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Committee on Technical Barriers to Trade Original: English

CHINA'S TRANSITIONAL REVIEW MECHANISM

Communication from the European Communities

The following communication, dated 16 September 2004, is being circulated at the request of the Delegation of the European Communities.

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1. The EC is transmitting comments and questions well in advance of the meeting of the Technical Barriers to Trade Committee of 4 November 2004, in order for the Chinese authorities to reply and to complete any information that may be lacking.

2. Once the information to be provided by China in accordance with paragraph 8 and paragraph IV.7 of Annex 1A of its accession protocol has been received, the EC may come back with additional questions.

3. The EC's comments and questions relate to the following priority items: the Chinese Compulsory Certification system (CCC), automobile, cosmetics, pharmaceutical and foodstuff (labelling, standards for wine and spirits).

4. It should be noted that some of the above-mentioned subjects are also covered in other committees but for different aspects, for instance automobiles in the Market Access Committee or cosmetics in the SPS Committee.

I. CCC SYSTEM

5. This issue was raised at the last TRM. The EC welcomes developments since then, in particular the establishment of a fruitful dialogue with the competent Chinese authorities (the Chinese State General Administration for Quality Supervision and Inspection and Quarantine – AQSIQ and the Chinese Certification and Accreditation Administration – CNCA) and their willingness to discuss our concerns and to clarify certain issues.

6. As a general remark, the EC would like to emphasise again that National Treatment should be ensured in the implementation of the CCC system, in particular as regards the administration of exclusions and exemptions.

7. The EC main outstanding concerns relate to:

(i) The list of products subject to the CCC

8. The system applies to 19 categories of industrial products, covering around 132 items, some of which are low-risk products that could be subject to simplified procedures (such as the supplier declaration of conformity). Furthermore, it appears that China will add additional industrial products to the list of products subject to CCC marking.

9. In addition, subject to very limited exemptions, 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 latter will be tested and certified in China. By the same token, 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.

10. In this context, the EC would be grateful if China could consider the possibility of:

- Reviewing the list of products subject to mandatory certification, in order to exempt low risk products;
- Excluding from such lists spare parts and components of products which are in any event subject to certification;
- Accepting one single certificate for the whole product instead of requiring separate certificates for each and every component in the case of products imported disassembled.

(ii) Fees

11. Conformity assessment fees for foreign manufacturers are significantly inflated by factory inspections performed by a team of Chinese auditors (initial inspection plus yearly follow-up inspections). Very often, manufacturers are requested to make use of consultants agreed by CNCA to deal with the CCC procedure. The EC understands that, several EC CABs have been authorised in certain cases to carry out the yearly follow-up factory inspections on behalf of China. However, the initial factory inspection must in all cases obligatorily be performed by a team of Chinese auditors.

12. In addition, recognition of foreign test results and certificates currently operates, on a purely voluntary basis and in any event often conditional on additional testing by a Chinese test laboratory, only with respect to some electrical products covered by the Certification Body scheme developed by the International Electrotechnical Commission (IEC) System for Conformity Testing and Certification of Electrical Equipment (known as IECEE/CB scheme). For those products to which IECEE/CB scheme cannot or does not yet apply, acceptance of the results of testing and certification done by CABs in the EC appear to be systematically refused by the Chinese authorities, even when the EC standards used and the relating testing requirements are identical to the relevant Chinese requirements.

13. Therefore, The EC would like to ask China:

- To exempt companies from factory inspections, at least those which have been certified according to international standards (such as ISO 9001), or to outsource all factory inspections to certification bodies established in the country of the manufacturer, or to accept factory inspection reports made by the latter for purposes of compliance with the health and safety regulations of the country of export;

- To fully accept tests results and certificates issued by foreign CABs according to the same standards applied in China for all products subject to the CCC system.

(iii) Double certification

- Certain products covered by the CCC system (such as medical equipment and radio and telecommunication equipment) are subject to double certification, by the Ministry of Information Infrastructure (MII) for telecommunication equipment and by the State Drug Administration (SDA) for medical devices.

14. It should be recalled that point 13 of the China's WTO accession protocol clearly states that imported products shall not be subject to more than one conformity assessment.

