

March 14, 2011

The Honorable Francisco Sánchez  
Under Secretary for International Trade  
United States Department of Commerce

The Honorable David Kappos  
Under Secretary of Commerce for Intellectual Property  
and Director of the U.S. Patent and Trademark Office

Ambassador Demetrios Marantis  
Deputy U.S. Trade Representative  
Office of the U.S. Trade Representative

The Honorable Robert Hormats  
Under Secretary Economic, Energy & Agricultural Affairs  
U.S. Department of State

The Honorable Pat Gallagher  
Under Secretary of Commerce for Standards and Technology  
and Director of the U.S. National Institute of Standards and Technology (NIST)

Dear Under Secretaries and Deputy USTR:

The co-signing U.S. industry associations applaud your agencies for their roles in advancing U.S. companies' China related standards and conformity assessment interests. While we recognize the achievements to date, several commercially meaningful problem areas remain which are of importance to U.S. companies doing business in and with China. We are writing to request the establishment of a routine dialogue between U.S. industry and government to enhance cooperation to resolve the most significant standards and conformity assessment issues U.S. companies face when doing business with China. We have organized our concerns into six main categories and outlined each in greater detail in the attached paper:

1. Transparency
2. Openness and Participation
3. Conformity Assessment
4. Uneven Implementation and Enforcement
5. Use and Recognition of International Standards
6. Intellectual Property Rights (IPR) and Standards

To ensure the success of the President's National Export Initiative (NEI) and the doubling of American exports over the next five years, U.S. businesses must be able to access and be able to compete fairly in the China market. In order to accomplish these goals, industry is seeking assistance and closer coordination with the U.S. government.

We commend the Obama Administration's significant efforts to date on these issues and recognize that continued progress requires significant collaboration between the public and private sectors. We stand ready and willing to cooperate with your staff where practical to achieve these shared goals.

To this end, we would appreciate the opportunity to meet regularly on these issues with appropriate staff within your agencies in order to discuss the key concerns outlined in the attached paper, share additional examples of these concerns, exchange information about new developments and issues, and develop a public-private sector strategy to achieve progress on these concerns. We are confident that such public-private cooperation will yield positive results for U.S. companies doing business in

China, and look forward to reviewing tangible progress on these issues within the next year. We will follow up with key offices within your agencies to set up these meetings.

The American National Standards Institute (ANSI), the U.S. China Business Council (USCBC) and the U.S. Chamber of Commerce (USCC) will be pleased to act as the contacts for the group of associations noted below and are available to coordinate a response to any questions. Elise Owen of ANSI can be reached at +1.202.331.3624 or [ewen@ansi.org](mailto:ewen@ansi.org); Ryan Ong of USCBC can be reached at +1.202.429.0340 or [ryanong@uschina.org](mailto:ryanong@uschina.org); Becky Fraser of USCC can be reached at +1.202.463.5890 or [bfraser@uschamber.com](mailto:bfraser@uschamber.com).

Thank you for your commitment to promoting U.S. competitiveness internationally, and working to ensure a level playing field for U.S. industry in China. We look forward to collaborating with you and your team toward these important goals.

Sincerely,

Advanced Medical Technology Association (AdvaMed)  
American Intellectual Property Law Association (AIPLA)  
American National Standards Institute (ANSI)  
Information Technology Industry Council (ITIC)  
Intellectual Property Owners Association (IPO)  
National Electrical Manufacturers' Association (NEMA)  
Telecommunications Industry Association (TIA)  
U.S. Chamber of Commerce (USCC)  
US-China Business Council (USCBC)

Cc: Christine Varney, Antitrust Division's Attorney General, U.S. Department of Justice  
Willard K. Tom, General Counsel, U.S. Federal Trade Commission  
Deanna Tanner Okun, Commissioner, U.S. International Trade Commission  
Leocadia I. Zak, Director, U.S. Trade and Development Agency



Information Technology Industry Council  
Leading Policy for the Innovation Economy



THE US-CHINA BUSINESS COUNCIL  
美中貿易全國委員會

## STANDARDS AND CONFORMANCE IN CHINA

*March 14, 2011*

### EXECUTIVE SUMMARY AND INTRODUCTION

In 2005, China launched an ambitious goal: to form a complete national technical standards system on par with international standards systems by 2010. China has made considerable efforts in the last five years to meet this goal, drafting and implementing new standards at home and dramatically increasing its participation in international standards-setting bodies. The global marketplace has witnessed considerable involvement from a variety of Chinese industries. U.S. industry and the international standards community welcome China's increased engagement in international collaboration and its contributions to advance and improve the global economy.

