INTERNATIONAL
Standards Worldwide

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Comments of ASTM International

Introduction

ASTM International is a recognized member of the global standards community with members and users in over 120 countries. Our members include 1,500 individuals from European companies such as Areva, BASF, and Siemens; numerous SMEs; and other important European stakeholder organizations such as the consumer advocacy group known as ANEC. Many of our European members are actively involved in the leadership of ASTM technical committees where they shape our standards to reflect their needs – including regulators from the European Aviation Safety Agency (EASA) working alongside counterparts from the Federal Aviation Administration to jointly address aviation safety issues.

ASTM supports the important objectives of the T-TIP including the elimination of non-tariff barriers and achieving greater regulatory compatibility. We welcome this opportunity to highlight fundamental differences between the standards systems of the EU and U.S. that complicate opportunities for greater standards and regulatory convergence as well as to make recommendations that promote the T-TIP objectives.

The United States is committed to a market-driven, private sector-led approach to standardization where standards are developed through an open, transparent, and balanced process. The ASTM standards development process meets international criteria established by the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Committee. The global standards that result from our process are utilized on a worldwide basis to improve the quality and reliability of products and systems, to advance innovation and interoperability, and to enhance public safety and the environment. When U.S. regulators look to reference standards as part of Federal regulations, they fulfill their WTO commitments and choose standards from ASTM and many other global standards bodies that meet WTO TBT principles.

The European approach to standardization shares many of the same objectives and common attributes as the U.S. system. However, one key difference is that the open development process of ASTM and other U.S. domiciled standards developers allows for the direct participation of individual experts from anywhere in the world in order to reach a global consensus, while participation in the European

standards development process of CEN and CENELEC is limited to European experts working to reach a European consensus. The European system, as embodied in 98/34/EC, has been very effective to facilitate free movement of goods in the Internal Market. Once a European standard is adopted, all other conflicting standards are withdrawn and it becomes the European Norm for all countries that participate in the Single Market. While this system works well at the European level, it is in conflict with the U.S. system and those of its bilateral and multilateral trade partners.

This issue is further complicated by the fact that the U.S. and the EU have different policies on what is considered an "international standard." The U.S. promotes the view that there are multiple paths to international standards and encourages the public and private sectors alike to make standards-related decisions through the interpretation and application of the WTO TBT principles. In Europe, however, the regulatory infrastructure established by laws and regulations such as the Regulation on Standardization (EU) No 1025/2012 restricts choice and flexibility by officially designating international standards bodies as "*the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU)"*. This conflicting policy on international standards complicates opportunities for EU-U.S. cooperation in standards unless it is pursued through the bodies officially recognized by EU regulation – ISO, IEC, and ITU.

Another issue that complicates EU-U.S. standards convergence is "indirect referencing" as part of the EU's New Approach to Technical Harmonization and Standardization. There are 30 New Approach Directives covering a broad range of products such as construction materials, toys, medical devices and pressure equipment. There are over 4,000 European standards that are indirectly referenced as part of the directives - which means that when they are used – on a voluntary basis – a presumption of compliance is attached which satisfies the essential technical requirements of the directive.

However, this presumption of conformity is exclusive to European standards - there is no legal mechanism that exists that permits global standards from U.S. domiciled standards organizations to receive the same benefit or to be treated on equal footing. Therefore, U.S. manufacturers that need to utilize the presumption of compliance in order to be competitive with their European-based competitors must take additional steps to ensure that their products are designed to conform to the European standards that are indirectly referenced by the directive. In most cases, it is unlikely that a U.S. manufacturer had the opportunity to provide technical input in the development of these European standards.

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 by a "Notified Body". Notified Bodies apply different standards of review depending on whether the product conforms to European harmonized standards or not. If a manufacturer declares that European harmonized standards are used, the notified body merely verifies "whether … these have actually been applied"; in that case, the notified body does not examine the safety of the product as such. If a manufacturer chooses not to use European harmonized standards, by contrast, the notified body must assess "whether … the solutions adopted by the manufacturer meet the essential requirements of the directive".

Hence, conformity assessment for products conforming to harmonized standards is considerably more straightforward than for other products. One of the most well-known Notified Bodies in Germany has thus expressly advised its clients against reliance on non-European standards when European standards are available: "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."

As an example, Article 3 of the European Pressure Equipment Directive specifies that all products that are covered by that directive "must satisfy the essential requirements set out in Annex I". Annex I, in turn, outlines the general safety requirements – in terms of design, manufacturing, and materials – under which a product can be considered compliant. More detailed safety specifications for various aspects of pressure equipment are defined in nearly 200 European standards through indirect reference. Article 5 of the Pressure Equipment Directive attaches a presumption of conformity to products conforming to these European harmonized standards:

> "Pressure equipment and assemblies which conform to the national standards transposing the harmonized standards … shall be presumed to conform to the essential requirements referred to in Article 3."