- The double certification requirements should be abolished. This is a common issue also for other sectors (such as motor vehicle components and cosmetics).

II. AUTOMOBILE

15. Similar to the CCC system, this issue was raised at the 2002 and 2003 TRM. There is an open dialogue with the Chinese authorities and the automotive issues will be discussed during a seminar in Beijing in September and in the context of the EU-China regulatory dialogue in Brussels in November. The EC expects that ongoing discussion will lead to concrete results.

16. The main concerns in this area relate to:

(i) Design, adoption and implementation of standards

17. China is not yet a member of the 1958 UN Agreement on world harmonisation of vehicle construction regulations. In some cases Chinese notified standards state that they are based on UN Regulations, but in fact contain elements of the UN Regulations, sometimes with the addition of some elements drawn from other systems, resulting in confusing and sometimes contradictory requirements.[1] In many other cases, Chinese standards are virtually identical to those under the 1958 Agreement, but are implemented in such a way as to require duplicative, costly, and time-consuming testing and certifications. In addition, not all stakeholders and interested parties are involved in the development of new standards. Were China to join the 1958 Agreement, both its industry and those of the many other member countries would benefit from reciprocal recognition of testing and from avoidance of duplicative measures which increase barriers to trade.

18. The CCC mark must be affixed on tires (car and truck), safety belts and safety glasses, although the Chinese standards are equivalent to the UN regulations and, therefore, the UN approval marks should be accepted as an alternative to the CCC mark.

- The EU strongly recommends that China accedes to the 1958 UN Agreement and to as many of the existing Regulations under that Agreement as possible.

[1] For example, in the case of notification G/TBT/N/CHN/26 on frontal impact protection for passengers, the standard is claimed to be based on an earlier version of UN Regulation 94, but with additions from an unrelated Japanese standard which tests frontal impact in a different way. The result is an unclear 'hybrid' test which will require additional, different, and duplicative testing.

(ii) Notification, adoption and implementation of technical regulation

19. China has issued a relatively large number of TBT notifications relating to the automobile industry (five in 2004), some of which are lengthy and constitute fundamental legislation for the industry, covering basic provisions of vehicle construction, safety, and fuel consumption. The EU has identified a number of areas of concern about these notifications.

20. Concerning notification of technical regulation, updates of "implementation rules for compulsory certification of motor vehicles" are announced with short notice and are enforced without sufficient lead time. Official English translations are not always available and not always in time.

21. Concerning implementation of notified regulations, apparently it varies depending on the implementing agency. In some instances it appears that there may be three or four agencies or organisations involved in a given regulation from its drafting through to its implementation[2], and the differing definitions or interpretations applied by each of them may result in possibly unintentional obstacles to trade.

- The EU would be grateful if all Chinese authorities involved in not only the drafting but also the implementation of regulations could be involved in the notification and dialogue processes with the industrial stakeholders.

III. COSMETICS

22. The main concerns in this area relate to:

(i) Registration of cosmetic products

23. Currently importers have to file an application with 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.

24. In addition, 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 asks China to ensure that, in line with its WTO commitments, the discrimination between domestic and foreign products be ceased forthwith.

- The EC would appreciate it, if China could phase out the current double registration system for imported cosmetics (Ministry of Health and AQSIQ).

(ii) Labelling of cosmetic products

25. 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.

[2] A policy may be developed by the National Development and Reform Commission, for example, for which regulations are drafted by AQSIQ or CNCA, which is applied to imported goods by the Customs authorities, who understand a particular product definition or other aspect of the regulation differently from CNCA. It is thus very difficult for industry to obtain clear guidance on how to comply with regulations.

- 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.

(iii) BSE issues

26. The EC has already made specific comments in the SPS Committee with regard to restrictive measures adopted in relation to BSE emergency. In this context, fruitful dialogue between China and the EC has already brought about the *de facto* removal of BSE-related trade impediments. However, some burdensome administrative requirements to export EU products to China are still in place. Given the well established fact that European cosmetic products are safe and abide by the WTO guidelines with respect to BSE,

- the EC asks the Chinese authorities to consider lifting the administrative requirements for cosmetic products originating from the EU.

