

THE US-CHINA BUSINESS COUNCIL

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USCBC Standards Review and Recommended Changes to the Development and Implementation of China's Standards and Conformity Assessment Policies and Processes

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Standards and conformity assessment procedures have gained global attention among regulators and companies alike in recent years. The procedures provide a set of tools for regulators to achieve policy objectives, such as improved public health and environmental protection. Such procedures also serve as critical thresholds for how companies can enter new markets and as guidelines for how they can succeed in those markets.

PRC government officials have significantly increased standards and conformity assessment-related activities in recent years, and officials are working to build a modern system of standards and conformity assessment procedures comparable to those in other countries. For example, according to the latest figures publicly available from the Standardization Administration of China (SAC), in June 2009 China had 23,843 national standards, 39,686 industry standards, and 14,142 local standards. The number of national standards rose from 20,906 in 2003 and included more than 12,000 standards that were under revision at that time.

Many foreign companies, however, still confront significant barriers in their attempts to understand, participate in, and comply with China's standards and conformity assessment regimes. The US-China Business Council's (USCBC) annual membership survey results show that US companies continue to identify standards and conformity assessment as one of their top overall challenges when doing business with China. They face problems that range from inadequate transparency to inadequate harmonization with international standards, and from limited market access to high costs of compliance. Though the individual standards in question differ across industries, the broader structural issues faced by US companies remain common. Ultimately, such barriers hinder the development of China's economy and of individual companies, and in some cases the barriers limit or slow the availability of products and innovations in the marketplace.

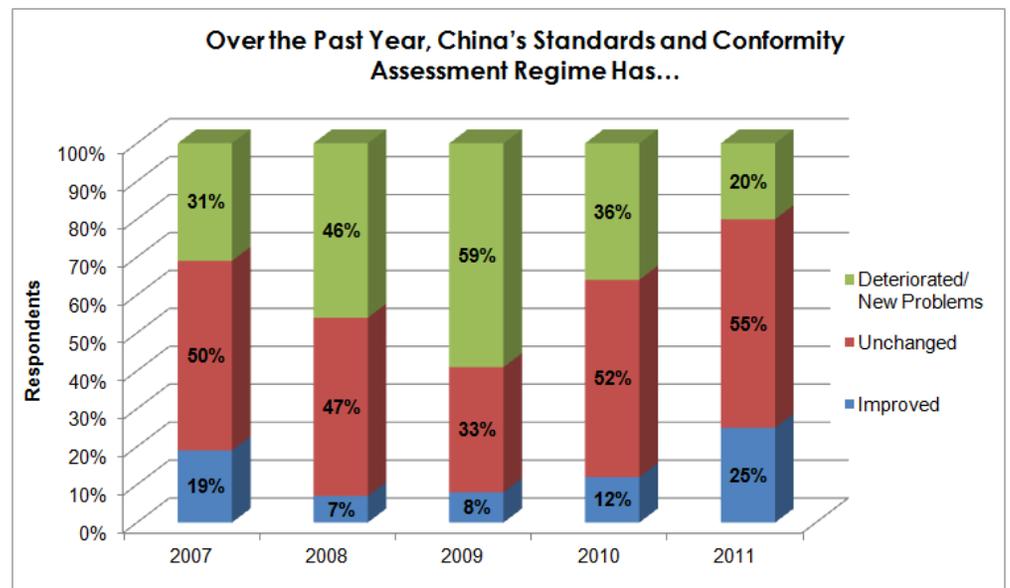
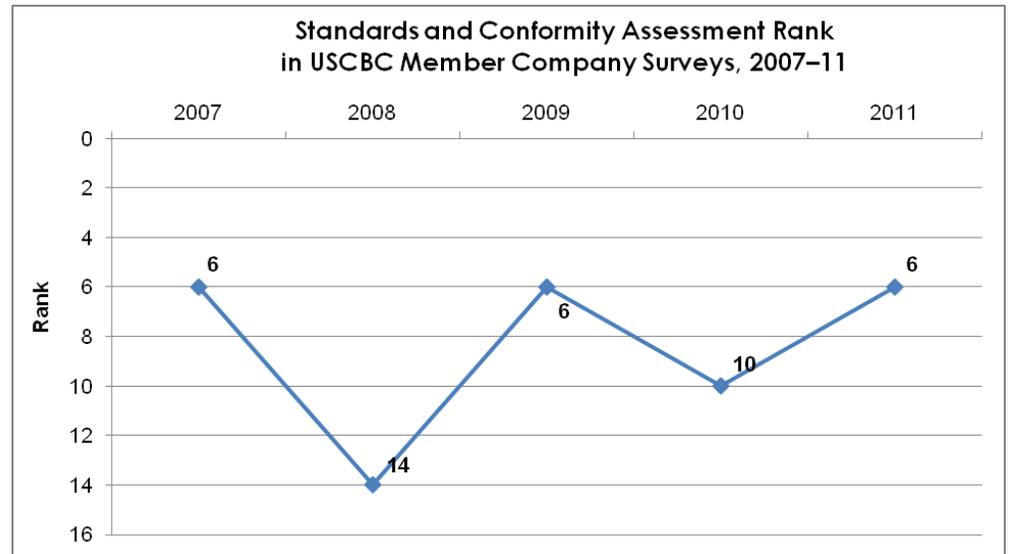
Standards and Conformity Assessment as a Top 10 Issue

