



**T R A N S A T L A N T I C
B U S I N E S S D I A L O G U E**

44.2 (103)

Rome, Italy
November 6-7, 1997

ROME COMMUNIQUÉ

FINAL DRAFT

November 7, 1997

INTRODUCTION

For the third consecutive year, the Transatlantic Business Dialogue (TABD) has assembled business leaders from across the European Union and the United States. Our common goal is to reduce existing transatlantic barriers to the movement of goods, services and capital and offer our full support for the rules-based multilateral trading system. Business, governments and consumers all have an interest in seeing implementation of its recommendations in order to stimulate new business opportunities, increase competitiveness, accelerate growth and create jobs. Since its inception this process has proven to be an effective mechanism to improve conditions for transatlantic trade and investment by focusing attention on issues where business consensus can be achieved. The TABD in cooperation with other business organisations will continue to advocate pragmatic steps to achieve its overall objective of an improved transatlantic marketplace.

Our Rome meeting is a landmark in the evolution of the TABD process. The large number of CEOs participating demonstrates a confidence in, and commitment to, the TABD process as a means to tackle the urgent business issues facing the transatlantic economy. We urge the EU and the U.S. administrations to seize the opportunity of the coming years to raise awareness amongst consumers and elected representatives of the importance of the issues facing us, and work to lay solid foundations for the administrative, regulatory and legislative changes which are required.

The TABD praises the achievements of our respective government leaders in 1997. In particular, we commend the European Commission and the U.S. Government for the successful conclusion of the Mutual Recognition Agreement (MRA). In addition, the completion of the worldwide Information Technology Agreement (ITA) is a significant accomplishment. In view of the success of the ITA and its contribution to the development of business and technology, we urge our governments to continue to pursue sectoral liberalization with the widest possible participation by other trading partners who make up the multilateral system.

CONTINUOUS IMPROVEMENT OF THE TRANSATLANTIC MARKETPLACE

The TABD has produced extensive recommendations and provided for detailed discussion of priorities to facilitate trade and stimulate transatlantic economic activity. The elements of a marketplace include, but are not limited to: elimination of excessive regulation; convergence and harmonization of regulations; elimination of non-tariff barriers; strong intellectual property protection; liberalization of services; and strong export growth from small and medium-sized enterprises. Where useful, the TABD will continue to establish specific target dates and detailed requirements for the achievement of specific goals.

We believe it is important to highlight the tremendous growth potential and to emphasize the revolutionary benefits of global electronic commerce. From giving small companies access to global markets to making delivery of government services more efficient, electronic commerce is a powerful driver to create new markets, new applications and new jobs. Incorporating a wide breadth of industry expertise, we have reached unprecedented consensus promoting an industry-led, market-driven, self-regulatory approach to global electronic commerce.

In order to achieve our goals, EU and U.S. business needs an efficient regulatory framework, which maintains high levels of consumer protection without unnecessary, and wasteful duplication. As globalization progresses, our regulatory agencies can no longer continue to function solely on the basis of national considerations. In particular, we urge the governments to establish a solid basis on which to build transatlantic cooperation between agencies aimed at achieving regulatory harmonization.

We are concerned that the implementation of many of our recommendations from the two previous CEO conferences has been slow, despite the fact that our respective governments accept their merits. The responsibility for action and results rests with governments and business in cooperation with one another. The rapid implementation of the Mutual Recognition Agreement will open the way to confidence-building between agencies and for this reason we urge that it becomes operational as a matter of priority. We urge governments to take bold action to ensure our recommendations are addressed in a more systematic way. We welcome the announcement that the U.S. Secretary of Commerce will establish an inter-agency group, headed by the Under Secretary for International Trade, charged with the task of ensuring the implementation of TABD recommendations.

