

CHINA'S TRANSITIONAL REVIEW MECHANISM

Communication from the European Communities

The following communication, dated 10 October 2005, is being circulated at the request of the Delegation of the European Communities.

I. CONSULTATION PROCEDURE

1. With regard to China's participation in the TBT notification procedure, the EC appreciates the effort that China has made in establishing their enquiry point and in being helpful in handling comments and enquiries. The EC also notes that over the last eight months China has already notified more than 75 draft regulations, and that, in general, they grant the recommended comment period of 60 days.

2. In spite of this the EC believes that the consultation procedure could be further improved as complaints have been raised by EC manufacturers in China with regard to the lack of participation of the foreign stake holders at the drafting stage of new technical regulations. The EC would like China to agree upon a more regularised and open consultation practice.

II. OVERREGULATION

3. The EC would appreciate it if China would refrain from developing national standards in areas where international standards exist. Too often national standards are developed or planned which deviate from international standards or concern areas where the market has already found satisfactory solutions e.g. the telecommunications field.

A. CCC SYSTEM

4. The EC would like to underline that a positive co-operation has been established with the competent Chinese authorities which allowed for encouraging improvements of the CCC system.

5. Among the improvements which have been brought into the CCC scheme, the EC observes that a reduction in the fees for factory inspections has been implemented and most of all follow up inspection can now be done by European bodies. These are positive steps towards the establishment of further co-operation between Chinese and European certification bodies.

6. Despite the progress in the implementation of the CCC system, it remains a burdensome, expensive and time-consuming conformity assessment procedure. It also leaves too much room for interpretation. The EC sees a general need for streamlining and simplification of the CCC system and welcomes the initiative of the Chinese authorities to launch, this year, a comprehensive review of the CCC implementation with a view to identifying areas for improvement.

7. The EC would like to recall its main outstanding concerns:

- (a) The uncertain application of national treatment.

This remains a subject of complaint from EC exporters. For instance, exemption procedures are still far from being transparent. The EC would appreciate it if the competent Chinese authorities would simplify and standardise the customs clearance for exemption.

- (b) The list of products subject to CCC.

It seems that it is the intention of China to add further industrial products to the list of products subject to CCC marking i.e. construction products as well as safety protection systems. The EC would suggest that low-risk products do not need to be subject to the CCC and that simplified procedures should be explored such as suppliers' declaration of conformity. In that context the EC would like to highlight the contrast with the market access rules in the EU, where self-declaration of conformity by the manufacturer is commonly used.

- (c) Certification requirements for spare parts, components and sub-assemblies.

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. Separate certificates for each and every component as opposed to one single certificate for the whole product are required in the case of products imported disassembled. The EC would like China to examine how CCC requirements could be simplified.

- (d) 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 required information should be simplified.

- (e) Double certification.

In the field of medical equipment it frequently occurs that safety and performance tests are conducted more than once by different organisations. The administrative authorities responsible for registering, evaluating and approving medical devices entering the Chinese markets are: the State Food and Drug Authority (SFDA), the State General Administration for Quality Supervision and Inspection and Quarantine (AQSIQ) and the Custom Authorities. Repetition of the same test for different authorities should be avoided as this causes delay and cost, without adding any value. The overlapping and unclear delineation of regulatory and market surveillance responsibilities often results in redundant requirements. An example of this is duplicative on-site audits and physical testing for several categories of medical devices. Repetitive requirements also cause inflated fees.

The double certification requirement is a common issue for other sectors like radio and telecommunication equipment, motor vehicles components, and cosmetics.

(f) Factory Inspections.

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

In conclusion: The EC request that China in its review of the CCC implementation strives for simplification in all the above areas. In particular, China should differentiate procedures depending on the level of risk the product imposes. It is also EC's expectation that China will associate the exercise with a consultation exercise to allow stakeholders to give valuable feedback.

B. ICT PRODUCTS

1. Certification

8. The Chinese Compulsory Certification (CCC) procedure is applied to a wide range of the ICT and Consumer Electronics Products. The ICT products are typically low-risk products that could be subject to simplified procedures. China's three-step certification system for certain ICT products incurs significant costs and delays.

(a) The EC considers that the scope of regulatory requirements should be confined only to essential requirements (e.g. safety, EMC and efficient use of spectrum) and be based on international standards. The verification of compliance with other requirements can be left as a matter between buyers and vendors.

(b) The EC considers that the test reports of competent European test laboratories including manufacturers' own laboratories should be acknowledged by the Chinese conformity assessment authorities.

9. 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.

