SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/50)

New Concerns

Mexico x Brasil - Food registration and notification procedures (G/TBT/N/BRA/362)

Brazil – Food registration and notification procedures (G/TBT/N/BRA/362)

The representative of Mexico noted her delegation's concern with Brazil's draft technical regulation on the list of foods that needs to be registered before marketing. It was Mexico's understanding that the notified draft regulation established the procedures required for food registration, as well as the notification procedures for food products exempt from registration. The regulation seemed to apply to the procedures for the registration and notification of domestic and imported food products, food additives, food processing aids and packaging. However, it was not clear what criteria would be used to determine whether or not a product was subject to registration before ANVISA. Concern was also expressed with regard to the obligation for food products sold in Brazil to be obtained, processed, packaged, transported and stored under conditions that did not produce, develop and/or aggravate physical, chemical or biological substances that endangered consumer health. The representative of Mexico invited Brazil to provide more information on this provision and the scientific evidence that justified its adoption.

The representative of Brazil explained that this draft technical regulation was aimed at facilitating trade by removing the obligation to register some products at local and regional offices of Brazilian health authorities. He emphasized that the main objective of this measure was to substitute the previous procedures of registration with a quick, online self-declaring notification. In this regard, the representative of Brazil noted that a notification form for the marketing of such products would be made available on the ANVISA's website. The notification form had to be filled out by any company involved in the supply chain of the products covered by the regulation, for example producers, importers and distributors. The delegate of Brazil explained that one of the criteria considered in selecting the products covered by the new regulation, i.e., products not subject to mandatory registration, was whether they were directed at infant and young child nutrition. Since these population groups were granted special rights by Brazilian legislation, most of these products remained subject to existing regulations. Finally, the representative of Brazil said that food packaging not produced with new technologies would also be covered by the new regulation, and therefore exempt from mandatory registration. His delegation was ready to provide any further clarification to interested Members.

UE, Mexico, EUA x Brasil - Alcoholic Beverages (G/TBT/N/BRA/348 and Suppl.1)

Brazil – Alcoholic Beverages (G/TBT/N/BRA/348 and Suppl.1)

The representative of the European Union raised concerns about Brazil's Ministerial Act No. 327 of 17 September 2009, which established certain criteria for the labelling of beverages as well as the procedures for production and bottling. The European Union was particularly concerned about the possible negative impact that some of the proposed labelling obligations would have on EU economic operators, which would have to redesign their labels for the Brazilian market only. Some of these requirements appeared to be particularly burdensome for EU exporters, such as: (i) the obligation to indicate the alcohol content on the front main label; (ii) the prohibition to use any abbreviations, including well-established ones, even when the respective information was provided on the label on a voluntary basis; and (iii) the requirement to translate all terms on the label into

Portuguese, including those with which Brazilian consumers were accustomed (e.g. "light" or "diet"). The EU representative invited Brazil to explain why a specific registration sign for imported products was considered necessary and to clarify whether this sign had to be part of the permanent label. It was her delegation's view that a registration sign on the permanent label would constitute a considerable burden for importers, which would need to modify their labels to include such a sign. In this regard, Brazil was asked to clarify why this requirement applied to imported goods only and what the nature of the rationale was for departing from the national treatment obligation. Finally, the EU representative noted that written comments had been sent to Brazil in December 2009 and her delegation looked forward to receiving a reply.

The representative of Mexico joined the concerns expressed by the European Union. With regard to the prohibition to use any abbreviations, she pointed out that abbreviations were often recognized by the Brazilian consumers. Mexico also expressed concern regarding the obligation contained in Article 8 of the proposed regulation, which required any label including a design, picture or illustration of any ingredients used to make a beverage to include all ingredients of animal or vegetable origin, regardless of their quantity. This requirement appeared to be very burdensome for products made with different ingredients, such as Tequila. In this regard, Brazil was asked to clarify whether it was obligatory to include the pictures of all ingredients or only the main ones. Concerns were also expressed about the requirements contained in Article 13, para. 12 of the draft Brazilian regulation, which prohibited the use of certain expressions associated with a trademark or the commercial name of the beverage, such as "handcraft", "colonial", "home-made", "family", "natural", "reserve", "special reserve" or similar. It was Mexico's view that this provision did not bring any benefits to Brazil and would effectively impede the marketing of internationally recognized trademarks, which traditionally used these terms. The representative of Mexico also noted that Articles 25 and 26 contained an obligation for imported beverages to be labelled with the importer's registration number. She stressed that this label could notably increase costs for industry. Finally, the representative of Mexico noted that the labelling requirements would come into force one day after the publication of the regulation and that a transition period of 180 days had been provided to adapt to these changes. Given that these new requirements did involve important changes in the design and printing of the labels, Brazil was urged to extend the transition period to 365 days and to clarify whether the new requirements would only be applied to beverages labelled after the entry into force of the regulation or also to beverages already on the market at the end of the transition period.

