SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/45)

New Concerns

México e UE - Regulation on Identification and Quality Standards of Eethyl Alcohol and other Spirits

Brazil – Regulation on Identification and Quality Standards of Eethyl Alcohol and other Spirits (G/TBT/N/BRA/276, Suppl.1)

The representative of Mexico raised concerns about a draft regulation on identification and quality standards for alcoholic beverages, notified by Brazil on 7 May 2008 (G/TBT/N/BRA/276), which set out, among other things, the specifications for identity and quality of different alcoholic drinks. Although the reference to tequila was of particular concern to his delegation, the regulation of other alcoholics such as rum and gin was also a matter of concern.

The representative of Mexico drew the Committee's attention to the fact that tequila had been an appellation of origin recognized by the Mexican government since 1974, and had been registered within the trademark office of the World Intellectual Property Organisation (WIPO) in 1977. He recalled that appellations of origin indicate the geographical nature of the country or the region used to designate a product from a certain place whose characteristics are essentially related to the environment, and in particular to natural and human factors. In this regard, the tequila originated from a Mexican region called "Tequila", where a number of natural factors combined and created a unique area which provided the product with its exclusive characteristics. Also, the antique tradition of tequila production, which had been transmitted through many generations, created human factors which permitted tequila to be recognized as a high quality product on international markets.

The representative of Mexico also informed the Committee that a complex regulation on the manufacturing of tequila had been in force since 2005 (006-SCFI 2006). In particular, to guarantee the authenticity of tequila, the Mexican government had implemented a protection system which included: (i) an identification of the geographical zone used for the production of tequila's raw material; (ii) specific technical regulations; (iii) a regulatory body which controlled compliance with technical requirements; (iv) export controls; and (v) inspection procedures. The Mexican technical regulation also set out other requirements for specific categories of tequila, including: controls on the manufacturing process, water quality, physical and chemical analysis, labelling and bottling requirements.

The Mexican representative emphasized that tequila was a product internationally recognized as originating from Mexico and needed therefore to be produced in compliance with Mexican legislation. It was the view of his delegation that Brazil set a definition of tequila and referred to requirements that were incompatible with those set by Mexican legislation, and there was no scientific justification. The Brazilian draft regulation was therefore incompatible with several provisions of the TBT Agreement, the GATT 1994 and the TRIPS Agreement. In particular, the draft regulation contained requirements that were inferior to those allowed for in Mexico with regard to methanol, aldehyde, lead, copper, and others which limited the percentage of alcohol per volume. It was pointed out that such measures would limit the types of tequila that could be commercialized in Brazil, and would favour the marketing of lower quality products.

It was Mexico's understanding that the legitimate objective identified by Brazil with regard to the draft regulation was: the protection of consumers from misleading or deceptive practices.

However, the representative of Mexico believed that the draft regulation would not fulfil such legitimate objectives, but would rather constitute an unnecessary barrier to trade. He therefore asked Brazil to clarify the legitimate objectives of the draft regulation in accordance with Article 2.2 of the TBT Agreement and stated that Mexico would present its written comments to Brazil in order to further discuss the issue.

The representative of the European Communities shared the concerns expressed by Mexico. She stressed that the proposed draft regulation would have a serious impact on European exports of spirits to Brazil. First, the draft standard defined the category of spirit drinks in terms of chemical components by means of analytical parameters; however, the European Communities - along with other countries - defined categories of distilled spirits in terms of raw materials and production processes. The divergence in standards could constitute an unnecessary obstacle to trade. Second, the alcohol content requirements established in the proposed Brazilian regulation did not conform to the international standards for most spirit categories; therefore, the European Communities urged Brazil to retain minimum strength requirements only and align these with internationally accepted values. Finally, the draft regulations restricted the use of certain flavourings in spirit drinks exported to Brazil, thereby causing negative impacts on European exports to Brazil. In concluding, the European Commission invited the Brazilian authorities to take into account both its oral and written comments.

The representative of Brazil recalled that the regulation at issue was still a draft currently under public consultation. He confirmed that Mexico had additional time to submit its comments, and recalled that any comments would be taken into account before the adoption of the regulation. However, Brazil stressed that the draft regulation on identification and quality standards for alcoholic beverages was intended to create identity and quality requirements for spirits, and had no relation with intellectual property issues.