(a) The EC would be grateful if China would abandon developing combined test specifications for dual or multi mode products (e.g. including GSM and WLAN). This is related to the rigidity of the CCC process and could be alleviated by adopting a simplified procedure based on the approval of each technology separately

2. Use and Development of national Standards when international standards exist

10. The Chinese approach to national standards was discussed actively by the industry during 2003 and 2004 with regards to the Chinese WAPI security standard for Wireless LAN (WLAN). In June 2004, China decided to indefinitely postpone the implementation of the WAPI decision and the discussion has been less active since. However there are still concerns with both the WAPI topic itself as well as with the principle of developing national standards when international standards exist.

11. WAPI: While the issue of WAPI seemed to be solved in June 2004 as a result of the indefinite postponement of the implementation of the regulation, the issue has resurfaced in some news articles and within the industry rumours during the spring of 2005. The EU understanding is that the implementation of the WAPI regulation would be complicated and costly to all parts of the industry, both Chinese and international.

- (a) The EC would appreciate more openness and transparency in the preparation of regulatory decisions, such as the WAPI.
- (b) The EC would also appreciate if China decided that the WAPI implementation is cancelled rather than only postponed.

12. Development of Chinese standards when international standards exist: As the WAPI development has shown in the WTO environment it is not possible to develop closed national standards which are mandated for all products to be allowed in the domestic market. However the industry is receiving signals that similar development continues in the Chinese ICT sector in other areas than WAPI, e.g. with the audio visual coding standards (AVS).

- (a) The EC would be grateful if China would stop developing national ICT and CE standards in areas where international standards exist.

3. Participation of European companies to the Chinese standardisation work

13. In China the interest of the government and industry to develop national standards to the ICT and CE areas has been continuously increasing. As agreed in the TBT agreement development of national standards is justified when international standards cannot be utilised. However, in the Chinese standardisation organisations the participating companies are classified as “domestic” or “foreign” and the “foreign” companies are not treated as full members of the community. Typically the “foreign” companies are expected to participate through joint ventures in order to have full membership rights and be able to vote. This approach is against the TBT Agreement and also reduces the value of the Chinese standards, as a major part of the industry has not been able to contribute to the process. In European and global standardisation organisations the nationality of the company does not matter.

- (a) The EU would appreciate if European companies were allowed equal rights in the Chinese standardisation forums and groups with all other participants. This would encourage the European companies to fully contribute to the development of the standards.

4. IPR (Intellectual Property Rights)

14. WTO-consistent IPR legislation is in place in China but efficient administration and enforcement is still missing. As Chinese companies are entering the global market, the recognition of patents and related royalty payments should be widely accepted according to China’s commitment to open standards. The recognition of individual owners’ patent rights and the need for payment of attendant royalties is fundamental to the development of a strong intellectual property and knowledge-based economy. That, in turn, supports the global community’s interest in and commitment to open standards embodying the best technology available anywhere in the world. In order to support these goals, it is important that companies who are attempting to license patents (in or out) do so in direct negotiations with the owners of such patents, subject to commitments made to standards bodies (e.g. to license essential patents under fair, reasonable and non-discriminatory terms). Without such direct negotiations, the open standards system is endangered, as companies will not contribute their best technologies because they fear not obtaining what they believe is a fair and reasonable return on their investment in R&D. Furthermore, failure to achieve agreements for what both parties believe to be fair value (which is best determined between a willing licensor and licensee) undermines the development of a healthy and strong intellectual property and knowledge-based economy.

- (a) The EU would request the Chinese Government to encourage direct, unencumbered negotiations between Chinese and foreign ICT and CE companies regarding patent licenses covering products and services they plan to sell in China or elsewhere.

In conclusion: The EC request simplification of certification procedures and that a procedure is introduced which is based on the risk that the product imposes. International standards should be used as far as possible. Consultation procedures should also allow input (equal) from stakeholders, both domestic and foreign. The EC also request a more efficient administration and enforcement of IPR issues for this sector.

C. AUTOMOBILES

15. 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 is particularly disappointing since, at our recent bilateral seminars and dialogues, where specific inquiries on these subjects were made, no mention was made by the Chinese side of the recent large-scale regulatory project.

16. The EC notes with particular concern that China has filed nearly twenty notifications of new technical regulations in this sector through the WTO TBT process in June and July of this year alone. The EC fully supports the goals of regulating safety, health, and environmental concerns with respect to motor vehicles, but feels these goals could be well achieved through harmonisation under the United Nations 1958 Agreement on Motor Vehicles (under the Economic Commission for Europe, UNECE). EC continues to urge China to become a Contracting Party to this Agreement.

17. Many of these new regulations are very similar to UN Regulations under the 1958 Agreement. Many of them nevertheless require duplicative, costly and burdensome inspections and testing for China's unique "CCC" certification and marking system, which seems 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.

