

**SUMMARY OF INPUT BUSINESS COMMUNITY INTO TEC CONSULTATION¹:
RECOMMENDATIONS TO THE TEC, APRIL 2008
CUMULATIVE AS FROM OCTOBER 2007**

(COLOUR KEY: 2007 CONSULTATION / 2007 CONSULTATION, REPEATED IN 2008 SUBMISSIONS/ NEW 2008)

Political Transition

- Adopt regulatory roadmap to ensure uninterrupted progress in a period of change in political leadership at the TEC meeting on May 13;
- Declarations coming out of the 2008 EU-US Summit should explicitly reference the TEC's work, its progress to date, formally endorse its program of work and set out deliverables for the TEC to achieve and report out at the 2009 US-EU Summit;
- Hold 3rd TEC meeting in Washington DC after the November election and include key representatives of the next Administration's transition team.

¹ From February 1 to March 10, the TABD conducted a web consultation. To date, contributions have been received from: BUSINESSEUROPE/ US Chamber of Commerce, the American National Standards Institute, the European-American Business Council, the Federation of German Industries, the Reinsurance Association of America, College of Europe, the Securities Industry and Financial Markets Association, the Group of North American Insurance Enterprises, the Association of Home Appliance Manufacturers, Underwriters Laboratories Inc., the European Banking Federation, Lloyd's, IBM, SITPRO, the Organisation of EC-Shipsuppliers, the National Electrical Manufacturers Association., the Association of European Airlines, AHIMA, Colipa, EU-US Coalition on Financial Regulation, EICTA. Others are in draft form or pending, and will be posted upon receipt.

Regulatory Cooperation

Horizontal:

- Invigorate the Regulatory Cooperation Forum and announce the names of the participants by June 30 2008 and schedule quarterly meetings of the RCF, including public sessions;
- Develop common Impact Assessment methodologies;
- Agree a methodology for developing future regulations addressing: impact assessments, cost-benefit analysis, disparity in timelines and transparency;
- Harmonise conformity assessment procedures (in particular concerning high-technologies);
- Engage in Concerted Cooperation on third country concerns;
- Create a common regulatory dossier.

Standardisation/ Harmonization/ Convergence:

- TEC should encourage EU and US regulators to use existing policies like the EU's New Approach Directives, and US Public Law 104-113 (NTAA) and OMB Administrative Circular A-119, to reference private sector standards to meet regulatory objectives;
- TEC should recognize the 20-year transatlantic dialogue between private sector standards bodies, involving representatives of the governments, i.e. ANSI, CEN, CENELEC, ETSI;
- TEC should recognize the ANSI-ESO dialogue to serve as the Standards Dialogue envisioned in the Framework Annex 7.1;
- TEC should discuss regulatory equivalence for issues where alignment is difficult. The UNECE International Model for Technical Harmonization provides a possible route for agreeing Common Regulatory Objectives through the use of international standards;
- TEC should direct the Occupational Health and Safety Administration (OSHA) to move speedily to recognize the equivalence of the Suppliers' Declaration of Conformity (SDOC) for exports of electrical products from the European Union.
- Existing US arrangements for safety inspections should be retained.

Regulatory Cooperation

Sectors:

Cosmetics:

- Cooperate on cosmetics regulations to reduce the need for animal testing;
- Agree on an effective and practical solution for REACH implementation.

Chemicals:

- Develop a joint approach on risk assessment and risk management with regard to chemicals;
- Cooperate on the implementation on the Globally Harmonised System (GHS) for the classification and labeling of chemicals;
- Develop a Global HPV (High Production Volume) information portal;
- Harmonise integrated QSAR risk modeling programs.

Pharmaceuticals:

- The June 2007 EMEA/FDA Implementation Plan for Medicinal Products for Human Use should add as an objective the clarification of the regulatory conditions intended to foster medicines innovation. As an example a matrix could be developed setting forth the preconditions for a policy framework in the field of **nanotechnologies**;
- Develop a common shared process for obtaining simultaneous scientific advice from regulators in both the US and EU to streamline the drug development process;
- Agree a pediatric development plan;
- Develop and deploy a harmonized approach on drug safety concerns;
- Agree on a common set of criteria for validation of (pharmaceutical) production sites and quality assurance measures.