Our communiqué from Rome presents the next steps towards the goal of a transatlantic marketplace. They set out a step-by-step approach to achieving broad commercial objectives. We call for our recommendations to be implemented or firmly adopted within timeframes that meet the needs for business to function properly within the global market. These actions will do more than anything else to build prosperity and to create jobs on both sides of the Atlantic.

PRINCIPAL OBJECTIVES:

ROUND TABLE 1 - STANDARDS AND REGULATORY POLICY

Business leaders have specific requests for regulatory reform in 13 sectors: Aerospace; Agri-Food Biotechnology; Automotive; Chemicals; Dietary Supplements; Electrical, Electronic, Telecommunications and Information Technology (EETIS); Food Additives and Flavors; Heavy Equipment; Medical Devices; Pharmaceuticals; Recreational Marine; Telecommunications and Tires. While the businesses and problems are diverse, leaders adhere to the TABD guiding principle: *approved once, accepted everywhere*.

TABD's bilateral efforts are breaking new ground to advance trade among competitive industries, but we view TABD ultimately as a bridge to global goals. All sectors participating in this Round Table strive to create EU-U.S. consensus on regulation and standard setting, testing and approval (certification) procedures and to develop close links to multilateral fora such as the World Trade Organisation and United Nations sponsored groups. This Communiqué is organised into two parts: sectoral reports and cross sectoral issues:

SECTORAL REPORTS

Aerospace: The aerospace industry endorses and encourages further progress towards harmonization of European and U.S. technical regulations and the establishment of a single European aviation authority with powers delegated from Member States, leading to

simplification and streamlining of joint procedures in Europe. The European and U.S. industries strongly oppose HR 145, proposed legislation that would restrict the ability of the FAA to certify foreign repair stations. This would have serious adverse consequences for the aerospace industry and for international aviation, with no safety benefit.

Agri-Food Biotechnology: Biotechnology in the agri-foods sector is rapidly becoming an important tool in global food production. Given the significant amount of transatlantic trade, future trade barriers can be avoided if the final safety assessment criteria are fully shared among the authorities and mutually accepted by political decision-makers. Industry concludes that the ultimate goal should be to arrive at compatible regulatory requirements leading to full consensus on and mutual recognition of safety assessments. To get action in the short term, the industry recommends formation of a joint EU-U.S. Industry and Government group to work on predictable and transparent regulatory requirements and mutual sharing of safety data and assessments. The industry is also committed to enhancing public knowledge about modified crops and food products and will work with authorities to accomplish this.

Automotive: Industry urged their governments to complete negotiations by early 1998 on an agreement that would allow the U.S. and other countries to participate in the process of international harmonization of automotive regulations and mutual recognition of certifications on an equal basis through the UN/ECE WP29. The industry will pursue its efforts to identify functionally equivalent standards and requests that the U.S. act expeditiously on the petitions now before the NHTSA, and the EU take corresponding action. Industry also seeks full partnership with their governments in the International Harmonized Research Agenda. Finally, the EU, the U.S. and other governments are asked to commit themselves not to introduce future automotive regulations without first consulting actively with each other in an effort to harmonize such regulations first. The EU and U.S. should invite Japan and other countries to join in multilateral discussions outside of TABD.

Chemical Sector: Industry called for the establishment of joint working groups to resolve non-tariff barriers. Three specific actions were recommended. First, the EU and U.S. sign a MRA regarding Good Laboratory Practice (GLP) and the Mutual Acceptance of Data (MAD) building on the OECD practice in this field. Second, to enhance innovation through modification of the current systems of new chemical introductions for three specific situations: R&D chemicals, low risk chemicals and for polymers. Third, to agree on the methods used for hazard assessment and for risk assessment. The working group will provide progress reports every four months.

