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CHINA'S TRANSITIONAL REVIEW MECHANISM

Communication from the European Communities

The following communication, dated 5 November 2008, 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 efforts towards improving transparency and predictability both in rule-making and administrative procedures. The most notable positive development has been the significant increase in the frequency of public calls for comments from the Chinese regulatory authorities on proposed legislation, especially in the food and public health fields. At the same time, however, periods for comments are sometimes still too short to allow stakeholders to adequately elaborate their position.

2. Pursuant to its WTO accession commitments, China is therefore encouraged to provide stakeholders with a reasonable period in which to make submissions to the relevant authorities prior to the formal adoption of new laws and administrative measures. The EC wishes to stress that public consultation is a key element of the regulatory process, not least because it allows the early detection and resolution of potential problems arising in the practical implementation and thus facilitates compliance.

3. With a view to ensuring a transparent and predictable regulatory environment, the EC would also recommend China to:

(a) systematically give public written notice of any regulatory change in accordance with Article 2.11 of the TBT Agreement;

(b) in keeping with its WTO accession commitments, establish a single official journal for publishing all laws, regulations and other measures pertaining to or affecting, inter alia, trade in goods;

(c) provide for a reasonable interval between the publication of technical regulations, including when they take the form of compulsory standards, and their entry into force in order for economic operators to adapt in accordance with Article 2.12 of the TBT Agreement.

II. CHINA COMPULSORY CERTIFICATION (CCC) SYSTEM

4. On 24 June 2008, China notified to this Committee a *Draft Amendment to Regulations on Compulsory Product Certification* (G/TBT/N/CHN/399). The EC welcomes this notification as a first step of a process involving a more substantive review of the CCC system.

5. The EC refers to the detailed comments made on the notification and would appreciate receiving further clarification in this transitional review in particular as regards the product scope of the proposed regulations and the criteria for the choice of the applicable conformity assessment module in the implementing rules that the Certification and Accreditation Administration (CNCA) will have to enact for each product category.

6. As mentioned in previous transitional reviews, the CCC system is one of the main obstacles foreign companies currently face in their trade with China due to the complexity, length and costs of the procedure. In particular for small and medium-sized enterprises, the burden is extremely heavy and in some instances simply impossible to cope with.

7. The EC considers that the current requirements of the CCC system are not always relevant to the level of risk the products within its scope present, which in the EC's views implies that the CCC system is more trade restrictive than necessary to fulfil China's legitimate objectives.

8. In addition, there is a growing concern about the progressive expansion of the CCC system to new products and phenomena. Since the CCC mark was introduced in 2003, new product categories have been added almost every year and plans have been announced to start applying the CCC procedures in relation to the Chinese legislation on the restriction of hazardous substances and, more recently, in connection with information security standards (see further in Section III below).

9. The EC therefore strongly encourages China to undertake a structural review of the CCC system as part of the implementation of the revised framework Regulation for Compulsory Product Certification. Specifically, the EC invites China to systematically apply a risk-based approach to conformity assessment with a view to reducing the number of products within CCC scope and ensuring that conformity assessment requirements (in particular those relating to factory inspections and testing and certification) are modulated according to the level of risk associated with the products to be regulated.

10. The EC stands ready to assist in the process by sharing experiences with CNCA experts on the management of managing conformity assessment systems for low-risk products based on the Supplier's Declaration of Conformity and effective market surveillance.

11. The EC also urges China to take the opportunity of this CCC review to eliminate redundancies with approval procedures managed by other Chinese regulatory authorities. In this regard, the EC notes as a positive development that measures to unify testing procedures for eight types of medical devices were announced jointly on 11 September 2008 by the Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) and State Food and Drug Administration (SFDA). The EC would be grateful if China could clarify the exact scope of those measures.

12. The EC hopes that the solution announced for medical devices will serve as an example to also address the equally long-standing concerns related to the double or even triple testing and certification for telecom equipment. The EC reiterates its request to AQSIQ, CNCA and the Ministry of Industry and Information Technology (MIIT) to work together with a view to removing these redundancies.

