WORLD TRADE ORGANIZATION

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Committee on Technical Barriers to Trade

EIGHTH ANNUAL TRANSITIONAL REVIEW MANDATED IN PARAGRAPH 18 OF THE PROTOCOL OF ACCESSION OF THE PEOPLE'S REPUBLIC OF CHINA

1. This report reflects the results of the Eighth Annual Transitional Review mandated in Paragraph 18 of the Protocol of Accession of the People's Republic of China (WT/L/432) that took place at the 5-6 November 2009 meeting of the Committee.

2. In the context of the Eighth Annual Review, submissions were made by the United States (G/TBT/W/324), Japan (G/TBT/W/325) and the European Communities (G/TBT/W/326). Issues raised in the US submission included: (i) China-specific telecommunications standards; (ii) medical device registration; (iii) regulations on the recall of defective products; and (iv) conformity assessment procedures. Issues raised in Japan's submission included: (i) filtering software; (ii) instructions on factory inspections; (iii) restrictive measure without legitimate objective; and (iv) IT security products. Issues raised in the EC submission included: (i) transparency and predictability of the regulatory environment; (ii) China Compulsory Certification (CCC) System; (iii) Information security testing and certification; (iv) standardization; and (v) a number of other concerns being raised in the framework of bilateral regulatory cooperation mechanisms between the European Communities and China.

3. Submission was made by the People's Republic of China on 4 November 2009 (G/TBT/W/327) providing information relating to Annex 1A of WT/L/432. The statements made at the meeting, where discussions under the transitional review took place, will be reflected in the minutes of the meeting, to be circulated as G/TBT/M/49.

ATTACHMENT – EXCERPT FROM G/TBT/M/49

AGENDA ITEM 3: EIGHTH ANNUAL TRANSITIONAL REVIEW MANDATED IN PARAGRAPH 18 OF THE PROTOCOL OF ACCESSION OF THE PEOPLE'S REPUBLIC OF CHINA

1. The Chairman recalled that, in accordance with Paragraph 18 of the Protocol of Accession of the People's Republic of China (WT/L/432), the TBT Committee would undertake an annual review for eight years of the implementation by China of the TBT Agreement.

2. The representative of the United States highlighted some issues contained in his delegation's submission (G/TBT/W/324). He welcomed the progress made at the 20th session of the US-China Joint Commission on Commerce and Trade (JCCC) on several issues that had been raised at previous TBT Committee meetings. On information security, he noted that China had confirmed the announcement made on 29 April 2009 by AQSIQ, MOF and CNCA, that the compulsory testing and certification rules for thirteen categories of information security products would apply only to products procured by agencies of the Chinese Government. He also noted that China had agreed to establish a dialogue on global practices for trade in information security products. According to the United States, substantial progress had also been made in the area of medical devices. In particular, he noted that China had reassured the United States that product recall regulations would not be duplicative or redundant, and the Ministry of Health and the State Food and Drug Administration (SFDA) would be the relevant authorities for medical device recalls. China had also indicated that a prior approval document of a medical device issued by a foreign country would be accepted regardless of its origin or country of manufacture. The representative of the United States stressed that, without such changes, trade in medical devices would have been seriously disrupted to the detriment of suppliers and traders, as well as Chinese hospitals, doctors and patients. In addition, he said that China and the United States had agreed to strengthen cooperation on standards and conformity assessment procedures, and to formulate a work plan for enhancing transparency and predictability in their respective regulatory systems.

3. Notwithstanding the progress in such areas, concerns remained about a number of issues that had been addressed in previous Transitional Reviews, including: favouritism toward home-grown 3G telecommunications standards; lack of transparency with respect to certain measures; and the failure to recognize the results of conformity assessment procedures conducted by accredited conformity assessment bodies located outside of China.

