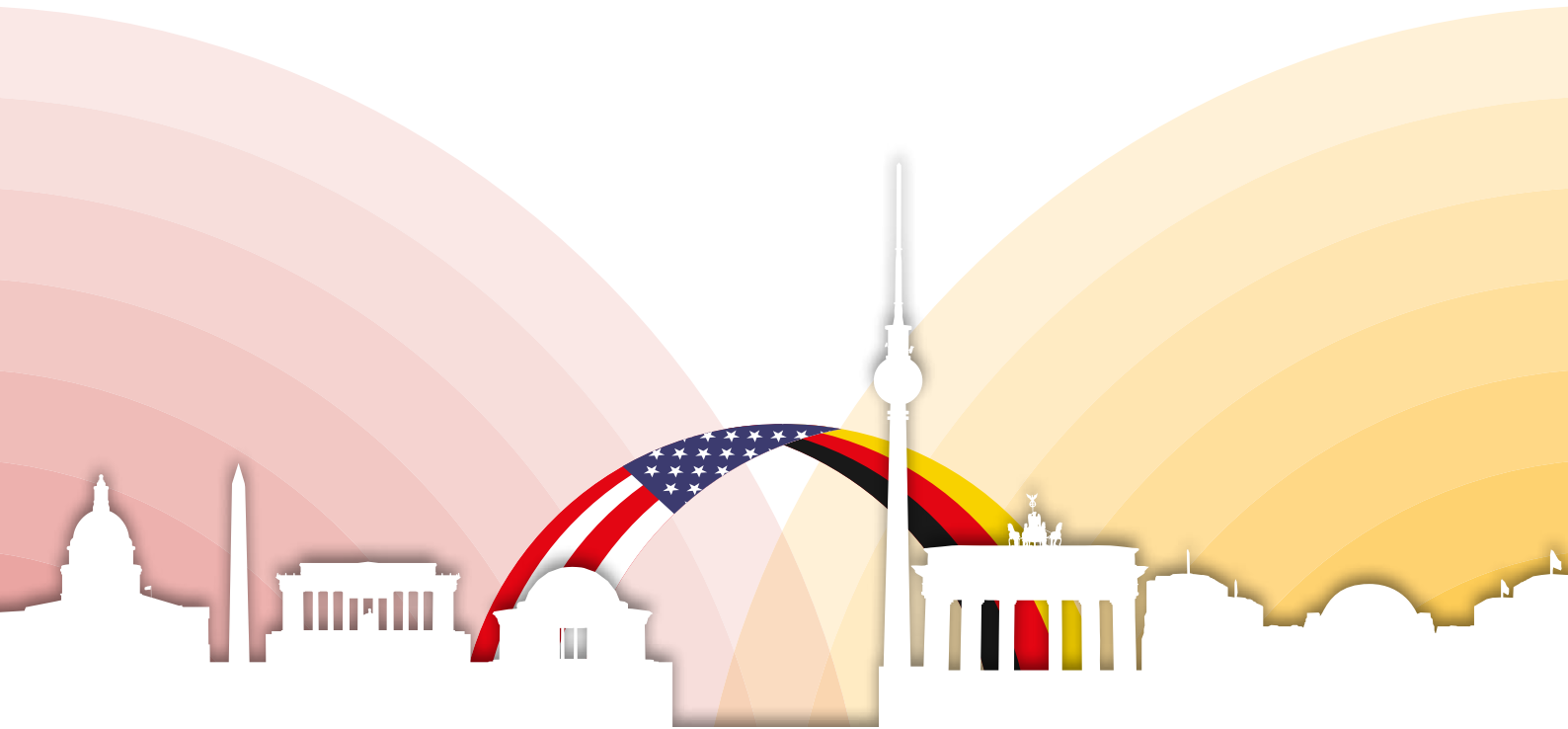


Transatlantic Trade and
Investment Partnership –
How can standards support?



U.S.-GERMAN STANDARDS PANEL 2013



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IMPRINT

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Editor: Sibylle Gabler

Designed and set by:
ERGO Industrierwerbung GmbH, Berlin

Photos: Christian Kruppa

Printed by:
Rotadruck GmbH & Co. KG, Berlin

94533/2013-11

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OCTOBER 14, 2013

06 WELCOME DINNER

Restaurant "The Oval Room"
800 Connecticut Avenue NW
Washington, D.C.

Guest speaker:
Caroll H. Neubauer
Chairman, Board of Directors, German American Chambers of Commerce

OCTOBER 15, 2013

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Academy Hall
1825 Connecticut Avenue NW
Washington, D.C.

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President and CEO, American National Standards Institute (ANSI)

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Dr. Christoph von Marschall

Chief Diplomatic Correspondent, Der Tagesspiegel

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States of America

Ann Weeks, Vice President, Global Government Affairs, UL LLC

Prof. Dr. Godelieve Quisthoudt-Rowohl, Member of the European Parliament

Frank Ennenbach, Sulzer Pump Solutions Germany GmbH

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• Marcello Manca, John Thompson



• Gary Kushnier, Richard Patterson



• Dr. Jens Albers, Prof. Dr. Joachim Ullrich, Gregory Cade



• Jack Pokrzywa, Frank Ennenbach

OCTOBER 14, 2013
WELCOME DINNER



• Martin Conrads, Rüdiger Marquardt, Peter Fischer



• Dr. Thomas Zielke, Dr. Christoph von Marschall



• Dr. Torsten Bahke



• John Kulick, Jim McCabe



• Dr. Ulrike Bohnsack, Terry de Courcelle



• Sibylle Gabler, Dr. Konstantinos Karachalios



• Gary Kushnier, Jessica Roop



• Ernst-Peter Ziethen, Bruce Mahone



• Marcello Manca, Joe Bhatia



• Caroll Neubauer, Friedrich Smaxwil



• Paul Gervais, Prof. Dr. Bruno Braun



• Markus Brombacher, Dorothee Berendes



Caroll H. Neubauer

Chairman, Board of Directors,
German American Chambers of Commerce

**TRANSATLANTIC TRADE
AND INVESTMENT
PARTNERSHIP – HOW CAN
STANDARDS SUPPORT?**

WELCOME

Why TTIP is relevant:

Transatlantic cooperation remains the foundation for global peace and security. Our shared commitment to free markets is the driving force for economic growth, innovation and jobs. It shapes not only the economic system of the EU and the United States but the international one as well.

Over the past six decades, the United States and Germany have established rules to govern international trade, investment and finance. In that same time frame, the German American Chambers of Commerce have supported the economic relationships between the U.S. and Germany and laid the groundwork for generations to come. Our economic partnerships have since then deepened in almost every measure.

Together, America and the EU account for around \$30 trillion in annual output, almost half of the world's total. They enjoy the most integrated economic relationship in the world. \$2.6 billion in goods flow between the U.S. and the EU each day, with almost \$4 trillion in investments in each other's economies, supporting nearly 7 million people who owe their jobs to the transatlantic relationship. Studies show that TTIP could add \$119 billion to the EU economy and \$95 billion to the U.S. economy.

Germany – economically the strongest among the European countries and the #1 export nation in the EU – will particularly stand to profit from a free trade agreement.

The two nations' economies are reciprocally important to each other both in the areas of trade and investment: 50% of German foreign direct investment goes to the United States (by country, Germany ranks 4th in foreign direct investment in the United States with \$216 billion invested).

The GACCs Annual Top 50 Ranking, which is conducted each year in spring, showed that German affiliates support about 540,000 jobs in the U.S., ranking it 3rd in insourced jobs by foreign affiliates.



Importance of standards:

The U.S. market for medical devices is estimated to be around \$120 billion and the EU market for medical devices is around EUR 100 billion. Enhanced trade has the potential to further grow jobs on both sides of the Atlantic. Currently, the medical technology industry employs more than 2 million people in the U.S. and more than 575,000 people in the EU.

As the DIN sees its task as a facilitator in the harmonization of the European and U.S. standard collections, the GACCs stand for the collective voice of German industries in the U.S. with a network of more than 2,500 member companies within the German-American business community. Many of these members are small and medium-sized enterprises (SMEs).

This happens to be also the case for my industry sector in which 80–90% of businesses are SMEs in both the U.S. and EU. The medical device industry on both sides of the Atlantic reinvests 8–10% of revenue into R&D.

The visions for the medical device industry:

- The alignment of regulatory processes brings significant gains and enhanced business opportunities that lead to minimizing redundant testing and to accelerating access to new, innovative medical devices for patients.

Priorities should include:

- Mutual recognition of ISO 13485 – in a single audit process, harmonized format for product registration submission and a common way to trace products through a single unique device identification (UDI) process.
- We see the TTIP as an opportunity to fully eliminate existing tariffs on medical devices, ensure greater transparency in both governments' rulemaking processes including reimbursement, create opportunities to engage third countries and promote greater harmonization.

Conclusion:

In times of slowing world economies, a transatlantic agreement could do more to strengthen growth, create jobs and raise standards to empower and enhance each other in an effort to reduce unnecessary costs and create simpler regulations.

