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Committee on Technical Barriers to Trade Original: English

TRANSITIONAL REVIEW MECHANISM PURSUANT TO SECTION 18 OF THE PROTOCOL ON THE ACCESSION OF THE PEOPLE'S REPUBLIC OF CHINA

Questions and Comments from the United States to China

The following communication, dated 20 October 2009, is being circulated at the request of the delegation of the United States.

I. INTRODUCTION

1. The United States continues to have concerns in a number of areas that have been addressed in recent transitional reviews before this Committee, including, for example, favoritism toward home-grown 3G telecommunications standards, failure to recognize the results of conformity assessment procedures conducted by accredited conformity assessment bodies, wherever they may be located, and the lack of transparency in the development of technical regulations, standards, and conformity assessment procedures. In connection with this year's transitional review, the United States would like to focus on these areas, as well as proposed Chinese measures relating to medical devices.

II. CHINA-SPECIFIC TELECOMMUNICATIONS STANDARDS

2. The United States continues to have significant concerns about China's use of China-specific standards in the telecommunications area, especially the WAPI standard. In 2003, China issued a mandatory wireless local area network (WLAN) standard named GB15629.11 that requires a security protocol known as "WLAN authentication and privacy infrastructure" (WAPI). Additionally, in 2003, China issued a measure requiring foreign wireless equipment makers to enter into agreements with certain Chinese companies to access a government-classified encryption algorithm needed to meet the WAPI standard, effectively forcing foreign equipment makers to transfer technology and share proprietary technical information to Chinese competitors to integrate WAPI into their equipment. In 2004, China agreed to indefinitely suspend the measure mandating the use of WAPI.

3. In the past several years, global mobile handset makers have increasingly added WLAN/Internet capability into their mobile handsets, expanding the interest in WLAN equipment from laptop computers and home computers to mobile handsets. The operative standard for this expansion of WLAN/Internet capability has been the relevant international standard, i.e., the ISO/IEC 8802-11 standard, otherwise known as "WiFi." To our knowledge no other competing standard is in commercial-scale use anywhere in the world. However, China has never issued type approvals for handsets that connect to the Internet through WLANs, and instead has only issued type approvals for handsets that connect to the Internet through cellular networks. This has required foreign equipment makers to disable WLAN/Internet capability before their handsets can be marketed in China. In 2009, however, in concert with its plan for encouraging an aggressive roll out of third generation (3G) mobile handsets by Chinese telecommunications operators, many of which are Internet-enabled via WLAN networks, China's Ministry of Industry and Information Technology (MIIT) established a

process for approving hand-held wireless devices such as cell phones and smart phones that are Internet-enabled. MIIT indicated to U.S. government officials in bilateral discussions in September 2009 that it will approve such devices that use the relevant international standard, i.e., the WiFi ISO/IEC 8802-11 standard, only if the devices are also enabled to the WAPI standard. MIIT officials indicated that there is no written or published measure providing for this requirement, and China has not notified this requirement to the WTO.

4. Can China explain why it is requiring that mobile handsets be WAPI-enabled, especially given that the United States is not aware of any other government that has mandated a particular commercial security standard?

5. Can China further explain why it is mandating compliance with a non-consensus based standard that does not appear to have been developed in an open and transparent process when there is a relevant international standard – WiFi – that has been in widespread use in the global marketplace? As part of this explanation, please explain why WiFi would be ineffective or inappropriate to achieve China's objectives?

6. Given that services and devices based on WiFi alone are now widely available and sold not just in the rest of the world but now legally in China as well, what is China's justification for requiring type approval in this subsector of the mobile equipment market?

7. What is China's justification for not mandating these particular technical regulations through written and published regulations, in an area as broad as type approval and network access for mobile devices in the world's leading mobile handset market?

III. MEDICAL DEVICE REGISTRATION

8. In April 2009, China's State Food and Drug Administration (SFDA) issued for public comment a draft *Administrative Measures on Medical Device Registration*, intended to supersede the *Administrative Measures on Medical Device Registration* issued in 2004. However, China has not notified this proposal to the WTO. Would China consider notifying the measure to the WTO so as to provide a full opportunity for all WTO Members and interested parties to submit comments and agree to take these comments and any discussions resulting from them into account?

9. The United States is also particularly concerned about the proposed requirement in the draft *Administrative Measures on Medical Device Registration* that a medical device must be registered in the country of export before it would be accepted for registration in China. We understand that Chinese regulators view such approvals as an additional indicator that the device is safe, and appreciate China's objective to ensure that the medical devices used in Chinese hospitals and clinics and by Chinese patients achieve the highest levels of safety and efficacy.

10. We further understand that SFDA is fast-tracking a new notice, independent of the draft measure discussed above, that would require a registrant to produce evidence that it has registered a device in its country of legal residence. For example, any U.S. firm manufacturing anywhere in the world would have to obtain a U.S. registration before registering a device in China. This requirement also raises concerns.

11. The United States requests that China re-consider both of these domestic registration requirements, as either one of them could block access for safe, high-quality medical devices to the Chinese market. There are many reasons why a manufacturer may not seek approval of a device in its home country or market of export. For example, a device may be manufactured in a country for export only, or it may be designed specifically for patients in a third country, such as China. In this situation, a company would have no business need to seek approval in its home country or the country

of export and would likely forego that process, which could impose burdens of time and money. Thus, the lack of registration in the manufacturer's home country or country of export would not necessarily be an indication that the device is unsafe. Would China consider making these changes?

IV. REGULATIONS ON THE RECALL OF DEFECTIVE PRODUCTS

12. The United States also notes its concern with the draft *Administrative Regulations on the Recall of Defective Products* issued by the General Administration of Quality Supervision and Inspection and Quarantine (AQSIQ), which would apply to medical devices. Given that the Ministry of Health and SFDA will shortly complete a recall system covering medical devices, begun in December 2008 with the publication of an adverse event reporting procedure, and SFDA is the agency that regulates medical devices, can China explain why AQSIQ is considering including such devices within the scope of the recall procedures it is developing? How would the AQSIQ recall procedures add value to the SFDA recall procedures?

13. In the United States' view, maintaining duplicative and perhaps contradictory recall procedures on medical devices will be highly confusing to medical device producers. Not only could this disrupt trade, but it could result in a negative impact on patient safety by causing delays in the reporting and recall process. SFDA officials also possess product-specific expertise with respect to medical devices that will be critical to effective post-market surveillance in the Chinese market. Thus, the United States urges AQSIQ to exempt medical devices, just as it has pharmaceuticals from the scope of its new recall procedures, and permit SFDA, which has regulatory authority for medical devices and pharmaceuticals in China, to be the sole recall authority for medical devices in the Chinese market. Would China consider making this change?

V. CONFORMITY ASSESSMENT PROCEDURES

14. This Committee developed an *Indicative List of Approaches to Facilitate Acceptance of the Results of Conformity Assessment* (see G/TBT/1/Rev.9, Annexes to Part 1, Section A), which includes several approaches for accepting the results of conformity assessment, including test results performed by laboratories located outside the territory of the importing Member. This list includes use of accreditation to ensure the technical competence of accredited conformity assessment bodies. There are a variety of accreditation approaches, and one approach that has been successfully employed by several Members is using accreditation by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) members as a basis for accepting test results performed by laboratories outside the territory of the importing Member. Has China considered utilizing this mechanism – or another mechanism such as government designation or recognition of foreign testing laboratories – as a basis for accepting test results performed by laboratories outside its territory including with respect to mandatory China Compulsory Certification (CCC) Mark or for SFDA requirements? If not, why not?

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