In conclusion: The EC is convinced that goals on safety, health and environment can be achieved through harmonisation of motor vehicle regulations under the UN-ECE 1958 Agreement. China implements regulations that are close to those under the UN-ECE Agreement but often with some small variation. Such variation often creates trade barriers that are disproportionate to the objectives they serve to achieve. The EC requests a more earnest effort by China to harmonise with the regulation adopted under the UN-ECE 1958 Agreement and to accept certificates for vehicles already approved under these regulations.

D. PHARMACEUTICALS: ACTIVE PHARMACEUTICAL INGREDIENTS

18. This is a long-standing issue of great concern to the industry. The difficulties faced by exporters of Active Pharmaceutical Ingredients (APIs) were first raised by the EU chemical industry in 2002. China is restricting market access for EU exporters of APIs by applying a series of discriminatory measures, including the application of stricter standards to importers than to local producers. The Chinese actions clearly aim to maintain a high import barrier against APIs. Despite continuous industry and EC action on this issue for several years, there has been no significant change to the Chinese practice.

19. Chinese authorities discriminate against APIs for import by applying higher quality standards on those. The stricter standards have no relation to international standards or to health and safety concerns. The quality of EU products is suitably controlled by the extensive and strict EU pharmaceutical regulations, guidelines and monographs. Local Chinese manufacturers only have to

comply with the monographs of the Chinese Pharmacopoeia and with the relatively low Chinese manufacturing standards. The discriminatory, higher product quality standards imposed by the Chinese authorities on APIs for import take various shapes, for example upper limits of any impurity, clarity of solution, content of a given substance, acidity, colour of solution, density, water content.

20. In addition, the quality standards imposed on imports are continuously raised because Chinese authorities request that importers meet the highest quality standards met by any other importer. Thus, the requirements for an established importer will change if a newly approved importer of the same API meets a higher standard. The rising standards can be met only by an ever-decreasing number of foreign manufacturers, while Chinese producers remain unaffected.

21. In a number of cases, the Chinese authorities are also imposing different testing methods on imports vs. locally produced products to verify the specifications. The different degree of sensitivity of these testing methods can make it easy for some (local producers) and difficult to impossible for other producers (importers) to meet the required standard. This clearly creates an additional disadvantage for importers.

22. The Chinese authorities charge a disproportionately high "Port Drug Inspection Fee" for the testing of APIs at the border. The fee is unrelated to the actual cost of testing, which is only a fraction of the amount charged. The fee adds significantly - and for products in the lower price ranges often decisively - to the difficulties for importers to be competitive in the Chinese market against local Chinese producers who are not subject to the fee.

In conclusion: In several areas China has different quality standards depending on whether the product is domestic or imported. China also applies discriminatory fees. The EC requests that China finds a solution to these concerns and, in particular, applies the same standards to imported and domestic goods.

E. COSMETICS

23. The EC is aware and welcomes that China is taking the scientific findings of the European "Scientific Committee for Cosmetic Products ("SCCP") into consideration when regulating cosmetic products for the Chinese market. The most recent example for this trend is the Chinese list of authorised hair dyes for the Chinese market ("positive list") which follows closely the scientific opinions of the SCCP. However, market access for European cosmetic products is difficult due to a number of obstacles in particular relating to the registration of imported cosmetic products:

(a) Registration of New Products

- (i) Chinese cosmetics regulation distinguishes between "ordinary cosmetics" (hair shampoo, hair conditioner, face wash, facial mask, colour cosmetics, perfume, nail decoration products) and "special use cosmetics" (sunscreen, hair grower and dyeing, deodorant, slimming products, freckle remover, breast beautifying, hair perming, depilatory products). Imported ordinary cosmetics have to be registered with the MoH (Ministry of Health) while Chinese products are subject to a facilitated regime. Hence delays (5-12 months) and additional costs (\$ 1300-3200) have to be borne by importing companies.
- (ii) The requested data to be submitted includes core confidential information such as exact percentage formula, manufacturing process, raw material specifications and analytical methods, etc.

- (iii) Furthermore, requests for additional information often delay the final approval. European companies consider these practices a violation of the national treatment principle.
- (b) Additional requirements of certificates
 - (i) In addition to the above-mentioned MoH registration, AQSIQ (State General Administration for Quality supervision and Inspection and Quarantine) requires a pre-import “labelling certification” for all imported cosmetics. The AQSIQ certification requisites for documents are almost a duplicate of those of the MoH. This process can take up to 4 or even 6 months and additional fees are charged. After registering the product, the importer needs to buy stickers from AQSIQ and to affix them on each and every package. The same products - when distributed throughout China – become *again* subject to *local* AQSIQ bureaux requirements and often additional fees.

In conclusion: Imports are subject to MoH registration which does not apply to domestic cosmetics. In addition, there are national and “local” certification requirements by AQSIQ. This leads to additional fees and unacceptable delays to market. The EC request that China apply the same requirements for domestic and imported goods and that the certification requirements are harmonised and simplified.