A key priority in the medical device sector should be regulatory convergence. As leaders in the global economy, the United States and Europe have the capacity to set standards for trade which can be adopted at an international level and have spill-over effects to

- increase demand and add to the world economy, and
- provide a basis for global standards to also be adopted by other countries, which would make trade more efficient and cheaper.

Besides tariff dismantling, the focus should lie on the area of regulations and standards to obtain improved market access, reduce cost differences, and develop rules to include provisions to promote the global competitiveness of SMEs.

The existing barriers do not only negatively affect our consumers and their competitiveness but have an impact particularly on small to mid-size entities.

The DIHK, the Association of German Chambers of Commerce and Industry, welcomes the launch of negotiations for a comprehensive and ambitious transatlantic agreement. The authority will support this project and engage in negotiation areas such as market access, regulatory cooperation and global rules.

To conclude on innovation, the ride won't be a smooth one as the TTIP will be a comprehensive and high-standard trade and investment agreement that offers significant support for trade which is also a long-term strategy for the economy, for growth and employment.

1. OPENING



WELCOME ADDRESS

Joe Bhatia

President and CEO, ANSI

Standards and conformance play a critical role in the economy, impacting more than 80% of global commodity trade. The jury's still out on what that will mean for 2013 ... but in 2012, that 80% impact came to more than 14 trillion dollars. It is clear that effective utilization of globally relevant standards and conformance promotes technological interoperability and the competitiveness of all businesses.

So what do I mean when I say "globally relevant standards"?

The U.S. endorses the globally accepted standardization principles of the World Trade Organization's Technical Barriers to Trade Agreement, which include openness, balance, consensus, and transparency, among many others. We believe that – as long as these principles are followed – a high-quality, globally relevant standard will emerge, regardless of which standards developing organization or which nation produced it.

ISO and IEC are some of the most recognized names in standards development, but it is important to note that other SDOs are also developing high-quality, globally relevant standards, and in some cases, have been doing so for well over 100 years.

For companies that develop, manufacture, and distribute their products and services all over the world, reliance on globally relevant standards and conformance programs is imperative. Otherwise, you have products, personnel, systems, and services that cannot cross borders.

That is why standards and conformance are so important to the continued health of the excellent trade relationship between the U.S. and Germany. As of June 2013, the U.S. has already exported nearly 24 billion dollars in goods to Germany, and in turn, has imported over 54 billion dollars in goods from them.

We have come a long way in this key trade relationship ... and as the components of Transatlantic Trade and Investment Partnership (TTIP) are implemented, the importance of our relationship is only going to continue to grow.

The U.S. and EU economic relationship accounts for half of global economic output and nearly one trillion dollars in goods and services trade. The TTIP provides an opportunity to build on one of the world's strongest trade alliances and further strengthen our trading relationship. And standards and compliance requirements that follow the principles outlined in the WTO agreements can further the goals of the TTIP.

That is why ANSI has been meeting with the European Standards Organizations – CEN, CENELEC, and ETSI – to negotiate an agreement that will support the TTIP objectives. Harmonized standardization between the U.S., the EU, and Germany will benefit the transatlantic market as well as global trade. Our international collaboration can foster comprehensive solutions to address some of the technological, economic, and societal challenges that we all face.

WELCOME ADDRESS

Dr. Torsten Bahke

Chairman of the Executive Board, DIN

It is with pleasure and pride that I welcome you, on behalf of DIN, to the U.S.-German Standards Panel. We have gathered eminent leaders and distinguished experts from the public and private sectors and from standardization to discuss the question:

“How can standards support the Transatlantic Trade and Investment Partnership?”

Forgive me if I dare to answer that question at the very beginning of our discussion: standards can make a tremendous impact on the Partnership!

Gabriel Felbermayr, a Professor of Economics who will speak to us this afternoon, and his colleagues have very recently published a study on the macroeconomic effects of the TTIP. Their findings support my claim. In a scenario in which non-tariff barriers to trade are liberalized in addition to eliminating tariffs, economies on both sides of the Atlantic benefit to a great extent. The trade volume of 83 billion U.S. dollars between Germany and the U.S. can potentially increase by over 90%! A significant reduction of non-tariff barriers to trade could create up to 2 million new jobs in OECD countries, more than a million for the U.S. and 180,000 for Germany. Within the “deep liberalization” scenario, the experts predict an increase of 13.4% in the per capita income of the USA.

With these amazing figures in mind, there is no doubt that standards are a crucial factor in support of the TTIP. So please allow me to rephrase the title of our panel, to give it a little more focus: “What can we do precisely to make the enormous effects of standardization work in favor of a Transatlantic Free Trade Zone?”

We are, of course, talking about the positive effect of common standards as opposed to the adverse effect of diverging standards.

In Europe, we have some experience with that. We have harmonized approximately 150,000 standards into a European body of 19,000 standards. It has taken us some decades of hard work – but – today we are benefitting from a European Economic Area with a gross domestic product of 13 trillion euros, for which European standardization has laid an important foundation.



In the beginning were the political will and an ever increasing belief of enterprises in the benefits of harmonized standards.

I am not trying to say that the European way is the right way for the Transatlantic Partnership. However, when 28 very diverse countries with a wide variety of economic players can agree on harmonized standards, it gives us hope that the U.S. and the European Union will find a way to do so, as well. We have to find new and unique ways of cooperation in order to be successful. It will take a while, it might be cumbersome, but the benefits are promising.

Industry in Europe has had a good experience with common standards, U.S. industry is in the process of being re-vitalized, and the current political will in favor of the TTIP has created a historic momentum.

I am happy to say that we are starting from a very fine basis. We are looking back on many years of close cooperation and friendship with our colleagues from ANSI. We are very grateful that they have put a lot of work into the preparation of this panel.

The German-U.S. friendship in standardization extends to ASTM, SAE, IEEE, UL, and many other organizations, thus providing a solid ground for the years to come.

Let's not get lost in the past by trying to re-negotiate the content of existing standards. Let's look ahead towards the future and find new topics and new ways of cooperation.

We are being faced with an excellent opportunity. The negotiations of the TTIP display the political will for a step forward. Now industry actors, standardizers and certification experts need to find solutions in their very own best interest.

I am looking forward to the discussions. Thank you!

2. THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP

POLITICAL BACKGROUND AND AGENDA



Dr. Berend Diekmann

Head of Division, External Economic Policy (G8/G20, OECD, United States, Canada, Mexico), German Federal Ministry of Economics and Technology

PROSPECTS FOR A TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP – A GERMAN PERSPECTIVE

Political timetable

The political timetable for TTIP was designed very tight from the outset. According to official statements, the formally sought negotiation period is max. 18 to 24 months. This ambitious timetable is due to the fact that European elections will take place in May 2014. A new European Commission can be expected as of Nov. 1st. In the USA, mid-term elections will be held on Nov. 4th, 2014. Obama's presidency will end Dec. 2016. Both parties apparently aim at having negotiations conducted with a continuous group of experts and politically responsible people. Accordingly, the first round took place July 8–12. The second round was scheduled Oct. 7–11, but had to be postponed due to the U.S. government shutdown. A second round, integrating what had been planned for the third round, will now start Dec. 16th. This can be called a negotiating staccato.

The EU negotiating mandate

As to trade in goods, improvement in market access, reduction of nearly all tariffs in bilateral trade to zero and moving of differing concepts closer to comparable rules of origin are in the focus. As to trade in services and investments, the partners will aim at market access for services and investments based on the highest level of liberalization and protection that contracting parties have agreed on in existing free-trade agreements. Moreover, provisions on the protection of investments and on dispute settlement between investor and state (ISDS) shall be included. As to public procurement, access to procurement markets at all levels of government (federal/sub-federal) should be improved. As to regulatory issues and non-tariff barriers to trade, a reduction of barriers to trade and investment through improvement of regulatory compatibility, incl. SPS, technical requirements, standards and conformity assessment procedures, horizontal rules for improved regulatory coherence and compatibility and sector-specific requirements in areas of considerable importance for transatlantic economic relations (automotive industry, chemicals and pharmaceuticals industry, medical devices, information and communications technologies, financial services) are included. Negotiations on rules include matters of intellectual property rights, environmental and labor law relevant to trade, provisions on competition policy and state owned enterprises, energy and raw materials and rules on capital and monetary transactions. The stipulated creation of an institutional framework means means monitoring obligations and taking steps to achieve compatibility between regulatory systems, including a dispute-settlement mechanism and a regulatory cooperation council.

