SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/49)

***New Concerns***

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

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

The representative of Canada welcomed steps taken by Brazil to ensure that the new regulation by ANVISA was understood by its trading partners and their respective manufacturing facilities and that the regulation did not create an unnecessary barrier to trade. Canada had understood that, to date, Brazil had received 89 requests for inspection, and had arranged meetings with the majority of these companies. Canada requested Brazil to provide further data with regards to the exact number of certifications that ANVISA anticipated would be necessary.

The delegate from Canada asked how the inspection, certification and registration would work. She also asked for clarification on whether companies which were not yet required to apply for certification because their registration had not expired would still be in a position to participate in public bids, or whether these companies would be disqualified from bidding and what their relationship would be with companies that were already certified.

Canada expressed concern that ANVISA might not be able to carry out all of the inspections necessary in the timeframe set out. The Canadian delegate therefore proposed that in the event that the required inspections were not carried out, Brazil should commit to granting exemptions to Canadian products already certified to internationally accepted Quality System Requirements (e.g. US Food and Drug Administration or Health Canada) and allow such exemptions to remain in place until Brazil had the capacity to inspect Canadian facilities.

The Canadian representative welcomed Brazil's efforts to inform interested governments as well as to the private sector to explain in more detail how to fulfill the requirements of this new regulation. Canada would also be interested in receiving in writing information pertaining to requirement of the inspections, the fees associated with these inspections, how companies applied for these inspections, and whether a company would be required to undergo an inspection each time it applied for the Good Manufacturing Practices (GMP) certificate from ANVISA. The Canadian delegate also asked whether it was possible for a company to extend their GMP certificate by an additional year if the company had already been inspected and had no records of non-compliance registered.

Finally, Canada emphasized that these concerns were raised independent of good cooperative activities between Health Canada and ANVISA regarding the regulation of pharmaceuticals and medical devices. In this respect, Canada appreciated the efforts Brazil had made to accommodate the concerns of trading partners.

The representative of the European Communities echoed Canada's comments. She was grateful for Brazil's clarification provided at the last Committee meeting. The European Communities understood from Brazil's answer that Brazil would stop accepting the ISO 13485 certification as evidence of compliance with GMP requirements and that Brazil intended to introduce new GMP requirements in this respect. The European Communities noted that these requirements seemed to diverge from the ISO standard 13485 which was the main international standard on quality management systems. Brazil had not given any justification why this standard would be ineffective or inappropriate to be used as a basis for the new requirements. The EC delegate argued that in the absence of such a justification, the new requirements had to be based on the relevant ISO standard as set out in Article 2.4 of the TBT Agreement.

With respect to the certification procedure, the representative of the European Communities stressed that note had been taken of Brazil's assurance at the last Committee meeting that ANVISA possessed the operational capacity to certify the companies that requested to be certified. In this context, the EC delegate also thanked Brazil for the important explanations given in a meeting between representatives of different Members and the Brazilian authorities in Brasilia at the end of October and requested confirmation that only those producers whose current certification would expire before the 22 May 2010 would need to have the new certification by this date. She further pointed out that the European Communities would closely observe the certification process, since industry had still expressed concerns that that there was a risk that this process would not be carried out in a timely manner, especially with regard to new products that needed to be certified. Finally, the representative of the European Communities proposed to discuss with Brazil possible solutions for the recognition of certification carried out by EC notified bodies.

The representative of Mexico supported the concerns expressed by Canada and the European Communities. In addition, she requested that Brazil carry out a seminar on the topic for national experts from Mexico.

The representative of Switzerland asked to receive a written response to the concerns raised and in particular to those about the transitional period foreseen during which medical devices could still be exported to Brazil. She said that Switzerland remained concerned about the question whether Brazil would continue to recognize quality inspection results based on the internationally recognized quality standard ISO 13485. This reliance on internationally recognized quality inspections would represent the same approach that the Swiss Government currently followed and was also consistent with the approach recommended by the Global Harmonization Task Force. If Brazil no longer accepted ISO 13485 certification as evidence of compliance with the Brazilian requirements, Switzerland urged Brazil to give the reasons for such a refusal.

