WORLD TRADE ORGANIZATION

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Committee on Technical Barriers to Trade

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CHINA'S TRANSITIONAL REVIEW MECHANISM

Communication from the European Communities

The following communication, dated 28 October 2009, is being circulated at the request of the delegation of the European Communities.

I. TRANSPARENCY AND PREDICTABILITY OF THE REGULATORY ENVIRONMENT

1. The EC welcomes China's continued work on improving transparency and predictability in rule-making and administrative procedures. It is encouraging to see that China uses public calls for comments on proposed legislation in important sectors; however, there is a lack of predictability in the use of this procedure. China is requested to consistently call for public consultations on all new draft laws and administrative measures that may have a significant effect on trade, and to provide a reasonable period for comments on these drafts in order to allow stakeholders to adequately examine the proposals and give considered comments.

2. In keeping with its WTO accession commitments China is asked to establish a single official journal for publishing all laws, regulations and other measures pertaining to or affecting, *inter alia*, trade in goods.

II. CHINA COMPULSORY CERTIFICATION (CCC) SYSTEM

3. On 3 July 2009, the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) released a revised version of China's *Compulsory Products Certification Management Regulation* (Circular 117/2009). The EC welcomes the clarifications of some aspects of the certification process, as well as the reinforcement of the confidentiality obligations of certification bodies.

4. The EC also welcomes the launch by the Certification and Accreditation Administration in March 2009 of a simplification process aimed at reducing administrative costs linked to CCC compliance, essentially focusing on the reduction of the number of key components to be tested and certified separately from the finished product. The EC encourages China to build on these positive steps in ensuring that the CCC system becomes more transparent and less burdensome for economic operators, and based on a risk-oriented approach.

5. Despite the above positive steps, the CCC system remains a major obstacle for foreign companies exporting to China, due to the complexity, costs and length of the procedure. The EC notes

with concern that since the implementation of the CCC in 2003, there has been a steady growth in the number of products and areas that are subject to CCC procedures, with an increased complexity of requirements. The process is particularly burdensome for small and medium enterprises operating in China.

6. The EC therefore reiterates its call for China to undertake a substantive review of the CCC process, taking into account the need for structural simplification and the adoption of a risk-based approach, as well as improving the transparency of the process and reducing the administrative burdens associated with it.

7. In particular, the EC asks China to review the current "one size fits all" approach based on comprehensive third-party testing and factory audits, which assigns the same high level of risk to all products within CCC scope, despite their evidently posing very different levels of health and safety risks. Alternative approaches should also be considered, such as Supplier's Declaration of Conformity for low-risk products such as low voltage and ICT products and offering a choice between quality assurance and product verification conformity assessment modules where third-party assessment is required.

8. The EC also requests China to consider wider acceptance of foreign test results via bilateral agreements between Chinese and foreign certification bodies and greater participation in existing multilateral schemes between international accredited laboratories.

9. In the meantime, the EC invites China to give positive consideration to the proposals for the short-term simplification of certain aspects of the current CCC system, as submitted to China both bilaterally and at the occasion of the last review.[1]

III. INFORMATION SECURITY TESTING AND CERTIFICATION

10. The EC continues to have concerns about the 13 proposed implementing rules for compulsory certification of various information technology products in relation to information security requirements (ref. G/TBT/N/CHN/278-290).

11. According to Circular No. 33/2009 issued jointly by AQSIQ, the Ministry of Finance and CNCA, the target date for the entry into force of the new requirements has been delayed until 1st May 2010. Furthermore, the scope of the measures has been reduced to public procurement only. The EC has welcomed this announcement by China.

12. Despite this positive development, outstanding issues remain in a number of areas. The scope for public procurement in this case appears to extend well beyond what the EC would consider justified for national security protection, which was cited by China as the legitimate objective to be achieved. The EC is also seriously concerned that state owned enterprises (SOEs) in non national security-sensitive sectors (e.g. energy, telecommunications, banking, insurance) would fall under the scope of the requirements. The EC would appreciate receiving confirmation from China in this Committee that SOEs will not fall under the scope of the Regulations.