4. The US representative noted that his delegation had significant concerns about China's use of China-specific standards in the telecommunications area, especially with regard to the Wireless Local Area Network Authentication and Privacy Infrastructure (WAPI) standard. He explained that China's Ministry of Industry and Information Technology (MIIT) had recently established a process for approving hand-held wireless devices such as cell phones and smart phones that are Internet-enabled. In September 2009, MIIT had indicated to US government officials that devices using the relevant international standard (WiFi ISO/IEC 8802-11) would only be approved if also enabled to support the WAPI standard. MIIT officials had indicated that no published or written measure containing this requirement existed, and China had not notified this requirement to the TBT Committee. Could China explain why it required that mobile handsets be WAPI-enabled, especially given that the United States was not aware of any other government that had mandated a particular commercial security standard? Could China further explain why it mandated compliance with a non-consensus based standard that did not appear to have been developed in an open and transparent process, when there was a relevant international standard, which was in widespread use in the global marketplace? Could China clarify why the WiFi standard was ineffective or inappropriate to achieve China's objectives? Given that services and devices based on WiFi alone were widely available and legally sold in China, what was

China's justification for requiring type approval in this sub-sector of the mobile equipment market? And finally he asked what China's justification was 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?

5. With respect to conformity assessment procedures, the United States noted that the TBT Committee had developed an *Indicative List of Approaches to Facilitate Acceptance of the Results of Conformity Assessment*,[1] which included 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 included use of accreditation to qualify conformity assessment bodies. It was also recalled that there was a variety of accreditation approaches, and that one approach successfully employed by several Members consisted of the use of 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. Had 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 the China Compulsory Certification (CCC) Mark and SFDA requirements? In concluding, the US representative noted that a discussion on China's consideration of alternative approaches could be helpful especially in the context of the JCCT outcomes.

6. The representative of Japan referred to his delegation's submission (G/TBT/W/325). He noted that the "Instructions on factory inspections" intended to be referred to when conducting factory inspections had been uploaded on the website of the designated certification body under the China Compulsory Certification (CCC) scheme. In this regard, China was invited to provide clarification on the legal relationship between such instructions and the mandatory requirements under the CCC scheme. Japan's view was that the instructions on factory inspection uploaded on the website of the certification body were for reference purposes only and did not entail any mandatory requirement. Could China confirm this?

7. Japan was also concerned that China had adopted certain national standards that appeared to deviate from the relevant international standards, causing unnecessary confusion among foreign companies. In particular, the Japanese delegation drew the Committee's attention to the voluntary national standard for labeling GB/T 191:2008, in which the calculation method for maximum allowance of piling up of cardboard boxes differed from the relevant international standard. Although GB/T 191:2008 was a voluntary standard, China made a reference to it in its mandatory standard GB 5296.2:2008. Therefore, Japan's view was that GB/T 191:2008 constituted a *de facto* mandatory standard. According to Article 2.5 of the TBT Agreement, Japan requested China to explain the justification for referring to this national standard and the objective sought. China was also encouraged to align this standard with the relevant international standard, according to Article 2.4 of the TBT Agreement. Finally, the representative of Japan noted that concerns remained with regard to the Chinese regulations mandating certification on IT Security Products, and those had been addressed under the Specific Trade Concerns part of the Agenda.

8. The representative of the European Communities highlighted some points in his delegation's submission (G/TBT/W/326), and noted that this document identified areas where progress had been made as well as areas where concerns remained. Nevertheless, he expressed satisfaction with the well functioning regulatory dialogue between China and the European Communities.

9. The European Communities welcomed efforts made by China in the field of good regulatory practice and highlighted the significant increase in the frequency of public calls for comments. The

[1] G/TBT/1/Rev.9, Annexes to Part 1, Section A.

importance of ensuring transparency in the regulatory process both in the development and enforcement of regulations was emphasized. Likewise, the importance of ensuring that all existing requirements which economic operators needed to comply with be made publicly available was stressed. In China this did not appear to be the case in all sectors and significant differences existed for regulations under the responsibility of different Ministries. The European Communities was particularly concerned about existing practices in the ICT area, where various mandatory requirements had been introduced without being notified to the TBT Committee or even without prior internal notice. In particular, the EC representative referred to several concerns previously raised in the Committee, such as the WAPI standard, the green dam internet filter, and the unified charger for mobile phones. China's Ministry of Industry and Information Technology (MIIT) was therefore invited to reconsider its practices in accordance with the transparency provisions under the TBT Agreement. China was also encouraged to systematically use regulatory impact assessment tools, at least in those cases where regulations had a significant impact on international trade. It was the European Communities' view that the introduction of Regulatory Impact Assessments could help achieving a better balance between the legitimate regulatory objectives pursued and the need to keep the level of regulation proportionate to the risks to be managed. The European Communities was willing to share experience with China on its own Regulatory Impact Assessments.