China has shown some improvement in standards and conformity assessment areas in recent years, yet improving China's standards regime remains a top priority for US companies. In USCBC's annual member company survey, standards and conformity assessment has ranked among US companies' top 15 operating challenges for each of the past five years, and it generally ranks in the survey's list of top 10 challenges. As with other operating issues, however, the level of concern will vary based on the industry and the company's situation. For companies impacted by rapidly evolving standards, such as companies in the information technology sector or whose plants or products are impacted by environmental pollution standards, this remains a top concern. The subject may concern sectors in which standards and conformity assessment activity is lower, such as financial services, less.

Though a small group of companies (less than one in four) have indicated some improvement on this matter in recent years, most companies have indicated that the issue has remained unchanged, or that they have seen deterioration or new problems. In 2011, for example, 20 percent of survey respondents indicated that the situation had worsened, 55 percent stated that the problem was unchanged, and only 25 percent indicated that they had seen some improvement in standards and conformity assessment.

Challenges of Participation in Standards and Conformity Assessment in China

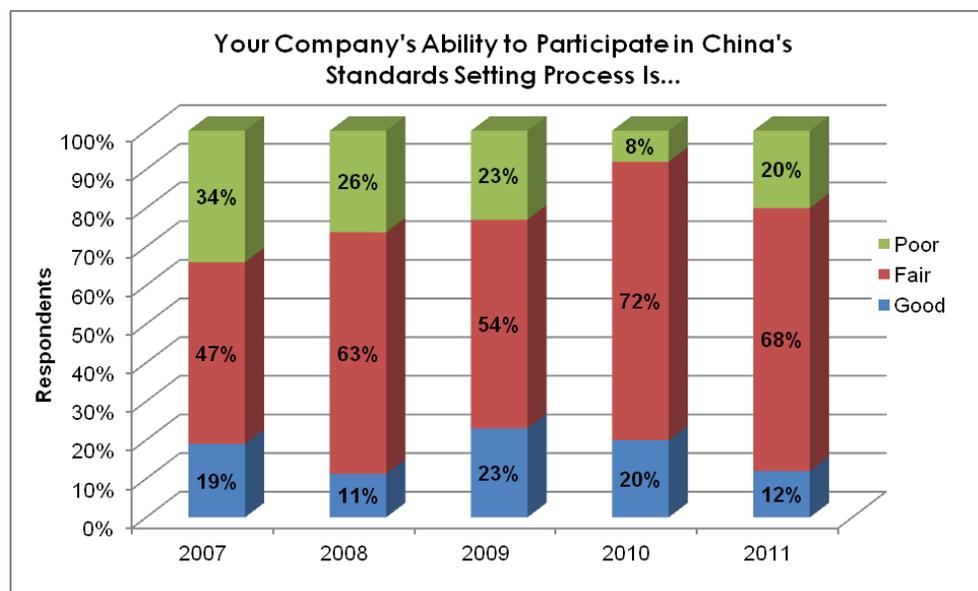
Of note, many respondents in USCBC's membership surveys indicate that they do not participate in China's standards and conformity assessment system. For example, in 2011, only half of respondents (50 percent) who would likely be able to



Source: USCBC

participate in China's standards-setting system indicated they do so, while the other half of respondents indicated that they do not participate. These statistics were actually down from 2010, when 57 percent of respondents indicated they do participate versus 43 percent who do not.

