

**TRANSITIONAL REVIEW MECHANISM PURSUANT TO PARAGRAPH 18  
OF THE PROTOCOL ON THE ACCESSION OF THE PEOPLE'S  
REPUBLIC OF CHINA ("CHINA")**

Submission by the European Communities to the TBT Committee

1. The EC is transmitting comments and questions well in advance of the TBT Committee meeting of 7 November 2003 in order for the Chinese authorities to reply and to complete any information that may be incomplete.
2. Once the information to be provided by China in accordance with paragraph 8 and Annex 1A of its accession protocol has been received, the EC might come back with additional questions.
3. The EC appreciates that the Chinese authorities have organised seminars open to government officials and industry to handle questions addressed by the EC in its submission G/TBT/W/182, in particular with respect to food labelling, cosmetics and the new certification system (CCC). However, there are still issues requiring further clarification.
4. EC's comments and questions relate to the following items: CCC system, automobile, cosmetics, food labelling and pharmaceuticals.

**I. CCC SYSTEM**

5. The China Compulsory Certification system is a step forward compared to the previous conformity assessment scheme. At the seminar on the China Compulsory Certification system, which was held in Beijing in September 2003, the China National Certification Administration (CNCA) provided several useful explanations. However, a number of issues are still a matter of concern for the EC.

- As a general remark, the EC would like to emphasise that National Treatment should be ensured in the implementation of the new Compulsory Certification system.

6. The list of products subject to mandatory certification (the First Catalogue of Products Subject to Compulsory Product Certification) includes spare parts and components, unless they are incorporated in whole machines. This creates trade difficulties, especially when spare parts are supplied separately for the purposes of repair or maintenance, or when components are assembled in China. In this context, the EC would be grateful if China could:

- grant spare parts and components an exemption, following a procedure as clear and easy as possible;
- in any event, avoid that end products and their components are subject to separate certification;
- make it clear with which authority the ultimate decision lies as to whether or not the mandatory certification is required, in cases of uncertainty.

7. The scope, the procedure and the related costs of conformity assessment fees are another matter for concern. Reportedly, fixed fees (covering the application, licensing and checking of accompanying English documents) are rather expensive. Conversely, conformity assessment fees vary considerably according to the specific product conformity assessment.

- China is requested to clarify whether fees reflect the real cost of certification and do not discriminate between domestic and imported products.

8. Conformity assessment procedures can include so-called factory inspections, where Chinese auditors perform on the spot checks at the manufacturer's premises. The related costs (\$ 3.000, plus the auditors' travel expenses) are charged to the importer, i.e. on the EC producer.

The EC would like to ask China to:

- specify if and when these inspections are compulsory;
- ensure that local manufacturer of like products are subject to similar treatments and conditions.

9. As well as other information, the Chinese authorities require, as part of the procedure, detailed technical documentation. Given the potential risks for the intellectual property rights, the protection of confidential is a matter of concern.

- The EC would like to know which procedures have been implemented to ensure that confidentiality of technical information about products is dealt in a manner that legitimate commercial interests are protected at both national and local levels.

10. Another issue that requires clarification is the recognition of different conformity assessment procedures. In this context, the EC would be grateful if China could:

- confirm whether products already certified according to the previous regime (for instance, CCIB certification) need to undergo the new certification system;
- explain how far foreign conformity assessment will be taken into consideration in the Chinese procedures, notably in sectors where similar requirements apply. The automotive sector described below is a good example.

## **II. AUTOMOBILE**

11. With regard to automobiles, one of the major problems seems to be that China is not part of the UN/ECE revised 1958 Agreement on world harmonisation of automobile regulations.

12. As a consequence, China does not accept the UN/ECE approval marks although they are based mainly on the same international standards applied by China (for instance tyres, safety belts and safety glass). The comparison between the Chinese regulation and the European regulation in those sectors shows that the texts are almost identical.

- The EC is deeply concerned about the significant hurdles, which are caused by the repetition of tests for several parts and/or components, and wonders whether China is willing to accept the results of foreign conformity assessment procedures based on practically the same standards.

