SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/46)

Previously raised concerns

UE, China e Tailândia X Brasil – Toys (G/TBT/N/BRA/259)

Brazil – Toys (G/TBT/N/BRA/259)

The representative of the European Communities recalled that concerns had been expressed about the conformity assessment systems applied to imported toys in Brazil. His delegation was of the opinion that those rules granted less favourable access to the Brazilian market for foreign toy suppliers compared to domestic toy suppliers. He recalled that, at the previous meeting of the TBT Committee, the representative of Brazil had indicated that changes to the rules were under consideration. He sought an update from Brazil on the state of play, an indication of what types of measures had been considered and also of the timeline for their adoption.

The representative of China believed that the measure by Brazil violated the provisions of non-discrimination and less trade restrictiveness under the TBT Agreement. The Chinese industry had indicated that the new Brazilian procedures added another 70 days for products to flow from the plant to the warehouse, which made the process 140 days long. Moreover, the certification process had added an additional 25 days. The Chinese industry estimated that the value of lost sales was USD 20 million due to the difficulty to meet the regulation requirements. His delegation understood that Brazil would notify the amended regulation and comments would be made on this new notification.

The representative of Thailand recalled that comments had been sent to Brazil and concerns raised at TBT Committee meetings in March and July 2008. In the comments sent in January 2008, her delegation had stressed that the Brazilian decree was inconsistent with the TBT Agreement. In particular, enforcing certification System 7 only on importers was discriminatory in practice, and recognizing only tests carried out by INMETRO laboratories created unnecessary trade obstacles to importers. She recalled that Brazil had been requested to consider accepting testing of foreign laboratories accredited to ISO/IEC 17025, or adopting alternative quality control approaches such as market surveillance for both imported and local products, that would ensure both safety objective and equal treatment. A subsequent request had been made on 26 February 2008 for cooperative direction to help ease the problems of Thai exporters.

The representative of Thailand noted that, in its reply, Brazil had stated that the measure did not create an unnecessary and illegitimate obstacle to trade and that Systems 5 and 7 only differed in the number of samples to be tested in a lot, and pointed out that it would accept only testing in laboratories accredited by INMETRO. She stressed that the reply had failed to clarify the discriminatory aspect of the decree. On the contrary, it had confirmed the unnecessary difficulties for exporters who were subjected to the unequal practice and selective recognition of conformity assessment procedure. She recalled that, at the TBT Committee meeting in March, Thailand had raised concerns about Brazil's discriminatory enforcement of its certification system. Brazil had been requested to consider accepting test reports of foreign labs accredited to ISO/IEC 17025 under an internationally recognized umbrella such as ILAC/ IAF, to which Brazil was also a signatory.

It was further recalled that, at the TBT Committee meeting in July 2008, as no changes had been made to the Brazilian measure, concerns were reiterated, in particular about less favourable treatment towards imports - in breach of Article 5.1.1 - and the creation of unnecessary obstacles to trade in violation of Article 5.1.2, despite other WTO-consistent alternative measures available, such as testing in the country of export. Brazil had also been requested to provide a written reply to the comments submitted. However, no such reply had been received.

The representative of Thailand stressed that the measure had been in place since 16 October 2007, which was a long period for a temporary measure. Her delegation was of the view that the measure was in violation Article 5.1.1 of the TBT Agreement, since Brazilian conformity assessment procedures were applied so as to grant access for importers under conditions less favourable than those accorded to local manufacturers. In particular, Brazilian manufacturers could choose System 5, which was pre-market approval, one-time sampling for type testing. However, importers had use System 7 only, where every lot had to be sampled, and tests could be done in Brazil only; this was not in line with Article 5.1.2 of the TBT Agreement. Brazil's measure was applied more strictly than necessary to give Brazil adequate confidence that imported toys conformed to its safety requirement.

The representative of Thailand further highlighted that every import lot had to be held at the port of entry, await sampling and testing by INMETRO only, and be detained until the test results were obtained. In the meantime, importers were in uncertainty about the test results, while costs kept increasing as the test was delayed and storage prolonged. She stressed that this was not in line with Article 5.2.6 of the TBT Agreement, as the siting of facilities used in conformity assessment procedures and the selection of samples were such as to cause unnecessary inconvenience to importers.