While China has made significant advances in creating a modern and efficient standards and conformance system, many trends in the evolving Chinese system have raised concerns for U.S. industry. U.S. companies continue to experience significant standards - and Technical Barriers to Trade (TBT) - related challenges in China. The U.S. government has been very responsive to industry's concerns to date. We commend the important work that has been done thus far and hope that these efforts will continue. Our coalition of U.S. associations hopes to lend additional input, support and cooperation to these U.S. government (USG) efforts, focusing on six key issues in China that are summarized below and which are outlined in greater detail in the following sections of this paper.

#### 1. Transparency

U.S. companies often encounter difficulties in accessing new and existing Chinese government standards and regulations that impact our products and services, and have limited opportunities to provide comments on these requirements or to otherwise engage with those drafting these regulations.

#### 2. Openness and Participation

While U.S. companies are able to participate in many Chinese standards development activities, concerns remain that some technical committees remain closed to "foreign participation." This negatively impacts U.S. industry, which has invested tremendous resources in order to participate and who sees this participation as a critical part of its overall engagement in and access to the China market.

#### 3. Conformity Assessment

China's conformity assessment policies require U.S. companies whose products have already undergone internationally accepted conformity assessment testing and certification in other markets to repeat these procedures through designated Chinese test labs and certification bodies in order to access the Chinese market. These requirements add significant cost and delay time-to-market for U.S. companies and put them at a disadvantage vis-à-vis their Chinese domestic competitors.

#### 4. Uneven Implementation and Enforcement

Despite efforts by China's government to make implementation of its standards and conformity assessment rules consistent, U.S. industry continues to confront problems with implementation, including differential treatment between foreign and domestic players and uneven implementation across Chinese jurisdictions.

#### 5. Use of International Standards

China has significantly increased its participation in and use of international standards in recent years. Such trends have the potential to benefit the entire international community. However, a number of key challenges persist in China. "Home-grown" standards continue to be developed. China's recognition of international standards is often overly narrow and may not encompass many international standards normally applied by U.S. industry. Finally, there seems to be a growing trend of removing or changing key portions of international standards for the purposes of creating China-unique standards. Additionally, U.S. visa policy sometimes makes it difficult if not impractical for Chinese participants to join in development work on international standards when conducted within U.S. borders.

#### 6. Intellectual Property Rights (IPR) and Standards

China in recent years has increased its efforts to create a modern standards system that also addresses Intellectual Property Rights (IPR). While many of China's efforts to implement rules relating to the inclusion of technology covered by patent claims are moving in the right direction, U.S. industry and intellectual property owners have significant concerns over several policies under consideration in China that would limit the legitimate rights of IPR owners.

## TRANSPARENCY

Lack of transparency continues to be a significant factor affecting the ability of U.S. companies to enter and compete in the Chinese market. Increased transparency has been consistently identified as a top priority by U.S. companies doing business in China. While inadequate transparency affects all companies doing business in China, small and medium-sized enterprises (SMEs) often find themselves with the least resources available to tackle these issues. These organizations are less likely to have representative offices on the ground in China and often have fewer resources to gain access to information through informal channels.

Since China's accession to the World Trade Organization (WTO), China has committed to increased transparency and has made notable progress. For example, the number of annual Chinese TBT notifications continues to rise – China notified 40 proposed technical regulations in 2003, compared with 200 in 2008. In the 2006 meeting of the U.S.–China Joint Commission on Commerce and Trade (JCCT), China's State Council committed to requiring that all laws, regulations and other measures of all government agencies (central, provincial, etc.) be published in a single official journal, the Ministry of Commerce's (MOFCOM) *China Foreign Trade and Economic Cooperation Gazette*. This commitment was followed in 2008 by a pair of transparency-related commitments: one from the State Council to publish “all trade and economic-related regulations and departmental rules” through the State Council Legislative Affairs Office (SCLAO) website for public comment of at least 30 days, and one from the National People's Congress to publish most laws and regulations that it reviews for public comment. Since 2007, China has improved transparency for a great deal of important information on its standards system, particularly through StandardsPortal ([www.standardsportal.org](http://www.standardsportal.org)), a cooperative initiative of the Standardization Administration of China (SAC) and the American National Standards Institute (ANSI).