The representative of the United States recalled that at the June meeting of the TBT Committee the United States had outlined its concerns regarding Brazil's inspection requirement for certain medical devices. His delegation noted that productive meetings had occurred between the US Food and Drug Administration (FDA) and Brazil's ANVISA during the medical device information exchange forum in Brasilia in September, and that the two agencies had agreed to further technical talks. The United States welcomed the ANVISA initiative to organize a meeting with local industry representatives and officials from various embassies to discuss industry's concerns and its offer to provide a technical note with replies to the questions raised by industry about the registration and inspection processes.

The US delegate emphasized that Brazil had clarified that class 1 and 2 devices would be exempted from the inspection requirement, that the inspections would only apply to the last place of manufacture and not to all the supplier facilities, and that only facilities that manufactured devices subject to re-registration or new registration would need to be inspected by 22 May 2010. The United States also noted that ANVISA had been hiring additional inspectors and apparently had started scheduling inspections as well. These were all very positive developments, and the United States hoped that Brazil could confirm these points in writing. However, the U.S. delegate conveyed serious concerns from US industry about ANVISA's ability and resources to conduct all the inspections by May 2010 as well as for subsequent inspections. The concern was that the implementation of this measure could substantially disrupt trade and jeopardize the adequate supply of essential medical devices to the Brazilian market.
The US delegate welcomed ANVISA's efforts to provide a technical note to clarify the application process. At the same time, he urged Brazil to clarify the number of facilities that were coming up for re-registration before the implementation date, and indicated that it would be helpful if ANVISA could share this information. Finally, he stressed the fact that the United States would monitor the situation closely and would work together with Brazil to ensure that trade in safe and effective medical devices was not disrupted.

The representative from Brazil offered some additional clarification to the TBT Committee on ANVISA Resolution number 25. He first noted that measures of the same nature were actually adopted by several other countries, and were justifiable as they pursued the legitimate objective of protecting human health. He recalled that the Certificate of GMP for medical devices that would be required from foreign companies exporting to Brazil was already required from domestic Brazilian producers and therefore would not constitute a discrimination against foreign producers. He emphasized that the main objective of the Brazilian authorities was to ensure access to good quality medical devices for the Brazilian population. Consequently, the Brazilian Government had no intention of implementing Resolution 25 in such a way which would represent a restriction in the flow of medical devices into Brazil.

Responding to concerns regarding the capacity of Brazilian authorities to carry out the necessary inspections by May 2010, he underscored that Brazilian authorities were fully prepared to deal with all the necessary inspections. He recalled that inspections were only necessary in order to renew registration or obtain a new registration for exporting medical devices. He further emphasized that inspections were due only in the plant of the final manufacturer of medical devices pertaining to risk categories 3 or 4 that would export the product to Brazil; there was no need for inspections in the plants of suppliers of parts of the devices. Regarding the inspections already required, he informed the Committee that 89 requests had been made, of which 50 were scheduled for 2009, 26 for 2010 and 13 were in the process of scheduling. He further noted that there had, to date, been no difficulties for scheduling the inspections. In addition, the Brazilian delegate recalled that Brazilian authorities had hosted seminars and other bilateral events to help to provide further information on the measure and to help build reciprocal confidence among trading partners. Brazil stood ready to maintain dialogue with all delegations in order to improve the understanding of Resolution 25.

