WORLD TRADE ORGANIZATION

G/TBT/W/279
22 October 2007

(07-4556)

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 19 October 2007, is being circulated at the request of the delegation of the United States.

I. MEDICAL DEVICE BORDER EXAMINATION

1. China's Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) issued the *Administrative Measures on Examination and Supervision of Imported Medical Devices* in late June 2007, to be effective 1 December 2007. Known as Decree 95, this measure imposes an examination and supervision regime on imported medical devices. China cites as underlying statutory authority for this measure its 2002 Law on Import and Export Commodity Inspection.

2. Decree 95 establishes three risk categories of medical devices and three categories for importers, based on their experience and other factors. It requires certain percentages (ranging from 10 to 100 percent) of imported medical devices in each risk category to be subject to inspection. The intensity and type of inspection vary based both on the category of the importer and the risk category of the product. For example, 100 percent of medical devices categorized in the highest risk category (e.g., MRIs and pacemakers) are subject to inspection. Decree 95 also calls for a product catalogue that specifies which medical devices are subject to particular inspection regimes. These inspections would be in addition to the existing certification requirements that foreign manufacturers must obtain, prior to exporting medical devices to China, through the normal regulatory process at the State Food and Drug Administration and the Certification and Accreditation Administration. In addition, Decree 95 sets out requirements for foreign manufacturers to report product defects, requirements on donated medical devices and requirements on remanufactured medical devices. Decree 95 appears to go substantially further than common international practice, where border inspection is generally done only on a very small percentage of already-certified devices, and done in response to targeted concerns.

3. The United States has serious substantive concerns about this measure, as well as concerns about China's failure to notify the measure to the WTO.

(a) Article 23 of Decree 95 provides authority for AQSIQ to conduct nine different types of inspection at the time a covered product is imported, including electromagnetic compatibility, emissions, and performance assessment of diagnostics. This inspection authority, whether it is exercised for 10 percent, 30 percent, 50 percent or 100 percent of imported medical devices (depending on risk categorization and company classification) as indicated in the measure, would mean exhaustive border inspection

in a manner going substantially beyond common international practice. Please clarify how frequently AQSIQ and its designees will conduct actual inspections of medical devices at the point of entry, and how frequently AQSIQ and its designees will merely conduct verification of required paperwork.

(b) Please identify and describe any regulations or other measures that require inspection of domestic medical devices manufactured and sold within China, after those medical devices have received type approval and SFDA certification.

(c) Does China have any regulations or other measures that regulate the domestic distributors of domestically manufactured medical devices in a manner similar to the scheme set out in Decree 95 for the importers of imported medical devices? Please explain.

(d) Please describe the fee that will be assessed when AQSIQ conducts an examination and supervision. How much will an individual examination cost? What is the purpose of the fee and on what basis is it calculated?

(e) In bilateral discussions with the United States, China has argued, among other things, that it sees no need to notify the measure, given that the overarching law (its 2002 Law on Import and Export Commodity Inspection) was notified to the WTO. However, the TBT Agreement notification obligation applies to any measure that fits the definition of a technical regulation under Annex 1 of the Agreement, subject to the provisions of Article 2.9. Thus, a WTO Member's characterization of a measure as a law, a regulation or some other type of measure is not determinative. The United States routinely notifies to the WTO changes made by not only laws enacted by the U.S. Congress, but also regulations and other measures issued by regulatory agencies. Please explain China's justification for not notifying Decree 95 to the WTO.

(f) China has also argued that notification of Decree 95 is not required because this measure does not impose any requirements on foreign manufacturers, and only impacts domestic Chinese entities involved in importation. By its terms, the measure requires the examination of imported medical devices, based on a scale from low-risk to high-risk medical devices. The measure also requires foreign manufacturers to report defects, and imposes penalties in the form of increased examinations of imported devices based on product returns or quality complaints. The measure additionally regulates medical devices imported for research purposes, as well as used medical devices, and provides authority to AQSIQ to stop the import of defective medical devices based on reporting from a risk alert system. The underlying law on which this measure is based, the Law on Import and Export Commodity Inspection, is focused on the inspection of import and export commodities. Given these facts, please explain China's position that this measure does not impose any requirements on foreign manufacturers, and only impacts domestic Chinese entities involved in importation.