The representative of the United States shared some of the concerns raised by the other delegations and informed the Committee that written comments on this measure had been sent to Brazil. He stressed that the proposed requirements had the potential to negatively impact trade in wine, beer and spirits. For example, it appeared that the new requirements could prohibit the use of certain common abbreviations, illustrations and expressions commonly used in the labelling of alcoholic beverages. Concerns were also expressed about the need for mandatory formatting and advisory statements, and about the potentially insufficient transition period provided for suppliers to comply with these requirements. The representative of the United States noted that his delegation looked forward to further discussions with Brazil on this issue.

The representative of Brazil thanked the delegations that had sent written comments on Ministerial Act No. 327 and noted that these comments were being processed and a reply would be provided in due time. He explained that the additional labelling requirements for imported products proposed by the new regulation were aimed at harmonizing the requirements imposed on both national and foreign products. He said that there was no intention to differentiate between domestic and foreign producers and stressed that it was in Brazil's interest to bring the new regulation closer to procedures that were commonly used by other WTO Members. The representative of Brazil also informed the Committee that a deadline for the conclusion of the amending process of this draft regulation had not yet been set. Although the period for comments had expired, the Brazilian authorities would continue to take into account the comments sent on this regulation and its implementation. Finally, with regard to the issue of the pictures to be included on the label, as

raised by Mexico, the representative of Brazil explained that the objective of the provision was only to prohibit the display of elements that were not contained in the product.

UE, Suíça, Canada, EUA x Brasil - Health products registration (G/TBT/N/BRA/328)

Brazil – Health products registration (G/TBT/N/BRA/328)

The representative of the European Union once again raised the issue of Brazil's new Good Manufacturing Practice (GMP) requirements for health products. In particular, she returned to the issue of Brazil's non-acceptance of certificates proving conformity with ISO Standard 13485 as evidence of compliance with its GMP requirements. In bilateral exchanges on this issue, Brazil had indicated that it could no longer accept ISO certification, due to the fact that ISO Standard 13485 only focused on the quality of the manufacturer, and not on risk control and product quality, which were the main objectives of the Brazilian GMP requirements. The EU representative highlighted that this answer did not provide adequate justification with regard to Brazil's refusal to continue to accept certificates proving conformity with the international standard. According to the EU's assessment, the scope and objectives of ISO standard 13485 were exactly the same as those of the Brazilian requirements for the manufacture of medical devices. Furthermore, many of the new Brazilian requirements did not go further than those provided for by ISO Standard 13485 and therefore did not aspire to a higher level of protection of public health.

She stated that the European Union found it difficult to understand why an international standard that had been developed specifically for medical devices, and whose objective was to protect public health through the use of an appropriate quality management system was considered by Brazil as ineffective or inappropriate in order to achieve the legitimate objectives pursued. She therefore, requested Brazil, in accordance with Article 2.4 of the TBT Agreement, to base its new GMP requirements on the international standard and to continue to recognize this standard as equivalent to its own requirements on GMP. The EU representative welcomed Brazil's continued willingness to discuss this issue with its trading partners, and reiterated her delegation's interest to bilaterally discuss possible solutions for the recognition of certification carried out by EU notified bodies.

The representative of Switzerland shared the concerns expressed by the European Union. She noted that her country remained concerned about whether Brazil would continue to recognize quality inspection results based on the internationally used quality standard, ISO 13485. She stated that if Brazil no longer accepted ISO 13485 certification as evidence of compliance with the Brazilian requirements, Switzerland would encourage Brazil to explain to the Committee the reasons for such a refusal.

The representative of Canada expressed his country's concern with resolution RDC 25 and its implementation. He appreciated the opportunity to discuss Canada's concerns with Brazil on a bilateral basis.

The representative of the United States thanked Brazil for the steps it had taken thus far to provide additional details to industry on the inspection process. He requested Brazil for a status update on further steps it was taking to ensure that trade in medical devices would not be disrupted after the 22 May 2010 deadline. The United States would continue to closely monitor the situation.

Concerning the point raised by the United States, the representative of Brazil underlined that trade flows would not be negatively affected by this measure. She noted that the Brazilian authorities had confirmed that Anvisa would be able to inspect all the companies once they were required to do so, preventing in this way an undesirable interruption of trade flows. The Brazilian representative reminded the Committee that the inspections had been scheduled while taking into account the date in which the existing registrations would expire, and not the date of entry into force of the new

regulation. In that sense, it was important to remember that companies which would register new products or products where registration was about to expire were encouraged to apply for their certification within a reasonable period of time. Furthermore, Anvisa had received 115 requests for certification and, until now, all of them had been processed. She highlighted that 45 inspection visits had taken place successfully and that 70 requests for inspection visits were already scheduled.

Concerning the points raised by the European Union and Switzerland, the representative of Brazil stressed that regulation RDC 25 of 2009 only applied to products under classification of higher risks for human health. As a result, Brazil did base its procedures on ISO standards but developed further procedures for these specific products. She said that Anvisa's Regulation 59/00 provided for the classification of products in four different types of risk to human health; Regulation 25/09 only applied to those products classified under risk 3 and 4. For the remaining products, she noted that companies were required to only fill out an electronic form which was available at Anvisa's website. The representative of Brazil said that additional clarifications were available at Anvisa's website and stressed that Brazil was open to holding bilateral meetings with Members.