Some potential obstacles

There are strong reservations in Europe against the importation of hormone-treated meat and genetically modified foodstuffs. While the USA usually stipulates basing SPS standards on science with emphasis on scientific risk assessment, the EU usually refers to the precautionary principle. It remains to be seen if these approaches differ fundamentally and if bridges could be built. The envisaged creation of exter-

nal arbitration proceedings despite the fact that the USA – as an OECD country – can offer foreign investors effective legal protection, could become a challenge to European firms and add uncertainty to foreign direct investment. European positions such as protection against ill-founded claims and national legal recourse first could become subject to transatlantic disputes. On the U.S. side, possible obstacles include public procurement (“buy American”), particularly at the federal level or access to ports as well as maritime services. Mutual recognition of regulatory certification procedures as a principle prima facie seems to be an easy way forward, but systems differ fundamentally. There is no competition in the field of accreditation in the EU. Thus mutual recognition of regulations, functional equivalence and technical harmonization all have to be carefully scrutinized with a view to applicability and potential for agreement. This is all the more so as mutual information on planned regulations and impact assessment cooperation are in their early stages. The role of and ability/willingness of many independent U.S. agencies and entities to cooperate has to be tested and defined. Under all circumstances, interaction between bilateral and internationally harmonized standards has to be taken into account in order to avoid parallel processes.

Last but not least the issue of data privacy will become a challenge on its own, irrespective of the ongoing NSA scandal.

Interaction with third countries

As a common goal serves the idea to create the basis for a new level of multilateral liberalization, TTIP could become an important field of experimentation for closing loopholes in multilateral rules. A regulatory convergence between the two leading and uniformly regulated economic areas could create global standards. Also, new proposals at multilateral level or the desire of third countries to accede to the Transatlantic Partnership automatically generate further momentum in the liberalization process.

Against this, a formation of regional free-trade areas between third countries which are inconsistent with the Transatlantic Partnership (“opposing blocks”) stands a challenge for international trade policy. Finally, the multilateral approach in trade policy, which from our perspective remains the first best solution in trade policy, could be neglected simply due to lack of resources as regional trade negotiations are spreading.



Michael Fitzpatrick

Senior Counsel and Head of Regulatory Affairs,
General Electric Company

“My experience shows that this is a complex discussion. Too often the two sides are talking past each other. Everyone means well, but there remains a conceptual dissonance, and even difficulties in terminology and definitions, in the way each side views and describes the other’s “regulatory” system. While I believe there is absolutely progress to be made here, progress will be made more difficult until the two sides can get to the point where there is more commonality in their understanding of each other’s systems. Efforts are clearly underway to fix this. It is a matter of finding ways in which the two systems can open up more to the other side, to create more communication, more information sharing and analysis, and, where appropriate, opportunities for mutual recognition and greater alignment and coherence where the regulatory outcomes are the same – even if the means to get there are different. And going forward, for future regulations, the ways we get to the same results can be better aligned with greater communication and cooperation. Neither side is seeking to radically or fundamentally change the way the other makes regulations, nor can they. But real bridges can be built across the Atlantic. So in the end I am very hopeful, but I am also struck by how I am hearing, or having, the same conversations with government officials last week that I had, or heard, four years ago – literally. That is the challenge.”

3. THE ADDED VALUE OF HARMONIZED STANDARDS

WHY INDUSTRY NEEDS NON-TARIFF BARRIERS TO TRADE REDUCED

Jens N. Albers

CEO, nanotron Technologies

Overview

Nanotron Technologies has developed its platforms protect and find that create virtual safety zones for people, animals and assets. The robust, energy efficient ranging and localization technology is standardized in ISO/IEC 24730.

Segments for nanotron’s real time location systems (RTLS) technology include advanced manufacturing, logistics, safety/security, and perimeter protection applications.

Market introduction requires certification, and the standard support for market access is vital.

Nanotron’s unique offering

Nanotron has a working wireless technology – for local positioning solutions (LPS), complementary to GPS, in- and outdoors. System components (hard- and software) have been developed and are employed globally.

The superior price/performance ratio of nanotron’s system solutions enables access to growing mass markets for RTLS.

Focus applications

Nanotron’s focus is on mass-market applications for various verticals such as mine safety, livestock management, and other safety/security applications.

The standardized technology offers a solution for Mine Safety, as globally more than 10 million workers in mines are in need of safety solutions. Nanotron’s solution exceeds not only the Chinese standard for mine safety, but is employed worldwide. Nanotron’s precise tracking improves safety in mines.

Nanotron’s technology offers a solution for Livestock Management, as health monitoring for more than 21 million farm animals in the EU and more globally kept in natural group accommodation is required. RTLS-based data provide man-



agement information for each individual animal in the group, and increased workflow efficiency through animal find function, as well as improved meat quality due to lower levels of medication. Animal health management based on individual location data enables economic payback for farmers.

The industrial revolution (“Advanced Manufacturing”/ “Industrie 4.0”) with its targets of production and logistics network and autonomously controlled processes is another focus area for RTLS. The methods to achieve this are known as: Internet of Things (IoT), Smart Objects, Cyber Physical Systems (CPS), Machine-to-Machine communication (M2M), and Artificial Intelligence (AI) require automatic and unambiguous identification (AutoID), offered by nanotron’s technology.

For all applications, nanotron offers components and modules for real-time location systems and is in the need for vertical market segment partners, e.g. system integrators and value-adding resellers, in order to provide a vertical-specific solution.

Obstacles to transatlantic business

For market access, a proof of application with pilot projects is required. Relevant certifications for the addressed market segments are needed. Furthermore, the access to business partners, who are willing to take the investment in application requirements, is mandatory.

Missing uniform standards are an obstacle to applying a proven application in transatlantic markets. Especially as an SME, it is sometimes hard to find and to be present to business partners in order to satisfy them.

For transatlantic business partners, nanotron offers globally proven application showcases, new business opportunities, and a technology and innovation advantage.

Nanotron's wireless technology is globally certified, but different national certifications are needed. Standards support global certification, but harmonization of standards and certification procedures reduce cost and time to market significantly! This is important as standardization is no longer done as following standardization in the maturity phase of the technology lifecycle (past), or parallel in the growth phase, but nowadays standardization is driven in the development phase of the technology lifecycle as proactive standardization.

Standards support innovation

There is a need for compatibility between different products and components. Harmonized standards allow easier market access and lead to reduced cost and time to market.

Therefore, SDOs should target joint mutual development of specifications, faster development of ISO/IEC standards, improved accreditation and regulatory conformance assessment procedures, technical harmonized standards, mutual supplier conformance declarations, and easier certification structures.

Outlook for overcoming transatlantic business obstacles

The TTIP will support overcoming obstacles to transatlantic business and should include harmonized industry standards. A true transatlantic market with growth of national economies without public spending will have positive impact for SMEs.

Summary

Nanotron has developed a working standardized LPS technology, which is globally employed in safety/security and industrial RTLS applications.

Obstacles to transatlantic business include certification needs, missing harmonized standards, and access to business partners.

TTIP will support overcoming the obstacles by creating a true transatlantic market with harmonized standards.



Gerald T. Lane

Information Technology Industry Council –
Standards Policy Committee, Vice Chairman
IBM – Director of Open Source and Standards

The trading relationship between the United States and European Union is one of the best examples of partnership between regions. During their discussions on the Transatlantic Trade and Investment Partnership (TTIP), we urge the negotiators to continue to refine and improve this important trading partnership. One key area that we would like them to address is the different approaches to standardization policy. By securing a central role for voluntary, consensus-based information technology standards, TTIP can establish a global model for accelerated economic growth and job creation while significantly reducing non-tariff barriers to trade.

Whether in functionality or interoperability, accessibility or technology, standards establish the common core of expectations for IT products and services. Voluntary, consensus-based standards are shaped by diverse stakeholders who bring expertise and creativity to the discussions via transparent and open processes. The results speak for themselves.

Many major digital innovations have been built on voluntary, consensus-based standards. This foundation has transformed our global society, moving economies from the industrial age into the digital revolution and dramatically affecting how we live, work, learn and play.

The TTIP is envisioned to generate new opportunities on both sides of the Atlantic. It will facilitate the creation of new jobs for SMEs as well as existing enterprises and will add or expand new products and new services in both regions. A strong TTIP agreement will support the global competitiveness of EU and U.S. industries/companies. For the U.S. and EU to cement their global leadership in innovation and to set the bar for other major trading partners to follow, the TTIP must adopt an effective approach to global, market-driven standards that is based on transparency, grounded in technical merit and open to all interested stakeholders.



The agreement must be forward-looking and reflect principles that would significantly reduce non-tariff trade barriers and could be used to establish global best practices for technical regulations. These principles include:

- An agreement which recognizes the international status of standards developed by a diversity of standards-setting organizations and voluntarily implemented or adopted in multiple markets throughout the world.
 - Standards development processes that include transparency, non-discrimination, open participation, consensus and the right of appeal; and
 - Appropriate preferences for such international standards over other types (i.e. local or regional) of standards.
- A prohibition of prescriptive technical regulations (i.e. mandating technology) except where a legislator meets its burden to justify them on narrow and proven public interest grounds; exceptions should also reflect a commitment toward global standards and full participation of global industry.
- Mutually agreed conformity assessment approaches that include transparency, international cooperation, proper impact assessment, involvement of industry and other stakeholders as well as non-discrimination and the right to appeal barriers or substantial delays to market entry.