Those companies that do participate or seek participation continue to face significant barriers. The percentage of respondents who characterize their ability to participate in standards setting as "good" – that they are able to obtain information, participate in the process, and influence standards – was only 12 percent in 2011, down from 20 percent in last year's survey. Most companies – 68 percent – answered "fair" (in Chinese, "一般") indicating that they had some ability to participate, but that ability remained limited; this number was down somewhat from 72 percent last year. The number of companies rating their ability to participate in standard setting as "poor" was 20 percent, up from 8 percent last year.



Source: USCBC

Specific Challenges and Concerns

Within the area of standards and conformity assessment, companies raised a wide variety of concerns. Again, some of the diversity is due to the broad impact of standards and conformity assessment regimes on company operations. For a company seeking to provide testing or certification services, market access barriers for these services in China may be their top concern, whereas for a manufacturer producing high-tech goods, the inability for foreign companies to participate appropriately on standards-related technical committees may be most vexing.

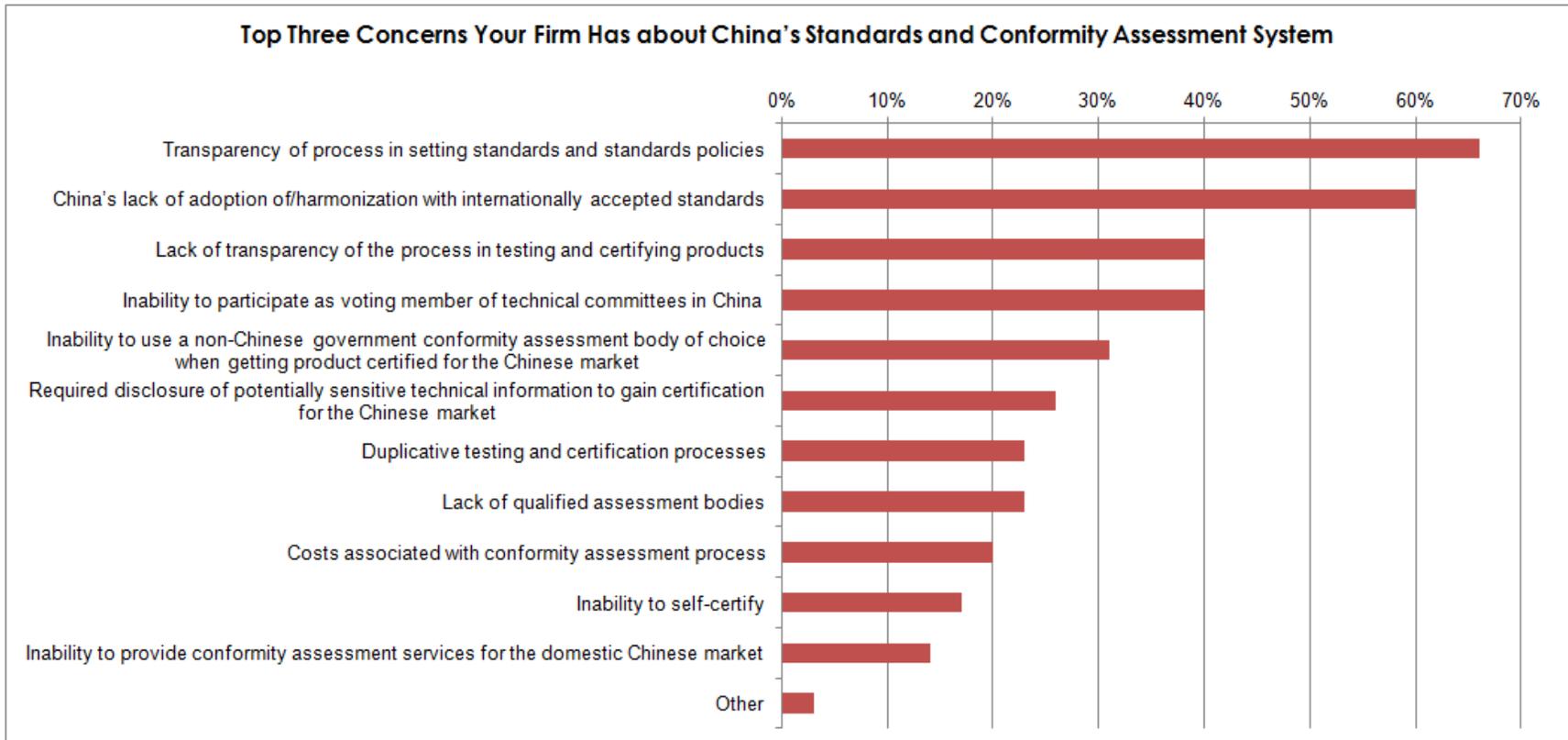
Despite this diversity of problems, however, the top concerns reflect a number of common themes, including:

- Inadequate transparency for draft and finalized standards and conformity assessment-related regulations and policies;
- Barriers to participation in standards-setting activities;
- Lack of harmonization with international standards;
- Inefficiencies and high costs for testing and certification; and
- Lack of testing and certification capacity coupled with an inability for foreign companies to fill the gaps.

USCBC's 2011 survey asked respondents to list their top three concerns with China's standards and conformity assessment system. The top concern, as in years past, was transparency in setting of standards and standards policies (66 percent of respondents). This was followed by

China’s lack of harmonization with internationally accepted standards (60 percent), and transparency in testing and certifying products (40 percent). Other concerns named by at least one-quarter of respondents include the inability to participate as a voting member of technical committees in China (40 percent), the inability to use a non-PRC government conformity assessment body (31 percent), and required disclosure of potentially sensitive technical information to gain certification for the Chinese market (26 percent).

Each of these concerns can negatively affect PRC regulators’ ability to build a robust, internationally accepted and respected system for standards and conformity assessment. Conversely, addressing these concerns in a meaningful fashion can help PRC government agencies to further improve China’s standards and conformity assessment system. Removing such barriers will expand the range of products and technologies that companies are willing and able to bring to China, increase the likelihood that PRC authorities will produce broadly accepted standards and policies, and improve the ability of companies and regulators to comply with—and enforce—such standards and policies. In addition, in the long run, eliminating China-specific barriers will raise the ability of Chinese companies and products to compete in international markets.



Source: USCBC

Specific USCBC Recommendations

International experience shows that open and transparent standards and conformity assessment frameworks are essential to facilitate the creation of internationally accepted and globally competitive products, and such frameworks can drive innovation and technology advancement. The World Trade Organization's Technical Barriers to Trade (WTO/TBT) agreement and the WTO/TBT Code of Good Practice for the Preparation, Adoption, and Application of Standards provide valuable guides for international best practices in the setting and implementation of standards used by countries with robust, innovative standards regimes. US policies and procedures, such as use of the Semiannual Regulatory Agenda and Federal Register, the US Standards Strategy, and the National Conformity Assessment Principles, also provide useful guideposts for increasing transparency and open participation in standards and conformity assessment, promoting cooperation between the public and private sectors on standards and conformity assessment outcomes, and promoting efficiencies in testing and certification.ⁱ

For example, in looking at transparency issues, provisions in the WTO/TBT Agreement require WTO members to notify the WTO Secretariat of proposed new or revised technical regulations or conformity assessment procedures that are not directly based on relevant international standards and that have the potential to significantly affect trade. Many countries take additional steps to promote transparency in setting and implementing policy, including collecting and publishing all proposed new or changed regulations in one location (such as in a national gazette) and building and maintaining a centralized database or source for relevant regulations. In the United States, agencies take various steps to increase and foster transparency throughout the rulemaking process:

- The Administrative Procedures Act requires agencies to ensure transparency, including taking steps to inform the public of their policies and procedures, to permit the public to participating in the setting of said policies and procedures, and to establish uniform standards for the conduct of formal rulemaking and adjudication.
- The US Office of Management and Budget coordinates varying federal agencies to gather information about planned regulatory developments and publish these twice each year in the Semiannual Regulatory Agenda.