Dietary Supplements Sector: Industry has formed a new issue group and will concentrate on the following agenda in 1998: Recognise supplements within food law, including ingredients such as vitamins, minerals, amino acids, herbs/botanicals and other food substances recognizing the current status of non-prescription medicines in this sector; promote appropriate claims and statements in labeling and advertising; remove barriers to trade in all supplements produced in accordance with Good Manufacturing Practices, fully and accurately labeled and which are within the upper safety limits developed on the basis of sound science. Government and industry should work together to achieve these goals. Further, the dietary/food supplement industry urges the European Commission and the U.S. Government to provide an exemption for dietary supplements in capsule, tablet, and

similar dosage forms as they consider amendments to the European Commission's Decision with respect to TSE.

Electrical, Electronic, Telecommunications and Information Technology (EETIS):

Industry calls upon the U.S. and EU governments, including regulators on both sides of the Atlantic, to implement, in consultation with private sector, all recommendations in the EETIS paper submitted November 7, 1997. In particular, EETIS stresses the need to work within the Information Technology Agreement discussions at the World Trade Organisation (WTO) towards conclusion of a Conformity Assessment Agreement (CAA), based on the principle "One Standard - One Test - Supplier's Declaration of Conformity". We also call for the rapid and full implementation of the WTO Agreement on Basic Telecommunication Services this year. Finally, industry urges rapid and full implementation of the MRA, which will save over \$ 1 billion each year the agreement is in force.

Food Additives and Flavors: Industry will investigate a new Issue Group and focus on a harmonized system of legislation and mutual recognition of certifications for their products.

Heavy Equipment Sector: Progress was achieved on all issues. In response to the TABD, the European Commission agreed to place utmost urgency on issuing a harmonized directive for non-road machines. Further, the European Commission stated that "...Commission services are ready to provide detailed information to the industry" on the proposed "noise" directive for equipment use outdoors and recommended that HEI communicate directly to DG XI for an update on the status of Stage I and II on non-road engine emissions. U.S. Department of Commerce agreed to forward U.S. and EU CEOs' strong request for product liability tort reform in the U.S. USDOC agreed to provide immediate clarification of the role of ISO 9000 in meeting the U.S. "Fastener Quality Act" requirements.

Medical Devices: Industry welcomes the conclusion of the MRA and supports its swift implementation, including U.S. FDA administrative and legislative reforms that complement the MRA. Industry commits to actively contribute to confidence building activities, including working with governments to broaden the scope of devices covered under the MRA and to reduce costs, redundancy and approval times. International standards should be adopted by both parties as a basis for product and quality system evaluation. Industry looks forward to working with administrations and the Global Harmonization Task Force on related issues. Industry and governments support the concept of a working group consisting of affected parties to adequately prepare the entry into force of the MRA. In addition, industry supports the united implementation of the European Directives on medical devices.

Pharmaceutical Sector: The pharmaceutical industry strongly supports the TABD process. Since last year, there has been significant progress on several of the issues identified by the industry, including agreement on the Mutual Recognition Agreement on plant inspections which now needs to be driven through to implementation. Industry believes the recent European Commission Decision to ban Specified Risk Materials (SRMs) has very serious implications on the continuing supply of medicinal products to patients and is not based on scientific facts and data. The ban could impact 85% of all medicinal products. Industry will work urgently with the European Commission to come to a solution, which ensures the continuity of supply of safe medicinal products, consistent with the industry's commitment to the highest standards of public health. This solution should include, but not be limited to

addressing the following aspects of this problem: tallow derivatives, gelatin, biological products, and clinical trial materials. With respect to Single Market issues, industry welcomes the European Commission's call for a conference to address industry problems with the European Commission's commitment to establish a working group with industry and Member States. Further, industry strongly supports the Bangemann process and reaffirms its commitment to the goal of creating a free and competitive market for pharmaceuticals in Europe. Further, industry seeks the transatlantic harmonization of data exclusivity to 10 years for all pharmaceuticals. Industry reaffirms that the exception to patent rights should only be allowed for genuine academic research purposes.