Electrical safety:

- Avoid old pitfalls, build on 1999 MRA discussions;
- Develop common standards for horizontal safety application (in particular for electrical safety of machinery) and common machine specific safety standards covering the most important machine families;

Regulatory Cooperation

- Cooperate on other technical subjects (e.g. exhaust emissions of mobile machinery);
- Recognize the equivalence of the Suppliers' Declaration of Conformity (SDOC) for exports of electrical products from the European Union;
- Existing US arrangements for safety inspections should be retained.

Vehicle safety and fuel economy:

- Work towards accelerated harmonization of standards in the framework of UN/ECE Agreements of 1958 and 1998, notably in the area of vehicle safety, through joint initiatives developed by EU and US regulatory agencies;
- TEC should establish a working group to formulate a resolution with the following elements:
 - before new regulations are proposed, an extensive impact assessment should be carried out including actual accident analysis;
 - the development of required new safety regulations as Global Technical Regulations (GTR);
 - implementing body should be the UNECE WP.29 (worldwide forum for harmonizing technical vehicle regulations).
- TEC should support the development of World-wide Light Duty Test Procedures (WLTP) be tackled in the UNECE WP.29;
- Cooperate in research and setting of standards and regulations in the areas of fuel –economy, vehicle safety, and alternative fuels, in particular bio-fuels;
- Set up a transatlantic expert group on the future regulation of fuel consumption/ CO2 emissions from motor vehicles to create a functional platform for systematic dialogue on the political concepts and their effects on the industry.

IPR

- Develop a globally reliable patent system;
- Harmonise EU and US patent systems based on the “first-to-file”- system;
- Deliver on the IPR objectives as laid down in the Framework;
- Develop principles and an action plan to counter emerging concerns regarding compulsory licensing of IPR;
- Strengthen cooperation in international fight against counterfeiting and piracy; Develop specific cooperative mechanisms to counter global counterfeiting of medicines, indicate support for repackaging bans;
- Endorse the International Anti-Counterfeiting and Piracy Agreement.

Investment

The EU - U.S. investment dialogue should:

- Seek to address current obstacles to transatlantic investment;
- Issue a strong statement underscoring the commitment of the US and EU to maintain an open investment climate;
- Develop strategy to guarantee open investment policies among OECD countries as mandated by G8;
- Coordinate positions on state-controlled financial vehicles in the discussions in the IMF and others, particularly concerning transparency both for sovereign wealth fund sponsors and recipient countries ;
- Engage in dialogue on regulatory framework concerning deployment of high-speed networks.

Themes for US-EU 3rd country discussions:

- Enhance regulatory transparency;
- Promote open markets and investment;
- Encourage facilitation of Cross-Border capital markets transactions;
- Expand best practices in Investment Protection.

Secure Trade

Free movement of people:

- The free movement of people should be included as integral part of the Framework
- Establish a priority project on the friction-free movement of people
- Form a government/business task force to study and make recommendations on a single transatlantic registered traveler program.
- Review conflicting passenger data requirements and provide a report and recommendations to consolidate, simplify and minimize the burden to business by the time of the November-December 2008 TEC meeting.

Cargo security:

- Deploy risk-based approach towards cargo security;
- Redress imbalance between trade and security imposed by the new US 100%-scanning measure;
- Prepare a technical and economic feasibility impact assessment of the US 100% cargo screening legislation and report findings at the November-December 2008 TEC meeting.

Supply chain security:

- Publicise and implement the roadmap to facilitate mutual recognition of secure operators under AEO and C-TPAT;
- Announce 1 July 2009 (when the EU customs security initiative enters into force) as the date by which the two programs will be mutually recognized, without any additional validation from the other side (avoid double certification procedures and double standards).

Visa and immigration

- Simplify visa and immigration rules for exchange of competent employees

Capital Markets

General statement

- The financial services industry supports ongoing informal Financial Markets Regulatory Dialogue.

Convergence of accounting standards

- Complete mutual recognition of US GAAP and IFRS without the need for reconciliation by 2009;
- The SEC should recognise both IFRS as published by the IASB and IFRS as adopted by the EU;
- End discriminatory taxation of European financial institutions that apply IFRS instead of US GAAP (section 475 Internal Revenue Code safe harbour for securities and derivatives valuations; eligibility requirement for FIN 48 interpretative standard).

