SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/48)

New Concerns

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 European Communities raised concerns about a Brazilian regulation concerning Good Manufacturing Practice (GMP) certificates for the registration of certain health products, which had been notified to the WTO on 18 May 2009. The EC representative regretted that this regulation had been published as an adopted text in the Brazilian Official Journal only four days after the date of notification to the WTO. She believed that Brazil had thereby failed to comply with Article 2.9.2 of the TBT Agreement. This was particularly troubling because some key issues of the Brazilian regulation required further important clarification. For example, the regulation did not indicate the competent authorities responsible for issuing the GMP certificate. In this regard, it was the EC delegation's understating that the objective of the measure was to reinforce the existing audit requirements by requiring submission of a GMP certificate at the time of application or re-registration of all, domestic and foreign, class III and class IV devices. The EC representative further inquired whether Brazil would continue to accept ISO 13485 certification as evidence of compliance with these requirements and if this would not be the case, Brazil was invited to give the reasons for such a refusal. Finally, she asked Brazil to clarify whether a GMP certificate would also be needed for low risk products that were currently excluded from registration.

The representative of the United States had serious concerns with Brazil's new inspection requirement for certain medical devices. In particular, the United States was concerned that the *Agência Nacional de Vigilância Sanitária* (ANVISA) could lack sufficient resources to inspect all Brazilian and foreign facilities subject to the new requirements by the deadline of 22 May 2010. As a result, a serious disruption in the trade in medical devices was to be expected. Brazil was therefore invited to clarify whether ANVISA planned to conduct all the inspections by May 2010 or would extend the deadline. The US representative further stressed that failure to clarify these issues would lead to serious trade disruptions, and would jeopardize the adequate supply of essential medical devices to the Brazilian market.

The United States was also concerned about the procedural history of this measure. While the US delegation was grateful that Brazil eventually notified the measure to the WTO, the adoption of the measure only four days after its notification denied foreign stakeholders a meaningful opportunity to comment. In this regard, US industry had submitted some suggestions that would ensure that trade in medical devices not to be disrupted in the event that ANVISA would be unable to complete all the inspections by the deadline. Brazil was requested to take those comments into account when implementing the new inspection requirement. In addition, the representative of the United States noted that, up until now, Brazil had been accepting inspection and quality system certification by US Food and Drug Administration (FDA) as a basis for allowing imports of US medical devices without requiring ANVISA inspections. ANVISA had not identified any specific problems with this system in terms of safety and effectiveness. Therefore, it was the US delegation's opinion that allowing imports of US medical devices to continue pending inspections did not compromise safety or efficacy concerns. Finally, the representative of the United States noted that his delegation continued to monitor the situation closely and looked forward to further discussion with Brazil on this issue.

The representative of Mexico shared the concerns expressed by previous speakers. In particular, he regretted that Brazil did not appear to have fulfilled the obligations under Article 2.9 of the TBT Agreement. Moreover, the Mexican representative sought clarification on the

issue of inspections and on whether Brazil would continue to accept ISO certification as evidence of compliance with the new requirements.

The representative of Switzerland shared the concerns expressed by other WTO Members and looked forward to a written reply to her delegation's comments. It was Switzerland's understanding that, so far, ANVISA had required suppliers of imported medical devices to be certified in conformance with international recognized quality standards such as ISO 13485, and that quality inspection carried out by conformity assessment bodies under this standard had been accepted. The representative of Switzerland noted that this reliance on internationally recognized quality inspections represented the same approach followed by the Swiss government, and asked Brazil to identify the part of its new regulation which deviated from relevant international standards. She also asked Brazil to explain why such deviation had been considered necessary. With regard to the deadline for inspections by ANVISA, the Swiss delegate emphasized that there were many plants worldwide producing medical devices to be imported in Brazil. Therefore, her delegation sought confirmation that registrations and re-registrations of medical devices for suppliers certified in conformance with international standards would still be possible if inspections by ANVISA would not take place within the deadline due to time constraints. Otherwise, the new regulation would create an unnecessary barrier to trade thus violating the less trade restrictive principle contained in Article 2.2 of the TBT Agreement.

