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To whom it may concern at the Chinese State Council:

The American National Standards Institute (ANSI) would like to thank the Chinese State Council for the opportunity to comment on the draft revised China Standardization Law. ANSI has a long history of cooperation with China, and Standardization Administration of China (SAC) in particular. The Institute applauds this demonstration of transparency and request for feedback on a fundamental component of the reform of China's standardization system.

By way of background, ANSI serves as the coordinator the U.S. voluntary consensus standards system. As coordinator, ANSI facilitates the public-private partnership that is at the core of the U.S. standards and conformance system, accredits standards developers and conformity assessment organizations, and represents the U.S. in various international fora, including ISO and IEC.

Since the State Council published the plan for deepening the reform of China's standardization system in March 2015, ANSI has closely monitored and engaged its Chinese partners on the details of the rollout. In November 2015, ANSI provided comments to "Association Standardization – Part 1: Guidelines for Good Practice." Those comments are available <u>here</u>.

ANSI commends China on its impressive effort to strengthen its standardization system. We fully support the underlying goal of fostering innovation and economic and social development, and agree that a robust standardization system is key to achieving this goal. In its comments, ANSI makes several specific suggestions, including a strong recommendation that China confirm its commitments under, and ensure all aspects of the law comply with, the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement. ANSI's comments also offer, for China's consideration, lessons and best practices gained from the U.S. experience in pursuing these goals. In particular, we emphasize the advantages of a system that is open and transparent, market-driven, diverse and flexible, and embodies a public-private partnership in which all stakeholders work together on equal terms.

ANSI is submitting its specific comments on the draft revised law as an attachment to this letter. In developing its comments, ANSI used the following documents to share its experience and perspective on relevant issues, and also solicited and considered comments from its membership:

• The ANSI Essential Requirements: Due Process Requirements for American National Standards, which govern the processes by which ANSI accredits standards developers and approves American National Standards (ANS). Due process is the key to ensuring that ANS are developed in an environment that is equitable, accessible and responsive to the requirements of various stakeholders. To date, more than 240 standards developers have been accredited by ANSI. In



2015, ANSI shared a Chinese translation of the ANSI Essential Requirements with SAC as a demonstration of its commitment to cooperation on the reform. The ANSI Essential Requirements are available (in English) <u>here</u>.

The United States Standards Strategy, which serves as a statement of purpose and ideals
resulting from a reexamination of the principles and strategy that guide how the United States
develops standards and participates in the international standards-setting process. It provides a
framework that can be used by all interested parties to further advance trade issues, and a
vision for the future of the U.S. standards system in today's globally competitive economy. The
United States Standards Strategy is available here.

Additionally, the comments reference two U.S. government-issued documents that give shape to the public-private partnership as it pertains to the U.S. standards system: (i) the National Technology Transfer and Advancement Act (NTTAA), Public Law 104-113, available <u>here</u>; and (ii) the White House Office of Management and Budget (OMB) Circular A-119, available <u>here</u>.

In closing, ANSI welcomes the opportunity to further discuss its comments and the referenced documents at any point, and looks forward to continued engagement with China throughout the reform process.