By working together in these trade negotiations, the United States and the European Union have the opportunity to set the 21st-century benchmark for global consensus-driven standards and sound regulatory practices. In addition, a mutually acceptable agreement will ensure that this approach is at the heart of the international digital economy and can be promulgated to other important trading partners.

Dr. Ulrich Eichhorn

Managing Director, German Association of the Automotive Industry (VDA)

HOMOLOGATION AND STANDARDIZATION IN CONTEXT OF THE TTIP - VIEWPOINT OF THE GERMAN AUTOMOTIVE INDUSTRY (GLR)

The worldwide harmonization of regulations and standards is for sure a key point of interest of more or less all industrial branches. Many industrial branches in Europe are following the so-called “New Approach”, by defining minimum requirements in European Standards. The aim is that those standards will be referenced in the regulations for the different regions or nations. The industry may conclude that if their products meet such standards, they will also fulfill the basic requirements for regulation. But this conclusion is not always right, since some nations are allowed to have different national requirements which also have to be fulfilled to achieve a certification to enter those national markets.

The automotive industry tried to overcome such problems by implementing Global Regulations (R) and Global Technical Regulations (GTRs). For this purpose, the “World Forum for Harmonization of Vehicle Regulations (WP.29)” was created under the umbrella of the United Nations Economic Commission for Europe (UNECE). Two agreements were signed to establish a legal framework for the active nations in UNECE WP.29. These two agreements (1958 and 1998) should guarantee that nations which have signed one or both of these two agreements accept in general products which meet the requirements given in the documents published under these agreements. Unfortunately, these agreements also give the nations the freedom to accept only selected Global Regulations or Global Technical Regulations. Even if



Discussion:
Rüdiger Marquardt,
 Member of the Executive
 Board, DIN German
 Institute for Standard-
 ization

all nations worldwide are invited to sign and implement these agreements, the number of nations accepting these agreements could and should be extended. The 1958 agreement currently covers 126 ECE Regulations (plus some under development) and is currently signed by 49 nations, while the 1998 agreement covers 12 Global Technical Regulations (plus some under development) and is currently signed by 31 nations.

Beside these regulations, in which basic requirements for safety and environment are given, the automotive industry also respects standards. Such standards are voluntary and primarily used to define “state-of-the-art” requirements for interfaces, quality, safety and to achieve cost reductions by defining basic products. The German automotive industry prefers International Standards for this purpose in order to avoid national divergences.

The companies of the automotive industry, including the supply industry, are mainly worldwide acting companies. They are focused with their products on worldwide international marketing. Their products are complex, requiring longer development and testing cycles. Consequently, modifications in standards and regulations in order to adopt regional and national requirements are usually cause a significant increase in the development effort and the homologation costs. This finally results also in higher product prices. Considering this, it is obvious that the harmonization of standards and regulations is of a key interest for the automotive industry, their suppliers and finally also for the clients who like to buy such products.

The lack of harmonization in regulation and standardization is a so-called “non-tariff barrier”. Even if it is non-tariff-based, it causes, as explained above, additional costs and burdens which should and can be avoided.

Regarding the regulations, the following three options are seen to achieve harmonization:

- a) The total vehicle certification of one nation/region is mutually recognized by all other nations/regions.
- b) The certification of a single legislative regulation of one nation/region is mutually recognized by the other nations/regions. Some other legislative regulations are not mutually recognized.
- c) The functional equivalence of a single legislative regulation can be achieved, but a certification is still required for all nations/regions.

Option a) is clearly the preferred solution (“certified once – accepted in both regions”) from the industries’ viewpoint since it creates the largest benefits.

From a short point of view, there is no reason that a product which is certificated as “safe” in one nation will not be “safe” in another region. But there are some differences caused by the way safety was introduced and implemented in the national laws. One typical example is the seat belt. While in all European nations there is legal requirement for using seat belts during driving, this is not required in every state in the U.S. Consequently, the calibration of the airbags needs to be different for vehicles used in Europe or in the U.S. In spite of mutual recognition, such differences in regulative requirements and basic conditions may remain and cannot be ignored. For these reasons, the question of product liability has to be discussed, especially in the U.S.

STATEMENTS OF PARTICIPANTS

Jack Pokrzywa, SAE

Jack, what modes and topics of transatlantic cooperation do you see for the near future?

“ It is a matter of establishing priorities and developing a common list with these priorities. We have done it in the past but we have not followed it up. Maybe the way to expedite the development of standards is not to have broader agreements but rather the two organizations, DIN and, for example, ourselves, to create joint specifications. There are a number of areas mostly in the electronics of the vehicle, issues like active safety and cyber security which could make a start. ”



John D. Kulick, Siemens

John, what is the view of Siemens in regard to closer transatlantic cooperation in standardization?

“ It is a great approach to engage both sides, the U.S. and European, on common standards. Automotive seems to be one promising area. The medical device industry could look at continuing to harmonize FDA requirements and ISO standards. That would greatly simplify the process also in the wake of the Unique Device Identifier initiative. If industry can be a champion in driving the process from both sides of the Atlantic that would be helpful. The medical device industry may serve as a best practice to other sectors. Siemens supports the work on common standards from both sides of the Atlantic. ”



Anthony R. Quinn, ASTM

Anthony, how does ASTM view a closer transatlantic cooperation?

“ I appreciate the leadership of DIN and Dr. Bahke and welcome the suggestion that there needs to be some flexibility to recognize non-European standards or non-ISO/IEC standards in this context. Standards developers should explore ways to formalize technical and commercial collaboration to advance the common interests of our stakeholders. DIN is in an excellent position of leadership for the standards community due to Germany’s strong manufacturing base and exporting interests, and TTIP has the potential to provide a platform to test mechanisms that can facilitate greater collaboration. ”





Terry deCourcelle, IEEE

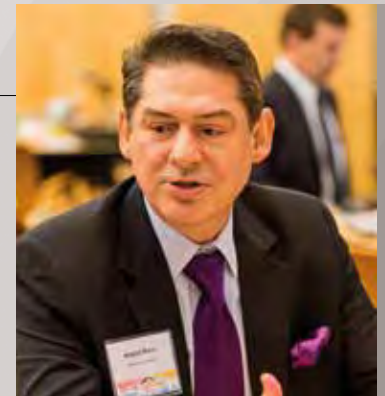
Terry, what would be modes or areas for a closer technical cooperation of the U.S. and European standardizers?

“ We may want to look at the example of ICT. ICT had successes in getting past the traditional divide. Those standards came from organizations which are very inclusive – there were no limitations on participation. That could serve as model for many if not for all sectors. ”

Khaled Masri, Standards Associates

Khaled, what can we do to improve the transatlantic cooperation in standardization?

“ We need to do a better job with getting SMEs more actively involved in this process. SMEs are sitting on the fence. On the EU side SMEs are getting pulled into the standardization process more systematically. On the US side we need to do more to engage them better and start dialogue to incorporate their ideas. ”



Heidi Hijikata, ASME

Heidi, how can we move closer in cooperating transatlantically in standardization?

“ I think we need to improve communication to understand better the real opportunities for cooperation. I have hope for the future, especially for new technologies, products, and services. ”

Dr. Konstantinos Karachalios, IEEE

Konstantino, what is your view on future transatlantic cooperation in standardization?

“ We have to create space where others can join, too. Whatever we do we must follow the European tradition of enlightenment to create a universalist approach. This is particularly true if we talk about global standards. We must not be the exclusive standards makers but allow others to be co-shapers. ”



4. IS CERTIFICATION AN ISSUE?

THE ROLE OF THIRD-PARTY CONFORMITY ASSESSMENT IN ENABLING FREE TRADE

Marcello Manca

Vice President, Government & Industry Affairs,
Europe
Underwriters Laboratories

THE U.S. CONFORMITY ASSESSMENT SYSTEM

- Conformity assessment may be defined as any activity to determine, directly or indirectly, that a process, product, or service meets relevant technical standards and fulfills relevant requirements.
- Conformity assessment activities form a vital link between standards (which define necessary characteristics or requirements) and the products themselves. Together standards and conformity assessment activities impact almost every aspect of life in the United States.
- Conformity assessment is the second side of the market access “coin”; without it, you don’t have a legitimate currency. Standards are good in so far as they are interpreted, applied, and enforced consistently. Conformity assessment is how you do that.
- As affirmed in the WTO TBT Agreement, regulators have the right to take measures they consider appropriate to ensure the quality of imports and domestic products on the market to protect human life and the environment. The need for conformity assessment may be driven by regulations at the federal state, and local levels and adjusted to reflect the needs of societies.
- Standards and conformity assessment programs form the basic “infrastructure” for regulatory efforts of many products and systems.
- Companies like UL participate in the alignment of standards across regions, and are thus uniquely positioned to provide counsel to government agencies on global regulatory efforts and conformity assessment.
- The four U.S government organizations (Federal Communications Commission (FCC), Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), and the Food and Drug Administration (FDA)) all mandate conformity assessment for different products and entrust private sector third parties with varying levels of responsibility in assessing compliance. They leverage the private sector in different ways. The FCC oversees IT/telecom for safety and EMC. OSHA addresses safety of products in the workplace. CPSC addresses safety of products in home and places of enjoyment. And FDA addresses medical devices.
- As an example, let’s look at the OSHA model in a bit deeper detail. The agency mandates third-party certification for a defined scope of products used in the workplace; the requirements apply to domestically produced and imported products alike. It recognizes (through accreditation) conformity assessment providers based on objective criteria, which is reflected in the range of NRTLs (Nationally Recognized Testing Laboratories) accredited. Manufacturers are free to choose which NRTL they use on a business case



basis. And OSHA leverages NRTLs' ongoing surveillance program requirements for cost-efficient and effective ways of ensuring ongoing compliance of products. 15 NRTLs are currently authorized – a mix of European owned organizations and U.S. owned organizations.