In addition, regulators provide information about proposed policies and regulations as well as their finalized versions through the US Federal Register. US regulators publish final federal regulations through the US Code of Federal Registrations. These publications are online, free, and open to all interested domestic and international stakeholders.

Undertaking further reforms in line with international best practices – such as those outlined above for transparency – can create more transparent and market-driven standards and conformity assessment systems and foster further participation by all relevant stakeholders in setting and implementing standards and conformity assessment procedures. Ultimately, such reforms will provide China with several economic benefits, which include maximizing its global commercial ties, attracting more products and technologies, and shaping global standards and conformity assessment rules and procedures. In addition, as Chinese firms expand their participation in global standards and conformity assessment regimes, their products will gain greater access to domestic and international markets. Greater market access can lead to greater international competitiveness and brand development for Chinese companies.

At the same time, standards and conformity assessment schemes that are open, transparent, non-discriminatory, and market-driven will help to attract further foreign investment and foster greater international cooperation. Foreign-invested enterprises contribute to China's economic growth, job creation, and tax base. Many foreign-based companies have established research and development (R&D) capabilities and conduct significant product development and innovation in China. An open and transparent system for developing and implementing technical standards and standards policies will signal to foreign and domestic companies alike that China truly desires to be an innovation hub. Foreign participation in the local product certification process can also drive improvements in product standards and conformity assessment processes, thus raising the quality and safety of goods produced and sold in China and the rest of the world while reducing the time and cost required to undergo such procedures.

USCBC member companies are global leaders in innovation and R&D across various industry sectors. They have a strong desire to work with China to develop its standards and conformity assessment framework. Based on our members' considerable experience around the world, we respectfully provide the following list of recommendations that USCBC hopes the PRC government will consider in its effort to develop its standards system and conformity assessment framework.

Development of Standards and Standards-Related Policies and Regulations Development

Issue

Representatives of all companies operating in China face difficulties gathering information about existing technical standards and standards-related laws, regulations, policies, and requirements that impact their products and operations. At present, there is no unified channel where these companies can find all standards and standards-related policies and regulations. Such a lack of transparency limits the ability of these companies to comply with PRC standards and regulations, and thus it creates a greater risk of non-compliant products reaching Chinese consumers.

Recommendation

Relevant PRC government and non-government bodies and organizations that are active in drafting and releasing mandatory standards should consider:

- Consistently publishing through a unified, dedicated information channel all standards and standards-related regulations set by government bodies or government-affiliated organizations, including mandatory and voluntary national, industry, and local standards, in addition to laws, regulations, and technical requirements.
- Encouraging non-governmental bodies and organizations that set standards, standards policies, or standards guidelines or that provide input to standards-related regulations, policies, and guidelines to increase transparency by making final versions of these documents freely and publicly available to members and non-members.
- Translating all laws, regulations, or other measures – including standards and technical regulations – related to trade in goods or services and issued by all levels of government into one or more of the World Trade Organization (WTO) languages no later than 90 days after they are implemented or enforced, as China committed during its WTO accession.

Representatives of companies operating in China often lack adequate opportunity to recommend and comment on draft versions of standards and standards-related policies and technical regulations before they are finalized. Presently, no unified channel exists for release of all proposed draft standards and standards-related policies, creating difficulties for domestic, foreign-invested, and foreign-based companies. Allowing all companies the opportunity to provide input on draft versions of standards and standards-related policies would result in stronger, more broadly accepted regulatory outcomes and help to ensure that such regulations are feasible for all stakeholders to implement.

Relevant PRC governmental and non-governmental bodies and organizations with standards policymaking authority should consider:

- Creating a designated unified channel to make draft versions of all standards (national, industry, and other types of standards) and standards-related policies and regulations set by government or government-affiliated organizations available to domestic, foreign-invested, and foreign-based companies for public comment for a period of at least 30 days. Such a channel would be consistent with the State Council's 2008 Regulations on Disclosure of Government Information and related transparency initiatives.
- Continuing to provide notification of all relevant standards and standards-related laws, policies, and regulations through the WTO's Technical Barriers to Trade (WTO/TBT) committee for at least 90 days before standards are finalized and implemented. Ensure that proper notification of all standards and standards-related laws, policies, and regulations that fall under the WTO/TBT umbrella occurs, regardless of the drafting government body or organization.
- Encouraging all non-governmental bodies and organizations that set standards and standards-related policies and guidelines to increase transparency by making draft versions of these documents freely available for public comment by all stakeholders regardless of nationality.