Sincerely,

Joseph Tretler, Jr. Vice President, International Policy



Chapter, article	ANSI comment/suggestion
1,1	ANSI encourages reliance on a robust, diverse and open consensus standards development process, consistent with World Trade Organization (WTO) Technical Barriers to Trade Agreement (TBT) principles, in order to achieve China's stated goals. To this end, ANSI recommends specific reference to China's WTO commitments at the outset of this law.
	Within the U.S., , the <i>United States Standards Strategy</i> (USSS) affirms the WTO TBT Agreement and articulates strategic initiatives for boosting the competitiveness of the U.S. economy and achieving a balanced global trading system through the use of voluntary consensus standards. ANSI's role as the accreditor of some 240 standards developers and of hundreds of conformity assessment bodies that work in all sectors of the economy provides confidence in the standards developed and the certifications issued. Similarly, a strong and open public-private partnership in these areas of work will contribute to China's innovation and economic development.
1,2	As China reforms its system to support standardization across such a wide range of areas, ANSI offers its experience, as articulated in the USSS, which finds that a standards development process based on, and implemented in a manner consistent with, WTO principles, provides an infrastructure that is effective in developing standards across all sectors. Such a system can be nimble, support innovative solutions and achieve broad-based policy goals. A sectoral focus allows interested parties to address their own issues and develop working methods that fit the problems at hand, since no single path in standards development can satisfy all needs. When cross-sectoral issues arise, sector definitions change, or a single national voice is required, the underlying standardization infrastructure should provide facilitation and mediation.
1,3	ANSI believes a strong public-private partnership is critical to standardization work. In the U.S., the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113 (available here: <a href="http://www.nist.gov/standardsgov/nttaa-act.cfm">http://www.nist.gov/standardsgov/nttaa-act.cfm</a> ), requires all federal government agencies to use, wherever feasible, standards developed or adopted by voluntary consensus standards bodies in lieu of developing government-unique standards or regulations. The U.S. system is distributed and relies on broad-based engagement of standards developers, stakeholders, industry and government. Government participates in the standardization process as an equal partner with industry and other stakeholders. With respect to American National Standards (ANS), ANSI serves as accreditor of standards developers, approves individual standards as ANS and ensures that the



	<ul> <li>underpinning system incorporates a series of oversight checks-and-balances, including annual compliance confirmations and regular procedural audits.</li> <li>With respect to funding the standardization system, the USSS explains that there is no single method of doing so in the U.S. and the need to protect the pluralistic manner in which the system is funded. Practically speaking, each U.Sbased standards developer is responsible for the funding mechanisms that support the standards development process sponsored by their organizations and they pay ANSI annual fees to maintain accreditation and support ANSI's oversight role. Participants in the standards development process – including government - in many instances contribute to the support of the system through participation fees or other mechanisms. Users of standards contribute through purchases of the standards that are developed.</li> </ul>
1,4	Cooperation among the organizations involved in the administration and oversight of the standards development system is essential. In the U.S., the voluntary consensus standardization system is a public-private partnership. ANSI is the leading U.S. organization for coordinating and promoting voluntary consensus standards. The aforementioned NTTAA encourages U.S. Federal Government agencies to use, wherever feasible, standards developed or adopted by voluntary consensus standards bodies in lieu of developing government-unique standards or regulations. The law names NIST as coordinator of U.S. Federal Government agencies' use and participation in the development of voluntary consensus standards.
1,5	ANSI notes the establishment of this coordinating mechanism in July 2015, and reemphasizes its comment on article 1.4 that coordination among administering organizations and standards bodies is essential. As stated above, the U.S. standards system is a public-private partnership and ANSI is the leading U.S. organization for coordinating and promoting voluntary consensus standards. Over the years, ANSI has established standards planning panels or collaboratives to address specific areas of standardization that require high level coordination among many interests and many standards developers. These include: nanotechnology, homeland security and many others (see a complete list at <a href="https://www.ansi.org/panels">www.ansi.org/panels</a> ).
1,6	ANSI recommends that China acknowledge and reinforce its WTO TBT Agreement commitments with respect to



	international standardization in this article, including the globally accepted principals of international
	standardization set forth in the TBT Committee decision (G/TBT/1/Rev.8, 23 May 2002).
	ANSI and the U.S. government promote participation in International Standardization activities in many ways. The White House Office of Management and Budget (OMB) Circular A-119 (revised January 2016 and available here: <a href="https://federalregister.gov/a/2016-01606">https://federalregister.gov/a/2016-01606</a> ) contains guidance for U.S. Federal Government agencies encouraging their participation in international standardization efforts. Participation in ISO and IEC activities as well as in the international standardization efforts underway at many U.S. domiciled standards development bodies should be encouraged to ensure the global relevance of resulting documents.
	ANSI also encourages coordination between the national mirror committees (known as Technical Advisory Groups) that represent the U.S. at ISO and IEC on the one hand and development of American National Standards on the other. For details concerning ANSI's coordination requirements within the ANS process, see in particular sections 2.4-2.5, 4.2.1.1 and 4.3 of the ANSI Essential Requirements: Due process requirements for American National Standard Standards ("ANSI Essential Requirements" available at www.ansi.org/essentialrequirements).
2,8	In the U.S., the Federal Government maintains a public infrastructure for the development of regulations, which may incorporate by reference voluntary consensus standards and other standards. Separate from this government- run structure is the voluntary standards process in the U.S., which is market-driven and led and implemented through a public-private partnership engaging hundreds of organizations and addressing thousands of topics. This diverse and distributed system, which emphasizes the voluntary nature of these standards, fosters innovation and benefits the U.S. economy as well as U.S. citizens and the rest of the world. The U.S. government benefits because voluntary consensus standards facilitate trade and commerce; advance scientific discovery and keep people safe by minimizing injuries and protecting key environmental resources; reduce costs incurred by the government because joint or private-sector efforts incur at least some of the costs that would have been borne by government; and these standards support interoperability in all areas of life and the economy.
	Consistent with the WTO TBT Agreement, ANSI recommends the addition of a clause to Article 8 such as, "Where international standards exist, they shall be used as the basis for national standards except where they would be ineffective or inappropriate."