As a consequence, pressure equipment conforming to the relevant European standards is presumed to comply with the general safety requirements of the Pressure Equipment Directive. On the other hand, pressure equipment conforming to non-European safety standards – even when these standards are of equal or superior quality – enjoys no similar presumption. The absence of such a presumption of compliance makes it more difficult for manufacturers of pressure equipment to design and market products in conformity with the Pressure Equipment Directive. U.S. manufacturers and suppliers have frequently expressed frustration over this unfair European technical barrier and USTR has noted it several times in the annual Technical Barriers to Trade Report. This is just one of many examples where U.S. manufacturers are not treated on equal footing in Europe due to the exclusive linkage of European standards and regulations.

Recommendations

1. Companies and consumers in the EU and U.S. stand to benefit from the ability to choose international standards from multiple sources based on the actual qualities of the standards, such as the excellence of its technical content and its relevance to world market conditions. This approach is embedded in the U.S. regulatory system and requiring the use of international standards that meet WTO TBT principles as the basis for underpinning effective technical regulations is an important benchmark provision in bilateral and multilateral free trade agreements. As such, bolstering existing commitments to reference international standards that meet WTO TBT criteria from a broad portfolio of standards development organizations should be a benchmark provision in the proposed T-TIP to help achieve greater standards convergence. In the U.S., regulators make effective use of this flexibility and reference standards from U.S. domiciled organizations along with those of ISO, IEC, and European standards bodies such as DIN and BSI.

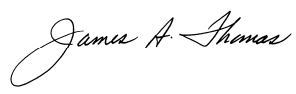
2. In most cases, U.S. agencies follow the Administrative Procedures Act (APA) and allow for public review and comment on the use of specific standards that are proposed to be referenced in U.S. regulations. Individuals from outside the U.S. are provided the opportunity to comment, and their input is taken into consideration by agencies. As part of T-TIP, there should be a horizontal measure that parallels the APA and that is embedded into the European regulatory process. This would provide more openness and transparency, particularly when the European Commission proposes to issue a standardization mandate to CEN or CENELEC to develop new European standards in support of regulations and directives.

3. T-TIP regulatory convergence mechanisms should include implementing more flexibility as part of New Approach Directives to provide indirect reference to non-EU standards (yet WTO TBT compliant) so that manufactures can benefit from the same presumption of conformity that extends to European standards. This would reduce operating costs and administrative delays for many manufacturers seeking access to the European market. On a very limited basis, a provision in European Regulation No 1025/2012 allows public authorities to make use of a broader range of relevant technical specifications when procuring hardware, software and information technology services - including referring to technical specifications that are not developed or adopted by European standardization organizations. This same flexibility in the legal framework of Europe recently created for ICT procurement should be broadened to include more industrial sectors or product categories, and the criteria referenced in Regulation 1025/2012 should serve as the basis for allowing a greater portfolio of global standards to be utilized in Europe for demonstrating compliance with the essential requirements of European technical directives or for public procurement.

4. The T-TIP should build upon existing formal and informal regulatory cooperation agreements and forums – such as the Civil Aviation Safety Agreement between the United States and the European Community. Under this collaborative approach, the relevant Authorities – the Federal Aviation Administration (FAA) and the European Aviation Safety Agency (EASA) - endeavor to cooperate and to jointly provide an alternative means to make their aviation safety and airworthiness findings by using the system of the other signatory country to the maximum extent practicable. Under this approach, the global aerospace industry - working in rulemaking collaboration with the relevant Authorities - have chosen the majority of their standards from U.S. domiciled standards development organizations such as SAE International, ASTM International, ASME, AIA, RTCA, and IEEE. European domiciled SDOs such as ASD-STAN, EUROCAE, ISO and IEC play a relatively minor role. For ASTM, EASA has become actively engaged in standardization activities for light sport aircraft and general aviation. As a result, standards from ASTM are now recognized by EASA under the Basic Regulation the European Aviation Safety as Certification Specifications, Acceptable Means of Compliance, as well as Guidance Material. For aircraft manufacturers, suppliers and owners, this means that they can focus on safety and innovation and do not have to waste time and expend resources in developing redundant equivalent standards for the European market.

In conclusion, we appreciate the opportunity to share our comments and recommendations. Broader Transatlantic agreement on these points would better equip the EU and U.S. to respond to new regulatory challenges while advancing the shared objectives of protecting consumers, advancing competitiveness, promoting SME engagement, and facilitating global trade. Please contact the ASTM Washington office for more information at (202)223-8505.

Sincerely,



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