UE x Brasil - Wines

Brazil – Wines (G/TBT/N/BRA/238)

The representative of the European Communities raised concerns about a measure on wine, notified by Brazil on 26 March 2007 (G/TBT/N/BRA/238), which imposed, among other things, an increase in the number of parameters that had to be evaluated and on certificates that were requested. At the time of notification the European Communities had submitted written comments, which had only been partially clarified by Brazil. In particular, the European Communities invited Brazil to indicate the reasons for departing from the levels and parameters established at the international level, and to explain the legitimate objective pursued by the measure. Finally, the European Communities invited Brazil to give further information on the public consultation launched on 2 June 2008 on import requirements for wines, and to clarify whether the parameters which had to be evaluated would be reviewed as a result of this consultation.

The representative of Brazil took note of the comments made.

Previously raised concerns

Brasil x UE - Regulation on the Registration, Evaluation and Authorization of Chemicals

European Communities – Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH) (G/TBT/N/EEC/52, Adds 1-5 and Add.3/Rev.1)

The representative of Brazil shared the concerns already expressed by others, stressing the difficulties imposed by the "Only Representative" requirement, especially in the case of SMEs. In particular, the representative of Brazil recalled that Brazilian industry was seriously concerned about the registration requirements for reacted monomers in polymers. He noted that REACH exempted polymers from registration and evaluation, as they were widely believed to cause minimal risk. Nevertheless, REACH required manufacturers or importers of polymers to register reacted monomers used in the production of polymers. It was noted that such a situation could constitute discrimination between EC and non-EC manufacturers, since only the monomers in the polymers created by the EC manufacturers would be registered. Therefore, the representative of Brazil encouraged the European Communities to clarify the rationale for the registration of reacted monomers in polymers and give further information on the status of the related case recently submitted to the European Court of Justice.

Brasil x UE - Dangerous Chemical Substances; Draft Commission Directive amending Council Directive 67/548/EEC

European Communities – Dangerous Chemical Substances; Draft Commission Directive amending Council Directive 67/548/EEC (G/TBT/N/EEC/151)

The representative of Brazil expressed his concerns with regard to the decision of the European Communities to adopt the 30th ATP without taking into account either the request by various Members of the TBT Committee to postpone its adoption until there was scientific evidence on the actual risk posed by nickel compounds, or the study presented by the industry that had brought new elements indicating that the proposed classification for nickel compounds could be based on wrong assumptions. It was pointed out that in this case the European Communities had adopted a disproportionate approach classifying nickel carbonates as a proven human carcinogen although there was no sound scientific evidence supporting this decision.

Bearing in mind that Article 2.2 of the TBT Agreement stated that regulations should not be more trade restrictive than necessary to fulfil a legitimate objective, Brazil invited the European Communities to review the classification of nickel carbonates under the 30th ATP, and not to extend the Category 1 classification to nickel compounds under the 31st ATP until the results of the studies conducted by the industry could be analysed.

Malásia (Tailândia, UE e China) x Brasil - Toys

Brazil – Toys (G/TBT/N/BRA/259)

The representative of Malaysia recalled concerns about a Brazilian notification on toys which had been raised by his delegation at the previous meeting of the Committee and pointed out that, since

then, bilateral discussions had taken place with the Brazilian delegation on the issue and a written communication had been sent to Brazil. However, no response had been received. He reiterated his delegation's request to Brazil that the technical regulation on toys be reviewed. In particular, he requested Brazil to accept the results of conformity assessment procedures of accredited conformity assessment bodies, without requiring the testing of Malaysian products to be conducted in Brazil. Additionally, both systems 7 and 5 certification procedures should be made available to Malaysian exporters.

The representative of Thailand recalled that at the previous meeting of the Committee, her delegation had noted that the INMETRO Decree resulted in unequal treatment for imports and was more trade restrictive than necessary. However, her delegation was concerned that no changes had been made to the Brazilian measure, which required imported toys be tested by lots or batches. This meant that the Brazilian regulation accorded less favourable treatment to imports in breach of Article 5.1.1 and also created unnecessary obstacles to trade in violation of Article 5.1.2, because it was more strict than necessary to give Brazil adequate confidence that imported toys conformed with its technical regulation on toy safety. There were other WTO-consistent alternative measures available to Brazil, such as testing in the country of export, especially when such testing was conducted by internationally recognized and accredited laboratories. She stressed that her delegation agreed with the objective to ensure that toys destined for children were safe. Nevertheless, such measures had to be applied in an equal way. She requested that the Brazilian Decree be brought into conformity with the TBT Agreement and that a written reply to comments sent be provided.

The representative of the European Communities pointed out that concerns remained about less favourable treatment of imported toys compared to domestically produced toys. It was his delegation's view that the so called "system 5" procedure, which was available only to domestically produced toys, was less burdensome than the so called "system 7" procedure which was available to imported toys. The European Communities appreciated Brazil's willingness to enter into bilateral discussions but urged Brazil to consider measures which would restore a level playing field between imported and domestically produced toys. He stressed that initial feedback provided by European Industry on the initial period of application of the new measures pointed to increasing delays for the release of imported toys into circulation in Brazil and to much higher costs compared to the previous regime. In addition, there were concerns about the abilities of the few test laboratories that had been agreed by INMETRO to perform the test required by the system 7 procedure.

