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CHINA'S TRANSITIONAL REVIEW MECHANISM

Communication from the European Communities

The following communication, dated 16 October 2006, is being circulated at the request of the delegation of the European Communities.

I. INTRODUCTION

1. The European Communities notes with satisfaction the increased co-operation between China and the European Communities on TBT issues. This is demonstrated by the increased frequency of bilateral contacts between the EC and China and the good functioning of a number of formal co-operation mechanisms in the TBT field.

2. This document identifies a number of concerns in the TBT field, which we will continue to discuss with the Chinese in a bilateral context. The EC also considers it is useful to table these concerns in a multilateral context in order to inform other Members of the WTO.

II. CCC SYSTEM

3. The EC would like to underline that a positive co-operation has been established with the competent Chinese authorities which has allowed the EC to raise concerns on the CCC system.

4. Despite the progress in the implementation of the CCC system, it remains a burdensome, expensive and time-consuming conformity assessment procedure.

5. The EC would like to recall what our main outstanding concerns are:

(a) The CCC scheme, including its product coverage, is still unclear, non-transparent and leaves room for interpretations. The EC is concerned that China is enlarging the list of products subject to CCC marking. The EC would suggest that low-risk products do not need to be subject to the CCC and that simplified procedures, such as suppliers' declaration of conformity, should be explored.

(b) Spare parts: components and sub-assemblies are also subject to mandatory certification, even when they are intended for incorporation in a finished product and the later will be tested and certified in China. The EC would request China to examine how CCC requirements could be simplified.

(c) Confidentiality: The information required for the purpose of certification procedure should be treated as confidential. In order to avoid any disclosure of commercially

sensitive information, the EC suggests that the CCC information requirements should be simplified.

(d) Factory Inspections: The EC considers that China should exempt the inspection of the manufacturing facilities of the companies having been certified to international standards (e.g. ISO 9001).

(e) The uncertain application of national treatment. In particular the EC is concerned that exemption procedures are not transparent. We would urge China to simplify and standardise the customs clearance for exemption.

(f) The surveillance for imported products is primarily carried out by the custom authorities. This means, that importing manufacturers are affected by an intensive control which doesn't exist for Chinese manufacturers.

6. As an example, as from June 2007 six categories of toys will be subject to the CCC certification requirement and toys without a CCC mark cannot be sold in China. To obtain the certificate, the toys will have to pass the test of "National safety technical code for toys" and "the safety for electricity powered toys". The EC would urge China to reconsider this approach and to allow the introduction of SDoc and also to implement reasonable market surveillance mechanisms (instead of compulsory custom controls).

7. In summary, technical requirements of the CCC system are not always relevant to the level of risk the product poses, which implies that the CCC system is more trade restrictive than necessary.

III. STANDARDIZATION

Cooperation in the field of standardization between Europe and China is effective. The EC especially appreciates efforts on the Chinese side to enhance transparency and cooperation in its standard development work – as demonstrated in:

(a) China's commitment to substantially increase the adoption rate of international standards

(b) China's commitment to play a substantial role in international standardization organizations and the related technical committees

(c) Chinese participation and relevant contributions in global standard making consortia such as 3GPP

(d) Chinese participation in international mutual recognition of testing results such as the IECEE/CB scheme.

8. There is, though, considerable concern about the development of so-called "home-grown" standards in China, especially in areas where internationally recognized standards already exist. The EC identifies here a contradiction with China's commitment to increase adoption of international standards. Especially in the ICT field the European industry is confronted with entire families of new Chinese standards which substantially differ from existing international standards serving identical purposes. The EC prefers to see the respective Chinese standardization efforts integrated in established international standardization organizations and consortia. The EC is committed to support all respective activities from Chinese standard developing organizations.

9. As an example the EC would like to refer to the WAPI security standard for Wireless LAN (WLAN). In the view of the EC this standard was developed in isolation and without due regard to the relevant international standards. In addition the EC is concerned that similar developments continue in the Chinese ICT sector in other areas, e.g. with the audio visual coding standards (AVS).

