White Paper

Strengthening Transatlantic Trade Through a Common Understanding on Standards

About ASTM International
Founded in 1898, ASTM International is a leader in the global standards community.

ASTM International members hail from countries that represent more than 90 percent of the world’s population.

Half of ASTM standards are distributed outside the U.S., and ASTM standards are cited in more than 7,700 non-U.S. laws, regulations, and codes.

EU legislation includes more than 400 references to ASTM standards. More than 1,500 ASTM members are from Europe, some of whom sit on ASTM’s board of directors. Several ASTM committees currently have European leadership. ASTM members regularly hold committee meetings, workshops and technical exchanges in Europe.

Executive Summary
Europe and the United States are leaders in producing many of the world’s highest-quality standards.

The Transatlantic Trade and Investment Partnership (TTIP) discussions provide a unique opportunity for these two superpowers to uncover more ways to cooperate on standards and regulations. Doing so will help unleash the full potential of the U.S.-EU commercial and economic relationship while also improving quality-of-life for more than one billion people.

Both parties can ensure mutually beneficial progress by supporting international standards – regardless of origin – that are: produced in accordance with WTO principles, technically advanced, and market relevant.

Introduction
High-quality technical standards are a pillar of the European and U.S. economies, two of the best-regulated and safest markets in the world. Not surprisingly, these markets have a strong and growing bilateral trade relationship, with about $700 billion in goods trade alone in recent years.

To further strengthen and modernize this mature relationship, the United States and the European Union launched TTIP negotiations in July 2013. With conventional trade barriers already low (average tariffs are less than 3 percent), the main focus of TTIP is to reduce or eliminate non-tariff barriers. Specifically, the Technical Barriers to Trade section of the agreement aims to cover regulations and standards associated with many heavily traded sectors (including cars, machinery, electronics, chemicals, medical devices, pharmaceuticals, cosmetics, textiles and more).

This paper explains significant challenges related to differences in the U.S. and European approaches to standards and standards development. Then, it offers suggestions for greater cooperation, innovation and joint leadership.
Issue #1: “International Standards”
As reaffirmed under the European Regulation on Standardization No 1025 in 2012, the EU officially designates ISO, the International Electrotechnical Commission (IEC) and the International Telecommunications Union (ITU) as international standards bodies.iii

The U.S. Trade Representative observed that the EU approach “includes efforts to establish ISO, IEC and other bodies in which Europe is represented by its 27 member states as the exclusive developers of ‘international standards’ and to require its trading partners to use these particular standards as the bases for their technical regulations. [...] In several venues the EU has sought to establish that the relevant international standards for a particular sector or sectors are developed exclusively by these bodies.”iv Generally, the EU has pushed for the exclusive “harmonization” to ISO and IEC standards where possible.

Conversely, the U.S. standards strategy views that there are multiple paths to viable international standards, supporting flexibility and competition. The U.S. system generally encourages governments and private sectors to make decisions on international standards by interpreting and applying globally-recognized tenets established by the WTO Technical Barriers to Trade Committee’s Decision on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5 and Annex 3.v This policy allows many of the most innovative companies in the world to choose standards that best reflect their global business objectives.

These fundamentally divergent views on what constitutes an “international standard” complicate opportunities for EU-U.S. cooperation. For example, in 2011, when EU negotiators proposed naming ISO and IEC as official international standards bodies in the context of the WTO Negotiating Group on Non-Agricultural Market Access negotiations, 20 major U.S. trade associations jointly urged the U.S. to reject the proposal.vi

Issue #2: Indirect Referencing
A recent issue affecting standards convergence between the EU and the U.S. involves the concept of “indirect referencing.”

About 4,000 European standards are indirectly referenced through 30 directives of the EU’s New Approach to Technical Harmonization and Standardization. These directives allow for a “presumption of conformity” with essential technical requirements. They cover an array of products and materials (construction, packaging, toys, medical devices, equipment, machinery, and more). This benefit is exclusive to European harmonized standards (hENs) which are developed by the ESOs following official standardization requests from the European Commission, or that are harmonized to ISO and IEC standards.

No mechanism exists to permit functionally equivalent standards from U.S.-domiciled SDOs to be treated on equal footing. Therefore, a manufacturer’s product that does not strictly conform to hEN or ISO and IEC standards must be further measured and tested against “essential requirements,” which are often vague and/or costly to pursue.

This complication has led some European Notified Bodies—the only recognized third-party bodies that can carry out conformity assessments—to advise against relying on non-European standards. One said: “When European standards (ENs) exist, it is always advisable to apply them to guarantee conformance with the European directives. In some cases one may take account of non-EN standards, but in this case one needs to justify their use. There is a chance that the application of non-European alternatives cannot be defended in court proceedings; such non-European alternatives may thus cause the manufacturer to be in non-compliance with the requirements.”vii

Some U.S. businesses are reporting that additional product or material testing to show compliance is unnecessary and burdensome, leading to higher costs and untimely delays in accessing European markets.
Issue #3: Participation Models
Both the U.S. and Europe are signatories to the WTO’s Technical Barriers to Trade Agreement which outlines six principles for global standards development: transparency; openness; impartiality and consensus; effectiveness and relevance; coherence; and, consideration of developing nations. These principles are the foundation for effective participation models in standards development organizations (SDOs).

