SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/44)

New Concerns

Malásia (Tailândia e UE) x Brasil - Toys

Brazil – Toys (G/TBT/N/BRA/259)

The representative of Malaysia raised an issue with respect to a Ministerial Act affecting toys, notified in October 2007 under Article 5.7.1 of the TBT Agreement as a matter of urgent protection of human health. The measure had entered into force in August 2007 and no opportunity had been provided for WTO Members to make comments. His delegation acknowledged Brazil's right to enforce a technical regulation for the purpose of ensuring safety of toys in its market. However, Malaysian manufacturers exporting toys to Brazil were encountering difficulties due to the new requirements for mandatory sampling and testing of samples for all toys in selected laboratories situated in Brazil, and also due to the non-recognition of test reports from any other laboratory, even if accredited. Additionally, the option of pre-market approval as an alternative which was available to Brazilian manufacturers was not available to Malaysian manufacturers.

The representative of Malaysia noted that bilateral discussions had been taking place on the issue, and Brazil's willingness to engage in a dialogue was appreciated. However, his delegation was of the view that the regulation was not consistent with the TBT Agreement and invited Brazil to bring it into line with obligations under the WTO.

The representative of Thailand echoed the concerns raised. Her delegation understood Brazil's reason of consumer protection, and had no objection to the required toxicology test for toys. However, her delegation considered that Brazil's requirement that imported toys should be tested under System 7 only constituted an unequal treatment, since local products had the option of either System 5 or 7. The measure was considered discriminatory in nature.

The representative of Thailand requested that Brazil accept test reports of laboratories accredited under international umbrellas such as ILAC-IAF. She stressed that Brazil should have confidence in the international standards that had been developed with the contribution of many Members, including Brazil. She asked Brazil to give consideration to less trade-restrictive alternatives and stressed that, should Brazil not introduce modifications soon, bilateral discussions should be pursued to settle the problem.

The representative of the European Communities sought clarification with respect to the rationale for the separate certification procedures for imported toys as compared to domestically produced toys. The European Commission had been informed by the toy industry of longer delays in the release from customs of imported toys due to the new testing requirements, which had been enforced due to the changes in the relevant procedural law.

The representative of Brazil pointed out that the new requirements for the certification of imported toys had the legitimate objective of protecting consumers' health, especially children, for whom those products were destined. The previous requirement for certification had proven to be insufficient to guarantee the safety of imported toys and several cases of accidents related to those toys had been reported in 2007. He explained that the new requirements applied to all imported toys, regardless of their brand or country of origin. Although delays in the testing and certification process had occurred during the initial months of the implementation requirements, the situation had been normalized and the five laboratories that were accredited to issue these certificates were

currently working below their full capacity. He noted that bilateral talks had already been held with the three countries that had raised concerns and that his delegation was ready to engage in further discussions.

Previously raised concerns

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 thanked the European Communities for the recently circulated answers about the proposed classification for nickel carbonates, under the 30th ATP and welcomed the announcement that the 31st ATP would be notified to the TBT Committee before its adoption. However, without prejudging the actual risk posed by the nickel carbonates, his delegation was not convinced that the classification as proven human carcinogens was justifiable with the scientific evidence as presented by the European Communities. He noted that it had been argued that the hazardous properties listed in the 30th ATP had been discussed by OECD experts who came to the same conclusions as the one proposed by the EC. However, he stressed that the OECD study case was a draft initial assessment profile of nickel compound chemicals, which recognised at the outset that there was no data available about nickel carbonates' carcinogenic effect on human health. The main focus of the OECD study was that five substances were candidates for further work, since there were indications of risks to human health. He pointed out that this was not the same conclusion as the one proposed in the 30th ATP, since the latter dismissed the necessity for further work by skipping testing requirements and jumping to the conclusion that nickel carbonates were proven human carcinogents.

The representative of Brazil requested to the European Commission to postpone the adoption of the 30th and 31st ATP until there was reliable scientific information on the actual risk posed by nickel compounds. He also asked why this issue had not been handled in the context of REACH legislation within existing timetables for testing and evaluation. In this regard, industry was conducting a programme to generate relevant data that could contribute to the appropriate science based assessment and classification of nickel compounds. Bearing in mind that TBT Article 2.2 stated that regulations should not be more trade restrictive than necessary to fulfil a legitimate objective, Brazil invited the European Communities to wait until such data became available.

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 and Brazil shared many of the concerns raised by previous speakers. Australia in particular was concerned about transparency and the impact of REACH on non-EC producers.

EUA (UE, Canadá e Suíça) - Registration requirements for medical devices

Brazil - Registration requirements for medical devices

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 above-mentioned measure, although his delegation still believed that Resolution 185 should have been notified to the WTO. One issue of concern was related to the difficulties with fulfilling the expansive information requirement as originally formulated and Brazil's efforts to address this, including through additional outreach to industry, were welcome. Nevertheless, he invited Brazil to take official action to clarify guidance for importers without delay. Greater clarity on the objectives of Resolution 185 would also be welcome, so that all involved parties could gain a sense of how those objectives could be met through this measure.

The representative of the United States further welcomed Brazil's receptivity to the suggestions made by US industry regarding their perceptions of the burden and uncertainty associated with this regulation. He invited Brazil to improve the ability of US industry to comply with the measure, while minimizing any unnecessary disruption to trade in medical devices through additional denials of commercialization.

The representative of the European Communities agreed with the points made by the United States. It was also his delegation's view that the measure should have been notified under the TBT Agreement. He 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 Canada echoed the comments made and noted that Canadian industry was seeking clear, transparent and predictable guidance for importers.

The representative of Switzerland shared the concerns expressed and believed that, since the TBT Agreement was applicable to the Resolution, this should have been notified.

The representative of Brazil reiterated his delegation's position that the Resolution 185 was neither a technical regulation nor a conformity assessment procedure. He stressed that the definition of a technical regulation in the TBT Agreement and the Appellate Body decision in the EC Asbestos case were illustrative of how to determine if a regulation was a technical regulation or not. A technical regulation had to be applicable to an identified product or group of products, define the characteristics of the product and determine that compliance with those characteristics was mandatory. While Resolution 185 was applicable to an identified group of products, it did not lay down any product characteristics that medical devices had to comply with. Resolution 185 only required producers to declare some economic information about medical devices.

The representative of Brazil stressed that Resolution 185 was not a conformity assessment procedure either, since it did not establish procedures to determine if medical devices fulfilled relevant requirements in technical regulations or standards as provided for in the definition contained in the TBT Agreement. Therefore, Resolution 185 was not covered by TBT provisions and did not need to be notified to the TBT Committee. He pointed out that the *Agência Nacional de Vigilância Sanitária* (Anvisa), had sought to ensure transparency in the process of elaboration and in the implementation of the measure. Public consultations were held, comments from companies and other stakeholders were taken into account, and time was given for companies to adapt to the new requirements. Representatives from the US, the EC, Canada and the private sector had also

met with Anvisa to clarify remaining doubts. His delegation was ready to continue to provide clarification about the measure bilaterally to interested Members.