- The NRTL program also positively affects the development of standards. Product requirements and standards are often updated as innovation occurs and product designs change over time to meet market needs and desires. Product certifiers also contribute to standards revisions based on their experiences evaluating products or investigating their impacts in the field. The standards development process is thus closely linked to the testing and certification process, and each informs and enhances the other.
- Last but not least, rather than posing a trade barrier to manufacturers in exchange for safety benefits, OSHA's NRTL system enables responsible reliance on internationally harmonized standards in two ways. First, OSHA has formally recognized U.S. standards that are harmonized with International Electrotechnical Commission (IEC) standards, with U.S. national differences. By recognizing these standards, OSHA indicates they are acceptable for use by NRTLs to certify products according to OSHA requirements. OSHA has also permitted NRTLs to use the Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE CB Scheme) for certifications to U.S. standards that have been harmonized with IEC standards. These OSHA practices recognize that internationally harmonized standards help streamline requirements in a way that makes conformity assessment less burdensome and expedites market access for manufacturers accordingly. OSHA also fosters international trade by accrediting foreign bodies to be NRTLs on the same terms as U.S. certifiers, as long as the host country also provides a similar mechanism for accrediting U.S. conformity assessment bodies.
- In conclusion, we like to think of the U.S. model as one that effectively helps prevent unsafe products, via pre-market testing and certification, from getting in the hands of consumers: it adapts to market dynamics because of its "closed loop" feedback structure, and balances twin tensions of safety and time-to-market.
- I hope that our "story" paints an effective picture of the U.S. conformity assessment system and the value of public-private partnerships. That value is as important for regulators as it is for manufacturers, retailers, and consumers – confidence and trade facilitation. There are lessons to be leveraged for TTIP and UL looks forward to being a constructive partner in the ongoing dialogue.



Prof. Dr. Bruno O. Braun

Chairman of the Supervisory Board, TÜV Rheinland AG

ONE STANDARD, ONE TEST, ONE CERTIFICATION? – THE TÜV PERSPECTIVE

TÜV Rheinland is one of the global leaders in independent quality and safety inspection services, founded over 140 years ago. Today, as one of the leading international service providers for quality, safety, and efficiency, we observe technical and economic trends for and together with customers and play an active role in shaping them.

World-class standards are indispensable for successful economies and our task within this is clear: we provide for more safety and quality. World-class standards and rigorous testing by independent bodies have also played a major role in building the reputation of products and services "Made in Germany." This underlines the importance of competent and rigorous certification in building confidence in products and brands in markets.

Organizations such as ours know of the challenges to create testing standards that are internationally valid and that can help to remove trade barriers step by step. With regard to that, the TTIP is a major prize but not an easy one to win. Apart from the very optimistic timescale for completing the negotiations, including political uncertainties in the U.S. and EU, we have differing safety philosophies for product testing or certification on both sides of the Atlantic that cannot simply be reduced to a common denominator.

But what are the negotiators to do when it comes to discussing all those cases with differing norms for the same products? Which safety standards should they adopt within the agreement – the higher ones or the lower ones? Mutual recognition would be a step in the right direction, but it would



Moderation:
Gerhard Luebken,
 President and CEO,
 TÜV Rheinland of
 North America

not take us far enough. We do not need new standards, we need good standards for consumers and the industry. The TTIP is our chance for more safety.

Creating a wide body of mutually accepted standards and testing criteria between the EU and U.S. is complex, yet there is another element of the TTIP well worth bringing into public debate: this is the effect on the international standards-making of creating a single market of almost 800 million relatively affluent consumers. Apart from the considerable sums and time saved by the industry in streamlining certification, the creation of converging or single standards between the two most lucrative markets for both consumer and capital goods globally will have powerful effects.

With so much manufacturing focused in China, and the emergence of world-class brands such as Huawei and Lenovo, it becomes clearer that the U.S. and EU risk gradually losing influence and control of the standards-setting for products which they need to import. Manufacturers and suppliers from outside the TTIP will have little choice but to conform to product standards agreed between the EU and U.S., whose combined influence in bodies such as ANSI and DIN will also have a strong bearing on the international standards that emerge. This should also help our organizations in developing further their offerings not only in the U.S. and Europe but in the Asian markets, particularly China.

Testing and certification bodies attach the utmost importance to a successful outcome to the Transatlantic Trade & Investment Partnership. The possible gains mean a major boost to our economies. Our organizations can play a major role in ensuring the success of what will surely be a very complicated and at points frustrating process of aligning more closely the different approaches to product safety standards and testing in the two markets.

Our opinion is that in order to establish an integrated transatlantic market, all of us have to be open for competition – from both sides and on both sides of the ocean. We need

to cooperate when it comes to testing and compliance methodology. And we have to consider mutual recognition of testing and certification.

But this only works well if both sides have confidence in the competence of the other certification body. These acknowledged rules and regulations then need to be brought from national to local levels of legislation so as to avoid market interference.

Another aspect is harmonizing norms, which is desirable in some cases but takes quite some time. A practical first step in the right direction would be to have a Mutual Recognition Agreement, then establish Notified Bodies and allow them to perform conformity assessments and certification. No one should underestimate the complexity of it all, or the strength of interest groups with reasons not to see progress as a good thing.

We will need mutual confidence – whether it concerns aligning existing regulation, and allowing for mutual recognition of certification or cooperation on drawing up new national or international standards – if the latter should be necessary. Our TTIP wish list reads as follows: common rules, standards, and test procedures with the aim to establish uniformly high levels of quality and safety, effective and efficient regulation of safety and testing standards on both sides of the Atlantic, unburdening of the authorities by an independent conformity assessment, strengthening the competences and expertise of standard setters.

We and other bodies intend to play our part in making sure that the negotiations succeed in making the world a safer place.

We add our voices to those urging regulators to make the right decision for the 800 million people living and working in the U.S. and Europe, and press on with creating a functioning and flourishing single market across the Atlantic, based on trust and confidence that certification bodies can uniquely contribute to the discussions.

5. WHAT CAN SDOs DO TO HELP REDUCE BARRIERS TO TRADE?

Joe Bhatia

President and CEO, ANSI

U.S. SUPPORT FOR TTIP AND THE MULTIPLE PATH APPROACH

As discussions surrounding the Transatlantic Trade and Investment Partnership (TTIP) continue, the American National Standards Institute (ANSI) affirms its support for a cooperative dialogue on standards and conformity assessment between the Institute and the European Standards Organizations – CEN, CENELEC, and ETSI.

Standardization matters will play a very significant role in ongoing TTIP discussions, and are expected to have a major impact on the long-term effects of the EU-U.S. trade relationship. We are proud to build on more than twenty years of productive dialogue with our partners in the European Union in support of what Ambassador Froman called “the world’s largest economic relationship.”

U.S. Trade Representative Michael Froman spoke in Brussels on September 30, 2013, stressing that TTIP remains a major economic priority for the United States.

“The greatest opportunity – and the greatest challenge – of TTIP is in the area of regulation and standards,” said Ambassador Froman. “When we talk about regulation and standards, we are talking about how to bridge the divergences between two well-regulated markets, not about launching a broad deregulatory agenda. We are focused on reducing unnecessary costs that damage our collective competitiveness in an increasingly competitive global economy.”

“TTIP should be an opportunity to set a high standard for global standard-setting, to unleash our collective creativity and encourage good practices around the world,” said Ambassador Froman.



When it comes to international standardization, good practices are measured against the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement Committee Decision¹, which states that the global relevance of a standard is determined by how it was developed, not where. More specifically, the Decision states that the development of international standards must rely upon a number of principles, including openness, impartiality, consensus, transparency, and coherence, among others.

In other words, the global relevance of a standard cannot and should not be measured by which organization developed it. The degree to which a standard is used in the global marketplace is, in ANSI’s view, the best measure of an international standard.

In a recent letter to European Commission leadership, CEN and CENELEC Director General Elena Santiago described the centralized European standardization marketplace, and underscored their adoption of international standards developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

¹ G/TBT/1/REV.10, “Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement”



ANSI joins Ms. Santiago in expressing full appreciation and respect for the differences between the European and U.S. standardization systems. As the U.S. member body to ISO and – via its U.S. National Committee – to the IEC, ANSI strongly supports ISO and IEC standards wherever they meet the needs of stakeholders, industry sectors, and regulators. But the U.S. standardization system is fundamentally built on the needs of the marketplace, where users decide which standards best meet their needs, and in which standards development venues they wish to work. Ultimately, ANSI supports the fact that there are multiple paths to global relevance – as articulated by the WTO TBT Agreement Committee Decision – and that it is the marketplace that decides the utility or applicability of any given standard.

