



October 31, 2012

Boris Bershteyn
Acting Administrator
Office of Information and Regulatory Affairs

Daniel Calleja Crespo
Director General
Directorate General for Enterprise and Industry

Jean-Luc Demarty
Director General
Directorate General for Trade

Ambassador Miriam Sapiro
Deputy U.S. Trade Representative
Office of the U.S. Trade Representative

Re: Improving Regulatory Cooperation between the EU and United States

Dear Sirs and Madam:

ASTM International (ASTM) is pleased to submit these comments on improving transatlantic regulatory compatibility in the future. Below we provide a background on ASTM International; address current regulatory barriers between the EU and United States, the costs arising from such barriers, and the solutions and benefits from removing the barriers; and, lastly, suggest areas of priority for future negotiations between the EU and United States.

ASTM International

ASTM International is a globally recognized standards development organization with individual members from over 135 World Trade Organization member countries. Our standards are used in research and development, product testing and quality systems. They are often a critical component of the information infrastructure that guides design, manufacturing and trade in the global economy. Chartered as an international not-for-profit organization, ASTM International currently has more than 1,500 members from Europe representing government bodies, academic and research institutions, civil society, small and medium enterprises (SMEs), trade associations, and large global companies such as AstraZeneca, Siemens, Areva, Philips, Bosch, Total and Solvay. Many of these European members are engaged in the leadership of ASTM technical committees where they are helping to develop and shape international standards of benefit to the industrial sectors they serve.

Our standards development process is designed in accordance with World Trade Organization (WTO) principles and allows individuals and governments to participate directly as equals, in a consensus based manner. As a result, ASTM International standards are grounded in the basic values of quality and relevance but are blind to national boundaries. Today, over 4,000 ASTM International standards are accepted and used in regulation in 75 countries around the world.

Regulatory Barriers Arising from European Regulatory and Standardization Policy

The EU and United States should address the regulatory barriers that arise from the EU's current regulatory and standardization policy. These difficulties are derived from the fact that in the context of the New Approach to Technical Harmonisation and Standardisation legislation (the "New Approach"), a presumption of compliance can only be attached to European harmonized standards. Therefore, products that do not conform to European standards need to be further measured and tested against the "essential requirements" outlined in a particular technical directive. This is true regardless of whether or not a product conforms to another widely accepted standard (such as an ASTM International standard). In other words, it makes no difference to EU law whether a product is carefully designed to conform to an ASTM standard or whether it is built in a completely non-standardized way. In either case, the manufacturer cannot benefit from a presumption that its product complies with the EU law, unless it is manufactured in accordance with European standards.

There are several examples which illustrate how restrictions in European regulatory and standardisation policy have limited solutions to safety-related challenges. For example in May 2007, the Commission issued a decision resulting in a standardisation mandate to CEN requesting the organization to develop safety specifications for magnetic toys, following hazardous incidents in Europe and the US. This led to a lengthy process of revising the European toy safety standard because the legislative instruments to adopt relevant provisions of the "state of the art" ASTM standard F963 were not in place, even if such adoption was intended as an interim safety measure until the CEN revision process was completed. In this context, it was the lack of flexibility in the European standard referencing system which led Arlene McCarthy, former Chair of the IMCO Committee in the European Parliament, to express concerns to the European Commission about the European standards revision process and the need to have recourse to utilize other internationally recognized standards – such as ASTM F963.

This inflexibility leads us to believe that non-European standards development organizations do not participate in the process on an equal footing. Within the context of "*Improving Regulatory Cooperation between the EU and United States*", a mechanism should be developed for extending the presumption of compliance to products in conformance with standards compliant with the WTO principles of international standards development. This mechanism would allow the European industry and consumers to make use of a much wider portfolio of international standards, reducing the time and money spent in developing European equivalents.

Solutions and Benefits from Removing EU's Regulatory Barriers

The recent revision of the Standardization Package represented a significant opportunity to move towards a more open market for standards. Except for some limited flexibility in the ICT sector for utilizing technical specifications from fora and consortia, the standardization reform process came to an end with no significant recognition of international standards outside those developed by Geneva-based standards bodies. We therefore hope that negotiations could reopen the discussion on this important topic.

In order to strengthen the Transatlantic economic partnership and to enhance the compatibility of regulation and standards, it is necessary to reiterate our shared commitment to the WTO principles that bind us, and through that commitment, implement measures that draw our systems closer together. In the context of the EU New Approach to Technical Harmonization and Standardization, it is necessary to

extend the presumption of conformity that exists to a broader portfolio of standards that can be found to fulfill the essential requirements of a Directive and that are developed in accordance with the WTO principles. Under this approach, there would be a wider choice of high quality standards to comply with legislative requirements. Companies and regulators could make their choices based not only on the source of the standard, i.e. its organization or process, but more importantly on its actual qualities, i.e. the level of its technical content and its relevance to market conditions. This would allow them to select standards that are most market relevant and have the best technical content, including those that are most up-to-date and comprehensive. Furthermore, companies could choose the standards which most efficiently cut manufacturing costs, contain the most advanced technology, utilize the most rapid revision of that technology and best fit their specific requirements or global business objectives.

Priorities for Future EU-US Trade Negotiations

Standards are the foundation for success in key priority areas for future negotiations: the new global trade system and the development of new and innovative areas. Given the already low tariff barriers and the many areas where the US and EU share a common approach and pursue similar goals, increased convergence of standardization and regulatory processes should be one of the main priorities for any negotiation. Additionally, when it comes to regulation, new and innovative technologies will drive future growth and should therefore be supported as priority areas in the future EU-US trade and economic relationship.

More collaboration is needed in areas of new and innovative technologies where standards have not yet been developed or are still in the development process, such as pharmaceutical manufacturing, additive manufacturing, 3D Imaging, and other innovative technology driven sectors. This is crucial to avoid the duplication of efforts and to ensure that the industry can make most efficient use of the standardisation processes. Another critical area for ASTM International is consumer safety as supported by standards. We would strongly welcome an opportunity to contribute to any efforts of making consumer products safer in both the US and Europe.

Conclusion

ASTM International is pleased for the opportunity to provide these comments about improving regulatory cooperation between the European Union and the United States. Please contact the ASTM Washington Office at 202-223-8505 for any additional information.

Sincerely,

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