10. The EC representative noted his delegation's concern with regard to the level of regulation in China. He noted that the Chinese approach, based on a systematic use of standards combined with third party conformity assessment, was a cumbersome system especially for Small and Medium-sized Enterprises (SMEs) exporting to China without a direct presence in the country. In this context, he reiterated concern about the Chinese Compulsory Certification (CCC) system, which was detailed in the EC submission and had been previously raised in the Committee. Despite some positive steps, the CCC system remained a major obstacle for foreign companies exporting to China. In particular, China was invited to review the "one size fits all" approach based on comprehensive third-party testing and factory audits, which assigned the same high level of risk to all products within the CCC scope, despite their different health and safety risks levels. It was the EC delegation's view that alternative approaches had to be considered by China, such as Supplier's Declaration of Conformity for low-risk products, for instance low voltage and ICT products. A choice between quality assurance and product verification conformity assessment modules needed to be offered where third-party assessment was required.

11. The European Communities joined the United States and Japan in requesting that China provide wider acceptance of foreign test results and explain what mechanisms were in place or were being considered in order to facilitate the acceptance of foreign test results. In the meantime, the EC representative invited China to give positive consideration to the proposals for short-term simplification of certain aspects of the current CCC system, as outlined in the EC submission G/TBT/W/326 and in the submission made on the occasion of the previous Triennial Review.[2] On the same topic, the European Communities also noted that China maintained an overly detailed regulation in specific sectors, such as the mobile phones area. There was also a tendency to regulate qualitative aspects of products that in most economies were instead left to the market, as for instance in the textile field with regard to colour fasteners.

12. The European Communities raised another concern with regard to the need for better internal regulatory coordination between Chinese Ministries or agencies having regulatory powers. It was the EC delegation's view that competition between Ministries or agencies over regulating the same product arose in a number of cases and resulted in the creation of multiple and partially overlapping requirements. Examples of this situation, such as the information security case and the certification procedures for ICT equipments, had already been raised under the Specific Trade Concerns item of

[2] G/TBT/W/300.

the Agenda. In this regard, China was invited to explain whether it intended to develop more effective internal regulatory coordination mechanisms.

13. In the area of standardization, the European Communities welcomed the announcement made by the Standardisation Administration of China (SAC) in January 2009, that foreign-owned companies established in China would be allowed to participate as voting members in technical committees responsible for the promulgation of national standards, pending the approval of the technical committee's Chairman. The European Communities further encouraged China to ensure effective access of foreign-owned companies to domestic standardization work, including with regard to the so-called industry standards. On the same topic, the EC representative also noted that, on several occasions, a number of Chinese standards deviated from international standards without any explanation being given that the relevant international standards were inappropriate or ineffective. Standards on wine and in the ICT field were examples of this situation. China was urged to limit such deviations to justified cases and provide justifications for deviations in all the other cases.

14. The European Communities reverted to various concerns which had been raised at previous triennial reviews, but that had not been addressed yet. A common feature of these concerns was that problems often arose from a regulatory approach that appeared to depart from international practice. Regarding the ICT field, the EC delegate echoed the concerns expressed by the United States on the proliferation of home-grown 3G telecommunications standards featuring unique Chinese technologies. China was encouraged to continue working with the international standardization community, rather than developing specific national standards. This would benefit all economic operators including China, which could take advantage of the best technology available. In the mobile phone area, concerns also remained about the systematic black listing of certain features of products, which prevented innovative products from being placed on the Chinese market.