While these developments have led to significant improvements in transparency, more needs to be done. Most notably, U.S. companies continue to encounter difficulties identifying and accessing standards and technical regulations that affect their products and services. While China's national “GB” standards – issued by SAC – have been consolidated into a centralized database, there is no similar centralized place where U.S. companies can find technical regulations (i.e., regulations mandated under Chinese law or as an administrative regulation required by a Chinese government ministry) developed by other Chinese government agencies, such as the State Food and Drug Administration (SFDA) or the Ministry of Environmental Protection (MEP) or other types of standards that are adopted or proposed by Chinese government bodies, such as industry standards (*hangbiao*) or local standards (*dibiao*).<sup>1</sup> Further, these types of regulations and standards are frequently not notified to the WTO Secretariat. This is due in part to lack of interagency coordination between the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), which serves as China's TBT enquiry point, and other PRC agencies, and in part to the lack of a common definition or understanding among PRC agencies of what constitutes a “technical regulation.” Mandatory technical requirements for products and services that meet the TBT Agreement's definition of “technical regulation” are often classified as “decrees,” “announcements” or “circulars” and therefore do not get notified to the WTO.

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<sup>1</sup> In the U.S., federal regulations are made available online through the Code of Federal Regulations (<http://www.gpoaccess.gov/cfr/>) and voluntary standards are made available through the NSSN ([www.nssn.org](http://www.nssn.org))

Some of these ad-hoc “technical regulations” have indirectly mandated standards that were previously voluntary. For example, China’s *Administrative Measures for the Multi-Level Protection of Information Systems*, otherwise known as MLPS, is a national-level decree that in a single stroke made over 30 voluntary technical measures mandatory.

Another trend that has caught the attention of foreign firms is the practice of enforcing standards via the procurement process of state-owned enterprises (SOEs). For example, an increasing number of these firms make compliance to voluntary Chinese standards (such as the WLAN Authentication and Privacy Infrastructure (WAPI), a home-grown and proprietary Chinese version of the international WiFi standard) a requirement to participate in bidding. Use of China’s WAPI standard is also required by the China Network Access License (NAL) conformity assessment regime.

Governments should avoid making voluntary standards mandatory except where necessary to meet legitimate objectives (e.g. protection of environment, health, safety). When mandating a specific standard becomes necessary, government should prioritize referencing existing standards over the creation of new technical requirements. Further, it is critical that U.S. companies be made aware of pending changes from voluntary to mandatory status through WTO/TBT Notification process and/or other appropriate mechanisms, and that they be given sufficient opportunity to comment.

The U.S. has had great success promoting use of voluntary consensus standards for regulation and government procurement through the National Technology Transfer and Advancement Act (NTTA)<sup>2</sup> and supporting policy Office of Management and Budget (OMB) Circular A-119<sup>3</sup>, which stipulate that “all federal agencies must use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical.” Further, stakeholders are consistently made aware of the government’s intent to incorporate voluntary consensus standards through the Federal Register (and, in the case of technical regulations, through WTO/TBT Notifications) and provided with an opportunity for comment. We believe China would benefit from a similar policy.

### Desired Outcomes

We would like the U.S. government to continue to promote increased transparency for standards, technical regulations, and other government rules and requirements in China. This includes increasing the ability of foreign companies to access current and proposed requirements and to comment on drafts, and for their comments to be considered by relevant Chinese policy makers.

Specifically, we recommend that the U.S. government encourage China to more fully live up to its transparency commitments under the WTO, JCCT, and S&ED. These include:

- Consistently publish all draft and final laws, regulations and other measures of all government ministries and agencies at all levels pertaining to or affecting trade in goods, services, TRIPS or the control of foreign exchange (to include Chinese government standards, conformity assessment procedures and technical regulations) in a single official journal (*i.e.*, the China Foreign Trade and Economic Cooperation Gazette, issued by the Ministry of

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<sup>2</sup> U.S. Public Law 104-113 “National Technology Transfer and Advancement Act” (1995) <http://standards.gov/standards.gov/ntta.cfm>

<sup>3</sup> White House Office of Management and Budget (1998) “Circular No A-119” <http://www.whitehouse.gov/omb/circulars/a119/a119.html>

Commerce) as committed by China during the 2006 JCCT Plenary Meeting<sup>4</sup>. The U.S. Code of Federal Regulations and Federal Register would be a good model for this effort.

- Allow a public comment period of not less than 30 days for all draft government rules, consistent with China's commitments under the S&ED<sup>5</sup> and under the State Council's 2008 "Regulations on Disclosure of Government Information."<sup>6</sup>
- Consistently notify the WTO Secretariat of requirements that meet the definition of "technical regulations" under the WTO/Technical Barriers to Trade (TBT) Agreement, regardless of which agency released the regulation, to consistently provide a comment period of at least 60 days, and to consider substantive comments from stakeholders WTO member economies.
- Translate all laws, regulations or other measures, at all levels of government, relating to trade in goods or services – including standards and technical regulations – into one or more of the WTO languages no later than 90 days after they are implemented or enforced, as committed by China during its WTO Accession.<sup>7</sup>

## OPENNESS AND PARTICIPATION

While industry has seen many examples of good cooperation and invitations to participate in Chinese standards development efforts, U.S. companies continue to express concern regarding instances of discrimination in China's standards development activities based on where a company is headquartered. We note that Chinese Premier Wen Jiabao's statement at Summer Davos in 2010 that "any company registered in China according to Chinese law is considered a Chinese company... Foreign companies registered within China's borders all enjoy national treatment," is still not universally applied within many standards development activities in China.

