SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/43)

Previously raised concerns

Brasil x UE - Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH)

European Communities - Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH) (G/TBT/N/EEC/52, Add. 1-4 and Add.3/Rev.1)

The representatives of Australia, Brazil and Thailand shared concerns expressed by other delegations on REACH.

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 reiterated the points made by others and stressed the need for a scientific basis for the classification of nickel compounds. Like other delegations, Brazil was concerned that the classification could be extended to other nickel compounds with possible impacts on the REACH system. He sought confirmation that the 30th ATP would be suspended.

EUA (UE e Suíça) x Brasil - Registration requirements for medical devices

Brazil – Registration requirements for medical devices

The representative of the United States wished to revert to an issue raised at the last meeting of the Committee in respect of medical device registration requirements in Brazil. The United States regretted that Brazil had failed to notify the WTO of Resolution 185 on medical device registration which would have afforded Members the opportunity to provide comments and have those comments taken into account. The United States disagreed with Brazil's position that Resolution 185 did not need to be notified to the TBT Committee; it was a registration system for medical devices and it appeared to contain aspects of both a technical regulation and a conformity assessment procedure. As had been noted in July 2007, the United States was concerned that the resolution did not seem to be related to an analysis of safety or efficacy of medical devices; it appeared to be burdensome and unnecessary and could potentially disrupt trade in medical devices. The United States industry, in concert with Brazilian counterparts, had raised concerns with Agência Nacional de Vigilância Sanitária (Anvisa) on these issues for the past 18 months. For example Brazil required suppliers wishing to register or re-register medical devices in Brazil to provide manufacturers pricing data from the country of origin as well as from ten other enumerated countries. It was the US understanding that there existed no independent objective publication of product comparisons and no independent reliable source of comparative product prices in the medical device industry. The national anti-trust laws prohibited companies from contacting each other to acquire this information. It was therefore unclear how it was possible for a medical device manufacturer to supply the pricing information required by Brazil. However, even if the data were available, it was not necessarily clear how a potential registrant was to determine which products would provide an appropriate price comparison. The medical device industry included over 10,000

different types of medical devices and new ones were introduced every month. For each type of product there could be many different feature combinations and other variations. These factors could make developing an appropriate price comparison extremely difficult.
The United States appreciated the efforts of Brazil to meet with the United States recently and urged Brazil to meet with relevant stakeholders to discuss their concerns as well, and to discuss their ideas for achieving a successful resolution of this matter. Brazil had noted that its regulators had already adopted flexible interpretations of many of the provisions of Resolution 185 on an ad hoc basis. The United States welcomed this development and hoped that a stakeholder meeting would take place in the near future to clarify and document these points of flexibility and resolve other outstanding concerns.

The representative of the European Communities shared the concerns expressed by the US delegation regarding Regulation 185 of 13 October 2006 adopted by the Brazilian regulator Anvisa, the Brazilian health agency. The European Communities also considered that the measure had, at the very least, to be considered a conformity assessment procedure as defined in the Annex to the TBT Agreement that stated, inter alia, that registration procedures were conformity assessment procedures. The new requirements regarding the provision of highly sensitive information was of great concern to the European industry which continued to seek dialogue with the Brazilian regulator, so far without success. It was regrettable that the measure had not been notified to the Committee and the EC delegation therefore requested more information about the measure.

The representative of Switzerland stated that reactions from the Swiss industry indicated that it was difficult to fulfil the data submission requirements of Resolution 185, especially because of the obligation to disclose confidential information. She asked Brazil to clarify the legitimate objective of the measure and requested that it be notified to the TBT Committee in order to give all Members the possibility to submit comments.

The representative of Brazil stated that his authorities had not notified the regulation because they considered it neither a technical regulation nor a conformity assessment procedure. It was not an issue that needed to be discussed in the TBT Committee. The regulation in question required that companies provide some information regarding prices in the process of registering medical products but this process of registration did not stop even if the company did not provide the information. Nevertheless, Brazil wanted to ensure maximum transparency and would remain open to discuss the matter bilaterally with interested Members.

UE x Brasil - Mandatory certification of batteries

Brazil – Mandatory certification of batteries

The representative of Brazil wished to follow-up on a concern raised by the European Communities at the previous meeting of the Committee regarding batteries. He informed the Committee that this regulation, after the consultation process, had been approved by the national agency of telecommunications. The measure was expected to enter into force in February 2008. He recalled that the European Communities had asked if it would be possible to obtain certification by means of a self declaration (Supplier's Declaration of Conformity - SDoC). Although SDoC was not possible in this case there were some types of required tests that could be performed in a foreign country and these types of tests generally were those that required more time. This meant that if a company had adequately done those tests in a foreign country, or in Brazil, it would also be necessary to do the more rapid tests which would facilitate the trade of the batteries.

The representative of the European Communities noted that this information appeared to be a positive step forwards – but she would need to discuss it with experts before responding. Nevertheless, one concern that remained was the requirement for third party certification.