15. With regard to the automotive sector, the European Communities encouraged China to join the United Nations 1958 Agreement on Motor Vehicles under the Economic Commission for Europe (UNECE).

16. With regard to active pharmaceutical ingredients, the EC delegation reiterated concerns about the routine multi-sampling and testing practice mandated for each imported batch of active pharmaceutical ingredients (APIs) imported in China. China was encouraged to intensify cooperation on quality assurance and Good Manufacturing Practices which could lead to mutual acceptance of quality certificates. On pharmaceutical products, the European Communities noted that registration periods in China could take three years or even more, due to a number of cumbersome, lengthy and costly requirements relating in particular to clinical trial approvals. China was therefore invited to expedite work towards the simplification of the clinical trial process, and develop practices compatible with those developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

17. Furthermore, the European Communities representative expressed concerns with respect to the lengthy pre-market approval procedures for non-special use imported cosmetics. In particular, he requested China to unify the notification system for imported and domestic non-special use cosmetics. However, the European Communities considered the simplification of procedures to be only a first step towards lifting all ex-ante approvals for imported cosmetics. China was also requested to develop a single hygiene standard for cosmetics that would replace the two standards separately enforced by the Ministry of Health on one hand, and the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) on the other.

18. Regarding medical devices, concerns remained on duplicative mandatory pre-registration requirements enforced by SFDA and AQSIQ. The EC representative reiterated his delegation's request to China to treat new or fully refurbished medical devices alike, since the existing ban did not

appear to be justified on health and safety grounds. China was encouraged to provide an update on the work under way with regard to this issue.

19. On textiles, concerns remained about the deviations from international standards in relation to import checks. China was invited to consider replacing systematic checks by batch with random checks, and to accept importers self-declarations of conformity based on tests carried out by international accredited laboratories. China was also encouraged to simplify the labelling requirements for textiles and footwear products. In this regard, the proposal on textile labelling submitted in the context of the NAMA NTB negotiations,[3] was seen by the European Communities as an example that could inspire a simplification of the Chinese requirements.

20. In concluding, the EC delegate requested China to provide an update on the state of play of the on-going revision of *Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals*.

21. The representative of China referred to her delegation's submission (G/TBT/W/327) providing information related to Annex 1A of WT/L/432. In respect of the comments on China's implementation of the TBT Agreement's transparency provisions, the representative of China noted that, to date, her delegation had made 695 TBT notifications, providing in each case a sixty day comment period and copies of full texts of notified measures upon request. Moreover, it was normal practice to extended this period upon a Member's request. The Chinese representative said China was an active participant in the Committee's work on transparency and information exchange and would continue this engagement.

22. Regarding information security testing and certification, the representative of China noted that information had already been provided under the Agenda item of Specific Trade Concerns. However, her delegation would nevertheless provide clarification on the existing relationship between information security testing and certification and the encryption codes regulation system. In particular, the Chinese delegate recalled that, among the thirteen products which needed to obtain the information security product certification, six of them contained encryption technology. These six products were therefore required to pass the detection tests for encryption codes, in accordance with China’s policy on the regulation of commercial encryption codes. It was further clarified that the State Encryption Administration Authorities (SEAA) were responsible for the testing of encryption codes, while the Certification and Accreditation Administration of the People’s Republic of China (CNCA) was responsible for the product certification. The representative of China emphasized that the current regulation on Commercial Encryption Codes had been enacted in 1999 and was functioning. However, to better adapt to late development of information technology, China was considering revising this regulation and had started investigation and research. Comments and suggestions by Members were welcomed by China in this regard.

23. In respect of the implementation of the CCC system, the representative of China noted that improvements were continuously being made. In the current revision of the implementation rules of the CCC scheme, China was committed to simplify the procedure, mitigate the burden of enterprises and further revise the parts and components report procedure and unit division. It was also stressed that interested parties, such as *EuropElectro*, were closely involved in the process of revision. In this regard, China welcomed any suggestions from Members and interested stakeholders and was ready to continue the cooperation with the European Communities.