Specifically, some companies have been unable to participate in technical committees in China because they are not headquartered in China. This may occur even in cases where the companies have a registered presence in China as well as considerable technology, experience, and management expertise to contribute to the standard. Additionally, China has barred foreign firms from participating in some standards groups claiming grounds of national security, particularly in the information technology sector. Such discrimination should be rare. If the national security exemption is applied too liberally, it can ultimately weaken standards development by limiting those who can contribute ideas and resources to standards development. In addition, such liberal use can negatively impact U.S. companies that are willing to invest resources in order to participate as members in Chinese standards development and who see this participation as a critical part of their overall China strategy. We also note that global standards development efforts hosted in other countries outside of China typically welcome participants based on technology, experience, and expertise and do not typically exclude international participants.

There has been some progress on this issue but problems persist. In 2008, SAC issued draft "Requirements for the Setup of National Professional Standardization Committees" that would have

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<sup>4</sup> [http://trade.gov/press/publications/newsletters/ita\\_0406/jcct\\_0406.asp](http://trade.gov/press/publications/newsletters/ita_0406/jcct_0406.asp)

<sup>5</sup> China committed to "publish for comment all trade and economic related administrative regulations and departmental rules" for at least 30 days on the State Council website. U.S. Treasury Department press release summarizing this commitment available at: <https://ustreas.gov/press/releases/reports/sedjointfactsheet.pdf>

<sup>6</sup> [http://www.law-lib.com/law/law\\_view1.asp?id=199898](http://www.law-lib.com/law/law_view1.asp?id=199898)

<sup>7</sup> See paragraph 334 of the "Report of the Working Party on the Accession of China": <http://docsonline.wto.org/DDFDocuments/t/WT/ACC/CHN49.doc>

limited participation on Chinese national technical committees for “foreign” companies (i.e. companies that are not headquartered in China) to observer status. This policy received considerable feedback and criticism from many organizations in the U.S. and around the world. With significant advocacy from many trade associations and other private sector organizations – and with strong support from the U.S. government, the most recent draft SAC policy did not include as express restriction on participation by “foreign” companies, but rather left this issue up to the discretion of the individual technical committees. This was a significant improvement for many companies. However, in the past year reports continue from some U.S. companies who are still unable to participate in specific national technical committees, as well as reports of such businesses not being able to participate as voting members in some technical committees for industrial or other standards in China.

### Desired Outcomes

We would like the U.S. government to continue to promote appropriately open participation in Chinese standards development committees, groups and activities (e.g. technical committees and subcommittees). This includes open participation in standards development processes and frameworks so that they are transparent, open, and non-discriminatory for all stakeholders.

Specifically, we recommend that the U.S. government encourage China to:

- Work closely with the private sector (including the signatories to this document) to monitor the extent of the challenges that companies face in being able to participate in China’s standards-setting activities as their domestic counterparts do. Particular focus should be on government-led or government-sponsored standards development initiatives.
- Use appropriate bilateral and multilateral channels to constructively reinforce the value of allowing appropriate participation from all interested entities, including foreign-invested enterprises.
- Based on the above, encourage China to remove policies that inappropriately withhold access based on where a company or organization is headquartered.

## **CONFORMITY ASSESSMENT**

Conformity assessment requirements in China have become a growing source of concern, as Chinese law requires that most certification and testing for regulatory compliance be performed in China, and only by designated Chinese bodies.<sup>8</sup> In practice, this means that companies whose products have already undergone internationally accepted conformity assessment testing and certification in other markets must repeat those tests through Chinese test labs and certification bodies in order to access the Chinese market. In many cases, these Designated Certification Bodies (DCBs) are established by and closely aligned with the Chinese government, creating potential conflicts of interest and additional sensitivities for foreign companies.

China’s conformity assessment requirements create unnecessary burdens for a broad scope of U.S. companies doing business in China, and deny market access to a key segment of the Chinese market for U.S. testing and certification services. Implementation of these requirements frequently puts U.S. manufacturers at a disadvantage vis-à-vis their Chinese competitors. U.S. companies have reported

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<sup>8</sup> *Regulations of the People’s Republic of China on Certification and Accreditation*, Article 30 ([Click here](#) to access the regulations online)



instances of preferential treatment for Chinese manufacturers who benefit from shorter process times for testing and certification services. U.S. companies also continue to run into language barriers in working with assessment bodies that make limited accommodation to non-Chinese speaking manufacturers. Given concerns about data protection, U.S. manufacturers undergoing conformity assessment procedures may also risk the compromise of proprietary product designs and manufacturing methods, given the close ties that many Chinese testing and certification bodies appear to have with Chinese manufacturers.