The representative of the European Communities further highlighted that summer and autumn were crucial periods for shipment of toys in view of the Christmas sales and that the difficulties that had been reported in the initial period of application of the measures were likely to be exacerbated in the coming months. He invited Brazil to consider measures that would allow equal treatment of imported and domestically produced toys and to allow the recognition of results of tests carried out in the country of origin of the toys.

The representative of China pointed out that the Chinese industry had reported that, further to the introduction of the new testing process, an average of 70 days delay had been experienced. This created a significant burden for China's exports of toy products. He requested that Brazil ensure toy safety in a non-discriminatory and less trade restrictive manner and that the measures be brought into conformity with WTO obligations.

The representative of Brazil pointed out that the new conformity assessment procedures had been adopted under urgent circumstances and with the legitimate objective of protecting the health of consumers. The previous conformity assessment system had proved to be inefficient and several

cases of non-conformity, recalls and accidents had been reported in 2007. He noted that these urgent measures were not permanent, and that the adoption of a new and definite system of conformity assessment procedures for toys was under consideration by the competent authorities in Brazil.

UE e EUA - Registration Requirements for Medical Devices

Brazil – Registration Requirements for Medical Devices

The representative of the European Communities reiterated her delegation's concerns with regard to the Brazilian registration requirements for medical devices introduced by Resolution 185 but not yet notified under the TBT Agreement. The Resolution 185 required the submission of an economic dossier for each version and accessory of every product covered by the resolution. The procedure required the submission of data which was extremely difficult for economic operators to provide, and in part was confidential business information. The regulation was therefore considered burdensome and not practicable.

The European Communities appreciated Brazil's confirmation that the *Agência Nacional de Vigilância Sanitária* (ANVISA) sought to ensure transparency in the implementation of the measure, but economic operators were still facing several problems. In particular, it was not clear what would happen if the economic dossier was not submitted. For instance, it was the European Communities' understanding that if the dossier was not submitted within 30 days after notice of approval of product registration, the product would not be able to be sold. Moreover, it was unclear what would happen if a dossier was incomplete, and when or how the submitting company would be informed about the evaluation of the dossier. Finally, the representative of the European Communities stressed that the procedure of the resolution of disputes had to be clear, transparent and predictable. She encouraged the Brazilian authorities to continue their exchange of views with the economic operators, to provide replies to the concerns expressed and to consider further amending the resolution.

The representative of the United States appreciated Brazil's efforts to engage in a constructive dialogue on the concerns which had been raised in respect of the Resolution 185, and thanked Brazil for the detailed replies provided to industry stakeholders on their recommendations to help clarify the information requirements contained in the Resolution. He reiterated his delegation's view that the requirement to submit economic data was not related to the safety or efficacy of medical devices, and was unnecessarily costly and burdensome. Furthermore, industry had indicated that some of the information required was impossible to provide, either because the information did not exist or could only be provided by contacting other companies to obtain it, which raised potential antitrust concerns. It was also noted that such problems had already led ANVISA to deny commercialization for certain products.

The representative of the United States noted that ANVISA had been working with interested stakeholders and appeared to be in agreement with the need for greater transparency and specificity with regard to adjustments in the reporting requirements, particularly given the difficulties associated with fulfilling the Resolution’s expansive information requirements. However, Brazil still had not taken any official actions to clarify those requirements for importers, and ANVISA seemed to be inviting suppliers to disregard informational requirements contained in the Resolution that suppliers, in their own judgment, might feel were burdensome or impossible to fulfil. However, companies that did so would operate in the Brazilian market under conditions of great

legal and economic uncertainty because such flexibility was not set out in the text of the Resolution and, in practice, ANVISA did not let companies know whether they had complied once they had submitted their data. Such uncertainty had the potential to create unnecessary disruptions regarding trade in medical devices, ultimately to the potential detriment of the Brazilian public. Therefore, the United States urged Brazil to continue working with interested stakeholders to clarify the informational requirements of the Resolution and provide legal certainty for the industry on how to comply with them.

The representative of Brazil reiterated his delegation's position that Resolution 185 was neither a technical regulation nor a conformity assessment procedure. His delegation believed that in previous meetings Brazil had clarified why Resolution 185 was not covered by TBT provisions and did not need to be notified to the TBT Committee; therefore, those points were not reiterated.