2,9	As stated above, the U.S. Federal Government maintains a public infrastructure for the development of regulations, which may incorporate by reference voluntary consensus standards and other standards. Separate from this government-run structure is the voluntary standards process in the U.S., which is market-driven and led and implemented through a public-private partnership engaging hundreds of organizations and addressing thousands of topics. As described the USSS, consideration of emerging national priorities concerns related to the environment, health and safety is not limited to regulations, but is also a factor in the development of voluntary consensus standards. The co-existence and complementarity of voluntary consensus standards and government regulations has served the U.S. economy well and is offered as an example of a successful standards development framework for China's consideration. ANSI notes that the phrase "compulsory standards should be available to the public free of charge" infers broad application of this requirement, and ANSI recommends China consider the following alternative language: "Compulsory standards shall be made reasonably available to the public." ANSI makes this recommendation in light of the challenges associated with allowing across-the-board free access to standards, including the financial sustainability of the groups that developed the standards and the protection of intellectual property. In the U.S., ANSI has helped increase access to standards incorporated by reference (IBR) in U.S. government rulemakings by developing the IBR portal (accessible here: <u>http://ibr.ansi.org</u> ), which offers "read only" access to many incorporated standards.
2,10	In delegating responsibility for the development of recommended standards, ANSI respectfully recommends that China consider the benefits of fair and open participation in standards development, through published procedures that allow engagement of all stakeholders, domestic and foreign. In the U.S., ANSI represents a public-private partnership with a goal of coordinating, promoting and advancing voluntary standards development for the advancement of technology, innovation and economic development, to the benefit of citizens, industry, the environment and U.S. quality of life. Many stakeholders contribute to the success of the diverse U.S. standards system, including the American National Standards system, which is implemented in accordance with published procedures that reflect WTO principles. The U.S. economy and society has benefitted greatly from the open public- private partnership model our system reflects.
2,11	As affirmed in the USSS, choice is a positive result of a diversified standards development ecosystem. While some solutions may be best addressed through government regulations, many others could be efficiently and effectively



	developed through voluntary standards-based solutions. An environment that recognizes the value of choice and market-drivers will likely benefit China's economy and its citizens.
	With respect to this law's guidance on the various categories of Chinese standards, ANSI recommends that the WTO TBT principles be applied consistently, including the preference for existing international standards.
2,12	With respect to this law's guidance on the various categories of Chinese standards, ANSI recommends that the WTO TBT principles be applied consistently, including rules on adequate public notice and comment included in the Code of Good Practice. Public notice and encouraging participation by diverse stakeholders at all levels of standards development will help with coordination efforts and the transition from one category of a standard to another. ANSI further recommends that China educate all levels of government engaged in standards development activities about adherence with the WTO principles, the goal of global relevance and the long-term benefits and efficiencies that will result.
2,13	ANSI recommends clarification of the relationship between association standards, and the other standards included in this law, e.g., national, industry, local and enterprise. ANSI offers its American National Standards (ANS) development model for China's consideration. The procedures that govern the ANS process are called the "ANSI Essential Requirements" (www.ansi.org/essentialrequirements) in addition to committee procedures for ANSI oversight bodies. ANSI oversees this process through its roles as: accreditor of standards developers in accordance with published requirements; approver of individual standards as ANS; auditor of procedural compliance; and fair arbiter of procedural disputes that cannot be resolved informally. ANSI oversight is provided through committees of its members who are standards experts and committed to working on behalf of ANSI's mission. All committee work is subject to a conflict of interest policy that is routinely enforced. The ANSI Essential Requirements is also subject to revision annually, based on proposed improvements by stakeholders. In November 2015, ANSI used the ANSI Essential Requirements as the basis for its comments on the "Association Standardization – Part 1: Guidelines for Good Practice," issued by the Standardization Administration of China.
2,14	ANSI recommends that China review the aforementioned OMB Circular A-119, which reflects U.S. recognition that adherence to a set of underlying principles and practices ensures that multiple options for standards development serve the economy and its people well.