13. The EC is also concerned with the implementation of the Multi-Layer Protection Scheme coordinated by the Ministry of Public Security and the Ministry of Industry and Information Technology and the Regulation of Commercial Encryption Codes administered by the Office of State Commercial Cryptography Administration (OSCCA). The EC requests China to clarify the rationale for these measures and their relationship with the CCC regulations for information security. The EC

[1] G/TBT/W/300.

also urges China to notify any implementing measure laying down equipment-related requirements pursuant to the relevant transparency provisions of the TBT Agreement

14. According to the OSCCA Regulation of Commercial Encryption Codes, the production and distribution of information technology products whose core function is encryption is reserved for approved Chinese companies. By the same token, only products domestically made are eligible for certification by OSCCA. Hence, foreign manufacturers are currently unable to export encryption products to China for commercial purposes under the terms of the Regulation. Foreign-owned companies established in China are equally denied access to the OSCCA business license and product certification. Both SOEs and the Chinese Government are required to only purchase OSCCA-certified encryption products.

15. The EC requests China to urgently revise the OSCCA regulation in order to ensure equal market access opportunities between domestic and foreign / foreign-owned companies based on technical standards and conformity assessment procedures aligned with international practice, without disclosing confidential information or taking over Chinese encryption codes. The EC also asks that the licensing procedures be made completely transparent, in order to allow foreign operators to operate in a predictable environment.

16. The EC appreciates China's continued willingness to maintain an open channel of communication on these issues with concerned WTO members and affected stakeholders. In the meantime the EC urges China to follow international practice to ensure continued and fair market access.

IV. STANDARDIZATION

A. PARTICIPATION OF FOREIGN-OWNED COMPANIES ESTABLISHED IN CHINA IN DOMESTIC STANDARDISATION WORK

17. In January 2009, the Standardisation Administration of China (SAC) announced 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 Chair. The welcomes this announcement and encourages China to ensure effective access of foreign-owned companies to domestic standardisation work, including as regards the so-called industry standards.

B. IMPLEMENTATION OF INTERNATIONAL STANDARDS – NATIONAL DEVIATIONS

18. The EC notes with appreciation China’s achievements with regard to the adoption rate of international standards and its commitment to the continuous alignment of its domestic technical regulations and standards with international standards. However, the EC has noticed that, on several occasions in the recent past, China has decided to put in place Chinese-specific national compulsory standards in various sectors, even in those cases where relevant international standards were readily available, without providing adequate justification with regard to its reasons from departing from the international standard. One example would be the case of sulphur dioxide levels in wines (G/TBT/CHN/197) raised by the EC in the TBT Committee on several occasions. In this instance, the EC would like to remind China of its obligation to comply with Article 2.4 of the TBT Agreement.

19. Lastly, concerns remain as to the availability of information regarding deviations of Chinese standards from corresponding international standards and the reasons for such deviations. The EC urges China to make information on those national deviations more readily available to economic operators and give justifications for deviations.

C. VOLUNTARY STANDARDS RENDERED MANDATORY THROUGH CONFORMITY ASSESSMENT PROCEDURES

20. A further source of concern for the EC is the practice whereby standards initially developed as "Voluntary Industrial Standards" are later made mandatory, typically by referencing them in mandatory conformity assessment procedures without any prior warning being given to the participants in the standard-making process about this policy change. By the same token, no notification in accordance with the provisions of the TBT Agreement is generally given.

21. As an example, please see the standard on a *Unified Charger for Mobile Telecommunications Terminal Equipment* (YD/T 1591-2006), which had been developed and initially adopted in December 2006 as a "Voluntary Industrial Standard" but was later rendered mandatory (as of 14 June 2007) on all mobile phones and chargers manufactured in China in the framework of the Network Access License procedure operated by the then Ministry of Information Industry.

22. The EC takes the view that the practice of rendering voluntary industrial standards mandatory trough regulatory type approval without any prior notification according to the TBT Agreement is inconsistent with the transparency obligations to be observed in the preparation, adoption and publication of technical regulations pursuant to the WTO TBT Agreement. The EC is of the opinion that, if a standard is made mandatory, it should take the form of a national technical regulation and **should** therefore be notified under the TBT Agreement.

V. OTHER CONCERNS

23. The following is a non-exhaustive list of concerns currently being raised by the EC with China in the framework of bilateral regulatory cooperation mechanisms:

A. ICT PRODUCTS

24. In addition to the issues related specifically to information security products presented in Section III, the EC is concerned with China's tendency to favour home-grown standards featuring unique Chinese technologies, the overly detailed technical specifications for mobile phone features and components, the difficulties in placing on the Chinese market innovative products having multimode capabilities, and the multiple and partially overlapping certification procedures managed by different authorities.

B. AUTOMOBILES

25. The EC has concerns about China's application of the CCC scheme for automotive components. The EC believes that the goals of ensuring safety, health, and environmental protection would be well achieved through harmonisation under the United Nations 1958 Agreement on Motor Vehicles (under the Economic Commission for Europe, UNECE).

