

## **CEN and CENELEC paper**

# ***The risks of mutual recognition of voluntary industry standards within the context of a future EU- US trade agreement (TTIP) and alternative approaches***

## Overview

As negotiations continue around a potential trade agreement between the US and EU or 'Transatlantic Trade and Investment Partnership' (TTIP), the concept of mutual recognition of European and US industry standards has been raised as an option to address perceived barriers to trade in certain sectors.

The European Single Market is underpinned by a voluntary, single standard model whereby one harmonized European standard, developed through consensus in accordance with the requirements of EU Regulation 1025/2012, is accepted as a means of compliance with a given European regulatory requirement for a market with over 500 million citizens.

This paper, prepared by the European Standardization Organizations (ESOs) CEN and CENELEC, sets out the risks to the voluntary single standard system that would arise from the mutual recognition of harmonized European standards with standards developed outside the framework of Regulation 1025/2012. (The paper does not address the opportunities that are known to exist in some industry sectors, where mutual recognition of regulatory requirements may be achievable and beneficial to those industries.)

The principal risks from mutual recognition to the European model for the use of voluntary standards in support of regulation are:

- Accepting more than one standard as a means of compliance with a European regulation would breach the fundamental principle that industry need only use one standard to trade across all member countries. It would also open the door to arguments that national standards should similarly be recognized, rather than withdrawn;
- Mutual recognition of US standards would increase costs for industry and other stakeholders, as they would need to be involved in more than one standards development process. It would also be more difficult for EU stakeholders to access US processes than those of the ESOs;
- A standard developed outside the governance requirements of European Regulation 1025/2012 would need to demonstrate that it had met the obligations placed on the European system to provide privileged access for European consumers, SMEs and other societal stakeholders in the standardization process;
- In the context of a free trade agreement with the US, mutual recognition in Europe of standards developed outside the governance requirements of European Regulation 1025/2012 would advantage US companies importing to Europe without creating any reciprocal benefit for European companies exporting to the US, where mutual recognition would make no change to market access requirements;

In this paper, detail is provided on the risks associated with the mutual recognition of standards in the context of TTIP. A range of alternatives to mutual recognition, that would have a more balanced impact in terms of trade and market access, are also explored.

## What does mutual recognition of standards in the TTIP context mean for Europe?

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Mutual recognition of European and US standards in the context of a transatlantic trade agreement would mean that the European Commission could grant standards developed by US domiciled Standards Developing Organizations (SDOs), which are not subject to the obligations of EU Regulation 1025/2012, the same status in European regulations as the 'harmonized standards' developed by the European Standardization Organizations (CEN, CENELEC and ETSI), which are recognized by EU Regulation 1025/2012. In practice, mutual recognition would mean that the European Commission could reference specific US originated standards in the Official Journal of the European Union (OJEU) in support of EU legislation alongside the harmonized European Standard. In the framework of EU harmonized legislation, mutual recognition would mean that the use of either the US originated or the harmonized European standard would then confer presumption of conformity with the essential health and safety requirements set by a given EU Regulation or Directive, and enable entry to and free circulation in the EU Single Market.

However, in the US market the reverse would not be true, as the Federal Government does not operate a harmonized standard model and there is no mechanism for the Federal Government to adopt standards and require the withdrawal of conflicting national standards as happens within the Member States of the European Single Market.

Mutual recognition of standards would create no new market access for European companies in the US, but would open up the European market to US imports, adding costs and complexity to European business and consumers.

## Risks associated with the mutual recognition of standards

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On the face of it, mutual recognition of standards can appear to be an attractive proposition, avoiding the need to create a single standard. However, by definition, mutual recognition means that the two standards must be different (otherwise they would not need to be recognized as equivalent; they would be identical).