Although not the only example, the implementation of product safety testing requirements for the China Compulsory Certification (CCC) program<sup>9</sup> exemplifies the problem of China's indigenous conformity assessment requirements. The U.S. Department of Commerce estimates that over 20% of U.S. exports to China must obtain the CCC mark prior to market entry.<sup>10</sup> For many products, however, there is only one DCB that is authorized to perform CCC testing, inspection and certification, a situation that can create critical bottlenecks for companies. This is the case even though PRC regulations such as the *Regulations on Certification and Accreditation* state that there must be at least two choices of DCB per CCC product scope.<sup>11</sup> For some products on the CCC Catalogue, there are additional PRC government certification schemes for the same product that may be conflicting or duplicative. This situation is also inconsistent with the *PRC Regulations on Certification and Accreditation* and can also lead to significant cost, delays to market, and other burdens for U.S. companies.<sup>12</sup>

Additionally, most Chinese DCBs generally do not have a presence outside of China. Companies manufacturing in the U.S. and exporting to China must arrange and fund travel for a pre-market inspection at the manufacturer's location by a Chinese inspector, and submit to subsequent routine factory inspections after receipt of the CCC mark. In addition, they must arrange to have their products tested and certified in China. All of this can lead to significant additions of time and cost. This initial factory inspection for CCC is a significant area of concern for U.S. companies. For products manufactured outside of China, this procedure takes at least four months (longer if inspectors encounter problems during the U.S. visa application process), as opposed to a few weeks for products manufactured in China. The lengthy process for overseas factory inspection is due, in large part, to Chinese government procedures required for inspectors to obtain authorization to use official passports and to gain other travel clearances. The time required to obtain a U.S. visa can also be a factor. China should address the discrepancy between the time required for an inspection of a Chinese factory and the time required for a factory located outside of China. This could be accomplished by authorizing qualified bodies with a presence in the U.S. to conduct inspections.

With regards to implementation of the CCC program, there are concerns that implementing requirements set by DCBs are often introduced or changed without advance notice or ability for companies to provide comments (see the "Transparency" section above).

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<sup>9</sup> While the majority of U.S. manufacturer concerns come from indigenous testing requirement under China's CCC program, it is worth noting that similar indigenous testing requirements also exist for other regulatory regimes covering specific industries (e.g. protective equipment, medical devices, etc.).

<sup>10</sup> [http://www.export.gov/china/exporting\\_to\\_china/chinaandstandards.asp](http://www.export.gov/china/exporting_to_china/chinaandstandards.asp)

<sup>11</sup> Citation from Article 32: "When designating certification bodies to undertake certification of products listed into the Catalogue, the certification and accreditation regulatory department of the State Council shall ensure that at least two certification bodies that meet the requirements of these Regulations are designated for each field of products listed into the Catalogue."

<sup>12</sup> Citation from Article 29: "With regard to products subject to compulsory certification, the State shall apply one product catalogue, one set of technical regulations, standards and conformity assessment procedures, one obligatory mark and one structural fee chart."

Companies have also expressed concern about duplicative and/or conflicting requirements between CCC and other mandatory Chinese testing and certification programs. The conformity assessment regime in China would benefit from coordination between CNCA and other government agencies, including MIIT, to streamline and avoid duplicative testing requirements.

### Desired Outcomes

We would like the U.S. government to encourage China to fully comply with its domestic regulations and international commitments under the WTO, focusing on recommendations that China:

- Ensure that there are at least two choices of Designated Certification Body (DCB) per CCC product scope by allowing qualified non-Chinese organizations to be accredited and designated to conduct product testing, initial inspections, follow-up audits, and certification work for mandatory and voluntary governmental conformity assessment regimes. This is consistent with the practice of U.S. regulatory agencies and would increase capacity and reduce delays that domestic and foreign companies currently face in obtaining certification. Such reforms would also promote greater economic efficiencies and would be consistent with principles of national treatment.
  - To assist with this process, publish the process for the selection of designated organizations whose conformity assessment work will be accepted for each mandatory and voluntary government-run conformity assessment regime, including the selection criteria and the list of organization(s) responsible for evaluating applications.
  - As an interim step until this recommendation can be fully implemented, China should accept test data from qualified foreign private sector test labs in order to reduce duplicative testing and reporting.
- Eliminate duplicative, overlapping, or conflicting government conformity assessment programs.
- Remove unnecessary bureaucratic procedures associated with China's conformity assessment regimes, including administrative processing and delays incurred during testing and factory inspection.
- Consistently notify the WTO Secretariat of new mandatory and voluntary government-run conformity assessment programs, as well as changes to the implementation procedures, policies and other requirements of existing government conformity assessment programs.