2, 15	ANSI recommends this article uphold related provisions under the WTO TBT Agreement, and notes that relevant provisions of the USSS provide additional strategies for achieving these goals. For example, the USSS recommends early collaboration and active coordination to ensure standards address emerging national priorities. The Strategy also encourages the development of online and electronic tools to ensure the efficient and timely development and distribution of voluntary consensus standards.
2,18	ANSI commends China on this provision. The synergy that results from meaningful participation by all stakeholders in standards development translates into standards that will be used and useful. ANSI offers ANSI's Essential Requirements as a framework through which this goal may be achieved.
2,19	ANSI offers the ANS Essential Requirements, which reflect WTO principles, as a framework through which such committees could undertake their work. We note as well that ANSI's procedures allow for participation by U.S. and non-U.S. domiciled stakeholders in recognition of the fact that some standards are local, while others are international. The procedures also recognize that non-U.S. stakeholders may be impacted by these standards when doing business in the U.S. market.
2,20	ANSI commends China on its efforts to coordinate the naming and coding of the various types of Chinese standards. ANSI's rule with respect to the identification of ANS is that the designation of each shall be unique. The designation, however, is decided upon by the ANSI-Accredited Standards Developer that sponsors the standard. See section 4.4 of the ANSI Essential Requirements; for the designation structure of national adoptions of ISO and IEC standards as ANS, ANSI defers to ISO/IEC Guide 21.
2,21	ANSI acknowledges China's efforts to protect the copyright on standards. ANSI's approach is that it requires that an accredited standards developer have an interpretations policy. If an interpretation is to be issued, it would only be issued in accordance with that standards developer's policy. See section 3.6 of the ANSI Essential Requirements.
2,22	ANSI encourages a regular review cycle for all standards to ensure currency, and commends China for its efforts in this regard. ANSI recommends clarifying the phrase "tracking and evaluating the enforcement of standards," since enforcement is covered in the subsequent chapter. For information on ANSI's requirements for ANS, please review section 4.7 Maintenance of American National Standards of the ANSI Essential Requirements. Review of compliance with maintenance requirements is one issue that is considered during a standards developer's routine procedural



	audit.
3,23	ANSI recommends this article uphold related provisions under the WTO TBT Agreement, including those calling for adequate transition time in the implementation of technical regulations, or mandatory standards, and those recommending the use of international standards as the basis of national standards where they exist.
3,24	<ul> <li>With respect to Chapter III of this law on the enforcement of standards and the provisions on public supervision of enterprise standards in particular, ANSI recommends a review of its role as "accreditor" (available here: www.ansi.org/accreditation) relative to both standards and conformity assessment bodies. ANSI views its accreditation role as core to our mission to enhance the global competitiveness of U.S. businesses and the U.S. quality of life. Accreditation provides assurance that standards, goods, and services meet essential requirements throughout the global supply chain – engendering consumer trust and fostering competitiveness. Increasingly, procurement authorities, government agencies, and program/scheme owners are specifying accreditation in order to demonstrate the technical competence and impartiality of conformance services and processes. These assessments enhance confidence between buyers and sellers as they mitigate risk. This view is elaborated in the USSS, as well as its sister document, the <i>United States Conformity Assessment Principles</i> document (third edition, available here: www.ansi.org/uscap), which articulates the principles for U.S. conformity assessment activities that will allow consumers, buyers, sellers, regulators, and other interested parties to have confidence in the processes of providing conformity assessment, while avoiding the creation of unnecessary barriers to trade.</li> </ul>
3,28	ANSI recommends further clarification on government use of standards as encouraged in this article, and offers the U.S. practice for China's consideration. The aforementioned NTTAA encourages U.S. Federal Government agencies to use, wherever feasible, standards developed or adopted by voluntary consensus standards bodies in lieu of developing government-unique standards or regulations. As is evidenced by the success of the U.S. economy, technology and innovation, standards and conformity assessment are important contributors to China's stated goals.