Moreover, since Brazil required that the test be conducted by INMETRO accredited laboratories only, and did not recognize laboratory accreditation under international umbrella such as ILAC/IAF, reports from exporters showed that the toy import process that used to take 50-70 days now took 140-150 days. Excessive costs were added to the process, related to product certification, storage, demurrage, amounting to 30 per cent of FOB. The testing capacity of Brazil was also questioned and test result delays were the main technical barrier for all exporters.

The representative of Thailand recalled that, at the July 2008 meeting of the TBT Committee, Brazil had indicated that a new and definite system of conformity assessment procedures for toys was under consideration. She sought an update about the definite timeframe for this system and whether it would comply with the TBT Agreement. She stressed that, since Brazil's consideration of a new system took time, the temporary measure should immediately be reviewed, and foreign test reports issued by accredited laboratories should be accepted. Market surveillance was also a non-discriminatory and effective system to protect health. Thailand had indicated to Brazil that, if no changes were envisaged or if foreign test reports would not be accepted, Brazil would be requested under Article 6.3 of the TBT Agreement to enter into discussion towards a bilateral arrangement that would benefit both Brazilian consumers and Thai exporters.

Finally, the representative of Thailand sought a written reply to the following questions: (i) had the decree been revised since the July 2008 meeting of the TBT Committee? (ii) if so, could the revision be described and a copy provided? (iii) if not, had INMETRO initiated any action or process for the revision? (iv) could any description of the process be provided, together with any relevant draft text? (v) if no revision process had been initiated, when would INMETRO begin the process? (vi) would Brazil enter into a bilateral dialogue with Thailand on the matter? She stressed that her country shared the objective of health and safety protection, but believed that discriminatory or trade restrictive practices would not serve the purpose. Her delegation was of the view that this regulation together with its conformity assessment procedures had been adopted, prepared and applied with the effect of creating unnecessary barriers to trade, contrary to the principle of good regulatory practice.

The representative of Brazil pointed out that the regulation on toys had been adopted on an emergency basis in order to cope with a situation of lack of confidence regarding the safety of imported toys. He recalled that in the year 2007 several cases of non-compliance, recalls and accidents had been reported. Therefore, Brazilian authorities had decided to require that

imported toys be tested under System 7 of certification, which, in his delegation's view, did not constitute a less favourable treatment to importers. In the previous TBT Committee meeting, Brazil had noted that the current regulation was being revised. He informed the Committee that the process of revision was complete and that Brazilian authorities had taken into consideration the concerns expressed by Members in the Committee and in bilateral meetings. A draft of the new regulation was published for public consultation and copies of the new draft would be provided. According to the draft new regulation, both domestic and imported toys would be allowed to use System 5 of certification. Moreover, tests performed by laboratories accredited by ILAC would be accepted again.

UE e EUA X Brasil – Wines (G/TBT/N/BRA/238; G/TBT/BRA/289)

Brazil – Wines (G/TBT/N/BRA/238; G/TBT/BRA/289)

The representative of the European Communities referred to the Brazilian Normative Instruction 33, regarding mandatory analytical parameters for analysis of certificates of origin for imported wine. She recalled that, at the previous meeting of the Committee, her delegation had indicated that no clarification had been received as to why the Brazilian authorities required the analysis of some parameters which were not provided for in the templates of analytical certificates for trade in wines set by the International Organization of Vine and Wine (OIV). She invited Brazil to explain the reasons for departing from the requirements set at international level. Her delegation was also interested in receiving additional information on the public consultation that was launched on 2 June 2008 on import requirements for wines and its potential impact on the provisions of the Brazilian Normative Instruction.

The representative of the United States shared some of the concerns expressed. He noted that both the Brazilian measure on wine and the measure on spirits[1] could restrict trade as many of these proposals contained elements which varied from internationally-accepted standards, or set out a unique approach to defining values and parameters for quality and identity. For both measures, he sought clarification on Brazil's objective. He also sought an explanation as to why both measures had also been notified as SPS measures.

