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Introduction

I am Gérard Depayre, Deputy Head of the Delegation of the European Commission in Washington and I am presenting a statement on behalf of the European Commission in place of two colleagues who were not able to come from Brussels for the hearing.

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

Your interest in EU-U.S. regulatory co-operation is helpful in furthering our mutual efforts to deepen the Transatlantic Economic Partnership, and in promoting regulatory convergence.

A recent study published by Joseph P. Quinlan of the Johns Hopkins University[1] 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 liberalisation, leading to reduction of costs for business on both sides of the Atlantic.

Regulatory barriers to trade and how to overcome them

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 liberalisation 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.

How can this be achieved?

A solution to both these problems can only be reached through dialogue and close cooperation between regulators.

The ideal result of such a dialogue should be to arrive at harmonised regulations. Failing this, efforts should be made to ensure maximum

[1] "*Drifting Apart or Growing Together? The Primacy of Transatlantic Economy*" by Joseph P. Quinlan, 2003.

convergence of regulations on 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 their own regulations. A solution, which requires the clear realisation 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 both regulators toward greater convergence, and thus create the basis for mutual recognition. Another alternative 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 dialogue between regulators takes place at the earliest possible stage. Early preventive dialogue between regulators, but also involving scientists, consumer groups, politicians and businessmen, is fundamental. Timely dialogue 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 approaches that are as compatible with one another as possible.

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

While many countries subscribe to 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 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 an improved dialogue 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.

Regulatory co-operation in EU-U.S. relations

Before entering into the details of our co-operation, I would like to recall the differences in our legislative and regulatory systems. These are the result of different administrative cultures and historical developments on both sides of the Atlantic. Any comparison between our systems should also take this into account.

First, the term "regulation" relates to different concepts. While in the US 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 decision-making process, technical regulations are adopted in the EU by the legislative branch (either the Council of Ministers on its own, or, more frequently, the Council of Ministers 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.

This is different from the situation where Congress initiates and passes legislation, mandating the subsequent adoption of regulations. Congress may, at times, in a specific political or economic context, act without giving a real opportunity to foreign stakeholders to effectively participate in the process and have their views taken into account. This may create transatlantic conflicts. The Bio-terrorism 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 (APA), which imposes largely standardized formal consultation requirements on US 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 dialogue 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 real consideration. Here implementation of the Bio-terrorism Act by the FDA is a good case in point.

This being said let me now turn to the EU-U.S. regulatory dialogue. 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 dialogue between EU and the U.S. regulators.

The Guidelines suggest that regulators should, inter alia:
- improve the planning and quality of regulatory proposals;
- pursue harmonized, equivalent or compatible solutions;
- obtain increased predictability and grant the opportunity for regulators of each side to provide meaningful input; and
- promote public participation through access to documents;

This framework is already up and running in a number of areas. In particular, ideas and recommendations stemming from civil society, such as the Trans-Atlantic Business and Consumer Dialogues, have received attention.

Current state of play in the implementation of the Guidelines

Four initial "pilot projects" to implement the Guidelines were agreed in November 2002: cosmetics, automobile safety, nutritional labelling and metrology.

In addition, two new areas have been agreed recently: co-operation on standards in information and communication technology sector, and pharmaceuticals.

It is clear 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 co-operation a more sustainable process. This could be done by various means: including the exchange of annual work programmes, organising dialogues horizontally and/or in specific areas, and enabling exchanges of regulators.

Areas of regulatory co-operation beyond the Guidelines

It is important to note that our bilateral regulatory co-operation goes far beyond the areas covered by the Guidelines, which only apply to trade in industrial goods.

Our cooperation now extends to a number of sectors and, in the first place, to financial services, the liberalisation of which could bring enormous benefits to both our economies. In that context, we are tackling both classic 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 dialogue with U.S. regulators, which has already yielded some positive results.

We have an intensive dialogue on transport security, notably on the Container Security Initiative and the Passenger Name Record. We hope this dialogue 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 concerns 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 initiated a dialogue with the FDA on the implementation of the Bio-terrorism 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 dialogue.

In the chemical sector, 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.

Thank you very much for your attention.