13. The EC understands that the substantive review of the CCC will take some time. Pending such review, the EC nonetheless believes that there is some scope for the immediate simplification of certain aspects of the current CCC system. The EC therefore invites China to give positive consideration to the five concrete proposals put forward to that effect by the EC in the last transitional review as well as bilaterally, as follows:

(a) provide wider exemptions for single spare parts, components and sub-assemblies which (i) are solely intended for assembly in China into a CCC certified final product and (ii) are not separately sold on the Chinese market;

(b) For companies that are ISO-9001 certified, requirements already covered by such a certificate should not be verified again in the context of the factory inspection under the CCC system.

(c) Foreign-based certification bodies should be allowed to carry out the initial factory inspection (as is already the case for the annual follow-up factory inspections).

(d) Allow foreign-owned certification bodies established in China to be designated and perform activities as CCC certification bodies under the same terms and conditions as apply to Chinese-owned certification bodies.

(e) Allow wider acceptance of test results based on international standards from foreign-based certification bodies by exploiting the full potential of international voluntary schemes such as the IECEE CB scheme[1] for electrical products or, where such schemes are not available, based on bilateral agreements between Chinese and foreign certification bodies.

III. INFORMATION SECURITY TESTING AND CERTIFICATION

14. The EC continues to have serious concerns about the 13 proposed implementing rules for compulsory certification of various information technology products in relation to information security requirements. Pursuant to the notified drafts, such products would be subject to the CCC procedures and have to comply with the Chinese standards on encryption referenced therein.

15. According to Decree No. 7 of 28 January 2008 issued jointly by AQSIQ and CNCA, the target date for the entry into force of the new requirements was 1st May 2009. Subsequently, China's Vice Premier Wang made in September 2008 a statement to the effect that China would delay publication of the final regulations pending discussions between Chinese and foreign experts on possible approaches to information security.

16. The EC would appreciate if China could confirm to this Committee the postponement of the publication and the entry into force of the proposed Regulations.

17. The EC welcomes the clarifications provided both in this Committee and bilaterally as well as China's continued willingness to maintain an open channel of communication with concerned WTO members and affected stakeholders. Nonetheless, serious concerns remain, as outlined below.

18. First, against the stated goal of national security protection, the EC strongly urges China to refrain from adopting any technical regulation mandating testing and certification for information security purposes for products intended for commercial or consumer use.

[1] Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE) Certification Body (CB) Scheme.

19. Second, the EC notes that China's proposed regulations would be unprecedented and unique in view of their very wide product scope, the depth of the conformity assessment envisaged and the corresponding very detailed information required of companies. The EC therefore encourages China to pursue the dialogue with other WTO members and stakeholders with a view to an exchange of experiences on current government and market practices with regard to information security.

20. Third, while sharing the objective of providing citizens with secure communication and information systems, product regulation is not always the right means to achieve this objective, in particular when, as in this case, the issues are technically extremely complex and require a flexible response. The EC considers that it will not be possible to reduce all information security problems into a single set of testable product requirements.

21. Fourth, technology in the field of information security progresses at a very fast pace. The EC considers that limiting the choice of applicable technical specifications to a single set of standard requirements would stifle innovation and foreclose the introduction of new, more advanced technologies in China. Also in light of the foreseeable very long certification process (according to the EC's best estimates, based on current industry practices, the kind of assessment envisaged in the proposed regulations would take no less than 9 to 12 months), the ultimate result would be that latest technologies could not be deployed on the Chinese market. The EC therefore has doubts whether the proposed regulatory approach would be effective in view of China's stated goal of upgrading the level of its national information security protection.

22. Finally, the EC notes that the information that companies would have to disclose under the proposed regulations is extremely sensitive IPR-protected proprietary information. It is the EC's understanding that companies would not be in a position to provide such information, which is vital for their business, to a foreign conformity assessment body. In this regard, the EC would also like to draw China's attention to the provisions of Article 5.2.4 of the TBT Agreement on the protection of legitimate commercial interests in the framework of conformity assessment procedures.

IV. STANDARDIZATION

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

23. The EC is concerned about foreign-owned enterprises established in China being granted less favourable access to the domestic standardisation-making process than Chinese-owned enterprises.