In February 2013 in Dublin, ANSI, CEN, CENELEC, and ETSI began the process of formulating an agreement that would help move these issues forward. This dialogue is meant to increase mutual understanding, facilitate trade, identify specific areas where U.S. and EU standards could be better aligned, and develop consistent messaging for public and private stakeholders on both sides of the Atlantic.

The debate over the definition of an international standard is nothing new. We look forward to continuing this critical and cooperative dialogue with our colleagues at the European Standards Organizations, and to doing everything possible to support an optimal TTIP agreement.



Friedrich Smaxwil
 President, European Committee for Standardization (CEN)

WHY DOES EUROPEAN STANDARDIZATION SUPPORT TTIP?

The European standardization model is unique. It has helped to shape the single market and supports European competitiveness by integrating all stakeholders' interests. It is based on the private sector's involvement and has therefore created an effective co-regulation tool.

The co-regulation tool has developed on the basis of the very successful "New Approach". Within the New Approach the protection levels of all Member States are harmonized while technical details for their implementation are developed by the European Standards Organizations (ESOs). When the EU issues requests for the development of standards, the balance between political requirements and technical feasibility is achieved because experts are mainly coming from industry.



European standardization helped to create the single market of 28 member states. CEN has 33 members which follow the same standardization principles. Next to the EU member states these are EFTA states and Turkey. If we talk about consensus it is the consensus of 33 different nations with diverse cultures and economic levels. All these members adopt the European standards into their national body of standards once a consensus has been reached. And even more important, they withdraw conflicting national standards. It is a powerful tool to create the single market.

European standardization is based on the private sector's involvement. 90% is financed by private industry. Inclusiveness has been mentioned very much today. In the European context one important aspect of inclusiveness is including the SMEs into standardization by ways of easy access at national level.

CEN's vision reads, "To make a major contribution to Europe's innovative capacity and global competitiveness and sustainable growth, and to welfare of citizens, by being the organization of choice for raising standards." Based on our vision we are contributing to European competitiveness by supporting European policies for growth and the EU strategy 2020. European Standards support the Innovation Union policy and the Digital Agenda with standardization activities in eHealth, eBusiness, and electronic invoicing, etc. Standardization plays an important role in support of a resource efficient Europe. Regulators rely on standardization as a critical enabler for change.

In the new Regulation on European Standardization there is one part addressing trade negotiations in which ESOs are asked to support trade negotiations. Our European industry promotes global trade. They are demanding close cooperation with other regions of the world. It is on this basis that CEN's ambitions for 2020 state "global influence" as one of six points. Global influence is a requirement of our industry and therefore it is part of our mission to support TTIP.

The question is: how can we support TTIP?

- We have to recognize that the U.S. and EU systems are different and cannot easily be changed and harmonized. We should avoid any discussions on what is better and what is worse. We have to find ways to bridge the two worlds in order to create the transatlantic economic area.
- Mutual understanding and transparency are very important as well as predictability in the sense of proactive standardization. On the European side we are in the process of consulting industry opinion. In Germany we have done so. We now have to continue this with other European countries and industries.
- Our organizations can support TTIP by being the standardization reference for EU-U.S. trade negotiators.
- Identify innovative areas where industries on both sides have an interest to develop standards jointly. We have to find sectors on both sides of the Atlantic which are willing to cooperate and willing to have a common, open market. This is the appropriate way for new topics. It will probably be more difficult in areas in which standards already exist.
- When we have the first good results of jointly developed standards we have to promote these globally. We should develop consistent clear messages as much as we are clear about the objectives, the open transatlantic market.

It does not seem to be difficult, but the further we go into the working level the more difficult it will be. It will take time and the mobilization of many people. That requires a lot of repetition and a lot of pressure particularly from the industry. We will need the pressure.

No question, CEN supports TTIP. Let's go forward with it.



Dr. Torsten Bahke

Chairman of the Executive Board, DIN

POSSIBLE MODES OF COOPERATION WITHIN THE CONTEXT OF THE TTIP

In the past, we have invested a lot of time and energy in tackling the differences between our standardization systems. I believe it is time to stop investing time and energy in analyzing the differences – we will have to accept them and nevertheless find ways to move on.

How can we find such ways?

Let me put forward one idea. When we decided to enter into a bilateral discussion between Europe and the U.S., I think this was also a decision to deviate from the ISO and IEC processes. ISO and IEC processes are the adequate way to fulfill WTO requirements. Between Europe and the U.S. we might go the way of bilateral or maybe double-logo products. That is a first step. Later on we will deliver the results to ISO and IEC whenever that is in the interest of the industry.

As standards development organizations on both sides of the Atlantic we have to focus on our major common trait: we are all service organizations of industry. Whatever serves industry best, whatever is in its best interest should guide us as standardizers. Industry and technical associations of all sectors will have to assess and prioritize topics for common transatlantic standards development. Common transatlantic standards and specifications on highly innovative topics will guide us into closer cooperation for the benefit of all.

In Germany we have had an initial workshop during which we worked on that question. We have identified a number of industries and technologies which are highly innovative, operate in a transatlantic environment, and will soon have a need for new standards. They are the automotive industry,

Moderation:
Ernst-Peter Ziethen,
Member of the
Management Board,
International
Cooperation, DIN



machinery equipment, the electrotechnical industry, and medical devices. We have to find those projects in which industry on both sides of the Atlantic will find a benefit. Only those projects which will bring a win-win situation will have a chance to be realized.

After having identified initial common landmark standards projects, we will sit down with experts from the U.S. and Europe at one table to create common standards or specifications for CEN/CENELEC and U.S. SDOs. The idea of bilateral transatlantic standardization might be new, but it will be in the interest of our industries – as much as the TTIP negotiations are in the interest of our countries.

I strongly believe it is our responsibility to tell the administration what best can be done in standardization. They have to get guidance from SDOs and the industry. Bilateral transatlantic standardization is not contradictory to the ultimate goal of one worldwide accepted standard. It could be a first move, a first step. Later on there is a good chance to transfer these joint standards to the ISO/IEC level.

It is a question of who moves first, who benefits first. I am sure once our large markets come to a joint view that we are the first movers to set standards in order to export technology, we will not run behind other drivers.

There are already excellent examples in place which prove that this idea is going to work. One example is the new and fascinating process of joining materials in order to manufacture objects, called “additive manufacturing”. ISO and ASTM signed a Partner Standards Developing Organization (PSDO) cooperative agreement on the topic of “additive manufacturing” in 2011. This agreement serves to maximize resource allocation within the additive manufacturing industry and to avoid another barrier to trade. In order to best achieve this, the ASTM and ISO additive manufacturing committees have agreed to normatively reference their standards in the publications of the other organization.

Another best practice example comes from the electromobility sector: SAE has aligned its SAE Recommended Practice J2847/2 “Communication between plug-in vehicles and off-board DC charges” with DIN SPEC 70121. These examples are promising and show how SDOs have worked cooperatively to best serve the interest of their respective industries.

For us to be successful there are some prerequisites: efforts towards the bilateral harmonization of new standards and specifications can only be successful if they are embedded within a framework set up by political as well as economic actors. Such efforts not only involve regulatory harmonization within the scope of the TTIP negotiations, but also shaping the details of the approaches discussed above.

Ladies and Gentlemen, let me summarize. We will only be successful if we look towards the future. Let us work on averting more barriers to trade a) by taking over the content of specifications recently developed on the other side of the Atlantic, and b) by singling out certain areas in which bilateral standards and specifications can be developed as landmarks for future cooperation.

There is a huge potential. We have to grab the fruits to the benefit of our industries on both sides of the Atlantic. We as standardization bodies have a major responsibility to come to new concepts and new ideas.

6. PANEL DISCUSSION

HOW CAN STANDARDIZATION FURTHER THE GOALS OF THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP?



Prof. Gabriel Felbermayr, Ph.D.

Head of International Trade Department,
Ifo Institute, Ifo Center for International Economics

CAN STANDARDIZATION, IF HARMONIZED BETWEEN EUROPE AND THE UNITED STATES, BENEFIT THE TRANSATLANTIC MARKET AS WELL AS GLOBAL TRADE?

The academic economic literature presents convincing evidence that import tariffs account for less than 10% of total trade costs across the Atlantic. The remaining frictions are either due to natural barriers, such as geographical, cultural, or linguistic distance, or due to regulatory behind-the-border measures. These take a panoply of forms, ranging from rules (e.g. customs administration), public procurement (e.g. local value-added requirements), mobility of persons or capital, to standards, norms, and issues relating to certification. Not all of these barriers belong to the public realm; some require private sector investment and cooperation. But the incentives for private sector action depend on public initiatives. Today, almost 50% of all trade complaints filed at the World Trade Organization relate to technical barriers to trade. Within that category, testing and certification arrangements have become increasingly important.