Although existing rules and practice allow foreign-invested enterprises (FIEs) some participation in standards development activities, FIEs are not consistently permitted full participation in China's standards development process, including as full voting members of technical committees responsible for standards setting. Permitting FIEs to seek participation in standards-setting activities on equal footing with their domestic counterparts would promote a more robust standards-setting process and may be more likely to produce standards that address Chinese and global market needs. Such consideration would also be in keeping with the WTO principle of national treatment.

Relevant PRC government and non-governmental bodies and organizations that are active in drafting and releasing standards should consider:

- Allowing FIEs to appropriately participate in standards-setting activities, such as government-sponsored or government-led standards development initiatives, based on membership criteria that do not discriminate against companies based on their nationality.
- Revising policies that inappropriately withhold access to participation or voting rights in standards-setting groups based on where the company or organization is headquartered.
- Working actively with FIEs to investigate claims or complaints about inappropriate limitations on membership or voting rights in standards-setting groups, and – if such claims are found to be valid – working with FIEs and standards groups to address the complaints.
- Continuing to promote exchanges among FIEs and relevant governmental and

non-governmental bodies and organizations – including Chinese industry associations, standards organizations, and government-supported institutes – responsible for standardization at the central, provincial, local, and sector levels to foster stronger and more broadly accepted standards outcomes.

Some PRC standards and standards-related laws, regulations, and policies that aim to improve China’s innovative capabilities or to boost PRC government objectives, such as national security (including China’s multilevel protection scheme), may impose overly broad requirements on governmental and non-governmental agencies and organizations as well as commercial entities, and may serve as effective market barriers. Such policies and standards could limit foreign companies’ ability to introduce products into the China market and restrict China’s access to technology used globally.

Relevant governmental and non-governmental bodies and organizations that are active in drafting and releasing standards should consider:

- Ensuring that technology policies and regulations – and practices related to developing technology policies and regulations – are developed in ways consistent with global best practices for openness, transparency, cooperation, and feasibility, and do not discriminate against companies based on where they are headquartered. In addition, such policies and regulations should comply with trade treaties and international organizations’ best practices so that the breadth of technology available to China is not unnecessarily narrow. This will enable Chinese companies to take better advantage of the global standards community and advancements in global innovation, and it will allow Chinese consumers access to a wider variety of products and technologies in a timely manner.
- Promoting a standardization environment that fully recognizes the role of the market in determining the best technologies and standards, and encouraging an approach to standards development that promotes standards and technologies based on technical merit and market potential, not on protectionist concerns.
- Ensuring that standards and standards-related laws, regulations, and policies are feasible, reasonable, and sufficiently targeted to achieve legitimate standards-related goals without imposing requirements on unrelated commercial bodies. Also, such regulations should not function as market access barriers by favoring domestic companies or manufacturers over foreign-based or foreign-invested companies.

At times, standards-related policies place unnecessary or unmanageable requirements related to intellectual property (IP) that place IP rights at risk. Such policies limit the interest and ability of FIEs to contribute positively to standards-setting activities and can harm Chinese companies that are developing their own IP and seeking to protect it in increasing numbers.

Relevant PRC governmental and non-governmental bodies and organizations with responsibility for standards-related policies should consider:

- Carefully reviewing the IP-related implications of existing and proposed standards-related policies and regulations to ensure that IP is properly respected and adequately protected.
- Adopting standards and IP policies that align with pro-competitive international principles for standards setting and that would allow Chinese

standards-setting bodies to be a fully participating part of the global standards development eco-system (such as global, industry-led, voluntary consensus-based standards that respect valid IP rights and are open and transparent to all interested parties).

- Consulting with industry participants by making draft versions of policies, regulations, and guidelines related to IP and standards available for comment before such documents are finalized, so that IP is treated appropriately and the rights of Chinese and foreign IP rights holders, IP users, and the public at large are balanced.
- Ensuring that any future draft versions of Standardization Administration of China and China National Institute of Standardization policies, regulations, and guidelines for incorporation of IP into national standards reflect concerns raised by USCBC and other stakeholders about patent disclosure, zero-royalty or low-royalty rates for licensed IP, and other areas.
- Encouraging technical committees and other standards-setting groups to draft and release clear policies to govern protection of IPR during the standards-setting and implementation process that incorporate international best practices and norms for effective development of standards. The China Electronics Standardization Institute's 2006 IP Policy Template provides a useful reference of a template that is aligned with international best practices.