24. As regards national standards, according to the Standardisation Administration of China's (SAC) announcement of 28 January 2008 updating the rules applicable to technical committees, foreign-owned companies are restricted to non-voting observer status in technical committees responsible for the promulgation of national standards.

25. As regards industry standards, according to current practice foreign companies, albeit having a legal entity in China, may at times only become observers of the relevant technical committees. In some cases, foreign companies are not even admitted as observers, thus placing them at a clear competitive disadvantage vis-à-vis their Chinese competitors.

26. The EC urges China to ensure a level-playing field among all companies established in China, regardless of nationality of the owners, by providing them with equal access to domestic standardisation work.

27. Full industry participation is the key to success for any standard development. Failure to involve foreign-owned companies established in China might result in the respective Chinese

Standard Development Organizations not gaining access to recent technological developments, to the ultimate detriment of the Chinese society.

B. IMPLEMENTATION OF INTERNATIONAL STANDARDS – NATIONAL DEVIATIONS

28. The EC notes with appreciation China's achievements with regard to the adoption rate of international standards and its commitments to the continuous alignment of its domestic technical regulations and standards with international standards.

29. The EC also wishes to positively highlight China's commitment to play a substantial role in international standardization organizations and the related technical committees.

30. At the same time, some concerns remain as to the availability of information regarding deviations of Chinese standards from corresponding international standards. The EC urges China to make information on those national deviations more transparent and accessible for economic operators.

C. COMPULSORY VERSUS VOLUNTARY STANDARDS

31. "Compulsory Standards" are a unique feature of the Chinese standardization system. They focus mainly on fields of specific public interest such as health and safety, environmental protection, data protection, etc.; however, they often include unrelated topics such as performance and interoperability requirements. Compulsory standards might create effective trade barriers, especially in cases where relevant international standards favour differing technical solutions, or where current Chinese standards do not reflect latest technical developments in this field.

32. The EC would like to draw the China's attention to alternative regulatory techniques to compulsory standards. In the EC's experience, compulsory standards have proven to constitute a major obstacle to technical innovation. They could even be detrimental to the legitimate aim being pursued when they are based on outdated technology. The EC therefore invites China to consider the benefits of a regulatory approach that combines legal requirements setting out the objectives to be attained in terms of health, safety, environmental protection, etc. with supporting voluntary standards containing detailed technical specifications and providing guidance how to meet those requirements.

33. In any event, the EC invites China to consider a specific approval procedure whereby manufacturers of new and technologically advanced products, whose technology is not yet reflected in existing Chinese standards, would be allowed to demonstrate, on the basis of technical data, that the performance of their products in terms of safety, electro-magnetic immunity or emissions, environmental performance, etc. is at least equal to that required by the applicable compulsory standards.

34. Another source for concern 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. 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.

35. The EC takes the view that the practice of rendering voluntary industrial standards mandatory trough regulatory type approval is inconsistent with the due process 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 then notified under the TBT Agreement to the WTO.

V. ICT PRODUCTS

36. The EC continues to have concerns on a number of issues that have been discussed in previous transitional reviews, including, for example, the practice of favouring home-grown standards featuring unique Chinese technologies, the overly detailed standardisation of 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.

VI. AUTOMOBILES

37. The EC continues to have concerns at the continuous broadening and deepening of the CCC certification as applied to automotive components regulations. The EC believes that the goals of regulating safety, health, and environmental concerns with respect to motor vehicles, which are shared by both administrations, could be well achieved through harmonisation under the United Nations 1958 Agreement on Motor Vehicles (under the Economic Commission for Europe, UNECE). Thus, the EC continues to urge China to become a Contracting Party to this Agreement, and also to work to eliminate the duplicative, costly and burdensome inspections and testing of China's unique 'CCC' certification and marking system.

VII. PHARMACEUTICALS

A. ACTIVE PHARMACEUTICAL INGREDIENTS

38. The EC recalls its concerns about the routine multi-sampling and testing practice mandated for each imported batch of active pharmaceutical ingredients (APIs) by SFDA regulations.