Survey data show that firms perceive the costs related to standards and certification as once-off fixed costs. Those barriers make it impossible for medium-sized firms to export to either the U.S. or the EU, as they are most likely to achieve insufficient foreign market turnover to cover the fixed costs. Lower fixed costs of market access will therefore increase the number of exporters. In the foreign country, this leads to more product variety. Moreover, stronger competition leads to lower prices. Thus, for TTIP to be successful, a strong focus on technical barriers to trade is needed.

The existing empirical evidence on the trade creating effects



of common standards or mutual recognition of standards is scarce. However, the small body of literature comes up with very clear answers: yes, cooperation on standards between two countries does indeed increase the amount of trade between these countries. This is most visible for exporters from developing countries to developed ones, but a positive effect has also been shown for previous U.S.-EU harmonization efforts (in the electronics industry). Trade expansion mostly derives from more products being traded rather than from higher sales per product.

Economic theory warns that preferential trade liberalization can lead to trade diversion, and thus harm third countries and, possibly, the liberalizing partners themselves. These arguments are based on tariff reform scenarios and not on regulatory cooperation. Nonetheless, the empirical literature shows that trade diversion due to bilateral standards cooperation has happened in the past: third countries can lose market share in the liberalizing countries, and this can harm their welfare. Such a possibility is most likely with mutual harmonization. Common standards, in contrast, automatically multi-lateralize, since they must ultimately extend to other trading partners with which the U.S. or the EU maintain comprehensive trade agreements.

While a multilateral approach to tariff reductions is always preferred to a bilateral one, the case for multilateral approaches to standards cooperation is less convincing. Mutual recognition agreements require institutional trust and international control. Presumably, these are difficult issues in the relationship between developed and developing countries. Moreover, in many instances, common world standards would fit neither the needs of developing nor those of developed countries. These concerns put limits to the possibilities of multilateral organizations such as the WTO to achieve much progress in the standards arena.

Summarizing, one can formulate five requirements for desirable standards convergence in the context of TTIP. First, regulatory cooperation must ease market access, otherwise it is worthless. This implies that negotiators



Moderator:
**Dr. Christoph von
 Marschall**
 Chief Diplomatic
 Correspondent,
 Der Tagesspiegel

should focus on certification. Second, the certification process should be transparent, at minimum costs, and available internationally. The establishment of trusted and truly global private certification organizations would be very helpful. Third, common standards are preferable to mutual recognition since the trade creating effects are larger and trade diversion effects are smaller. Fourth, due to the automatic multi-lateralization of common standards, countries with which either the EU or the U.S. have or currently negotiate deep trade agreements should be included in the process. Fifth, preferences from mutual recognition of standards should extend to third country firms once conformity is proved in either the EU or the U.S..

6. PANEL DISCUSSION

HOW CAN STANDARDIZATION FURTHER THE GOALS OF THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP?



Isabel Pastor Arenillas

Trade Attaché, Delegation of the European Union to the United States of America

On regulatory compatibility:

“We are looking at a broader concept of harmonization that can be extended to instruments like equivalence. I will very briefly tap into how we are going to organize work in TTIP and regulatory compatibility. That work will be divided into two areas: sectorial and horizontal.

“First sectorial: We are working on a specific set of existing regulations where there are divergences. Even though the level of health, safety and environmental provisions in public policy objectives is high enough on both sides, they still pose barriers to trade. We made a call for comments from stakeholders. We had 98 submissions from stakeholders, mainly from industry. 23 of them were trade submissions from both sides of the Atlantic. We have started to work on areas that range from medical devices, chemicals, automotive, to pharmaceuticals. For example, when I am talking about regulatory compatibility in the chemical sector we all know that our regulations are very different. We are not seeking to harmonize the systems. The industry has come up with certain ideas in the alignment of the assessment of chemicals for further analysis, which pose important benefits. In the area of medical devices, we are talking about mutual recognition of good manufacturing practices and good clinical practices and inspections.

“The horizontal cooperation is very important as well. It would mean establishing a mechanism: when any regulation is going to be developed, regulators cooperate from the very beginning to avoid any new barriers to trade. It is easier to tackle barriers to trade before they emerge than afterwards. How do we do that? We come from the principle which is already applicable to the standards area: we have two different systems. Those systems stem from different realities. We need to be able to come up with compatible outcomes from different processes. This is not a beauty contest. We need to cooperate while being mindful to the differences in our systems.

The EU has an interest in both the horizontal and sectorial approach. ”

On talks between standards development organizations:

“ We welcome the work that is undertaken by the different standards development organizations. We are very hopeful about the talks between the ESOs and ANSI. We would like to see in the talks something that SMEs have indicated to us: to have good information on what standards have been developed. An interesting thing would be to have a single entry point, particularly for standards used in support of regulations.

Carol Herman

Senior Vice President, Standards Policy and Programs,
Association for the Advancement of Medical Instrumentation (AAMI)



On standards and regulations in the medical device industry:

“I was a regulator with FDA for many years and I am now a standards developer. There are many challenges and opportunities. The challenges include the very different and divergent regulatory approaches between the EU and U.S. The European Directives change too fast for the medical device industry. But the U.S. regulations are far too slow in changing to meet the needs of modern technologies. Another challenge is the unpredictability of funding for the activities the U.S. needs to be engaged in.

“There are opportunities for this to be very useful and fruitful: transparency reforms, less redundancy, and acceptance of multiple SDOs and not being limited to just ISO/EIC standards. This could have a positive impact on the SDOs’ processes becoming more effective and efficient.

“The medical device sector has seen this as a challenge and opportunity for a very long time. The GHTF, the Global Harmonization Task Force, was formed by 5 different countries around the world that wanted to encourage convergence of regulations. It was founded in 1992. We are in 2013 and the work continues. The GHTF did not just look at the pre-market implications of standards development but also at the product life cycle: post-market surveillance, quality systems, auditing, clinical safety, and performance. In the wake of this process came mutual guidance documents and MOUs with standards development organizations. They did not want to be a standards developer. Where they identified needs and gaps they wanted to make sure they had an arrangement with standards developers in place to make that process more efficient.

“I have an example of how TTIP could move forward. The FDA had a quality system regulation. In 2003 ISO developed ISO 13485, which was a convergence of three different standards from 1997 and 1996. When that standard was published, it was far apart from the FDA QSR. But over the last decade they continued to work in a unified way, the U.S. [experts], even though they have the QSR, worked side by side with the international community on this standard. Today ISO and QSR are almost identical. Even where safety is paramount, successes can occur.

On organization following GHTF:

“We do not have national sectors anymore. It is a global market place. It was difficult to regulate from a national approach. It was common knowledge that we need an international approach to regulate. I want to know as a potential patient, if I have a medical event anywhere in the world, that I will get access to the same care and same medical equipment, and that they work in the way they are supposed to. The U.S. and the other countries in this process are committed to that.

On next standardization issues within TTIP:

“I am wondering whether or not we should be bringing ISO and IEC into the discussion. Because there are policies and procedures in standards development in Europe that are very Europe-centric, and that present challenges for us in the U.S.. If we are thinking about a partnership, we need to think about a partnership with a level playing field in many ways. And that is one of them. ”



Prof. Dr. Bruno O. Braun

Chairman of the Supervisory Board, TÜV Rheinland AG

“In the testing, inspection and certification industry we certainly have strong competition. But at the same time we are finding ways to closely work together on certain issues internationally. I am thinking of the international organization IFIA (International Federation of Inspection Agencies) in which both UL and TÜV Rheinland are members. ”



Frank Ennenbach

Sulzer Pump Solutions Germany GmbH

On regulation and standards:

“ We have to have common standards. We have to look for common ground. We do have a lot of common ground. The pump industry has some very good experiences. In Europe we have the ATEX Directive that is covering equipment use in explosive atmosphere, here in the U.S. there is the National Electrical Code Article 500, which is totally different than ATEX. On the other hand we also have the Article 505, which is very much in line with ATEX. What the larger manufacturers doing business on both sides of the Atlantic have to do: they have to do a market transformation over here convincing our customers and their customers that the NEC 505 Article is as good as the 500.

“We also have to start very early in the process. The pump industry in Europe is regulated by the so-called Energy Related Product Directive. In the U.S. the Department of Energy is trying to do something very similar. So we supplied our friends at the Hydraulic Institute with all the information we collected in Europe, all the research information, so that the Department of Energy can do something very similar to what the Europeans did. I personally feel if we have a common ground, if we have a common standard, both sides will benefit the most.

On which approach to standardization is preferable:

“Both approaches are different but comparable. It depends very much on the industry. For example, the American Petroleum Institute standard API 610 is very well accepted within the petroleum and gas industry. We do not need an ISO standard for that. Every refinery is using that standard. There is no need for more.

If we go into the mechanical equipment industry there might be the need for ISO standards. It depends very much on the sector and very much on the product.

