SPECIFIC TRADE CONCERNS (*Retirado do documento G/TBT/M/52*)

New Concerns

EUA, UE, Suíça x Brasil - Instructions for Registration for Labels of Imported Products of Animal Origin (G/TBT/N/BRA/385)

Brazil – Instructions for Registration for Labels of Imported Products of Animal Origin (G/TBT/N/BRA/385)

While the representative of the United States appreciated that Brazil had postponed the implementation of its new labelling requirements for products of animal origin from 1 October 2010 to 1 January 2011, concerns persisted. It was the US delegation's understanding that according to section 2 Field 6.2 of Brazil's Circular Letter, US regulatory authorities would be required to certify to Brazilian market requirements. Although they would have the authority to certify that US food products were produced in accordance with U.S. requirements, US regulatory authorities would not be able to certify products for compliance with Brazil's private market standards, which were outside the scope of US legal authority. As a consequence, the US representative claimed that these requirements would significantly disrupt trade. In addition, the representative of the United States pointed at another concern related to Field 10.1 of the Circular Letter (Field 10 of the Registration: "Composition" and "Ingredients"), which would require suppliers to list all of their ingredients and their respective percentage in the product in order to be registered. The representative of the United States was concerned that this requirement could result in the disclosure of confidential information. Instead, the US delegate proposed to list ingredients in descending order as a less onerous option.

The representative of the European Union also expressed appreciation for the postponement of the entry into force of the measure and the granting of a longer comment period. She asked for clarification about the rationale for requesting that all labels of products of animal origin be approved before they could be marketed in Brazil. In addition, she asked for an update on the state of play of the notified measure and looked forward to receiving a written reply to her comments from the Brazilian TBT enquiry point.

The representative of Switzerland echoed the concerns raised by the representatives of the United States and the European Union and drew the Committee's attention to three points. First, since product labels already contained an expiry date, she asked if Brazil could provide further clarification for the reasoning behind the requirement to include the date of manufacture. Second, since Swiss companies exporting to Brazil were already subject to Brazilian approval procedures, she requested clarification regarding the separate approval process for these labels. Finally, the Swiss representative was pleased to hear that Brazil had extended period for comment.

The representative of Brazil recalled that his delegation had provided several clarifications on the measure at issue during the last meeting of the Committee on Sanitary and Phytosanitary Measures (the "SPS Committee"). He noted that there had been no indication whatsoever of interruptions or difficulties in the flow of exports to Brazil of products covered by the measure. Second, the objective of the measure was to facilitate trade by simplifying the formalities for the registration of labels, without adding or changing any substantive requirement, thus facilitating the process of complying with mandatory registration requirements for products of animal origin. Finally, the entry into force of the measure had been postponed to 1 January 2011 and the comment period to 1 November 2010 in order to allow for interested parties to become acquainted with the measure and so as to grant an additional transition period. Regarding the comment of the European Union about the date of adoption, the Brazilian representative explained that April 2010 had been the date on which the public consultation on the draft regulation had started. Therefore, Brazil remained open to comments and would respond to them until January 2011, the date of entry into force.

UE, EUA, México, Suíça, Singapura X Brasil - Health Products (G/TBT/N/BRA/328)

Brazil – Health Products (G/TBT/N/BRA/328)

The representative of the United States reiterated concerns on Resolution 25 requiring Good Manufacturing Practice (GMP) inspections of medical devices before re-registration and new registration of medical devices. Concerning re-registration of medical devices, the representative welcomed reports from United States industry that ANVISA was demonstrating flexibility to enable products to remain on the market pending inspection. However, United States industry was also reporting lengthy delays for registration of new medical devices and was concerned it could take two years to clear the current backlog. The delays for United States medical devices exports to Brazil had resulted in patients being denied access to innovative medical technologies. The United States was disappointed by this development given assurances from Brazil at the last TBT Committee meeting of not intending to disrupt the entry of medical devices into Brazil due to their essential nature. The United States requested Brazil to provide sufficient resources for both its inspection and registration programs in order that new applications could be processed as efficiently as possible so as to ensure trade in these new medical device products could resume. The United States would continue to monitor the situation closely.

The representative of the European Union noted that at the previous TBT Committee meeting Brazil had provided assurances that there would be no disruption of imports of medical devices into Brazil. However, according to the Technical Note 1/2010 of ANVISA of 5 October 2010, any company wishing to register a new medical device would have to present a GMP certificate as part of the application process for registration. If the GMP certification had been requested after the deadline of 21 May 2010, a receipt of the request for a GMP inspection would not be accepted. The European Union's understanding was that in the case of applications for renewals of registration and in the absence of a new GMP certificate, companies would be able to submit the receipt of the request for a GMP inspection in order to advance the application process. If this understanding was correct, the European Union expressed concerns that this might potentially lead to restrictions of new medical devices not previously registered into the Brazilian market, with a possible negative effect not only on trade, but also on access of Brazilian consumers to the best and most advanced medical care.