10. The EC would like to recall a number of other concerns in the standardisation field:

(a) Compulsory Standards:

The Chinese standardization system distinguishes between voluntary and compulsory standards. "Compulsory Standards" are a unique feature of the Chinese standardization system and 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 other international standards favour differing technical solutions, or where current Chinese standards do not reflect newest technical developments in this field. In order to reduce the potential of compulsory standards to hinder trade, the EC would urge the Chinese side to:

(i) Create a transparent set of procedures to acknowledge, review and approve alternative systems and processes equally complying with needs of Chinese regulators.

(ii) Restrict compulsory standards to few well defined areas where there is a clear public interest for having such standards.

(b) Participation of European companies in Chinese Standardisation Work:

In addition, the EC wants to emphasize that full industry participation is the key to success for any standard development, and urges China to increase its efforts in this regard. European companies – despite having established operations in China – are often excluded from participation in Chinese Standard Development Organizations and their Technical Committees. Contrary to international practice, Chinese Standard Development organizations do not apply the principle of national treatment, by restricting access for "non-Chinese" organizations. Exclusion of European organizations might also imply that the respective Chinese Standard Development Organizations do not gain access to recent technological developments.

(c) Standards for Accreditation of Testing Laboratories:

The EC urges China to fully implement international standards as provided by ISO/IEC for the accreditation of China based testing labs.

(d) Need for greater transparency of deviations of Chinese standards from corresponding international standards:

Many of the Chinese compulsory standards are based on ISO/IEC standards, albeit often with certain Chinese national deviations. Another source of difficulty is the delay between different versions. Due to the national standardization process (including translation of ISO/IEC standards into Chinese), Chinese standards often lag 1 or 2 versions behind the ISO/IEC standards from which they were originally derived.

The EC would request China to consider ways to make information regarding those national deviations more transparent and accessible for economic operators.

IV. ICT PRODUCTS

11. EU industry reports that the overall approval system incurs significant costs and delays due to the existence of multiple procedures managed by different authorities.

12. The Chinese Compulsory Certification (CCC) procedure is applied to a wide range of the ICT and Consumer Electronics Products. ICT products are typically low-risk products that could be subject to simplified procedures.

13. In addition, telecommunications products (terminal equipment and networking interconnecting equipment) and radio communications equipment have to obtain, respectively, a Network Access License and Network Access License plus a Radio Certificate before they can be placed on the market.

14. The EC would like to urge China to consider simplifying the current system by merging the existing separate procedures into a single approval procedure overseen by one authority.

15. In addition, when a single device contains a combination of features (e.g. GSM and WLAN), the current approval process is pending the development of a test procedure for a dual mode product although all relevant specifications are available. This results in the supplier of the equipment having to remove specific functions from the device in order for it to be placed on the Chinese market.

V. AUTOMOBILES

16. The EC appreciates that, over the last three years, the contacts between our administrations have increased in frequency and also in the depth of detailed discussion. Nevertheless, the apparent broadening and deepening of Chinese regulations remains disappointing. The EC appreciates the increasing possibilities for representatives of the EC and of its automotive sector to be involved in consultations with the Chinese authorities on issues of standards, regulations, and conformity assessment and fully supports the goals of regulating safety, health, and environmental concerns with respect to motor vehicles which are shared by both administrations.

17. The EC believes that these goals could be well achieved through harmonisation under the United Nations 1958 Agreement on Motor Vehicles (under the Economic Commission for Europe, UNECE) and 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, which seems at present to offer very little possibility for non-Chinese firms to perform inspections or offer certifications, although there are UN and ISO standards for doing so.

18. In light of the fact that many of China's regulations in this sector are very similar to UN Regulations under the 1958 Agreement, the EC would like to pursue full consultation with the Chinese authorities from the earliest possible time.

VI. PHARMACEUTICALS

19. The EC would like to draw China's attention to the following issues:

(a) Active Pharmaceutical Ingredients

The issue of active pharmaceutical ingredients (APIs) remains of great concern to the EC. Specifically the fact that each imported API batch in China remains subject to the routine multi-sampling and testing practice carried out by the Port Drug Inspection. Systematically batches are sampled and tested 6-7 times resulting each time in an identical outcome.

The EC urges China to clarify the rational for carrying out the multi-sampling and testing practice on batches that are intrinsically homogeneous and of consistent quality throughout? It should also be stated that the homogeneous quality is already guaranteed by the applied manufacturing method (ICH/Q7A Guideline on cGMP for API manufacture) which is one of the criteria for receiving a Chinese import registration licence from the SFDA in the first place.