Media reports have suggested that setting comparable levels of health and safety in Europe and the US could form the basis for mutual recognition of standards in some areas. However, reality is more complex as legal and regulatory frameworks are different. In the absence of an identical standard on a given issue, then mutual recognition of voluntary industry standards would bring the following ten major risks for the European Member States:

1. **Equivalent standards does not mean an equivalence of results in terms of health and safety** – There are a number of published examples of areas such as firefighters' clothing, showing how different approaches can lead to standards whose content cannot actually be compared. The clothing example is described in a position paper developed by KAN (German Commission for Occupational Health and Safety and Standardization), the DGUV (German Social Accident Insurance) and CIOP-PIB (Polish Central Institute for Labour Protection – National Research Institute)<sup>1</sup> and demonstrates how mutual

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<sup>1</sup> DGUV, CIOP-PIB and KAN [Position Paper](#) on 'Technical regulations, standards and conformity assessment methods within the TTIP: The issue of mutual recognition' (November 2014)

recognition could potentially jeopardize safety levels ensured by specific European standards, due to the differences in the legal, safety and standardization philosophies of the US and Europe.

2. **Fragmentation of the European market and increased costs** – Mutual recognition of standards would lead to more standards in circulation in the market place, not fewer, as the abandonment of the principle of a single standard providing a means of conformity would open the door to multiple standards being referenced in the OJEU. This would reverse European policy over thirty years, where the single standard model has successfully reduced the number of industry standards in circulation across the single market from 160,000 to just 19,000. A reversal of this policy would bring new costs to industry, reducing the competitiveness of European companies in their home markets. Multiple standards also reduce consumer choice, as markets become fragmented. (This is the existing challenge for European companies seeking to export to the US.) Such a development would run against the basic principle of the New Approach<sup>2</sup>, which is to reduce the number of standards used by industry to a minimum, reflecting the wish of European industry for one single standard to be used in all markets.
3. **Loss of coherence in the European market** – Europe has a governance system that is capable of identifying, adopting and maintaining one single standard across 33 countries. Additionally, National Standards Bodies withdraw any national conflicting standard. Mutual recognition would undermine the coherence of this system as US domiciled SDOs do not operate under the framework of European Regulation 1025/2012 and cannot provide the same assurance of European stakeholder engagement, including national committee structures, consumer and SME consultation.
4. **Challenge the consolidated European approach** – The acceptance by Member States that any national standards conflicting with a new European standard will be withdrawn is dependent on the presumption that mutual recognition is not an option<sup>3</sup>. Once it is clear that more than one standard can be referenced in the OJEU as a means of conformity with a European regulation, then the argument for withdrawal of conflicting standards by Member States is undermined and the *single market-single standard* model breaks down.
5. **Set a precedent for further claims of equivalence** – If mutual recognition of standards developed by US domiciled SDOs is permitted under a trade agreement between Europe and the US, this will set a precedent for future trade agreements outside Europe and for claims from Member States to grant a similar status to their national standards.
6. **Complicate existing structures of conformity assessment and market surveillance** – The successful implementation of a harmonized European Standard by the European Commission as a means of conformity with a European regulation is dependent not only on the content of the standard itself but on the related systems of conformity assessment and market surveillance. Multiple standards will add costs and complications, given the different regulatory approaches in the US and Europe on issues such as health and safety.
7. **Loss of openness and inclusiveness** – SDOs in the US have a variety of membership models and are not required by law to demonstrate the same level of governance process as CEN, CENELEC and ETSI, which operate under EU Regulation 1025/2012. The ESOs are

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<sup>2</sup> Source: European Commission DG GROW [webpage on the EU Single Market for Goods](#)

<sup>3</sup> See Article 3 of [EU Regulation 1025/2012](#)

obliged to encourage and facilitate the participation of under-represented stakeholder categories in standardization work and to take account of their interests.