The representative of Switzerland said Switzerland supported the intention behind ANVISA resolution number 25/09 which aimed at guaranteeing the quality of medical devices sold in Brazil in order to protect human health. However, Switzerland remained concerned about the change in Brazil's regulation regarding market access for medical devices classified in Brazil under risk categories 3 and 4. He reiterated particular concern that Brazil no longer recognized quality inspection results based on the International Standard ISO 13485 for medical devices. At the last TBT Committee meeting, Brazil had informed Members that inspections necessary for granting certificates of good manufacturing practices had been carried out in a timely and orderly manner by ANVISA. In addition, Brazil had stressed that the sanitary authorities of Brazil had not received any complaints related to the importation or commercialization of medical devices. In this regard, the representative informed Brazil that the Swiss medical device industry continued sharing with the Swiss Government difficulties related to the Brazilian inspection regime, which Switzerland would like to discuss with Brazil on a bilateral basis.

The representative of Brazil said that since Resolution RDC 25 of ANVISA had entered into force in May 2010, there had not been any reports of trade disruptions related to the implementation of the measure. Imports of health products into Brazil had not been affected and companies had managed to comply with requirements of the resolution. The representative added that ANVISA had been able to respond to all requests of inspection in a timely and orderly manner.

Regarding the United States' comment of an alleged backlog of two years for inspections to be concluded on new registrations, the representative of Brazil said Brazil would talk to the United States bilaterally in order to find out what data the United States had used, given that the regulation was in force for only around six months. The representative shared with Members some statistics regarding the pace of inspections that had been conducted by ANVISA. He said ANVISA had performed 171 inspections so far and 50 more inspections were to be concluded by the end of 2010. Moreover, 397 inspections were expected to be performed in 2011, of which 40 were already scheduled.

Regarding Switzerland's comment on non-acceptance of ISO 13485 certifications, the representative said Brazil had already provided extensive explanations on this issue and he invited Switzerland to consult the minutes of the last TBT Committee meeting. He emphasized that it was essential that companies revalidate their existing registration and request the necessary inspection from ANVISA well in advance. This request should be submitted six months before the expiration of the existing registration. The representative recalled that Resolution 66 of 2007 of ANVISA ensured that if a company requested a GMP inspection at least 120 days before the expiration of its existing certificate, the latter could remain valid if no problem had occurred with the current certification.

EUA, México e UE x Brazil – Alcoholic Beverages (G/TBT/N/BRA/348)

Brazil – Alcoholic Beverages (G/TBT/N/BRA/348)

The representative of the United States noted that Brazil had issued a proposed revision to this regulation in September and several matters the United States had earlier raised had been addressed. However, a number of issues remained unresolved. The representative noted the proposed revision omitted a previously included requirement prohibiting the use of abbreviations for common terms. He requested confirmation from Brazil as to whether abbreviations for common terms would be allowed.

The representative said the United States agreed with the intent behind Brazil's plan to prohibit illustrations on labels which could mislead consumers. He referred to Article 8 of the measure stating that labels that displayed a drawing, figure or illustration of any ingredient used to prepare the beverage must indicate all of the ingredients of animal or plant origin, regardless of quantity. The representative requested clarification as to whether the proposed revision to the regulation retained the prohibition against illustrations or statements on the label of ingredients that were not present in the composition.

The representative further sought confirmation that the provision concerning illustrations would not apply to fanciful drawings and illustrations which were well-established elements of trademarks and which did not purport to represent ingredients. Examples included the Grey Goose logo which pictured flying geese, the "striding figure" portrayed in the Johnnie Walker logo, and the Bacardi bats, which represented the fruit bats that inhabited the distillery where the rum had been first produced.

The representative sought explanation of the requirement that cans bear the statement "This container must be washed prior to consumption". Specifically, did this requirement address a health or safety concern? Also, the representative expressed concern that the requirement in Article 13(II) of the draft proposal would effectively bar the use of the trademarks of certain internationally-traded spirits brands, including spirits produced in the United States. Even where such terms had not been incorporated expressly into a registered trademark, some of them have been used for years without incident on the labels of internationally-traded distilled spirits. The representative requested Brazil to explain the rationale for its decision to restrict the use of such terms.

The representatives of Mexico and the European Union requested an update from Brazil on the revision of the proposal.

The representative of Brazil informed the Committee that Brazilian authorities were still examining comments received on the draft regulation on beverage labelling. Members comments would be taken into account before publication of the final measure. The representative said although the deadline for submitting comments on the draft proposal had expired, Brazilian authorities remained available for questions concerning the proposal's content. Authorities in the Ministry of Agriculture had received visits from representatives of other countries and remained open to dialogue.

The representative of Brazil said the draft measure had the legitimate objective of guaranteeing an adequate level of protection and information to consumers, without creating an unnecessary obstacle to the regular flow of beverage exports to Brazil. Requirements in the draft regulation would apply equally to domestic and imported alcoholic beverages.

The representative explained that because comments from Members were still being processed, it was not possible to provide definitive answers on most topics. However, he provided some preliminary remarks. On the abbreviations provision, the objective was to avoid consumers being misled. On illustrations, the objective was to avoid illustrations leading to confusion among consumers. The representative assured the United States there was no intention to prohibit wellestablished pictures associated with trademarks, such as the striding Johnnie Walker figure.

Regarding expressions such as "hand-crafted", "colonial" or "home-made", the draft regulation aimed
to prevent their indiscriminate use. Such expressions could sometimes mislead and confuse consumers, giving the wrong idea of superior product quality.

The representative reiterated that comments received would be taken into account and Brazil would try not to make the provision restrictive of trade. As soon as the revised proposal was published, it would be notified to the Committee.