Furthermore, encourage additional reforms and changes to China's conformity assessment programs, including recommendations that China:

- Accept supervised manufacturing testing data already obtained. If a manufacturer is deemed proficient by an appropriately qualified certification body and testing laboratory, it should be able to submit test data directly to PRC conformity assessment authorities for a certification body certificate.
  - To assist with this process, publish clear criteria for the acceptance of supervised manufacturer testing data, and ensure that this data is accepted by DCBs.
- Accept foreign-based companies' suppliers' declaration of conformity for certain products, based on acceptable levels of known product risk.

- Promote open participation in working groups and technical committees for CCC and other Chinese government conformity assessment programs for all stakeholders who may be impacted by these programs.
- Fulfill Chinese accreditation commitments for mutual recognition of equally reliable accredited third Party Conformity Assessments in accordance with International Accreditation Forum (IAF)/International Laboratory Accreditation Cooperation (ILAC) signatory status for these arrangements.
- Ensure that China's conformity assessment requirements and procedures are technology neutral, neither discriminating between technologies nor promoting one technology over another in the marketplace. Conformity assessment requirements should also be adaptable in order to enable the quick introduction of new and innovative technologies.

## **IMPLEMENTATION ISSUES:**

### **UNEVEN ENFORCEMENT AND NATIONAL TREATMENT**

Despite efforts by China's government to make implementation of its standards and conformity assessment rules consistent, many U.S. companies continue to confront problems with implementation: differential treatment between foreign and domestic players as well as uneven implementation across jurisdictions. Some of the problems mentioned previously, particularly lack of transparency, fuel these concerns, as regulators in different provinces and cities interpret rules in different ways and expect companies to comply. Foreign companies may also run into uneven implementation – and lack of national treatment – vis-à-vis their domestic counterparts, as domestic companies may not be held to the same stringency of compliance. In some cases, lack of local resources can impact the ability of local and provincial regulators to enforce rules. In other cases, local regulators may be unaware of changes to national regulations. For example, in some cases, local regulators continue to require labels to be placed on devices whereas the current national regulations only require proof of conformity in the products packaging.

Product safety and public health provide a perfect case study: recent public health issues with Chinese imports of tires, food, and toys have raised pressure on the Chinese government. The response to this pressure has generally been to focus on creating more stringent standards and technical regulations. However, this approach does not always address enforcement and verification that the new rules are being followed. Further attention to infrastructure and follow up would help ensure successful compliance.

In addition to creating a public health concern for the United States, this reality can place U.S. companies at a significant disadvantage within the Chinese market. In general, U.S. companies appear to exceed Chinese requirements and therefore have no concerns with the stated requirements themselves. However, the procedures required to demonstrate compliance (often imposed as part of the customs clearance process) can be onerous and can place U.S. companies at a competitive disadvantage to their Chinese competitors who often do not complete the same procedures. Unrealistic implementation timelines for new Chinese regulations can also be a significant barrier for U.S. companies. Inability to participate in related standardization activities, problems with accessing or translation of regulations and incompleteness or complexity of requirements often contribute to this problem.

## Desired Outcomes

We would like the U.S. government to work with the private sector to promote the concept of the necessity for a global “culture of compliance”, and encourage China to ensure that its government regulations, policies, and other requirements are consistently and uniformly enforced for both domestic and foreign products. We encourage the U.S. government most immediately to encourage China to:

- Conduct risk assessments and impact analyses prior to introducing new regulations, posting results in MOFCOM’s *China Foreign Trade and Economic Cooperation Gazette* for public comment, and address substantive stakeholder comments in writing. The U.S. Administrative Procedures Act and U.S. regulator best practices for risk assessments and impact analyses would be a good model for this effort.
- Ensure that standards and certification regimes are applied uniformly to domestic and foreign companies and do not act as a market access barrier.
- Provide public assurances that standards and certification regimes are implemented evenly throughout China to ensure that foreign and domestic companies can best comply.
- Ensure that enforcement for regulatory, standards, and certification regimes is feasible, reasonable, and targeted to achieve legitimate regulatory goals, and does not favor domestic companies or manufacturers over foreign companies.
- Engage with local enforcement officials on capacity-building programs in ways that promote open, non-discriminatory, efficient regulatory practices.
- Ensure that timelines for implementing regulations take into consideration the completeness and availability of documentation and other resources necessary for industry compliance.