C. ACTIVE PHARMACEUTICAL INGREDIENTS

26. The EC recalls its concerns about the routine multi-sampling and testing practice mandated for each imported batch of active pharmaceutical ingredients (APIs) by the State Food and Drug Administration (SFDA) regulations and the method of establishing standards that foreign APIs have to meet. The EC would like China to intensify cooperation on quality assurance and Good Manufacturing Practices which should lead to mutual acceptance of quality certificates and the abandonment of import testing. The EC believes that China's legitimate objectives could be better fulfilled by relying on international practices.

D. PHARMACEUTICAL PRODUCTS

27. Registration periods in China may take 3 years on average or even more for vaccines, due to a number of cumbersome, lengthy and costly requirements relating in particular to clinical trial approvals. This results in the most innovative drugs being made available to Chinese patients with a significant delay. The EC therefore invites China to expedite work towards the simplification of the clinical trial process, as well as of the overall registration process for new drugs .In this regard, the EC would like to highlight the importance of adopting International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)-compatible practices.

E. COSMETICS: PRE-MARKET APPROVAL PROCEDURE FOR NON-SPECIAL USE IMPORTED COSMETICS

28. The EC recalls the concerns raised in the last transitional review with respect to the pre-market approval procedures for non-special use imported cosmetics, which delay their time to market by 4-6 months, when compared to domestic non-special use cosmetics. The EC reiterates its request for China to unify the notification system currently in force for imported and domestic non-special use cosmetics. The EC considers that the simplification of procedures should be only a first step towards lifting *all* ex-ante approvals for imported cosmetics

F. COSMETICS: STANDARDS

29. The EC recalls its request for Ministry of Health and AQSIQ to develop a single hygiene standard for cosmetics that would replace the two standards that are being separately enforced by the Ministry of Health (the Hygiene Standard for Cosmetics 2007) and AQSIQ (the already outdated Standard for Cosmetics (GB 7916-1987) issued in 1987).

G. MEDICAL DEVICES: REGISTRATION AND RE-REGISTRATION PROCEDURES

30. The EC refers to the concerns raised in the last two transitional reviews regarding the duplicative mandatory (re-)registration requirements enforced by SFDA and AQSIQ offering no additional safety benefit for patients and users.

H. MEDICAL DEVICES: REPROCESSING AND REPROCESSED MEDICAL DEVICES

31. The EC reiterates its request for China to treat new or fully refurbished medical devices alike. The EC believes that the ban on refurbished products is not justified on health and safety grounds. The EC welcomes the fact that work has started in relevant Ministries towards establishing a regulatory framework for refurbished medical devices that should facilitate their placing on the Chinese marketing. The EC would appreciate it if China could provide an update on the state of play.

I. TEXTILES: STANDARDS

32. The EC reiterates its request for China to, whenever revising or producing new textile standards, refrain from introducing technical changes/national deviations in Chinese standards as compared with existing ISO standards.

33. The EC would like to recall its request for China to refrain from rendering compulsory qualitative aspects of textile/clothing products (e.g. levels of colour fastness) which should be left to market operators to decide upon without state intervention.

J. TEXTILES: CONFORMITY ASSESSMENT PROCEDURES AND MARKET SURVEILLANCE MECHANISMS FOR TEXTILES AND FOOTWEAR

34. The EC would like to recall its request for China to progressively replace systematic import commodities inspections for textiles, clothing and footwear with random import commodities inspections, and for China to accept suppliers' declarations of conformity and EU test reports as assurance of conformity with applicable requirements.

K. TEXTILES: LABELLING REQUIREMENTS

35. The EC reiterates its request for China to simplify labelling requirements for textiles and footwear products. This would mean also no requirements for any form of prior approval registration or certification of labels as a condition for allowing the textile and footwear goods to be placed on the market. The EC notes that China is interested in the WTO proposal on an understanding on the simplification of labelling requirements at international level (TN/MA/W/93). Joining the proponents of this proposal would allow China to show its leadership in the work of facilitating trade in a sector of great importance to developing countries.

L. TOXIC CHEMICALS

36. The EC refers to the concerns raised in the last two transitional reviews with respect to the *"Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals"*, in force since 1 January 2006. China has repeatedly indicated in this Committee that the Regulations were being revised and that foreign stakeholders could participate in the process. The EC would appreciate if China could give an update on the status of the revision.