39. The EC submits that this practice is unnecessary and should be abandoned as, in accordance with Article 100 of the *Drug Registration Regulation*, APIs are subject to the Good Manufacturing Practice (GMP) standards. It follows that the applied manufacturing method already effectively guarantees the identical nature and consistent quality of batches, which are among the criteria on the basis of which SFDA issues the import registration license.

40. The EC is also concerned about the method of establishing standards that foreign APIs have to meet. The setting up of quality standards based on the highest standard met by any given importer at the border is difficult to understand, as APIs from different importers can feature different specifications. Hence, this approach does not necessarily ensure better quality/health protection in many cases. Conversely, domestic Chinese manufacturers only have to comply with the monographs of the Chinese Pharmacopoeia.

41. Finally, the EC welcomes the fact that China has started looking into ways of reducing the costs of importing APIs in relation to both registration and testing fees and that a consultation of interested parties will soon be launched.

42. In light of the above:

(a) Could China please clarify the rationale for carrying out multi-sampling and testing on batches that are intrinsically homogeneous and of consistent quality throughout?

(b) Could China please inform of its plans to improve the current situation as regards applicable standards and testing methods with a view to ensuring an effective level-playing field for domestic and imported APIs, e.g. by rendering the Chinese Pharmacopeia applicable to imported APIs as well?

B. PHARMACEUTICALS PRODUCTS

43. Registration periods in China may take 3 years on average or even more (e.g. 6 to 8 years 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.

44. Although SFDA has acknowledged the problem, no tangible progress has been made towards addressing it up to date. 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;

45. Another source for concern relates to the National Reimbursement Drug List (NRDL). It is the EC's understanding that he list has not been updated since 2004. Since only products on the list can be reimbursed, failure to update it puts more recent and innovative drugs at a competitive disadvantage. The EC urges China to ensure the regular and systematic update of the NDRL.

VIII. COSMETICS

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

46. 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.

47. In this regard, 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 – regardless of the level (central or regional).

B. COSMETICS STANDARDS

48. The EC recalls its request for MoH 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).

IX. MEDICAL DEVICES

A. REGISTRATION AND RE-REGISTRATION PROCEDURES

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

50. The EC recalls SFDA's intention to work towards aligning its provisions with the AQSIQ legislation by prolonging the validity of registration from 4 to 5 years, as outlined in the draft revision of State Council Decree 276 on the Supervision and Administration of Medical Devices. While welcoming this alignment and looking forward an update on the state of play on the revision, the EC reiterates its preference for a single, unlimited registration.

51. As regards the safety requirements applicable to medical devices, the EC would like to recall its suggestion to China to follow the guidelines developed by the Global Harmonisation Task Force (GHTF) for medical devices. For the ongoing revision of Decree 276 as well as the subsequent more specific regulation SFDA is urged to follow GHTF guidelines as much as possible. In this context, the EC also recommends that SFDA adopt the GHTF classification of four categories of medical devices into the new legislation.

B. REPROCESSING AND REPROCESSED MEDICAL DEVICES

52. 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.

X. TEXTILES

A. RAW SILK QUALITY COMPULSORY CERTIFICATE

53. The EC refers to the concerns raised in the last transitional review regarding the raw silk quality export compulsory certificate, which unduly restricts access of foreign buyers to this important raw material. As there are no health and safety issues at stake, the EC is of the opinion that the evaluation of quality of raw silk should be left to market players. Moreover, this export certificate is based on outdated technology and is having a negative impact on the whole production line. The EC therefore urges China to eliminate the quality certificate.

B. CONFORMITY ASSESSMENT PROCEDURES AND MARKET SURVEILLANCE MECHANISMS FOR TEXTILES AND FOOTWEAR

54. 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. Furthermore, whenever appropriate, China is urged to accept suppliers' declarations of conformity as assurance of conformity with applicable requirements.

C. LABELLING REQUIREMENTS

55. The EC reiterates its request for China to simplify labelling requirements for textiles and footwear products. This would mean 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. Furthermore, the amount of compulsory information required on labels should be reduced to the minimum necessary.

XI. TOXIC CHEMICALS

56. The EC refers to the concerns raised in the last transitional review 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.

57. At the last transitional review, and in the successive TBT Committee meetings, China indicated 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.