## **USE OF INTERNATIONAL STANDARDS**

China has significantly increased its participation in and use of international standards in recent years. This includes using relevant international standards as the basis for Chinese technical regulations, as is encouraged by the WTO/TBT Agreement. This practice benefits industry and reduces the likelihood that companies will encounter unique requirements in one country. China has also become more active and taken greater leadership responsibilities in their participation in international standards bodies. Both China and the international community benefit when Chinese stakeholders bring their contributions to these international standards bodies, and so this trend is welcome.

China’s adoption of international standards has been set as a national policy and implemented by the Standardization Administration of China (SAC). Under this policy, China’s participation in and adoption of international standards has increased significantly over the past several years. However, we observe that the push for increased harmonization with international standards is not universal and that this policy is often not reflected in the practice of other agencies and organizations involved in standards development in China. Chinese “homegrown” standards persist in sectors ranging from machinery to information technology and serve as an effective barrier for foreign products looking to serve the China market.

In some cases, these standards are developed in parallel to their international counterparts, while in others, China-specific standards are similar to international standards but contain key differences. Companies have observed a growing trend in China and other emerging countries to adopt standards

developed by ISO, IEC, or other international standards development organizations and then remove or change key portions of the standard without consultation or permission from the originating body. While ISO/IEC rules generally allow latitude for changes necessary to achieve national adoption – such as conversion from a Celsius temperature in an international standard to a Fahrenheit one for adoption in the U.S. – the intention has always been to maintain a common standard. Similarly, ideas for improvements are normally welcome by all international standards organizations, carefully considered for compatibility, and often included in future revisions of that common standard. Changes meant to intentionally disadvantage foreign companies without an otherwise useful purpose are barriers to trade and fragment the global market, unnecessarily raising costs for everyone participating in the global economy (including Chinese companies when they export products and Chinese consumers when they purchase products).

Companies have also raised concerns that Chinese officials often define an international standard too narrowly, to include only those standards developed by treaty- and non-treaty- organizations such as the International Organization for Standardization (ISO), International Telecommunications Union (ITU), and the International Electrotechnical Commission (IEC). This definition excludes other important international standards used by global industry and developed by other standards development organizations (SDOs), such as IEEE and ASTM International, and is not consistent with the principles for development of international standards identified by the WTO/TBT Committee.<sup>13</sup> China’s policies do not recognize the importance of standards from organizations such as the World Wide Web Consortia (W3C) or the Internet Engineering Task Force (IETF) that are widely and internationally accepted and used globally. Without Chinese government recognition, there are limited mechanisms for these standards to be adopted in China or for Chinese experts to participate in their development. This can lead to the development of “home-grown” standards in China or to use of such global standards without appropriate attribution and without adequate background for implementation.

### Desired Outcomes

We would like the U.S. government to continue to reinforce the value of private-sector-led global and international standardization work in China, and to encourage broader Chinese participation in and use of international standards, including:

- Aligning Chinese standards (including national, industrial, and provincial standards) with international standards and using international standards as the basis of Chinese standards and regulations wherever practical. China should modify international standards only where permitted and when justified to achieve legitimate objectives such as the protection of environment, health, safety, or national security.
- Broadening recognition of international standards to include any standard that meets the principles for the development of international standards identified by the WTO/TBT Committee.
- Recognizing the importance of other widely recognized, globally used standards by allowing mechanisms for use and adoption of these standards where applicable in China, especially when those standards are accepted and used by a majority of the rest of a global industry sector.

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<sup>13</sup> “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”: <http://docsonline.wto.org/DDFDocuments/t/G/TBT/1R8.doc>

- Wherever the majority of the rest of a global industry sector has adopted a voluntary consensus standardization forum as the preferred venue for the development of certain standards, encouraging Chinese industry to join the rest of that industry sector in the development of such standards.

Further, we would like the U.S. government to allow expedited visa interview appointments for Chinese technical experts wishing to participate in international standards meetings. In order to support the process, U.S. industry and standards organizations are prepared to provide information on upcoming conferences and expected attendance, or through other mechanisms as appropriate.

U.S. government actions to promote China's use of international standards should be closely coordinated with the U.S. private sector, which leads the U.S. standardization system and which represents the U.S. in many international standards development organizations.

## **INTELLECTUAL PROPERTY RIGHTS (IPR) AND STANDARDS**

China in recent years has increased its efforts to create a modern standards system that appropriately addresses intellectual property rights (IPR). In 2006, the Chinese Electronics Standardization Institute (CESI) developed a template IPR policy for use by Chinese standards developers that is, for the most part, consistent with international practices and norms aimed at effective development of standards.<sup>14</sup> When followed, this template has allowed for the equal participation of all interested parties (including foreign companies) under reasonable terms and conditions. Such efforts should continue to be acknowledged and supported.