Specifically, with respect to wine, the United States had three main concerns with the proposed requirements. First, the registration requirements appeared to be burdensome and duplicative. Brazil was invited to clarify why the Ministry of Agriculture, Livestock, and Food Supply (MAPA) was proposing to require foreign wineries to register and have their premises subject to inspection, in addition to complying with the existing requirement for registration by the local importer. Second, it appeared that minor modifications made to the wine label, such as a change in the label's colour, would require re-registration of the wine and Brazil was requested to clarify the purpose of this requirement. Third, it was noted that geographic and regional factors could influence the alcohol content of wine. Thus, clarification was sought as to why Brazil was proposing to limit the alcohol content of wine to 14 percent by volume unless it carried a statement clarifying that the wine had "typical" or "distinctive" characteristics of a region. Such a measure could have the effect of blocking imports.

The representative of Brazil explained that the intention of the proposed measure was to expedite wine imports. In particular, the measure was intended to shorten the period during which imported wines were kept stored while official laboratories performed analytical tests. Given the large number of imports, official laboratories were operating over their capacity, and delays were being reported. Therefore, the regulation allowed the acceptance for test carried out abroad. He noted that the regulation notified as G/TBT/N/BRA/289 would replace the above mentioned regulation. Regarding the objectives of the analytical parameters, he pointed out that analytical parameters for chemical components were an important instrument to attest the

[1] See below, paragraph 48.

quality of spirits, including to verify raw materials, thereby preventing fraud in production and process.

UE, México e EUA X Brasil - Regulations on Identification and Quality Standards of Ethyl Alcohol and other Spirits (G/TBT/N/BRA/276-278 and Suppl.1)

Brazil - Regulations on Identification and Quality Standards of Ethyl Alcohol and other Spirits (G/TBT/N/BRA/276-278 and Suppl.1)

The representative of the European Communities recalled that her delegation was concerned about the fact that the draft measures notified by Brazil seemed to divert from the international practice and could constitute an unnecessary barrier to trade. For example, the draft standards defined spirit drink categories in terms of chemical components rather than defining them in terms of raw materials and production process, as was the commonly accepted practice. Furthermore, the alcohol content requirement established by the proposed measure also diverged from internationally accepted standards. The draft regulations also seemed to restrict the use of certain flavouring in spirit drinks exported to Brazil. She sought confirmation from Brazil that these requirements would only apply to domestic products and not to beverages from third countries, and that these could enter the Brazilian market if they complied with the requirements set in the country of origin. She also invited Brazil to indicate whether the notified measures would be modified as a result of the public consultation process that had been launched on 24 April 2008.

The representative of Mexico recalled the concerns expressed by his delegation on the Brazilian regulation, in particular with respect to tequila. Comments had been submitted to the Brazilian authorities and various bilateral meetings had taken place. However, concerns remained with respect to the consistency of the regulations with the TBT Agreement. He sought clarification on the scope of these measures and on the applicability to products originating from third countries. He invited Brazil to provide a response to the comments submitted and a confirmation that the measure did not apply to imported products.

The representative of the United States noted that, with respect to spirits, Brazil had chosen different requirements from what normally were used in the market. For example, its proposed minimum alcohol content requirement was different from globally accepted standards. In addition, Brazil was proposing a maximum alcohol content level, which would be unique in the world. He sought clarification as to why Brazil would set a maximum limit, given that no health and safety concerns had been identified.

Furthermore, it was noted that Brazil's proposals on both whisky and rum specified analytical parameters for higher alcohol levels. Such alcohols were naturally occurring constituents produced during the fermentation, distillation, and maturation processes that did not raise any health and safety issues. The representative of the United States recalled that, for this reason, in September 2006 (following a similar discussion in the TBT Committee), China had agreed to withdraw its proposed limits on higher alcohols in distilled spirits in line with international practice, including the Guidelines of the UN FAO/WHO Expert Committee on Food Additives. He invited Brazil to clarify its reasons for utilizing such parameters.