Recreational Marine Sector: Industry is pleased with the progress achieved to date via the TABD process. The European Commission's draft emissions legislation is at its second formal draft stage. Further work is required and industry will continue to participate fully in the development of this directive in order to avoid unnecessary trade barriers. Industry continues to support the concept of harmonization between a finalized EU Directive on engine emissions and any future equivalent USEPA regulations to the greatest extent possible. Industry has defined specific required actions which will be submitted jointly to the European Commission and the U.S. Government.

Telecommunication Sector: The U.S. and European Business Communities request U.S. and EU governments continue consultations in order to discuss: WTO – effective implementation of all commitments undertaken as part of the WTO Basic Agreement on Telecommunications Services, which includes the three critical components: Establishment of an independent regulator, transparent and non-discriminatory licensing requirements, and clear time frames, definitions, and negotiating principles for interconnection; Spectrum – non discriminatory, transparent and equitable spectrum assignment and standards processes with a view towards allowing a healthy competitive environment; Licensing – development and implementation of non-discriminatory national licensing rules and procedures for telecom services, including satellite services, that allow financially and technically qualified applicants to obtain national licensing generally in accordance with their system implementation plans; Accounting Rates – expeditious reform of the accounting rate system based on cost-oriented, transparent, and non-discriminatory principles. The business communities jointly agree to continue to co-operate closely with the governments of the U.S. and EU to ensure the effective implementation of the above recommendations. The business communities will also review issues related to convergence and globalization.

Tire Sector: The manufacturers support efforts to harmonize existing tire regulatory standards worldwide. Such harmonization would result in uniform regulations based on the concept of "approved once, accepted everywhere". Therefore, over the next several months, the industry will initiate a complete review of existing tire regulations to identify testing, labeling, certification and inspection/surveillance criteria that may need to be changed to achieve harmonization. Specific recommendations for regulatory changes, to enhance transatlantic/global trade, will be presented at the 1998 TABD Conference. UN/ECE WP 29* will be the forum for promulgation of the global regulatory system for tires. An integrated regulatory model that improves safety, free trade and the environment on a global basis without the added cost of unnecessary duplicative conformity assessment will help mitigate the global proliferation of redundant regulations and better serve the consumer.

CROSS SECTORAL ISSUES

The TABD Conference of Chicago of November 1997 called for work towards the principle "approved once, accepted everywhere in the New Transatlantic Marketplace". Guided by this principle, industry continues to develop and to implement work programmes in several sectors whose objective is to eliminate technical barriers to trade. This highlights the need for a substantially enhanced degree of regulatory harmonisation and mutual recognition of market access procedures. The TABD calls on the U.S. Government and the European Commission to make a joint commitment to achieve this goal.

Progress Report on MRA Implementation: Industry wishes to receive a progress report from U.S. and EU authorities on the implementation of the MRA as input to the TABD interim report in preparation for the EU-U.S. Summit of May 1998.

Regulatory Cooperation: The sectors involved in the TABD are asking for the mutual recognition of testing and approvals (albeit with reference to different requirements), a wider acceptance of Suppliers' Declarations of Conformity (SDoC), the harmonization of regulations, the recognition of functionally equivalent foreign regulations and more reference to international standards. Particularly for products with an ever shorter product cycle it is important not to increase cost and lose any time with duplicative conformity assessment procedures. While presently most attention is concentrated on the trade in goods, trade in services suffers equally from the said differences and divergences in EU or U.S. regulations. Hence the TABD is urging the EU and the U.S. to agree on certain guidelines for regulatory co-operation: Whenever adopting new or amending existing regulations, engage in consultations at an early stage to avoid the creation of different, divergent or incompatible initiatives. Any such regulation should be based on scientific evidence and governments should make greater use of each other's technical infrastructures. More sectors and product characteristics should be included into the Mutual Recognition Agreement (MRA) on testing and conformity assessment. Whenever possible the EU and the U.S. should participate in efforts to harmonize regulatory requirements, best on an international level in conformity with the WTO/TBT and WTO/SPS Agreements. Greater transparency and more opportunities for both governments and industry to comment on any significant changes in regulatory policy should be created.