24. In respect of the comments on China's conformity assessment procedures, it was emphasized that the regulations on Certification and Accreditation and on Management of Compulsive Product Certification clearly indicated how to accredit the certification bodies and laboratories to undertake

[3] TN/MA/W/93/Rev.1.

CCC certification. It was also recalled that the CCC system recognized the CB reports within the scope of the IECEE/CB scheme. The Chinese representative explained that the International Laboratory Accreditation Cooperation (ILAC) was the cooperative organization of the laboratory accreditation agencies, and the ILAC Mutual Recognition Arrangement (MRA) was the key technical base for mutual recognition between China and other countries.

25. In respect of the comments raised by Japan on "Instructions on factory inspections", China confirmed that these documents were only intended to facilitate factory inspection operations and did not impose any mandatory requirement.

26. Regarding the relationship between standards GB/T 191-2008 and GB 5296.2 2008, the representative of China explained that according to Article 5.2.5 of GB 5296.2 2008: "the products with special requirements in the process of transportation and storage should be labelled with the graphic signs and according with the provisions of GB/T 191-2008". She noted that, as the only Chinese recommended standard to regulate the graphic signs of package, transportation and storage, GB/T 191-2008 was quoted in GB 5296.2-2008, with the aim of protecting consumers and helping enterprises to harmonize their operations.

27. On the subject of standardization, the Chinese delegate emphasized that all the foreign-funded enterprises legally registered in China could participate in standardization activities, and all foreign-funded enterprises could participate in the revision activities of China's recommended standards as observers. With regard to the questions on national deviations from international standards, the Chinese delegation noted that China's deviations were necessary in light of geographical and technological differences. Regarding the comments on the maximum sulphur dioxide levels in wines, the representative of China noted that information had already been provided under the Agenda item on Specific Trade Concerns.

28. Regarding the concern raised by the European Communities on voluntary standards rendered mandatory through conformity assessment procedures, the Chinese delegate recalled that the recommended standards were voluntary standards but became binding once incorporated into a mandatory act.

29. With regard to the use of the WAPI standard, the representative of China noted that the Chinese operators decided that the WLAN network and relevant equipment would support both WAPI and ISO/IEC 8802-11 standards. This was to ensure the safe operation of network and businesses, and provide the users with safer and more reliable wireless wideband communication services. Mobile phones meeting the requirements and supporting both WAPI and ISO/IEC 8802-11 standards were allowed to enter the WLAN network. In this regard, it was also recalled that MIIT had launched a pilot programme of network access for WAPI and ISO/IEC 8802-11 dual-mode mobile phones. Enterprises were free to apply for participation in this program. So far, more than thirty types of mobile phones had passed the test. China would continue to improve work related to the management of network access of mobile phone in light of the progress of the pilot programme and market demand. It was China's view that the WAPI standard did not deviate from the ISO/IEC 8802-11 standard, it was rather a supplement that enhanced the latter. It was also recalled that China had submitted the WAPI standard to the International Organization for Standardization (ISO) for recognition as an international standard.

30. Regarding the draft measure on Medical Devices Registration Administration Method, China reassured Members that it would be notified in due time.

31. Regarding the comments raised by Japan on the Chinese measure notified under G/TBT/N/CHN/426, the Chinese representative noted that a sixty day comment period had been

provided but comments had not been received from Members. It was stressed that China had fully fulfilled its transparency obligations under the TBT Agreement.

32. Finally, the representative of China drew the Committee's attention to a question from one Member regarding measures "without legitimate objectives". China strongly refuted the premise of this statement and recalled that the measure at issue had been notified to the TBT Committee in 2008 (G/TBT/N/CHN/426), and that no comments had been received even though 60 days had been provided. The reason for the notification had been because of a deviation from certain international standards and China was, in this regard, in full compliance with its obligations under the TBT Agreement. In addition, it was noted that there was still no definition of an international standard on which Members could agree. Therefore, in reply to other Members' comments, the representative of China doubted that there existed a definition of international practice.

33. The Committee adopted its report of the Eight Annual Transitional Review (G/TBT/27).