The representative of the United States also sought clarification as to why the proposed requirements for gin only permitted it to be produced by the redistillation of potable ethyl alcohol of agricultural origin and stressed that such a definition would block certain US exports of gin to Brazil. Also, why did the proposed requirement for rum include rum produced from sugar beets? It was also his delegation's understanding that Brazil intended to drop its regulatory references to Bourbon and Tennessee Whisky and add a provision that these products were distinctive of the United States. He requested confirmation of this intention and encouraged such an action. Finally, like the European Communities, his delegation's

understanding was that the proposed measures would not apply to imports and Brazil was requested to clarify this, as well as to take oral and written comments into account.

The representative of Brazil noted that the proposed regulations were the only update to existing regulations adopted in 1973. The process of updating had been conducted in a transparent manner: public consultations had been held and additional time for comments had been granted to interested parties. He pointed out that all comments received would be analysed before the final regulations would be published. With respect to the analytical parameters, Brazil's proposed regulations defined categories of spirits in terms of raw materials, production processes and analytical parameters for chemical components. Analytical parameters for chemical components were considered as an important instrument to attest the quality of spirits, including to verify the correct use of raw materials, thereby preventing fraud in the production processes.

The representative of Brazil further noted that the proposed regulations reproduced the minimum and maximum levels of alcohol already contained in other national legislation (Decree 2314 of 1997), and Mercosur rules. However, Decree 2314, in its Article 34, maintained that beverages which were produced abroad and did not comply with Brazilian standards could be imported, provided that a certificate was presented attesting that: the beverage was a typical product from its country of origin; that it was produced in accordance with its country's laws and regulations; and it was regularly consumed in that country. He stressed that Brazil's proposed regulations would not restrict the importation of beverages regularly produced and consumed abroad. Finally, he noted that bilateral meetings at the technical level were ongoing with Mexico to discuss recognition of tequila as Mexican geographical indication. His delegation would also be willing to engage in similar talks with the United States regarding Bourbon and Tennessee whisky.

EUA e UE X Brasil - Registration Requirements for Medical Devices

Brazil – Registration Requirements for Medical Devices

The representative of the United States reiterated his delegation's concerns about Brazil's Resolution 185 on ANVISA's registration and re-registration requirements for medical devices. The United States were concerned that ANVISA's requirement to submit certain economic data with each registration did not appear to be related to the safety and efficacy of medical devices, and was unnecessarily costly and burdensome. US industry had indicated that some of the information required by ANVISA was impossible to provide, either because that information did not exist, or existed but was sensitive commercial information or could only be provided by calling other companies to obtain it, which raised potential antitrust issues.

The representative of the United States further noted that ANVISA had already denied commercialization in certain instances due to a failure to provide economic data. The requirement also created substantial uncertainty for medical device companies that operated in the Brazilian market, because ANVISA did not let suppliers know whether the economic data that they had submitted was sufficient. This meant that ANVISA could potentially issue a denial at any time, blocking trade in that product and forcing industry into a situation of constant uncertainty.

It was also pointed out that industry continued to try to engage Brazilian authorities so that these information requirements were implemented in a clear, transparent, and predictable manner to avoid creating unnecessary disruptions of trade in medical devices. However, ANVISA had thus far failed to address in a meaningful way the constructive and detailed industry proposals to ameliorate the situation, and had not modified Resolution 185 in any way. Finally, the representative of the United States stressed that Resolution 185 posed a real barrier to open and

fair market access for medical devices, and should be either amended or withdrawn. He urged Brazil to devote positive, high level attention to this issue as the only way of resolving it.

The representative of the European Communities recalled that her delegation had raised concerns about this measure at previous meetings of the Committee. She invited Brazil to take into account the comments made and to reinforce discussions with economic operators, which were currently encountering problems.

The representative of Brazil reaffirmed his delegation's position that Resolution 185 was not a technical regulation nor a conformity assessment procedure, and therefore it was not covered by the TBT Agreement. His delegation was open to discuss the issue bilaterally with interested delegations.