* under either the 1958 Agreement or the proposed Parallel Agreement

Framework Agreement on Horizontal Considerations: CEOs endorsed a broad framework agreement to break down technical barriers to trade in the new transatlantic marketplace and beyond. The framework agreement takes the form of an action programme - including timetables for implementation of specific recommendations - to create a single transatlantic marketplace for regulated products in both the U.S. and EU, guided by the principle "one standard, one test, with suppliers' declaration of conformity accepted".

It was recognised that a prerequisite to the creation of the new transatlantic marketplace would be the establishment of common standards. The U.S. and EU were urged to explore approaches for basing their legal provisions on the Suppliers' Declaration of Conformity (SDoC) - supported by an effective post-marketing surveillance systems limited to legal and regulatory requirements - without necessarily precluding the supplier from choosing the third-party certification route. The action plan includes a call on governments to adopt a single, internationally recognised product mark to indicate conformity to standards and technical regulations.

Fasteners: Industry is aiming at creating a harmonised EU-U.S. system to assure the quality and safety of industrial fasteners with global harmonisation as the ultimate goal. The fastener manufacturers believe that existing international standards provide the necessary assurance of fasteners quality and safety. The implementation of the U.S. Fasteners Quality Act (FQA) should be postponed until such internationally recognised standards are covered by the regulation. The FQ regulations should eliminate any possible discriminatory provision between EU and U.S. suppliers/manufacturers, for instance in the form of request for extra documentation to be presented as a condition for customs clearance.

"Metric Only" Labeling: Industry urges the adoption of an amendment to EU Council Directive 80/181, as amended by Directive 89/617, that mandates the use of "metric only" labeling in Europe by the end of 1999. Implementation of the directive should be delayed indefinitely, and the directive should continue to allow supplemental units of measurement on packaging and labeling on products sold in EU countries. The 1999 deadline is impossible to meet. Labeling requirements for units of measurement must not create barriers to trade.

ROUND TABLE 2 - BUSINESS FACILITATION

The Business Facilitation Group focuses on the implementation of the Chicago recommendations and on preparing recommendations on important new commercial issues. The two business communities applaud the governments' commitment to adopt an OECD Convention on Corruption and Bribery in early 1998, and governments' willingness to remove unnecessary and ineffective export controls on dual use items. By contrast, we see very little progress in implementing recommendations on taxation (e.g. elimination of withholding taxes on inter-company payments of interest and royalties- tax treatment of cross border business integration - binding arbitration agreement on transfer pricing disputes) and customs (e.g. rules and certificates of origin - minimum data - and harmonization customs valuation practices). The two communities reaffirmed their support for global best practices and multilaterally agreed approaches to sanctions. They urged the U.S. and EU governments to intensify their efforts to find a long-term resolution to the problems raised by the unilateral economic sanctions, extraterritoriality and secondary boycotts. In electronic commerce, the EU and the U.S. should resolve their differences and lead in creating a globally harmonized,

market-driven legal framework. They also should cooperate to accelerate harmonized international accountancy standards that would benefit all. EU and U.S. business also share an interest in the United States adopting a fair and rational federal product liability system.

INTERNATIONAL BUSINESS PRACTICES

The TABD urges governments to move quickly to complete a comprehensive OECD convention to criminalise the bribery of foreign public officials. We also ask that the views of business be taken into account to assure a balanced approach and to avoid potentially conflicting obligations imposed by different international organisations. Finally, we continue to urge governments to eliminate the tax deductibility of bribes paid to foreign public officials.