To the address of standards development organizations for possible next steps:

“Do not focus just on new standards and new technology. Let’s have the mature standards in mind as well. Look for an open-minded industry which will help and support you in the effort. There are plenty of old standards out there which have to be improved. ”



Ann Weeks

Vice President, Global Government Affairs, UL LLC

On concrete possibilities of cooperation:

“ We need a hard-core comparative of standards in that space. How are they similar and how are they dissimilar. UL has experience in helping clients penetrate the Korean or the Columbian market where UL standards are technically equivalent to the local standards. By comparing those standards we make clear how they are equivalent and that they should be accepted.

On restrictions for the TIC industry to serve clients:

“Third parties view accreditation as an important tool for leveling the playing field and making sure that those undertaking the services have competency in delivering that confidence to regulators and to the public that products do and deliver what they say. In that regard we have operating costs that inflate our business costs as a service provider. We have multiple accreditations to maintain in Europe. We have to have a physical presence. We cannot make laboratory placement decisions purely on a business case basis. These costs for us as a service provider end up spilling over into the costs the manufactures that utilize our services will have to undertake. [...] If we across the Atlantic begin to address some of the impediments on the services industry that support the manufacturing industry, it will help boost not only transatlantic trade but will also serve as a platform to drive innovation and growth both in the goods and services industry outside of the Atlantic. ”

Prof. Dr. Godelieve Quisthoudt-Rowohl

Member of the European Parliament

“ I do not see TTIP only as a technical problem. It is also a political issue. During the next months you will see a lot of discussions coming which will have nothing to do with anything that you discussed today.

I urge every one of you, if you are convinced that TTIP is a good thing, go public, explain it everywhere, write about it in every social and other media. Because ACTA at the end failed because only people against it were campaigning in a way we never experienced before. Everyone who would have had a profit from it kept silent. The industry said, ‘We do not want a shit storm’ – we did not want it either. At the end there was no ACTA, which is a negative sign. [...] Explain why standards are good for citizens, for men and women in the street. Convince everyone, that it is not for you, it is not for the big industries and big organizations but that TTIP is of advantage for every consumer! ”



OCTOBER 15, 2013

RECEPTION BY INVITATION OF PETER FISCHER, MINISTER AND HEAD OF ECONOMIC AFFAIRS, GERMAN EMBASSY



Peter Fischer

“The German Government considers your meeting as very important. Your group showed a lot of optimism. Your meeting also raised many questions. It would be transformative if the two largest and most sophisticated markets in the free world lower the barriers to trade and investment. When people set standards and draft regulation they should from the beginning think transatlantic.”



MinDirig Dr. Rainer Jäkel

“We had a very good meeting today. Above all, I appreciated the optimistic outlook Dr. Bahke and Mr. Bathia gave in their closing remarks. And I would be happy if this optimism would result in some concrete projects by the time we will hold our next meeting.”



• Prof. Dr. Bruno Braun, Sylvana Ricciarini, Bruce Mahone



• Joe Bhatia, Dr. Torsten Bahke, Punita Bhatia, Peter Fischer



• Frank Ennenbach, Dr. Jens Albers, Dr. Karlhanns Gindele, Rüdiger Marquardt



• Peter Fischer, Joe Bhatia, Dr. Torsten Bahke, MinDirig Dr. Rainer Jäkel



• Joe Bhatia, Terry deCourcelle



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• Martin Conrads, Dr. Ulrike Bohnsack



• Carol Herman, Dorothee Berendes



• Dr. Jörg Eduard Hartge, MinDirig Dr. Rainer Jäkel



• Frank Ennenbach, Dr. Karlhans Gindele, Rüdiger Marquardt

STANDARDS PANEL DOCUMENTATION OUTLOOK



- DIN and ANSI have agreed to continue and deepen their close cooperation and extend it to U.S. standards development organizations (SDOs) affected by specific topics.
- DIN and ANSI agree that though the systems of standards development in Europe and the United States are different, this fact should not prevent bilateral progress being made in the interest of industry and its needs.
- The ongoing discussion between ANSI and the three European Standards Organizations (ESOs), CEN, CENELEC, ETSI, were noted, with the intention to have an agreement by the first quarter of 2014 that would be supportive of the current TTIP negotiations, including the possibility that not all standards alignment work had to ultimately lead to ISO and IEC standards.

- The discussions of the U.S.-German Standards Panel revealed the possibility of working on bilateral common standards in the area of new technology where no standards yet exist or are under development.
- The impact on SDOs and their business models regarding sales of standards will have to be considered.
- Where standards exist, it is stakeholders who, in a sector-specific approach, will have to specify to governments and SDOs their preferences in terms of mutual recognition of technical rules or harmonization of existing standards.
- Sectors with a high volume of transatlantic trade, such as the automotive sector, mechanical engineering, electrical engineering, and the chemical industry, have come forward with a wish list for standardization and conformity assessment.
- DIN and ANSI identify industry-related services as another field for cooperation.
- German and U.S. roadmaps in standardization in the automotive sector are being compared.
Besides others, high-priority projects could include the following
 - Electromobility
 - Batteries
 - Uniform technology
 - Uniform human machine interfaces
 - Uniform definition of requirements and test processes
 - Definition of and requirements for road boundaries, road surface markings, and shoulder markings
 - Definition of safety-relevant traffic info and the associated data transmission requirements
- DIN and ANSI will exchange information on respective workshops and roadmaps in the field of smart cities and invite each other to provide comments.



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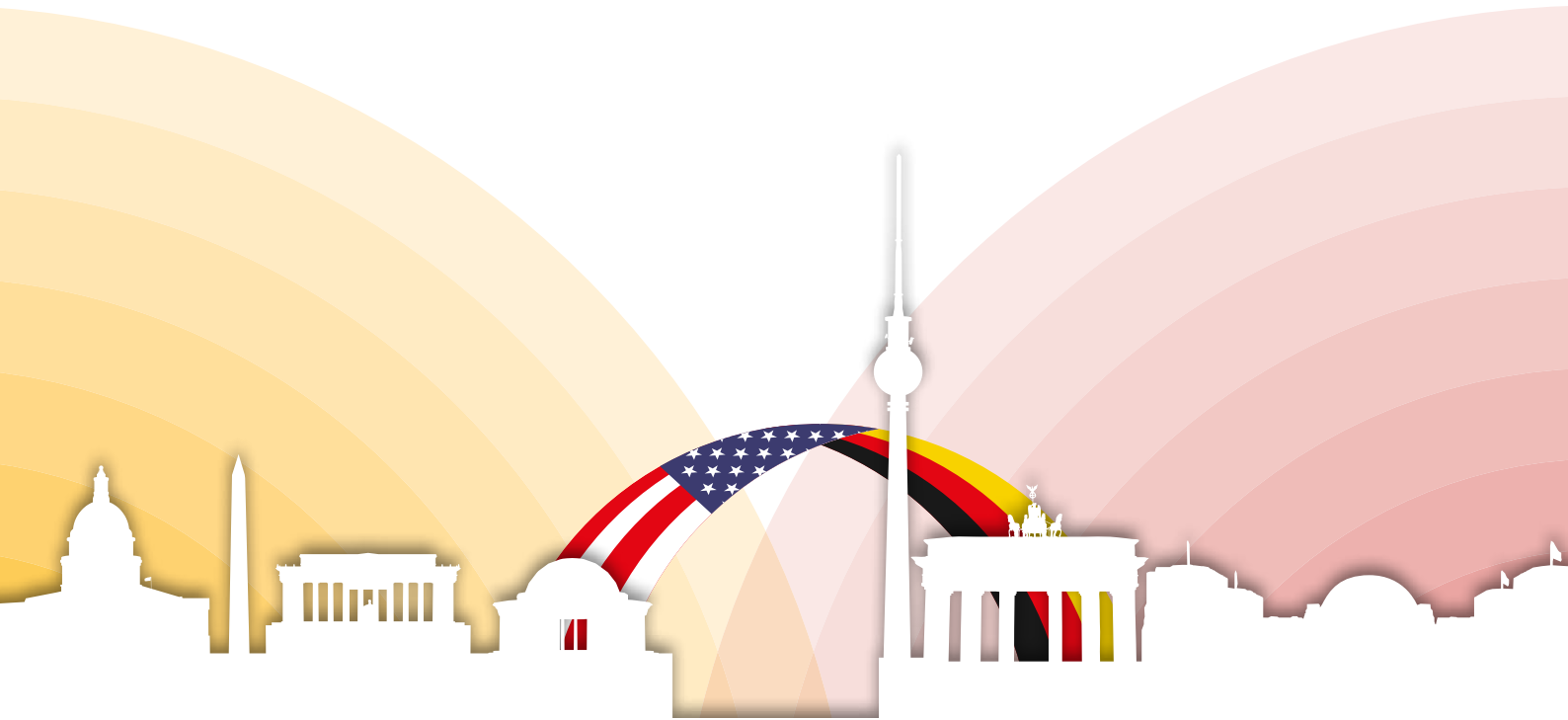
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