3,30	ANSI offers to China the resources developed through various initiatives it has led to promote reliance on voluntary standards, for example: Standards Boost Business at <a href="http://www.standardsboostbusiness.org/">http://www.standardsboostbusiness.org/</a> ; and Educational online training resources <a href="http://www.standardsboostbusiness.org/">www.standardsboostbusiness.org/</a> ; and Educational online training resources <a href="http://www.standardsboostbusiness">www.standardsboostbusiness</a> .
4,31	ANSI offers its proven practices for China's consideration. With respect to American National Standards, ANSI conducts procedural audits on a 5-year cycle to evaluate procedural compliance. The rules of the audit are established in published procedures. Audits are conducted subject to conflict of interest rules. With respect to ANSI's accreditation of conformity assessment bodies, the governing rules of each program apply and compliance is assessed accordingly by independent assessors.
4,32	With respect to ANS, ANSI's procedures require timely maintenance, but also allow for extensions for cause. That said most ANS cannot retain that status for longer than 10 years without substantive review. To understand ANSI's maintenance requirements, please see section 4.7 Maintenance of American National Standards within the ANSI Essential Requirements.
4,33	While ANSI is not a government agency, the ANSI Essential Requirements and ANSI Audit Procedures address consequences for procedural non-compliances. All non-compliances that result in a status change or withdrawal of an ANS are subject to ANSI's published appeals procedures.
4,34	ANSI commends China on the inclusion of a dispute resolution mechanism. ANSI recognizes the great value in accessible mechanisms for addressing disputes – informally and formally. With regard to American National Standards (ANS), the ANSI Essential Requirements establishes coordination mechanisms that must be satisfied in order for a standard to progress through the approval process (see for example, section 2.5.1 Project Initiation Notification (PINS)). In addition, ANSI requires standards developers to offer a fair appeals process with published procedures. ANSI itself offers multiple levels of appeals in addition to encouraging informal dispute resolution whenever feasible.
4, 35	Such authorization should consider an assessment of the competence, capabilities and qualifications of any conformity assessment (testing and inspection) body in accordance with the accreditation criteria of internationally recognized accreditation bodies like the Chinese National Accreditation Service (CNAS) and peer signatories of the IAF-MLA such as ANSI.



5,37	Standardization in the U.S. is governed by all applicable laws. In addition, within the ANS process, an accredited standards developer may lose its status as such and a standard may lose its status as an ANS if warranted based on evidence of procedural non-compliance. This evidence is usually identified as a result of an appeal or an audit. Before either action is taken, a due process-based review of the facts is undertaken by a fair adjudicative body, subject to at least two levels of appeal through ANSI.
5,40	China may wish to consider a code of ethics as one document to establish general expectations for behavior. For example, a copy of the ANSI Member Code of Ethics is available here: <u>http://www.ansi.org/publicstatements/codeofethics.aspx?menuid=1</u> . In addition, each ANSI oversight body operates in accordance with a specific conflict-of-interest policy that is respected, fully implemented and effective.
6,41	U.S. law governs all activities undertaken in the U.S. For reference, ANSI's By-laws are overseen by ANSI's Board of Directors, the membership of which reflects all stakeholders. Members are subject to ANSI's Code of Ethics. The ANSI Essential Requirements contains the specific rules for ANS-related consensus development, accreditation, audit authority, etc.; revisions to these rules may be submitted to ANSI for consideration by any stakeholder. All such proposals are considered and vetted and if accepted, issued in the next year's edition of the Essential Requirements. This process has resulted in continual improvement and ANSI highly recommends it.