Representatives of companies operating in China, including domestic companies, foreign-invested companies, and foreign-based companies, continue to experience challenges stemming from inconsistent interpretation and uneven enforcement of standards and standards-related policies across agencies and jurisdictions in China. The situation confuses companies and regulators alike and limits the ability of those who enforce standards and standards-related policies to set and implement effective policies.

Authorities who are responsible for standards-related policies should seek to ensure that standards and standards-related policies are applied uniformly and consistently to domestic and foreign companies and do not effectively function as market-access barriers. They should also consider:

- Engaging with local government officials on capacity-building programs for standards enforcement in ways that promote open, non-discriminatory, efficient regulatory practices.
- Working with stakeholders during the drafting process for standards and standards-related laws, regulations, and policies to ensure that implementation and enforcement of standards regimes is feasible, reasonable, and targeted to achieve legitimate regulatory goals, and does not favor domestic companies or manufacturers over foreign-based or foreign-invested companies.
- Ensuring that planned schedules for implementing regulations consider the availability of complete documentation and other resources necessary for

industry compliance.

China's increased participation in, and engagement with, international standards and international standards groups represents a positive step forward. Despite this progress, foreign companies continue to observe the persistence of Chinese "homegrown" standards and the adoption of revised versions of international standards that serve as effective barriers for foreign products in the China market. Such barriers again hinder the ability of Chinese consumers to benefit from the latest products and technologies and may hinder the ability of Chinese markets to access foreign markets.

Authorities who are responsible for standards-related policies should consider:

- Aligning Chinese standards (including national, industrial, and local standards) with international standards and using international standards as the basis of Chinese standards and standards-related regulations wherever practical. China should limit modification of international standards only to those cases where permitted and justified to achieve legitimate objectives, such as to protect consumer safety, the environment, health, 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.

Development and Implementation of Conformity Assessment Processes

Issue

China's domestic test laboratories do not accept foreign laboratory test data as evidence of certification for regulatory compliance in accordance with internationally accepted agreements, causing companies to face unnecessary and costly testing requirements and delays in getting their products to market. Ultimately, these inefficiencies have a negative effect on end users and consumers in China by increasing product costs and slowing their access to the latest products.

Despite provisions in the Regulations on Certification and Accreditation that require at least two choices of designated certification bodies (DCBs) for each product area in the China Compulsory Certification (CCC) regime, many product areas continue to have only one DCB. Foreign-based certification and testing companies cannot offer CCC conformity assessment services, limiting the ability of

Recommendation

China's certification authorities should consider:

- Removing requirements that overseas factory audits must be conducted by Chinese conformity assessment bodies and allow qualified foreign-based certification and testing organizations to conduct initial and follow-up factory inspections related to mandatory certification in overseas markets so that Chinese inspectors do not have to travel overseas to conduct these inspections.
- Accepting laboratory test data from qualified foreign-based certification and testing organizations and test laboratories. Acceptance of this data would reduce duplicative testing and data creation and would lower product costs for users and consumers in China.

The China National Certification Administration (CNCA) should consider:

- Ensuring that there are at least two choices of DCBs per CCC product scope by allowing qualified non-Chinese testing and certification 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. Such accreditation and designation would increase capacity and reduce delays that domestic and

domestic and foreign companies to choose among DCBs. Foreign-based companies that seek certification in China are limited in their choices for certification labs. Both of these serve to add to increased time and cost for companies and ultimately create time delays, increased costs, or limitations in product availability to Chinese end users.

foreign companies currently face in obtaining certification. Such reforms would also promote greater economic efficiencies in China and would be consistent with WTO principles of national treatment.

- Reducing or eliminating unnecessary bureaucratic procedures associated with CCC administrative processing, testing inspections/audits, and certification procedures. In addition to accepting factory inspection and test data from foreign-based certification and testing organizations mentioned above, CNCA should:
 - Allow all companies to apply simultaneously for both initial type testing and a factory inspection, thus shortening the product certification process and shortening the time to market for products.
 - Allow all companies to test by product family, instead of by shipment or individual product model, to decrease the time and cost burden for companies seeking to bring products to Chinese consumers.

