



U.S. –EU High Level Regulatory Cooperation Forum
U.S. Chamber & BUSINESSEUROPE
Suggestions 2010

The U.S. Chamber and BUSINESSEUROPE are pleased to have served as supporters and advocates for the U.S.-EU High Level Regulatory Cooperation Forum (HLRCF) from its outset in 2005. In light of its meeting on June 28 and 29 2010, we send below a series of recommendations, both for the discussion between regulators themselves and for the public stakeholder session taking place at BUSINESSEUROPE on the afternoon of June 29.

As a general point we would like to underscore that in everything the HLRCF does, it should be forward looking and focusing its efforts, conversations, and programs of work on emerging regulations and regulatory policy. While the HLRCF was initiated to work on the “cross-cutting” issues common to the process of regulating it is important that its work be grounded in practice and not simply theoretical. Therefore, the HLRCF should always be looking to apply its process-based discussions to specific emerging areas of regulatory consideration or concern.

Precisely because the HLRCF was founded to be cross-cutting and to give Transatlantic regulators a forum to discuss best practices in regulatory cooperation, high level participation from the broadest spectrum of EU and US agencies responsible for regulation is essential, especially in priority areas (see annex).

Proposals for the discussions between regulators:

Risk

The Chamber and BUSINESSEUROPE believe that risk measurement and management is central to many regulations and therefore the approach to risk taken by regulators is important to ensure regulations developed in both the U.S. and Europe are done so in a relatively consistent and compatible manner. The HLRCF should make risk a focus of its work and find regulations that are currently in process that involve risk evaluation and management in the U.S. and European systems to be discussed at a future HLRCF.

In addition, in 2008, the U.S. and the EU launched a Global Risk Conference which was designed to be a biannual event. The first conference was in Brussels in November 2008 and was largely comprised of U.S., Canadian, and European officials. The HLRCF should ensure that the conference continues and should work to hold the second conference this fall and include additional countries.



Standards

The HLRCF already has standards on its agenda. To advance this work further, the Chamber and BUSINESSEUROPE suggest that the HLRCF take the same approach with standards that it took when it examined the U.S. and EU approach to considering the impact potential regulations have on trade and investment. In doing so the EU and the U.S. would each build on the papers they have issued on how standards are used in regulation. These papers should be made available for comment, requesting input on how to move forward on standards cooperation. Following this the HLRCF should issue a final paper on the subject. This approach has previously translated into important changes to the EU impact assessment checklist with regard to monitoring regulatory impact to international trade and investment and to the U.S. considering ways to underscore its existing practices in this area. The Chamber and BUSINESSEUROPE believe that capturing the HLRCF's work on standards on paper would provide a similar basis for progress toward greater understanding and convergence among regulators.

Behavioral Economics

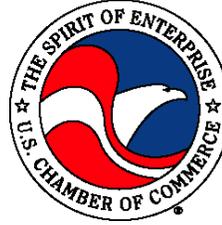
An increasingly "hot" and important topic in regulation is the intersection of regulation and behavioral economics. The Chamber and BUSINESSEUROPE have made better regulation a foundation for our cooperation to spur greater transatlantic regulatory cooperation. Better regulation requires regulators to better anticipate the response "the market" will have to the issuance of a new regulation. The HLRCF should use the upcoming public stakeholder's session to focus on these issues and take suggestions from stakeholders on future HLRCF programs of work in this area. The Chamber and BUSINESSEUROPE also note the close alignment of this suggestion with the suggestion of an ex-post assessment.

Ex-Post Assessment of Regulation

The Chamber and BUSINESSEUROPE believe that two regulations, one promulgated on each side of the Atlantic, should be identified as case studies for the HLRCF to conduct an impact assessment on now that these regulations have been in force in the market. The aim of such an exercise is not to review the regulation with the intention of changing it, but rather to generate new learning and understanding as to how to use impact assessment in the future to better capture the regulatory impact of future regulations. In particular, the two regulations chosen for an ex-post assessment should be chosen from industries or sectors of the economy where there is a fair amount on transatlantic trade. A decision on the issues and basic methodological principles for ex-post assessment should be taken at the June meeting, with a report to be given at the next meeting of the HLRCF.

Mutual recognition

The November 2009 invited the HLRCF to deepen discussions of possible future approaches to regulatory cooperation, including through mutual recognition agreements.



The Forum had previously noted that experiences with mutual recognition to date have been disappointing, but this is because previous MRAs were too narrow and technical. We call for a more ambitious approach. U.S. and EU regulators of goods generally seek similarly high levels of protection for our consumers and the environment, and this similarity of desired outcomes should allow mutual recognition of comparable regulatory regimes. To achieve such determinations, the HLRCF should launch, as a pilot project, an external study of one of the priority areas for regulatory cooperation (say, motor vehicle safety) to determine if outcomes are in fact broadly consistent. The relevant US and EU regulators should comment on the study; the full HLRCF should then review the study and the agency comments to recommend if it should be possible for the two regulatory agencies to accept products approved for use in the other's market –reserving the right to make exceptions for an individual product if they have reason to believe that product is unsafe. If the HLRCF believes this should be possible, the agencies would state, for public comment, whether or not they will seek legislative authority for mutually recognizing one another's regulatory regimes for that product range. This whole "confidence building" process should take no more than two years, although the necessary legislative changes may take longer. If the process appears viable, other sectors could undergo similar evaluations.

Proposals for the public stakeholder session:

Ex-Post Assessment of Regulation

We believe there would be considerable value in a session that looked at ex-post assessment in general terms, integrating concepts from behavioral economics regarding unintended consequences of regulatory initiatives.

Sectoral State of Play: Pharmaceuticals and Motor Vehicles

Stakeholders would benefit from an overview from regulators in one or two key sectors of the full extent of transatlantic regulatory cooperation in their area. A discussion would allow the affected business and consumer representatives to outline where they would like to see such cooperation go in the future.

ANNEX: Key subjects and concerned agencies and directorates-general

Food safety

- US Department of Agriculture
- Food and Drug Administration
- Animal and Plant Health Inspection Service
- Food Safety and Inspection Service
- DG Health and Consumer Protection
- DG Agriculture
- European Food Safety Agency

Chemicals

- Environmental Protection Agency
- DG Enterprise
- European Chemicals Agency

Pharmaceuticals and medical devices

- Food and Drug Administration
- DG Health and Consumer Protection
- European Medicines Agency

Motor vehicles

- National Highway Traffic Safety Administration.
- DG Enterprise

Electrical equipment

- Occupational Safety and Health Administration
- Federal Communication Commission
- DG Enterprise

Green technologies

- Department of Energy
- Environmental Protection Agency
- DG Enterprise
- DG Environment
- DG Energy

Toys

- Consumer Product Safety Commission
- DG Health and Consumer Protection

Nanotechnology

- Office of Science and Technology Policy
- Food and Drug Administration
- DG Enterprise
- DG Environment
- DG Health and Consumer Protection

Supply chain security

- Customs and Border Protection
- Transport Safety Administration
- DG Taxation and Customs Union