(g) Will China notify Decree 95 to the WTO and permit WTO Members and interested persons the opportunity to present comments in writing, and for China to hear the concerns of Members and interested persons and make appropriate modifications to the regulations, and for China to allow exporters time to adapt their products and export procedures to China's requirements? Given the short time before the measure's effective date, will China consider suspending the measure, including its 1 December 2007, effective date, so that this process can take place?

II. BATTERY STANDARDS

4. China's Ministry of Information Industry (MII) is developing a standard that would specify requirements for the size, electrical performance, safety performance, and labeling of mobile phone batteries ("Specification for General lithium batteries of Mobile Telecommunication Terminal Equipment," YD/T xxxx-xxxx). MII justifies the need for this standard on the grounds of consumer convenience, development of the mobile phone industry and environmental and safety concerns. U.S. and foreign mobile handset makers maintain that compliance with this standard will, in fact, have the opposite effect in each of the areas identified by MII. The United States is concerned that the standard, which does not appear to have been developed in accordance with the principles contained in the relevant WTO TBT Committee decision (G/TBT/1/Rev.8, section IX, 23 May 2002), will be integrated into a technical regulation, such as MII or National Certification and Accreditation Administration certification and type approval schemes, thereby making compliance with the standard mandatory. Further, the United States is concerned that China may not notify the proposed technical regulation to the WTO.

(a) Please explain the purpose of this standard.

(b) Is this standard based on any international standard? Please explain.

(c) How will conformity assessment with respect to this standard be conducted?

(d) Please explain how MII's development of this standard has met each of the six criteria contained in the relevant WTO TBT Committee decision (G/TBT/1/Rev.8, section IX, 23 May 2002): (a) transparency, (b) openness, (c) impartiality and consensus, (d) effectiveness and relevance, (e) coherence, and (f) development).

(e) When does China anticipate the draft battery standard will be finalized?

(f) Can China confirm that demonstrating compliance with the battery standard will *not* be a requirement for mobile phone manufacturers or battery manufacturers to obtain type approval, CCC mark registration or other approval before selling their products in China?

(g) If the battery standard *will* be a requirement for mobile phone manufacturers or battery manufacturers to obtain MII type approval, CCC mark registration or other approval before selling their products in China, will China notify the WTO of the change in MII type approval rules, CCC mark rules or other approval rules, and provide an opportunity for interested parties including governments and industry representatives to comment on that change, before it takes effect?

III. ADMINISTRATION ON THE CONTROL OF POLLUTION CAUSED BY ELECTRONIC INFORMATION PRODUCTS

5. The United States continues to have concerns about China's *Administrative Measures on the Control of Pollution Caused by Electronic Information Products*, issued by several Chinese agencies effective 1 March 2007 (notified in G/TBT/N/CHN/140). Specifically, China has neither issued the catalogue of products for which mandatory testing will be required under this measure, nor provided any details on the testing and certification protocols, which China has indicated will be forthcoming.

(a) Please provide an update on when the product catalogue for products requiring certification under this measure will be issued.

(b) Please reconfirm that the product catalogue will be notified to the WTO and that China will allow a reasonable interval between the publication of the final product catalogue and its entry into force.

(c) Please provide a list of all laboratories that are currently accredited to perform hazardous substance testing for China. How many more laboratories does China anticipate accrediting? How quickly will this accreditation process be completed?

(d) Will China accredit laboratories physically located in China that are wholly-foreign owned facilities or majority-foreign owned facilities? If not, why not?

(e) Will China accredit certification bodies located in other countries or recognize certification bodies in other countries which have been accredited by other accreditation bodies? If not, why not?