Duplicative requirements between overlapping testing and conformity assessment schemes (such as CCC and Network Access License requirements in telecommunications) present companies with unclear – and frequently conflicting – procedures and rules, which often leave companies with significant questions about compliance. This not only raises the costs for companies and consumers, but it also increases the chances of non-compliant products entering the Chinese marketplace.

CNCA and other relevant testing and certification authorities (such as the Ministry of Industry and Information Technology, State Food and Drug Administration, and Ministry of Environmental Protection) should consider:

- Eliminating duplicative, overlapping, or conflicting government conformity assessment programs, including duplicative testing in areas ranging from telecom to medical devices.
- Coordinating more closely among relevant certification authorities during the drafting process for government conformity assessment programs to streamline and avoid duplicative testing problems prior to release and implementation of conformity assessment programs.

The CCC mark program is expanding to encompass additional product categories and to include different types of testing and certification, such as certification for information security products, energy efficiency products, and compliance with restrictions on hazardous substances (“China RoHS”). Qualified non-Chinese testing and certification organizations, however, continue to be blocked from providing these services.

CNCA and other relevant testing and certification authorities should consider:

- Accrediting – and designating – qualified foreign conformity assessment bodies to test for, and certify compliance with, all relevant existing standards related to CCC certification.
- Ensuring that future conformity assessment regimes or expansions of the CCC system similarly allow qualified foreign conformity assessment bodies to participate in the market and provide conformity assessment services.

China's conformity assessment regime relies on third-party certification models to determine conformity, and it excludes the possibility of self-certification, such as a suppliers' declaration of conformity.

CNCA and other relevant testing and certification authorities should examine broadening China's current conformity assessment model by:

- Accepting foreign-based companies' suppliers' declaration of conformity for certain products, based on acceptable levels of known product risk.
- Accepting supervised manufacturing test data already obtained by the manufacturer. If a manufacturer is deemed proficient by an appropriately qualified conformity assessment body, it should be able to submit test data directly to PRC conformity assessment authorities for a certification body certificate.

Representatives of companies operating in China often lack adequate opportunity to recommend and comment on draft conformity assessment policies and procedures set by government agencies before they are finalized. No unified channel exists for release of all proposed policies related to conformity assessment. The contribution of broad stakeholder views and international best practices will provide these government agencies that have conformity assessment policymaking authority with additional input for consideration and may result in better policy outcomes for China.

Government agencies with conformity assessment policymaking authority should consider:

- Creating a designated, unified channel to make draft versions of all conformity assessment policies and procedures set by government agencies available to domestic, foreign-invested, and foreign-based stakeholders for public comment for a period of at least 30 days.

Representatives of companies operating in China report difficulty confirming with non-CNCA officials, including local Customs agents and local representatives of the Administration of Quality Supervision, Inspection, and Quarantine, whether products must be CCC-certified. This can lead to unnecessary costs and delays for companies, as well as regulatory burdens to resolve these issues.

CNCA and other CCC-related government agencies should consider:

- Coordinating closely and regularly at multiple levels to promote an aligned interpretation of rules, tackle regulatory gaps and issues between the agencies, and establish set processes to handle disputes and questions quickly and easily.
- Engaging in dialogue on how to harmonize existing catalogues—for example, standardizing CCC product scope and the Harmonized System codes used by local Customs officials—and working to educate local officials on standard case handling in these situations.

Representatives of companies operating in China are inconsistently able to access or comment on conformity assessment policies and procedures set by individual DCBs. DCBs lack a common set of best practices for promoting transparency. This results in difficulties for those companies

CNCA and other relevant government agencies should encourage DCBs to solicit feedback from stakeholders on relevant conformity assessment policies for a sufficient period of time.

in ensuring full compliance with PRC conformity assessment policies and procedures, and thus it increases the chances that Chinese consumers may see non-compliant products.

ⁱ For more on these and other features of the US system and about the WTO/TBT regime, see the American National Standards Institute's "US Best Practices for Standards and Conformance."