8. **Loss of opportunity to contribute** – Due to the differences in the standardization models, European stakeholders may be unable for reasons of cost or accessibility to contribute to the development of a future US standard that was intended to be recognized under a European regulation. Industry experts, consumer groups, environmental and labour organisations would face double the work to contribute not only to the development and maintenance of a European standard but also a US standard.
9. **Create unbalanced market access opportunities** – Even if it were determined by regulators that an EN and a US SDO standard were equivalent and should be mutually recognized as a means of compliance with a comparable US and European regulatory requirement, there would remain a total lack of reciprocity in terms of improving access for European industry to US markets. Whereas under European law the ‘recognized’ US SDO standard would offer a presumption of conformity with the legislation, this would not be the case in the US as the US Federal Government has no mechanism to require the withdrawal of conflicting standards or existing standards already incorporated by reference in regulation. Additionally, the US Federal government cannot prevent individual States from requiring the use of additional specifications for products or services offered in the market.
10. **Challenge the commitment of European countries to their obligations under the WTO and support for ISO and IEC as international standardization organizations** – European Member States are committed to the WTO Agreement on Technical Barriers to Trade. For the Member States, the primacy of ISO and IEC standards is fundamental to maintaining European competitiveness in global markets, where voluntary standards play a vital role in creating a level playing field and facilitating trade. US and European experts work side by side in ISO and IEC to create standards, many of which are adopted in Europe through formal agreements. Recognizing standards developed by US domiciled SDOs as equivalent to harmonized European standards would challenge the essence of the European Standardization System, with its emphasis on the involvement of European stakeholders and commitment to creating a single standard, used everywhere.

## **The EU and US have fundamentally different approaches to the use of voluntary standards in the marketplace**

The risks to Europe from mutual recognition of voluntary industry standards emanate mainly from the differences between the European standardization system and the US standardization model. The vast majority of industry standards in circulation are not related to regulation but are used directly by industry to support the delivery of products and services, addressing issues that improve the quality or performance of their commercial offering. A small proportion of industry standards are used by regulators around the world to support policy by providing a means (or the means) of compliance with a given regulatory requirement. However, the systems for standards development and the referencing of standards in official publications in the US and Europe is very different. In the sections below, these differences are explored further. In the final part of this paper alternative approaches, including existing approaches, to mutual recognition of standards are described that would deliver the same effect without incurring the same level of risk to European industry and consumers.

## The European single standard model is a pillar of the European Quality Infrastructure and Single Market

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CEN and CENELEC standards are developed under the **national delegation** principle. They reflect a **consensus** achieved among delegates representing the views of stakeholders from business and industry, SMEs, labour and environmental organizations, consumers and regulators expressed in 33 countries.

Once approved, CEN and CENELEC standards (ENs) are identically adopted by all their national members and any national conflicting standard is withdrawn. Hence, one EN replaces up to 33 differing national standards. Whenever standardization work started at European level on a given topic, any national work on the same topic is stopped so that efforts are focused on the regional level. This ensures **coherence** in the market, avoids confusion for stakeholders and the effective use of their resources.

The European standardization system also is particularly **inclusive**. The ESOs and their national members have the legal obligation to ensure and report on the effective participation of SMEs, consumers, workers and environmental organizations in their work. Dedicated resources are made available by the European Commission to support the participation of these categories of stakeholders, complemented by a variety of regional and national initiatives and projects.

European standards facilitate **compliance** with EU harmonization legislation and enable the placement and free circulation of goods in the EU Single Market, based on a set of requirements equally applicable in all Member States of the European Union.

Via the New Approach and New Legislative Framework<sup>4</sup>, European Standards remain **voluntary**. Market operators are free to use alternative routes to demonstrate compliance with EU regulatory requirements. This freedom fosters innovation among market operators.

The European Commission announces in advance its requests for standards likely to support EU legislation in the Annual Work Plan. This enables all interested parties, including those from outside Europe to **anticipate** the possibility to contribute in standardization work.

Each of the three recognized<sup>5</sup> ESOs cover specific fields of activity. They **coordinate** to address horizontal or cross-cutting issues collectively.

Whenever possible, CEN and CENELEC standards are aligned with ISO and IEC standards. 31% of CEN standards are identical to ISO standards and 72% of CENELEC standards are identical to (and another 6% based on) IEC standards<sup>6</sup>. ISO, IEC (and ITU for telecommunications standards) are recognized by the European Union as the only International Standardization Organizations in the context of the WTO Agreement on Technical Barriers to Trade. This approach fosters the **competitiveness** of European companies in global markets and the **openness** of the European market.