## Tailândia, China, UE, EUA x Brazil –Toys (G/TBT/N/BRA/259; 313 and 339 and Add.1)

*Brazil –Toys (G/TBT/N/BRA/259; 313 and 339 and Add.1)*

The representative of Thailand recalled that Brazil's proposed INMETRO Decree for toy testing and certification had been notified to the TBT Committee in document G/TBT/N/BRA/339 on 24 July 2009. A reply to Thai comments was still pending. It was Thailand's understanding that Brazil had revised its seal affixation requirement, but, unfortunately, not for the better. A new body called "Product Certification Agency" (PCA) had been introduced with new responsibilities for: issuing the compliance identification seal; ensuring that the quantity of seals requested was compatible with the production capacity of the certification holder; and asking INMETRO to grant numbers in sequential order for the seal. Also certified businesses or individuals were required to "keep records and sequential control over the numbering on the seals granted that are used or in stock." This appeared to be complex. Thailand questioned whether the new provisions on seal affixation had anything to do with ensuring toy quality or safety. They appeared to add in procedural complexity, escalating administrative burdens and delaying costs for importers. In Thailand's view, the measure was more strict than necessary to give Brazil adequate confidence that toys conformed with Brazil's technical regulations on toy safety; as such the measure would create an "unnecessary obstacles to international trade" within the meaning of Article 5.1.2 of the TBT Agreement. Moreover, the measure appeared to be inconsistent with Brazil's obligations under Article 5.2.1 of the TBT Agreement to ensure that conformity assessment procedures were undertaken and completed as expeditiously as possible.

The representative of Thailand noted that transitional provisions of the proposed decree discriminated against imports because they effectively granted a one-year grace period for domestically manufactured toys, while requiring immediate compliance by importers. This was inconsistent with Brazil's national treatment obligation under Article 5.1.1. In fact, the imposition of

the requirement of immediate compliance on imports meant that imported toys had access to the Brazilian market under "less favourable" conditions than domestic toys.

The representative of Thailand also noted that Brazil required reports on tests performed abroad to have a "sworn translation into Portuguese (Brazil)." In Thailand's view this would lead to increased delays and costs for imported goods and was more strict than necessary within the meaning of Article 5.1.2. A reasonable alternative would be for INMETRO to accept conformity assessment reports in English, as did many importing countries around the world.

Also, in the view of Thailand, the proposed decree appeared to provide excessive penalties for non-compliance. It stated that if the non-compliant product had been evaluated in accordance with System 5 "the licensed business will be suspended for a period of four months from the time of the last removal of the non compliant products". It was not proportionate that one failed product test be the basis for the "licensed business" itself to be suspended. Such a provision was more strict than is necessary within the meaning of Article 5.1.2

With respect to the WTO notification, it was noted that Brazil had notified the proposed decree under Article 5.7.1 of the TBT Agreement, which allowed for the omission of the steps enumerated in Art. 5.6 "where urgent problems of safety, health, environmental protection or national security arise or threaten to arise for a member ". In such urgent cases, Art. 5.7.1 provided that the Member adopting the measure was required to "notify immediately other Members through the Secretariat of the particular procedure, including the nature of the urgent problems". However, Brazil's notification sought to justify its derogation from the notification requirements in Article 5.6 with a single brief reference in Section 7 of its notification on the "Protection of human health". This fell short of the standards set out in Art. 5.7.1. Thailand strongly urged Brazil to revise the proposed decree so as to bring Brazil's toy testing and certification requirements into conformity with Brazil's obligations under the TBT Agreement.

The representative of China echoed the concerns expressed by Thailand and noted that written comments had been sent to Brazil on 7 August 2009 and a formal reply had only been received shortly before the Committee meeting; it was currently being considered. On a preliminary basis, the representative of China said that, in its reply, Brazil had mentioned that some changes had been introduced to the draft regulation taking into account Members' comments, and that the final regulation, adopted on 29 October 2009, would soon be notified to the WTO. While China appreciated the progress made, her delegation still shared some of the concerns expressed by Thailand, especially on the discriminatory treatment against imported toys in terms of the transitional provisions. He invited Brazil to confirm that the "Compliance Identification Seal" could be affixed in exporting countries as indicated in the bilateral talks so as not to be more trade restrictive than necessary.

The representative of the European Communities noted that, according to his understanding, the final decree had been issued and published on 29 October 2009 as Ministerial Act (PORTARIA) No. 321. The European Communities had therefore not yet carried out a detailed assessment of the final text. The EC representative asked for confirmation that, pursuant to the final decree: importers would be free to choose between the System 5 and System 7 procedures; that there would be no seal requirements based on sequential numbers; and that there would be more reasonable penalties in case of non-conformity, linking the suspension of the validity of certificate to the period necessary to bring the product into compliance. With respect to the System 5 procedure in particular, the European Communities asked for confirmation that: it would be possible to affix the seal in the country of export; that tests carried out by ILAC-accredited foreign laboratories would be accepted and therefore there would be no requirement for duplicative in-country testing; and that companies holding ISO 9001:2008 certificates would be exempted from the factory audit on their quality assurance system.