IV. PHARMACEUTICAL

27. With regard to pharmaceuticals, the main issues at stake are:

(i) Active pharmaceutical ingredients (API): requirements

28. The issue of API was raised at the last TRM. However, the statement by China replying to the submissions by other WTO members was not satisfactory regarding the issue of APIs.

29. The requirements and specifications, including test methods, for the drug import registration certificate (IDC) applications for APIs issued by the State Food and Drug Administration (SFDA) are not the same as the ones in the Chinese Pharmacopoeia, but in some cases stricter than those for domestic Chinese products.

30. Article 15.5 of the Chinese "Provision Governing Import Drugs" stating that drugs should not be approved for import registration if their 'quality index' was lower than the one for the same products of another company that already holds an IDC has been repealed. However, in practice there is still discrimination against foreign producers. Domestic producers only have to meet the requirements established in the Chinese Pharmacopoeia, whilst EU exporters have to meet at least the same standards of other APIs previously registered. Thus, standards for IDCs are continuously rising.

- The EC would be grateful if China could ensure that the national authorities implement the newly enacted rules in conformity with the obligations under Article 2.1 of the TBT Agreement. In particular, China should ensure that APIs imported from the territory of any WTO Member should be accorded treatment no less favourable than that accorded to domestically produced APIs.

(ii) Active pharmaceutical ingredients (API): registration

31. Companies face additional difficulties and long waiting periods to obtain an IDC. In this context, the EC would be grateful if China could:

- ensure that the relevant procedures are undertaken and completed as expeditiously as possible according to Articles 5.2.1 of the TBT Agreement;

- ensure that information requirements are limited to what is necessary and confidentiality of information is respected in a manner that legitimate commercial

interests are protected at both national and local levels according to Articles 5.2.3 and 5.2.4 of the TBT Agreement;

- ensure that the Port Drug Inspection Fee complies with the requirements of Article 5.2.5 of the TBT Agreement in terms of reflecting the real cost of certification and do not discriminate between domestic and imported products.

(iii) Active pharmaceutical ingredients (API): transparency

32. When applying for an IDC 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, creating a clear lack of legal certainty.

- China is requested to ensure consistency of standards used for APIs in the IDC requirements and to respect the transparency obligations set in Article 2.9 and 5.6 of the TBT Agreement in order to allow for comments and to enable interested parties to become acquainted with new technical requirements.

(iv) Monitoring period for products manufactured in China for the first time

33. As regards the monitoring period stipulated by Section 4 (Art. 70-79) of the Drug Registration Regulation, the regulation provides a period up to five years of *de facto* market exclusivity for drugs that are produced in China for the first time, regardless of whether and for how long the drug may already have been marketed in/imported into China.

34. The EC acknowledges the need to ensure a high level of drug safety by implementing a pharmacovigilance scheme. However, the Chinese measures potentially prevent the access of the originator's (normally the non-Chinese competitor) drugs from serving the Chinese market since the monitoring period grants a market exclusivity to the company which is the first to manufacture the product in China, irrespective of the fact that the product may be already imported by another (presumably foreign) company. This legal provision inherently discriminates against (non-Chinese) importers.

- China is requested to ensure that its legislation is amended in a way that products imported from abroad can enter the Chinese market although a product containing the same active ingredient is manufactured in China for the first time. China has to put in place legislation which ensures that any pharmaceutical product imported from the territory of any WTO Member is accorded treatment no less favourable than that accorded to domestically produced products.

V. FOODSTUFF (LABELLING, STANDARDS FOR WINE AND SPIRITS)

35. The EC notes that some improvement has been made on food labelling. 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:

- apply transparent criteria for the approval of labels. In particular, the *date of manufacture* indication for wines and spirits should follow international practice and the listing of ingredients/additives should include exemptions for one single ingredient spirits drinks;

- 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, for instance requiring mandatory information in Chinese to be of a minimum size for purposes of legibility, but not linking the size of characters in foreign language to the size of Chinese words;

- guarantee that only the trademark owner/producer could apply for the label, in order to protect products against counterfeiting.

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