In our opinion the practice is not in line with Article 5.1.2 of the WTO/TBT agreement which calls for assessment procedures not to create an unnecessary obstacle to trade and of Article 5.2.6 which specifies that the selection of samples are not such as to cause unnecessary inconvenience to applicants or their agents. As the substantial testing costs (from 20% to 100% of the market value) are to be carried by the products, this practice unnecessarily results in increased cost of APIs and has already in some cases acted de facto as an import ban of valuable drugs precursors for Chinese consumers.

(b) Non Tariff Barriers

Some trade impediments originate in a variety of unnecessary, burdensome or costly registrations, licensing, certification and reimbursement procedures:

(a) Imported active pharmaceutical ingredients as well as finished medicinal products face stricter testing requirements compared to local manufactured products.

(b) It typically takes 6 to 12 months to obtain clinical trial approval in China, as clinical trial approval can usually be obtained within 3 months in other major markets.

(c) Medicinal products registration timelines are extremely long and requirements are not always clear.

(d) One problem relates to the National Reimbursement Drug List (NRDL). As the lists are not updated annually the most innovative products are not included.

In this regard, the EC would be grateful if China could:

(a) Ensure imported and locally manufactured products are treated equally.

(b) Ensure the regular, systematic updates to reimbursement lists are made for newly registered drugs

VII. COSMETICS

20. The EC would like to draw China’s attention to the following issues:

(a) The approval procedures for imported non-special use cosmetics still differ from that of domestic non-special use cosmetics. For imported products, a multiple approval

procedure is still compulsory, leading to extensive workload, misallocation of personnel and financial resources and delays in product introduction to the market.

This measure is likely to invalidate some of China's WTO commitments (national treatment obligation).

In this regard, the EC would be grateful if China could unify the notification system currently in force for imported non-special use and domestic non-special use cosmetics.

(b) EC notes with interest that there has been an important change in authorisation procedure in China. It is understood that the approval of the labels of imported cosmetic products has been delegated to local AQSIQ-offices.

The EC welcomes this decision as one step towards reducing the multiple registration requirements for the import of cosmetic products.

21. However, the EC would like to outline two things:

(a) First, there is a risk that the decentralisation of authorisation procedure means different practices and interpretations of the applicable rules. Therefore, the EC urges China to ensure a uniform application of the existing rules by the different local AQSIQ offices and requests explanation how to ensure such a uniform interpretation.

(b) Secondly, the EC considers that this should be only a first step towards a lift of all ex-ante approvals for imported cosmetics – no matter on which level (central or regional). They are impediments to free trade and a disproportionate hurdle for market access for European products.

VIII. MEDICAL DEVICES

22. The EC would like to draw China's attention to the following issues:

(a) Double certification

The Chinese authorities have been requiring double certificates, from third party conformity assessment bodies, regarding medical devices. AQSIQ informed the EC that the Chinese authorities were considering enacting legislation requiring a single certification. The EC would welcome official confirmation when the implementation of that legislation will start, as well as the official text where such provisions are laid down. We would also welcome clarification concerning a single test procedure.

(b) Reprocessing and reprocessed medical devices

The EC urges the Chinese authorities to treat new or fully refurbished medical devices in the same way. The EC believe that the ban on refurbished products is not justified In Europe refurbished medical devices are subject to the same requirements as new medical devices and therefore are safe once they bear the CE mark. The EC would urge China to take a similar approach.

IX. TEXTILES

(a) Raw Silk Quality Compulsory Certificate

CIQ (regional branches of AQSIQ) carry out export quality tests of raw silk and thrown yarns and provide a compulsory certificate of silk quality which is required before the raw silk can be exported from China. According to the European Silk industry, domestic buyers of raw silk are not obliged to have or pay for this certificate whilst international buyers have to pay for the test/certificate (up to 2% of the value). EU industry claims that this quality control does not provide any real quality insurance as the testing methods are not in line with modern industrial requirements for silk use. China benefits from a virtual monopoly in the silk market, so the European industry has no real alternative sources of supply.