The European Communities understood that the final version of the decree established a so-called "system certification authority" (the acronym in Portuguese being OCS) which had to be accredited

by INMETRO. The European Communities asked for confirmation that INMETRO would accept accreditation certificates of inspection bodies issued by IAF members meaning that foreign inspection bodies would be able to perform the necessary factory audits. In other words, the European Communities was looking for confirmation that foreign inspection bodies would be able to be accredited by INMETRO for the purposes of a quality assurance system and that if they held international accreditation certificates, this would mean that accreditation by INMETRO would be quite smooth. The representative of the European Communities said that if these understandings were confirmed, the amendments to the initial draft INMETRO decree were indeed welcome improvements, which, based on an initial assessment, would appear to effectively address most of the concerns raised by the European toy industry.

With respect to the requirement for importers to supply a "sworn translation" into Portuguese of foreign test reports and of any other relevant documents that should be submitted for the purpose of the System 5 procedure, while the representative of the European Communities fully understood the need to provide the translation, he asked if a local sworn translation was always necessary and noted that, perhaps, considering the context, this might be considered an excessive requirement. The representative of the European Communities encouraged Brazil to consider whether some flexibility could be introduced as to how this translation could be provided. For instance, the European Communities asked whether this translation could be made by a sworn translator in the country of export or whether the Brazilian authorities could allow the importer to provide a self-guaranteed translation, coupled with the possibility of a penalty for non-conformity of the translation with the original documents. The representative of the European Communities finally thanked Brazil for the transparency and regard for trade partners' concerns that had been shown by INMETRO in the revision of the decree.

The representative of the United States welcomed the announcement that Brazil would eliminate the requirement that imported toys undergo a second set of testing in Brazil. Furthermore, the United States welcomed Brazil's decision to allow imported toys to be marketed in Brazil based on testing performed by any laboratory that had been accredited by a ILAC MRA signatory, at least in some circumstances; to give foreign producers the option to import under Systems 5 or 7; and to provide a transition period for producers to comply with the new regulation. The United States thanked INMETRO for having incorporated these elements in the final regulation and having, in the US understanding, published it the day before the current TBT Committee meeting. The regulation would be reviewed and the United States would revert to Brazil with any remaining concerns. With respect to cases where INMETRO did the accrediting, the United States welcomed receiving additional information from Brazil to clarify the accreditation criteria and application process for test laboratories. The United States noted that it looked forward to continuing to work together with regulators from Brazil and other countries on devising appropriate measures to ensure that children are protected from potentially unsafe toys.

The representative of Brazil stressed that the measures adopted by the Brazilian Government regarding the toy sector had been designed to ensure safety through the enhancement of conformity assessment procedures that were applied to products whether imported or domestically produced. These measures acquired a special importance since the products – toys – where were destined for children. The representative of Brazil informed the Committee that the regulation had been published on 3 November 2009 in the Ministerial Act No. 321, dated 29 October 2009, replacing Ministerial Acts No. 326 and 376 of 2007. Ministerial Act No. 321 had some new dispositions concerning the conformity assessment procedures applicable to toys aiming at the simplification of those procedures without jeopardizing safety. He stressed that it granted equal treatment to both domestic and foreign producers. Ministerial Act No. 321 was drafted taking into account comments made by the public in general and by other Members through public consultations which had be held since November 2008. The Act had been notified the previous day to the WTO. Brazilian authorities were confident that, after almost a year of work on this matter, the conformity assessment procedures laid down in Ministerial Act No. 321 were the most adequate to ensure the safety of children and were in accordance with the Brazilian obligations under the TBT Agreement.

In response to specific questions, the representative of Brazil noted that his delegation had recently sent a reply to the Thai focal point on comments received. With respect to the need for sequential numbers in the seals, the Act did not require the presence of this sequential number, and the seals could be affixed to toys in the territory of the exporting Members. Moreover, the exporter could choose between Systems 7 or 5 if it complied with the requirements of those certification systems.