- Exempt US and EU firms which only transact business on cross border basis with institutional investors from local licensing requirements.

- Work towards mutual recognition and convergence of securities market rules.

- Develop a Transatlantic "Register" for capital markets regulations, i.e. web based tool.

- Encourage greater dialogue amongst transatlantic legislators on financial markets issues.

Convergence:

- work towards convergence of classification of counterparties;
- work towards convergence of requirements on disclosure of large shareholdings, convergence of requirements on segregation of client assets;
- work towards convergence of reporting standards and marketing of US/EU investment funds;
- work towards convergence of auditing standards and enforcement mechanisms.

- Reduce duplicative consolidated supervision of European Banks by both SEC and Federal Reserve.

- Ensure equal application of Basel II rules in US and EU.

Insurance and Reinsurance:

- Establish a dialogue on insurance issues to cover the EU's draft Solvency II Directive and the state-based approach the US takes on reinsurance;
- Bring reinsurance regulation to TEC work program;
- Bridge regulations within the transatlantic insurance market;
- Develop supervision for insurers on a principles based, risk focused regulation.

Financial Sanctions:

- Adopt a more coordinated approach towards financial sanctions and AML/CFT.

Innovation and Technology

Biofuels:

- Develop and deploy compatible standards for biofuels;
- Give early warning on potentially misaligned assessments of the sustainability criteria and well-to-wheel greenhouse gas emissions for different biofuels in different regions;
- Look forward to the completion of the standardization work currently underway, including the comparative report of US-EU-Brazilian standards alignment, as a milestone deliverable for the purposes of the TEC's goals in 2007.
- Agree:
 - procedure for setting down quality standards for biofuels (identification of technical institutions to do this, timeframe, determine which economic areas are to be involved, determine which political agencies and entities are to be involved)
 - procedure for determining internationally harmonized methodology for measuring the CO2-balance.

e-Accessibility:

- Implement 2nd phase of the standardization mandate to CEN, CENELEC and ETSI in support of e-Accessibility requirements;
- Adopt international standards; avoid discussion on labels, mandatory 3rd country certification and US TEITAC requirements;
- Increase high-speed Internet connectivity (missing element in Framework) by deploying *Next Generation Networks* as a facilitator for eHealth and eAccessibility.

eHealth:

- Agree a roadmap for convergence towards Interoperability of Electronic health record systems.

Pharmaceuticals:

- Support efforts to propose a new legislative framework for providing non-promotional information about legal pharmaceuticals to patients;
- Deploy product identification technology.

- Deploy Health Technology Assessments on the basis of common standards;
- Cooperate to adopt consistent solutions for public data disclosure;
- The EU should improve climate for fundamental research.

- Establish a series of high level exchanges on “Frontiers of Innovation”.

- Add to the Innovation and Technology Work Programme:
 - virtual worlds (particularly issues relating to identity management);
 - autonomous systems (e.g. self-piloting plane in civil aviation).

- TEC to establish working groups comprising of EU and US regulators and industry, for the emerging commercial technologies. Working Groups to develop a program on regulatory cooperation and compatibility, to be approved and monitored by TEC

- Increase cooperation on Radio Frequency identification (RFID) policy formulation, [in particular on the drafting of the Recommendation for RFID Privacy Protection](#);

Nanotechnology:

- [Develop a roadmap for US-EU Cooperation on Nanotechnology](#)

Other
Transatlantic Open Sky
<ul style="list-style-type: none"> ▪ Work towards the creation of a genuine transatlantic open sky (as a Lighthouse Priority Project)
Energy
<ul style="list-style-type: none"> ▪ Energy issues should be brought into the Framework, e.g. the TEC should: <ul style="list-style-type: none"> - cooperate on minimum energy efficiency requirements; - discuss extending Energy Star to other product categories. ▪ EU-US should collaborate so that their respective emissions trading systems work together and energy efficiency standards facilitate greater transatlantic trade and investment; ▪ TEC should lead policy discussions on issue of treatment of carbon-intensive imports.
International Trade
<ul style="list-style-type: none"> ▪ Establish a European-American working group to develop a proposal containing: <ul style="list-style-type: none"> - mandate and composition of a EU-US trade-policy committee, with a mandate to exchange information early, coordinate between EU and US trade-policy decision makers; - involve relevant EU and US agencies; - involve industry.