TAXATION

The U.S. and EU business communities wish to express their strong disappointment that no progress has been made on the TABD tax recommendations, and they urge the European Commission and the governments of the U.S. and E.U. Member States to make a priority of resolving the tax issues identified by TABD. In particular, the still existing tax barriers to cross-border investment and trade within the EU are a problem for both U.S. and EU companies. The European Company Statute affords an opportunity to address those problems by instituting a single European market from a tax standpoint, mirrored by U.S. treatment of the EU as a single country under its controlled foreign corporation rules. The need to include binding arbitration in EU-U.S. tax treaties has become more urgent since the tightening of transfer pricing rules by several EU Member States is likely to increase the number of EU-U.S. transfer pricing disputes. TABD also calls upon the U.S. government to withdraw proposed regulations that appear to require long-term amortization of short-term cross-border licenses, thereby creating a mismatch in the taxation of transatlantic transfers of technology and other intangible property. The transatlantic business community was encouraged by the U.S. government's willingness to reexamine these regulations and to meet with a TABD delegation to find a solution.

CUSTOMS

Import and export procedures remain one of the main non-tariff barriers for both large and small companies. The transatlantic business community appreciates the cooperation of the U.S. and the EU administrations to reduce costs and barriers to trade through the convergence and modernization of customs practices. We urge the U.S. and EU Administrations to accelerate the process of implementing the recommendations which the Administrations accepted in Chicago last November. There are major savings to be made if we can, on both sides, simplify, harmonize and computerize procedures, make origin and valuation decisions more clear and uniform, improve cargo release, customs inspection and licensing rules, streamline payments systems, and make all countries border procedures more transparent and accessible. Transaction costs, in short, can be vastly reduced. The U.S. and EU Administrations are urged to consult with the TABD in the implementation process.

EXPORT CONTROLS AND ECONOMIC SANCTIONS

Issue (1): Secondary Boycotts

The U.S. and E.U. business communities support the objectives of promoting democracy, combating terrorism and safeguarding fundamental human rights. We call on all companies doing business internationally to adhere voluntarily to international-recognized principles and global best practices, including providing non-discriminatory employment, safe places of work and other core principles of workers' rights. Following the Chicago Declaration in which the TABD urged the withdrawal of the objectionable extraterritorial provisions of the U.S. sanctions laws enacted in 1996, the U.S. and EU entered into consultations. Prompt resolution of the issues raised by these measures is essential so that governments will not be forced to take defensive measures under national and international law. The TABD strongly urges the U.S. and E.U. to promptly reach a long-term resolution of the problems raised by these sanctions which may include secondary boycotts or extraterritoriality. The U.S. and the E.U. should intensify their consultations to develop effective, concerted responses to threats to common interests and arrive at an agreed approach. The TABD strongly reaffirms its position that economic sanctions, if imposed, should be done on a multilateral basis. The TABD also urges the U.S. government to work with the states to obtain the immediate cessation of economic sanctions at the sub-federal level.

Issue (2): Control Lists

The TABD asks the U.S. and E.U. governments to create a level playing field in imposing export controls and strongly urges these governments to immediately eliminate unnecessary and ineffective controls on mass-market dual-use items that have already been "de-facto" liberalised by major exporting countries. Removing these items from the control lists will free approximately \$20 billion in exports from internal company red tape.

Issue (3): "Catch All" Non-proliferation Controls

Ill-defined "catch-all controls" imposing license requirements for any products to be used by a proliferator of weapons of mass destruction place an unnecessarily heavy burden of responsibility on industry. The TABD urges the E.U. and the U.S. governments to review the Japanese example in publishing a short list of non-controlled products subject to these controls, a list of exempt countries, and by making available to exporters a database of proliferation-sensitive customers.

ACCOUNTANCY STANDARDS

Business leaders stressed their active involvement in support of international accounting harmonization and pointed out the benefits to both preparers and users of corporate financial information. They urged the International Accounting Standards Committee (IASC) to complete its work in developing a core set of high-quality International Accounting Standards as soon as possible, with appropriate input from preparers and other affected parties. They further expressed their strong hope that regulators on both sides of the Atlantic, as well as in other major markets, would accept the IASC's work as the basis for cross-border offerings