Raw silk testing seems to be a discriminatory practice, a way to limit raw material export and to distort its price as it constitutes a de facto export tax.

The EC would encourage China to allow market forces to operate in its trade in raw materials in general and in particular to abolish the compulsory nature of raw silk testing and terminate discriminatory treatment of foreign buyers.

(b) Conformity assessment procedures and market surveillance mechanisms for textiles and footwear

All imported textile and footwear products are subject to the compulsory Chinese National General Safety Technical Code for textiles (GB 18401-2003) and several other standards for footwear products. The compliance of products with Chinese standards is verified at the borders. Additional checks are carried out by Market Surveillance Authorities.

In this context would like to recall its requests related to textiles, clothing and footwear:

(i) The EC would urge China to progressively replace customs controls at the border controls since double checking for imported goods is discriminatory.

(ii) To accept ISO standards and take the necessary steps for mutual recognition of test reports issued by international recognised laboratories.

(c) Labelling requirements

China informed the EC that they have compulsory specifications for clothing marking (GB 52964/1998) and that all garment products sold in the market have to have information on: name of the product, size, composition, washing instructions, life span, quality control n°, name and address of manufacturer, etc. However, according to the MAIA study, China does not have particular requirements for labelling of leather and footwear products.

In this context, and considering that excessive labelling requirements can hinder trade, the EC would like to urge the Chinese authorities to simplify labelling requirements at international level for textiles and footwear products. Ideally this would mean no requirements for any form of prior approval or registration of labels as a condition for allowing the textile and footwear goods to be placed on the market, and for the reduction of the information required in permanent labels.

X. TOXIC CHEMICALS

23. With regard to the Chinese "Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals" of 1 March 1994, the Chinese authorities amended, on 27 December 2005, the relevant annexes: list of severely restrictive toxic chemicals (SEPA announcement 65/2005) replacing SEPA announcement 83/1993 and 29/2005. In addition, the Chinese authorities submitted on 31 December 2005 a list of toxic chemicals banned in the PRCR (Chinese Customs Announcement 116/2005). Both new lists entered into force on 1 January 2006 and contain an extended list of chemicals.

24. So far, China has notified only SEPA announcement 65/2005 under the TBT Agreement, while a notification as regards the Chinese Customs Announcement 116/2005 is still expected. As both lists have entered into force, one only four days after being published, trading partners could not properly respond and adapt to the new situation. As a result, shipments that have been sent to China in good faith have been blocked at the Chinese border.

25. For these reasons the EC would like to raise the following issue:

(a) The EC would request more information concerning the rational for the list of chemicals covered, which goes beyond those chemicals subject to the Rotterdam PIC Convention and the Stockholm Convention on Persistent Organic Pollutants. The EC would like the Chinese authorities to clarify how the relevant risks have been assessed. The EC would be pleased to receive a copy of the available technical and scientific information used as the basis of this assessment;

(b) A clarification of the legislative and operational requirements especially as regards the rules on mixtures and articles containing strictly restricted would be also appreciated; The EC would suggest that China publish guidance material on the internet in this context.

XI. MEASURES ON THE ENVIRONMENTAL MANAGEMENT OF NEW CHEMICAL SUBSTANCES

26. New measures on the Environmental Management of New Chemical Substances entered into force on 15 October 2003. While sharing China's objective to protect the environment, the EC is also concerned about the impact of this legislation on EU exporters.

27. Article 8 determines the data requirements for newly produced or imported chemicals in China. However, there is no detailed specification regarding these data requirements. The EC would therefore like to ask which data requirements are actually applicable. Additionally, the same data requirements are applied for chemicals in any quantity. As a consequence, the data testing requirements for low volume samples could be very significant, including the requirement to conduct some of the environmental studies in China.

28. The EC would like to ask China whether there are reduced testing schemes for low volume chemicals. This would aim to develop a notification scheme that continues to protect the health and environment but also allow business to introduce new technology through innovative substances.

29. The EC also would like to know whether the data requirements are comparable to the OECD Minimum Pre-marketing set of data.

XII. FOOD LABELLING

30. The EC notes that some improvement has been made on food labelling. However, some issues still remain open and require further clarification, notably as regards registration procedures for labelling. The EC is concerned that there should be a homogenous application of registration procedures throughout China.