However, in some instances, Chinese officials from various ministries and agencies have proposed other, more burdensome policies, or have modified existing policies to make participation from U.S. companies more difficult. Some Chinese stakeholders have argued the need to stipulate compulsory licensing at zero or very low royalty rates well below a reasonable rate. China has used a broad range of arguments to justify such policies, including:

- Licensing IPR is a trade barrier against developing countries like China.<sup>15</sup>
- Foreign IPR, including IPR developed and licensed by U.S. companies on a global basis, is too expensive for developing economies such as China's.

While these statements and policy directions are troubling and can have significant negative impact for U.S. companies – particularly in the short term – we recognize that Chinese companies are also increasingly moving to become IPR holders. We note that such statements could be harmful to Chinese companies developing their own IPR and therefore should be avoided.

Several years ago, some Chinese standards development organizations developed IPR policies that were contingent on mandatory participation in Chinese government run patent pools at minimal royalties as a type of compulsory licensing. Many of these policies have improved or been scaled back (e.g. the China Electronics Standardization Institute CESI's patent policy designates

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<sup>14</sup> The CESI IPR Policy Template is available at <http://www.cesi.ac.cn/datumview.aspx?sort=3&id=5631>

<sup>15</sup> For example, in 2005 China tabled a paper (G/TBT/W/251) to the WTO/TBT Committee that stated that “China is of the view that, IPR issues in preparing and adopting international standards have become an obstacle for Members to adopt international standards and facilitate international trade.”

participation in patent pools as an option). However, since 2009, we have seen a renewed effort by some Chinese regulators to invoke compulsory licensing for mandatory standards and new language in China's antitrust laws and regulations to support compulsory licensing.

This corresponds with statements from a variety of key Chinese IPR and standards agencies that indicate a push for locally developed standards while minimizing royalty fees. In November 2009, SAC released its draft "Provisional Administrative Measures for the Formulation and Revision of National Standards Involving Patents," which discusses the rules for incorporating patents into national standards. This was followed in January 2010 by the China National Institute of Standardization (CNIS) notice of a proposed standard No. 20090445-Z-424, "Guide for Implementation of the Inclusion of Patents in National Standards." Both draft notices were posted for public review and spurred considerable comments by many different industry associations and individual companies worldwide. Many international comments echoed a common point of view: the draft measures arguably undervalue the patented technology necessary to implement Chinese national standards. While standards developers must appreciate the need for widespread access to and implementation of the standard, there is also a need for investment and innovation which benefits users and adopters of the standard. Such international comments also reflected several other points relating to potential misconceptions about the way global standards development functions and the potential for ineffective and harmful outcomes. To the credit of SAC and CNIS, we understand that this industry and market response was taken very seriously and that SAC has put the project on indefinite hold rather than risk producing a cumbersome policy that could harm Chinese industry as much as it could harm foreign participants.

In sum, while China's efforts to encourage Chinese national standards development organizations (SDOs) to adopt IPR policies are moving in the right direction, U.S. industry and intellectual property owners have significant concerns over China's draft policies and how they differ from international norms. At this point we feel that industry has been able to communicate its concerns with the two draft rules documents and we are encouraged that they seem to be delayed indefinitely. Chinese authorities are watching standards and IPR policy debates in Europe and the United States very closely for discussions on compulsory licensing, patent disclosure requirements, and other relevant topics for indications that international positions on IPR and standards are changing.

In the event that China feels that they need to take more action on this subject, it will be important for the U.S. government to monitor this issue carefully and work with the private sector to define appropriate next steps.

### Desired Outcomes

We would like the U.S. government to work closely with the private sector to monitor these general issues and if they become active again, to work with industry to define appropriate next steps. In general, we should encourage China to:

- Carefully review the IPR-related implications of all related policies or regulations to ensure that IPR is properly respected and adequately protected.
- Consult with industry participants by making draft versions of laws, rules, and regulations related to IPR and standards available for comment before the regulations are finalized, so that IPR is treated appropriately and the rights of Chinese and foreign IPR holders, the users of IPR, the policy makers and the public at large are balanced. Such comment periods should

provide ample time for all interested parties to learn of, review and respond constructively to the proposals. (See Transparency section above for additional information on China's related commitments)

- Adopt standards and IPR policies that are aligned with pro-competitive international principles for standards setting and that will allow Chinese standards setting institutions to be a fully participating part of the global standards development ecosystem (e.g., global, industry led, voluntary consensus standards that respect valid IP rights and are open and transparent to all interested parties).