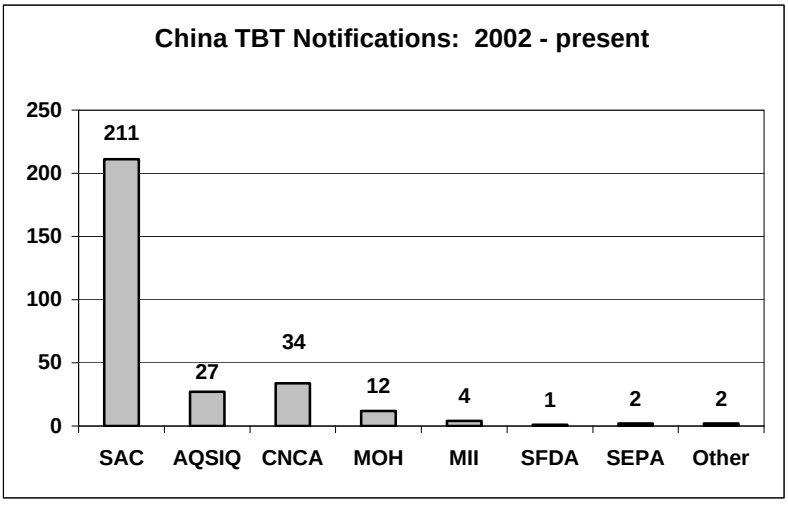
(f) Please provide information on the status of the testing standards that will be used for certification of products contained in the product catalogue. We understand that China has published testing standards that are based on draft IEC standards. In the event that the current draft IEC standards are revised, will China promptly amend its testing standards?

(g) Will China institute a system for Supplier's Declaration of Conformity for compliance with these measures?

IV. TRANSPARENCY

6. The United States appreciates China's efforts to improve transparency within its regulatory system. However, a significant number of technical regulations continue to be introduced or amended without the advance notification required by the TBT Agreement. This is particularly the case for regulations issued by agencies other than AQSIQ and its sub-unit, the Standardization Administration of China (SAC). In addition, even when information is available on new regulations or regulatory proposals, the opportunity for foreign stakeholders to comment is either limited or does not exist at all.

7. The chart below provides a breakdown of notifications by agency.



8. The United States urges China to notify the TBT Committee of all draft technical regulations and conformity assessment procedures that may affect trade. The United States also urges China to provide a reasonable period for comment and a reasonable interval between publication and entry into force.

(a) Please describe any steps that China has taken during the past year to improve its record with regard to TBT Agreement notifications.

(b) Please describe any steps that China has taken during the past year to institute improvements with regard to notice-and-comment procedures for draft technical regulations and conformity assessment procedures.

V. INTERNATIONAL STANDARDS

9. As explained in connection with prior transitional reviews before this Committee, the United States remains concerned that China may be unnecessarily restricting itself to the use of standards from certain identified bodies, as the implementation documents associated with China's Law on Standards limit its definition of "international standards" to standards issued by the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC), International Telecommunication Union (ITU) and other international organizations recognized and publicized by ISO. The United States appreciates the explanations that China has previously provided. Nevertheless, the United States recalls that the TBT Committee has agreed upon a Decision containing principles for international standards (G/TBT/1/Rev.8, IX) to assist Members in implementing relevant obligations under the TBT Agreement. In considering future amendments to its Law on Standards and/or implementing measures, the United States encourages China to take these principles into consideration. At the same time, the United States welcomes the serious efforts that China has made to contribute to the development of standards from a broader range of bodies, and the United States welcomes China's utilization of these standards in its domestic regulatory system. The United States encourages China to continue to consider the use of these standards from a broader range of bodies when appropriate for domestic purposes, while continuing to take into consideration the principles of G/TBT/1/Rev.8, IX.

VI. CONFORMITY ASSESSMENT PROCEDURES

10. During last year's transitional review before this Committee, when addressing the China Compulsory Certification (CCC) system, China again noted that it had been studying the possibility of adopting different conformity assessment procedures, including Supplier's Declaration of Conformity. Can China provide an update of its review and explain whether it has taken any concrete steps to adopt different conformity assessment procedures?