



07 February 2008

Susan E. Dudley
Administrator of the Office of Information and Regulatory Affairs
Office of Management and Budget

Alexander Italianer
Deputy Secretary General
European Commission

Dear Ms Dudley,

Dear Mr Italianer,

We write to you in response to your request for comments on the Draft Joint Report on the Review of the Application of European Union and United States Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment. We applaud your initiative and make some general comments before providing our views in response to the topics posed. We also welcome the focus provided for your work in the *Framework for Advancing Economic Integration* of 2007

We refer also to our letter dated 7 November 2007 immediately ahead of the third meeting of the Regulatory Co-operation Forum and the inaugural meeting of the Transatlantic Economic Council.

General comments

The TransAtlantic Business Dialogue (TABD) believes that effective regulatory cooperation is at the heart of the transatlantic economic relationship. Improvements in regulatory co-operation translate into more jobs and increased growth and prosperity, good for citizens, consumers and producers alike. As our economies globalise and as the economic cycle tightens, every effort needs to be made to drive the closest possible alignment between your two approaches, and in particular to the methodologies adopted to assess impacts and examine costs and benefits. This we view as a necessity not an option if our two economies are to meet the challenges ahead.

We believe that a formal EU-US regulatory co-operation agreement should be formalised so as to underpin and support ongoing efforts and to help in connecting up accountabilities and processes on both sides. Present ad hoc co-operation is often successful but is insufficiently systematic. Formal agreement should also include principles for regulatory co-operation, stressing the need for example for transparency, access, evidence based on sound analytical and

scientific justification and peer review, consultation, and post implementation effectiveness review. Formal agreement should guarantee the application of guidelines, such as the 2002 Guidelines for Regulatory Co-operation and Transparency, and the enforcement of parallel administrative mechanisms such as the European Commission's Impact Assessment Guidelines and the US Office of Management and Budget's Circular A-4.

We welcome the analysis of both systems presented in the draft report, the case studies evidencing existing good practice, and the acknowledgement that impact assessment underpins regulatory cooperation. Placing the descriptions of the two current approaches you have alongside each other is a key analytical first step. We now need a step change in the pace and depth of co-operation if we are to meet the challenge of globalisation effectively.

In the short term immediate improved regulatory cooperation can be achieved through consistent implementation and application of the *2002 Guidelines* which, as you know, require early warning through notification of anticipated new regulations and systematic completion of impact assessments for all proposed regulations so as to take into account the effect of the regulation on transatlantic trade and investment.

Transparency, consultation of stakeholders and publication

Greater transparency and stakeholder consultation are essential to meaningful regulatory co-operation. Stakeholder participation needs to be guaranteed in agreed processes. We reiterate our recommendation that annual work plans should be published on horizontal and sector priorities, together with a timetable towards resolution and results. All known proposals with potential transatlantic impacts should be included, and based on early assessments of trade and investment impacts in impact assessments and cost benefit analyses. As you know we have in the past offered to host on our website a common calendar of transatlantic meetings of regulators, to help enhance transparency. Ideally the regulatory co-operation process should be entirely visible on line from the earliest stages of impact assessment and cost benefit analysis.

We welcome progress made in the first three meetings of the RCF, and re-iterate our view that the RCF should be the focal point for integrating and delivering tangible results from the various co-operation initiatives both methodological and sectoral. It should also be the focal point for transparency and progress reporting. The existing forums for regulatory cooperation and the RCF need to convene regularly in order to ensure close dialogue on proposed policies and accompanying impact assessments expected to raise significant international trade and investment issues, as well as for the sectors. As stated in our 2007 recommendations, we continue to believe that the RCF holds great promise to drive the process of transatlantic collaboration, particularly in areas that are not yet regulated, such as nanotechnologies. The EU and US must nominate and routinely convene a core group of regulators who participate in the RCF and find a means to keep legislators apprised of the work of the RCF. This will help to boost the stature of the regulatory cooperation effort, facilitate interaction and cross-dialogue among regulators, and provide an excellent opportunity to determine the roadmaps and timetables for action in key areas.

Timelines

The timely announcement of planned legislative and regulatory initiatives across the Atlantic and transparency concerning corresponding impact assessments are key objectives for EU-US regulatory cooperation, both for those affected and those who will assess impacts cost and benefits. Information and assessments must be made public well in advance of the adoption of

the regulation to ensure that authorities and stakeholders on both sides of the Atlantic have ample time to evaluate possible effects of regulation on transatlantic economic relations.

Elements for inclusion in respective methodologies

Here we re-iterate the value of the 2002 Guidelines and welcome the three suggestions that would call for analysis of need, degree to which interested parties will be affected, and assessment of alternative international standards or regulatory approaches potentially available.

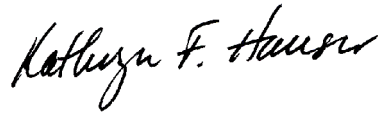
Finally we encourage the EC and OMB to develop, as the step change to be achieved in 2008, a consolidated transatlantic regulatory impact assessment methodology and to define the steps necessary to complete this consolidation in time for the 2008 EU-US Summit.

We hope that the comments outlined above, which all have been expressed on previous occasions, will be of assistance in the preparation of the final version of the Report.

Kind regards,



Jeffries Briginshaw
TABD EU Executive Director



Kathryn Hauser
TABD U.S. Executive Director