The representative of Singapore echoed the comments made by the European Communities, the United States and Mexico about the Brazil's new inspection requirement for certain medical devices. In this regard, she urged Brazil to provide a sixty-day period for comments on the regulation, as recommended by the TBT Committee. Furthermore, her delegation invited Brazil to clarify whether ANVISA inspections could be completed by the deadline and whether there were plans to extend the deadline if inspections could not be completed.

The representative of Brazil pointed out that the adoption of Resolution 25 had been preceded by one month of public consultation during which interested parties had had the possibility to comment on the draft text of the regulation. However, since Brazil's Federal Prosecutors had determined that ANVISA should treat equally national and foreign suppliers, it was impossible to further delay the adoption of the measure. In fact, before the adoption of Resolution 25, only national producers were required to present a GMP certificate. The Brazilian representative stressed that this situation illustrated how difficult it could be to comply with more stringent notification obligations, as it had been demanded by some delegations during the preparation of the Fifth Triennial Review.

Furthermore, the representative of Brazil drew the attention of the Committee on the simplification of registration procedures related to health products, which had been reoriented to focus essentially on risk. He explained that Resolution 25 was aimed at implementing provisions contained in the Brazilian Federal Law 6360 (1976) regulated by Decree 3961 (2001), which established that the register of products subject to the Brazilian Health Surveillance required the presentation of a GMP certificate. He further clarified that Brazilian health products were categorized in four risk-levels. Categories I and II were classified as low risk levels, while Categories III and IV were high risk. In this regard, the Brazilian representative noted that health products under low risk categories were now exempted from registration obligations. No certification was required for these products, which had simply to be notified through an electronic form on the ANVISA webpage. The Brazilian delegate stressed that these new provisions were laid down in Resolution 24, which had been published jointly with Resolution 25, and significantly simplified a wide range of procedures.

Brazil confirmed that Resolution 25 would enter into force within one year, and reassured WTO Members that ANVISA had the operational capacity to certify all companies that required to be certified. The Brazilian delegate also noted that the majority of health product companies that

supplied the Brazilian market had already requested certification. ANVISA had increased the number of inspectors responsible for issuing GMP certificates and was fully prepared to meet demand. Moreover, it was emphasized that Resolution 25 was not a new subject for health product companies. Since 2001, Brazilian legislation established that a GMP certificate had to be presented to register health products, but such determination was not being fully implemented. Finally, the representative of Brazil reaffirmed his delegation's position that Resolution 25 was not discriminatory and was intended to achieve the legitimate objective of protecting human health. His delegation was open to further discuss the issue bilaterally with interested delegations.

Previously raised concerns

Tailândia, China, UE e EUA X Brasil –Toys (G/TBT/N/BRA/259 and 313)

Brazil –Toys (G/TBT/N/BRA/259 and 313)

The representative of Thailand thanked Brazil for holding a public consultation on its toy import measures in April 2009 in Sao Paulo. She recalled that the "temporary" measure had first been enforced in October 2007, subjecting imported toys to be retested in Brazil, incurring unpredictably long waits and additional costs for imports. In response to comments from WTO Members, Brazil had modified the measure in June 2008 with even more stringent effects. The modified measure included provisions on consideration of foreign test reports, but not on acceptance. It further required that foreign test reports had to be translated into Portuguese. Additionally, all imported toys had to undergo additional tests in Brazil. Only after completion of the repeated testing and certification process, could importers affix the conformity mark on each toy item, one by one.

The representative of Thailand further recalled that these concerns had been raised at the public consultation in Sao Paulo. About a month later, Brazil had responded in writing, in Portuguese. According to the translation, Brazil insisted on requiring translation of test report into Portuguese. The official reply mentioned that product sampling for supplement test had to be done after the arrival at the port, but that additional tests were removed from the toy safety certification in light of the comments received. She noted that Brazil had also mentioned a new certification procedure and greater transparency for the revision of its toy safety measure without providing other specific details. While the removal of additional tests from the toy safety certification procedure was a positive development, clarification was still needed about whether or not imports still required sampling. Moreover, it was Thailand's understanding that Brazil would consider a review of the measure for greater flexibility shortly after the consultation. To date, no update had been received. In concluding, the representative of Thailand requested that: (i) Thailand’s concerns be taken into account; (ii) Brazil ensure flexibility for exporters; and (iii) any new burdens to undermine fair trading be avoided. Brazil needed also to ensure that the review bring the measure into conformity with the TBT Agreement.