Based on national bodies within the EU, the European standards system was conceived to support the Single Market and its regulatory framework. It admits delegations of experts from each European Member State and represented by relevant national standard organizations (NSOs) through the Brussels-based European Standardization Organizations CEN (trans-sectoral) and CENELEC (electrotechnical sector) as well as ETSI (ICT), which has a direct membership model and is based in France. In this model, standards development is based on the “national delegation principle,” where voting rights on the final standards are in the hands of national Members of CEN-CENELEC. So-called “weak stakeholders” (including SMEs, consumers, environmental groups and labors) are granted “observer” status through relevant Brussels-based advocacy organizations.

SDOs that are U.S.-domiciled are private sector-led and thus organized along industry lines, with some SDOs spanning several industries (e.g., ASTM International). The participation model usually allows for direct individual membership, granting each participant an equal say in the standard development process. As the interconnectedness of the global economy has grown in recent decades, U.S.-domiciled SDOs have become increasingly driven by broad international participation and global market demand. Also, these SDOs generally reflect an array of stakeholders who represent companies of all sizes, trade associations, government agencies, consumer groups, and more. Notably, in the U.S. and among its free trade agreement partners, regulators reference standards from many international standards bodies (e.g., ASTM International, ISO, IEC) as well as other national standards bodies (e.g., DIN, BSI).

Overall, the approaches to participation in standards development between the U.S. and the E.U. are quite different. The European system has been very effective to facilitate the workings of the internal market of Europe, but it does not connect well with the U.S. system nor the systems of trade partners in the Asia-Pacific and Latin America. Also, U.S.-based SMEs and companies that do not have a European presence have limited opportunities to contribute to the European standards development process.

Recommendations

Recommendation #1: Craft a Modern Policy on International Standards
Europe and the United States can prove their continued joint leadership in standards development by crafting a modern and mainstream policy on international standards that better reflects today’s global standards community. This policy should take into account the years of work and guidance established by the WTO TBT Committee.

The elements of choice and flexibility should be increasingly considered in order to create an environment that fosters the highest levels of technical quality, competitiveness and innovation.

Recommendation #2: Support Equivalence When Justified
Given the U.S. and E.U.’s shared culture of high quality and technical excellence in standards, initiatives such as Europe’s New Approach Directives should provide for flexibility for standards developed by U.S.-domiciled SDOs that can demonstrate technical equivalence and global relevance, particularly when such actions would support WTO principles. This would be done with strong respect for the attributes of the European system, allowing European manufacturers and consumers to continue to use European-based standards as they wish.

Recommendation #3: Foster Choice, Innovation and Competitiveness
On a broad level, EU and U.S. companies (including SMEs) – as well as consumers – would benefit from the ability to choose international standards based on the excellence of their technical content and their relevance to global market conditions.

As previously mentioned, the U.S. regulatory system often references ISO, IEC, and European standards bodies such as DIN and BSI. Stronger joint support for choice would better position both the EU and the U.S. to nimbly respond to new challenges and opportunities while promoting innovation and enhancing competitiveness.

Recommendation #4: Support Broad Participation in Standards Development
There is a direct correlation between level of participation in standards development and technical quality. Standards organizations on both sides of the Atlantic should continue to reach out and involve a broad array of voices, including SMEs, industry leaders, consumers, and other stakeholders on both continents – and provide them with a direct vote in the development of standards.

Cross-fertilization of ideas is particularly crucial in supporting emerging technologies, fostering entrepreneurship, maintaining strong consumer protections, maximizing bilateral trade and investment, and ensuring continued EU-U.S. leadership – overall – in the 21st century.
Success Story: Aerospace/Aviation:
Many European members of ASTM are actively involved in shaping aviation standards. Regulators from the European Aviation Safety Agency (EASA) and the U.S. Federal Aviation Administration (FAA) work side-by-side due to the fact that globally recognized standards that ensure safety are of utmost importance.

In this area, European legislators and agencies have endorsed the principle of “choosing standards based on merit,” which follows the needs of the aerospace industry. This involves using the best standards from a wide array of U.S. and European domiciled SDOs. For example, several ASTM standards are accepted and listed by EASA as a means of compliance to airworthiness.

Success Story: Tires & Carbon Black
Carbon black, the primary reinforcing agent in rubber, is used in manufacturing tires. The carbon black committee (D24) and the tires committee (F09) are the world’s source for practices, definitions, and test methods used in transactions everywhere tires are sold. The committees are home to technical experts from major tire manufacturers, including Bridgestone/Firestone, Michelin, and Goodyear. The resulting standards and test methods are referenced in several regulations in Europe and worldwide.

A new committee, also with broad global participation, focuses on recovered carbon black (D36).

8.  This private-sector-led approach was reaffirmed by the Obama Administration in 2012: “The vibrancy and effectiveness of the U.S. standards system in enabling innovation depend on continued private sector leadership and engagement.” White House Memorandum for the Heads of Executive Departments and Agencies.