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<sup>4</sup> Source: European Commission DG GROW [webpage on the EU Single Market for Goods](#)

<sup>5</sup> Source: [EU Regulation 1025/2012](#)

<sup>6</sup> Source: [CEN-CENELEC Statistical Pack, consolidated date for Q1 2015](#)

## The US standardization system is highly flexible but extremely fragmented

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In the US, **over 280<sup>7</sup> Standards Developing Organizations (SDOs) are accredited to develop US national standards**, using as many sets of rules and procedures. Stakeholders that want to contribute to standardization have to identify those organizations relevant to their needs. Those stakeholders may also have to engage with a number of these SDOs, leading to increased participation costs.

**The use of ISO and IEC standards in support of US regulation is not particularly encouraged.** The US government considers that many SDOs, welcoming direct participation with no geographical eligibility condition, qualify as international in the same sense as ISO and IEC. However, the ISO and IEC standards are approved by their national Members and Committees, which convey the national viewpoints of respectively 163 and 60 countries.

There is **no systematic withdrawal mechanism** in the US to avoid the coexistence of diverging specifications covering a given product or service. Organizations accredited to developed US national standards only commit to making “good faith efforts” to resolve potential conflicts among existing or candidate US National Standards<sup>8</sup>.

Standards are often ‘Incorporated By Reference’ (IBR) in US Federal or State regulation and therefore have **mandatory** application.

Executive authorities at US Federal and State levels can incorporate by reference any existing standard or technical specification. The notification of the intended use of a given standard in support of regulation **does not allow stakeholders to anticipate their involvement** and contribution to its development.

The US is not a single market in the sense of the Single Market for Goods<sup>9</sup> that exists in Europe. US State-level authorities can impose stricter legal requirements through regulations and standards than those decided at Federal level. This results in a **fragmented market**, difficult to access in particular for SMEs with limited resources.

Regulators in Europe and the US rely heavily on voluntary standards to support legislation. Voluntary standards play an essential role to help market operators comply with applicable legislation, while ensuring the safety of products and services on the market.

The European and US standardization models are successful, but fundamentally different. Given the different market structures in Europe and the US, introducing the concept of mutual recognition of standards in a EU-US trade agreement would undermine the EU Single Market and unfairly favour US exports to Europe. It would not bring any significant advantage to European industry and companies targeting the US market.

Alternative solutions exist to foster technical alignment between the two economic blocks and effectively support a future EU-US free trade agreement. These are discussed below.

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<sup>7</sup> Source: ANSI Public Document Library, [list of ANSI Accredited Standards Developers](#)

<sup>8</sup> Source: [ANSI Essential Requirements: Due process requirements for American National Standards](#)

<sup>9</sup> Source: European Commission DG GROW [webpage on the EU Single Market for Goods](#)

## Other options: mutual recognition of standards is not necessary for a future EU-US trade agreement

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**The development of identical voluntary standards for use in Europe and the US in support of regulatory requirements is entirely practical but to be effective would require strong regulatory cooperation mechanisms.** Such mechanisms would need to accommodate the alignment of regulatory requirements and conformity assessment schemes, a prerequisite for technical alignment to deliver tangible outcomes in both markets.

**A number of solutions already exist that can foster the alignment of technical requirements between Europe and the US** which would not have the same damaging consequences as mutual recognition of standards. The main alternatives are listed here:

- International standardization. The US is very active in ISO and IEC work, as are the National Standardization Bodies (NSB) in Europe. **Should the US make more use of ISO and IEC standards in support of its legislation, the level of alignment between both sides would dramatically increase.** This would be fully in line with WTO criteria for removing non-tariff barriers to trade and in line with European stakeholders' expectations.
- In cases where no ISO or IEC solution is available or can be achieved, **CEN and CENELEC have proposed specific mechanisms to achieve technical alignment between US and European standards.** This approach, to create a 'transatlantic standard', would result in one single standard available both to European and US regulators for use in their markets, fully respecting existing procedures and requirements of both sides. Such mechanisms would be inspired by existing cooperation agreements in place between CEN and ISO and CENELEC and IEC, which have proved to be very effective over many years.
- In Europe, the provisions of EU Regulation 1025/2012 require that stakeholders from any geography have access to information in advance on when and where to contribute to the development of a standard that will facilitate compliance with a given regulatory requirement. Should the US adopt a comparable approach to the development of new standards for use with regulation, European stakeholders would have a fairer opportunity to contribute. This would itself be likely to **improve the alignment of technical requirements without altering the structure of the US standardization model.**
- And finally, mechanisms already exist for a US standard to be adopted as a harmonized European standard. Provided that the proposed standard is accepted as satisfying the European regulatory requirement and is accepted by European stakeholders through the usual consultation processes, then **an existing US standard can be adopted as a European standard.** This process is managed through CEN and CENELEC and is detailed in a publicly available<sup>10</sup> guide. This approach ensures that the resulting harmonized European Standard meets all the requirements set by European regulators and standardizers, notably in terms of transparency and inclusiveness, even though it was developed outside Europe. It may then become an international standard via the implementation of the Vienna or

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<sup>10</sup> Source: [CEN-CENELEC Guide 23 Consortium bridge – Adoption of third-party specifications as European Standardization Publications](#)

Dresden Agreement (linking CEN with ISO and CENELEC with IEC, respectively). Although this does not change market access in the US for Europeans, this existing process allows for the adoption of standards of US origin in place of home-grown European standards whilst maintaining the governance and due process of the European system.

The EU Single Market is unique and has created unprecedented value for Europe. Europe has invested heavily in developing a system that allows free circulation of goods and a level playing field for industry and SMEs. This system also ensures a European governance of the standards used to oversee the health and safety of European citizens and fully addresses the major challenges of the resource-efficiency and sustainability of our economy.

The mutual recognition of standards in the context of an EU-US trade agreement would have unbalanced outcomes and fundamentally damage an essential pillar of the European Single Market.

Mechanisms exist for the development of standards by US and European experts working together and this is recommended as the preferred route to create one single standard for use in the European and US markets, where such work cannot be undertaken at ISO or IEC.

Existing processes already provide for the adoption of US standards in the European context, where this is deemed desirable, requiring only due process and consultation.

Mutual recognition of voluntary standards should not be confused with mutual recognition of sector specific aspects of technical regulation, which is a separate and achievable goal.

## Useful links

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- [CEN and CENELEC comments on the Initial EU Position Paper on Technical Barriers to Trade in the TTIP context](#) (September 2013)
- [CEN and CENELEC Open Letter to European Commission President José Manuel Barroso, Vice-President Antonio Tajani and Commissioner Karel De Gucht, Regarding standardization-related aspects of the Transatlantic Trade and Investment Partnership negotiations between the European Union and the United States](#) (October 2013)
- [CEN and CENELEC provide clarification on standards-related aspects of issues to be addressed during EU-US trade talks](#) (October 2013)
- [CEN and CENELEC response to the public consultation on the proposed revision of the US Office of Management and Budget \(OMB\) Circular A-119 "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Act"](#) (May 2014)
- [DGUV, CIOP-PIB and KAN Position Paper on 'Technical regulations, standards and conformity assessment methods within the TTIP: The issue of mutual recognition'](#) (November 2014)

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## About CEN and CENELEC

**CEN (European Committee for Standardization)** and **CENELEC (European Committee for Electrotechnical Standardization)** are recognized by the European Union (EU) and by the European Free Trade Association (EFTA) as European Standardization Organizations responsible for developing and defining standards at European level. These standards set out specifications and procedures in relation to a wide range of products and services.

The members of CEN and CENELEC are the National Standards Bodies and National Electrotechnical Committees of 33 European countries including all of the EU member states plus Iceland, Norway, Switzerland, Turkey and the former Yugoslav Republic of Macedonia.

European Standards (ENs) are developed through a process of collaboration among technical experts nominated by business and industry, research institutes, consumer and environmental organizations and other societal stakeholders. Once adopted, these standards are implemented and published in all of the 33 countries covered by CEN and CENELEC.

CEN and CENELEC also work to promote the international harmonization of standards in the framework of technical cooperation agreements with ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission).

For more information, please see: [www.cencenelec.eu](http://www.cencenelec.eu)

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