The representative of China shared the concerns expressed by Thailand. In particular, China remained concerned about the discriminatory treatment imposed on imported toys in terms of additional tests and other burdensome conformity assessment procedures. He recalled that, in the public hearing held in April, Brazil had made it clear that additional test requirements on imported toys would be eliminated and that the final test would be available in June. However, no information had been received on the final regulation. He informed the Committee that, in a bilateral meeting, Brazil had confirmed that additional testing requirements would be eliminated. His delegation was also informed that a new draft text would be notified to the WTO and that another public consultation would be held at the end of July, after which a new public hearing would be heard in August. The final regulation would then be published within 30 days. He invited Brazil to confirm that this was the case and, if so, he encouraged Brazil to

take WTO Member comments' into account and to ensure that the final regulation was fully in line with the TBT Agreement. He further pointed out that the current toy regulation, which had been notified on an emergency basis, had been implemented for almost two years and that Chinese toy exports had been seriously affected.

The representative of the European Communities thanked the Brazilian authorities and INMETRO for organizing the public hearing in Sao Paolo and for the transparency with which INMETRO officials had discussed the issue and handled the comments received from his delegation. He invited the Brazilian authorities to confirm that the modifications announced during that meeting would be implemented in the revised version of the Decree. In particular, he pointed out that the modifications concerned the elimination of the requirements for duplicative local testing and the acceptance of testing performed by foreign, ILAC-accredited laboratories. He also sought confirmation that companies holding ISO 9001 (2008 version) certificates would be exempted from the factory audit on their quality assurance system in the context of the so-called System 5 procedure.

With regard to the requirement to provide a full official translation into Portuguese of foreign test reports, the representative of the European Communities requested INMETRO to consider in the framework of implementation that a translation requirement should only apply to those parts of the test reports that were necessary to establish the conformity of the product with the applicable Brazilian requirements. Finally, he sought an update on the state of play of the measure.

The representative of the United States welcomed the fact that Brazil would no longer impose additional in-country testing requirements on imported toys. He sought an update on the status of the measure and would review the new draft when published. He looked forward to continuing to work with regulators from Brazil and other Members on devising appropriate measures to ensure that children's safety was protected from potentially unsafe toys.

The representative of Brazil informed the Committee that the regulation on toys was still under revision. He recalled that, on 14 April 2009, INMETRO had held a public hearing about the draft regulation, which had been attended by representatives from national and foreign producers, as well as government officials from several countries which had had the opportunity to express their views on the draft text directly to INMETRO's regulators. During the public hearing, INMETRO had received significant contributions from interested parties. In view of that, INMETRO was working on a final version of the draft regulation that incorporated some of the comments received. Once concluded, the final version would be submitted to a brief period of public consultation and public hearing and then it would be published as a new regulation. He further informed Members that, in the new draft text, the requirement that complementary tests be made only in Brazil had been removed. Foreign products would be allowed to be certified under System 5, as long as the tests are performed by laboratories accredited by ILAC. Moreover, INMETRO would require that conformity assessment bodies collected samples in the marketplace for performing toxicological tests, so that controls on the borders could be simplified, whilst enhancing market surveillance and other non-trade restrictive control methods.

With respect to the requirement that foreign tests reports be translated to Portuguese, the representative of Brazil pointed out that this could not be removed from the revised text. Brazil's Constitution established that Portuguese was the official language of Brazil: therefore, only documents in Portuguese had official status in Brazil's public administration. He confirmed China's understanding about the timeline for implementation, although slight variations could occur. Finally, he stressed that the process of revision of the Brazilian regulation on toys had been conducted with impartiality and transparency and had been open to all interested parties. The new draft regulation would strike a balance between the need to avoid trade restrictions and the objective of protecting the health of consumers.