13. Another trade obstacle comes from the so-called Unit Classification Guidelines issued by the Chinese authorities, since they deviate from international practices. For instance, identical products manufactured in different plants must have different certificates. Separate applications are required

depending on engine power and displacement, while these two features do not influence safety-related items.

- The EC strongly recommends that China accede to the 1958 UN/ECE Agreement and consequently sign up to the majority of the existing Geneva regulations.

14. It would avoid unnecessary trade barriers such as, for example, the recent Chinese notification (G/TBT/N/CHN/26) on the protection of the occupants of a passenger car, in the event of a frontal collision, which deviates from the corresponding UN-ECE regulation.

### **III. PHARMACEUTICALS**

15. With regard to pharmaceuticals, the main issues at stake are the hurdles encountered by EC producers for active pharmaceutical ingredients (API) when exporting to China.

16. Considerable progress has been achieved from a formal-legal point of view, by means of the repealing of Article 15.5 of the Chinese “Provision Governing Import Drugs”. However, in practice Chinese authorities still require quality standards on imported products that are higher both compared to the domestic product standard and compared to international standards.

- The EC would be grateful if China could ensure that the national authorities implement the newly enacted rules in conformity with the requirements stemming from the WTO – TBT Agreement.

17. Furthermore, according to industry sources, domestic producers only have to meet the requirements established in the Chinese pharmacopoeia, whilst EC exporters have to meet at least the same standards of other APIs previously registered.

18. Moreover, when applying for an import drug licence registration (IDL) for a new API, the exporter does not know the internal specifications required by the State Drug Administration (SDA) for each product. Those specifications are frequently changing (getting stricter) without any external communication or consultation about the changes.

- China is requested to ensure consistency of standards used for APIs in the IDL requirements and to respect the transparency obligations set in Article 2.9 of the Agreement.

### **IV. COSMETICS**

19. At the present time, importers have to file an application to the Ministry of Health to obtain a pre-market registration, which is lengthy (6-9 months), onerous (between \$ 1300 and \$ 3200) and requires the disclosure of confidential data (formula or manufacturing process). On the other hand, domestic producers simply notify the local authorities two months after the launch of the product.

- The EC asks China to ensure that, in line with its WTO commitments, this discrimination be ceased forthwith.

20. In addition, the Administration for Quality Supervision and Inspection and Quarantine (AQSIQ) requires a pre-import registration for imported cosmetics. This procedure is expensive, takes time and for products marketed outside Beijing it must be repeated at local level.

- The EC would appreciate it, if China could phase out the current double registration system for imported cosmetics.

21. Another matter of concern is the labelling. For the time being, new products are required to bear a label that gives a literal translation of the original label. However, sometimes the Chinese authorities oppose the assertions and advertising on the label. With specific reference to the advertising, there are several provisions sometimes contradicting each other.

- The EC requests China to reconsider its legislation on labelling and advertising in order to achieve transparency, compliance with global practice and a rule-based system.

22. Finally, as it is known, the EC has already made specific comments in its SPS Committee with regard to restrictive measures adopted in relation to BSE emergency.

23. In this context, fruitful dialogue between China and the EC has already brought about the *de facto* removal of BSE-related trade impediments.

- The EC asks the Chinese authorities to formally endorse the important achievements in this field.

## V. FOOD LABELLING

24. The EC notes that a very constructive seminar on food labelling was organised in Beijing on 15 July 2003. The seminar was open to officials and industry representatives. The meeting allowed for the clarification of a number of issues. However, many issues still remain open and require further clarification, notably as regards registration procedures for labelling. In this context, the EC would ask China to:

- ensure that registration procedure for a label be no more time-consuming than necessary (currently, it takes more than 90 days);
  - apply transparent criteria for the approval of labels. In particular, the *best before* indication for wines and spirits should follow international practice;
  - allow economic operators to decide how to present the required Chinese-language information on the product label(s) as long as the objective of consumer information is met;
  - accept that approved labels are attached after the goods enter China, but before the AQSIQ inspection takes place;
  - clarify the labelling requirements for products in 'large-scale' or bulk packaging;
  - guarantee that only the trademark owner/producer could apply for the label, in order to protect products against counterfeiting.
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