Previously Raised Concerns

xvi) Brazil – Instructions for Registration for Labels of Imported Products of Animal Origin17

104. The representative of the United States appreciated bilateral discussions and was pleased with Brazil's indication that it would consider a Food Safety Inspection Service (FSIS) proposal, to be sent by letter as soon as possible, addressing the concerns of both countries.

105. The representative of Brazil noted that the bilateral videoconference allowed Brazilian experts to better explain to their US counterparts the requirements of the Brazilian regulation. Brazil remained open to receiving the US proposal.

xx) Brazil – Draft Resolution No. 112, 29 Nov 2010; maximum levels of tar, nicotine and carbon monoxide permitted on tobacco products and prohibition of additives (G/TBT/N/BRA/407)

114. The representative of the European Union asked Brazil for an update on this proposal, as the EU had learned that a text had been adopted and published on 16 March 2012 as ANVISA Resolution 14/2012. The EU also asked Brazil to provide an outline of the changes contained in the adopted Resolution, compared to the notified draft, and a timeline of implementation of the measure. She reiterated her request for Brazil to reply in writing to the EU's written comments.

115. The representative of Mexico associated her delegation with the EU's statement regarding possible breaches to the TBT Agreement in this draft technical resolution. She asked Brazil for a formal response on Mexico's comments on the draft resolution presented on 31 March 2011.

116. The representative of Honduras considered that the Brazilian measure seemed to be incompatible with the TBT Agreement; Article 2.1 of the Agreement required that technical regulations not discriminate against domestic and like imported products. Depending on market conditions, the prohibition on the use of components may be incompatible with this obligation because it would be a de facto prohibition of traditional US-blend cigarettes, whereas Virginia-type cigarettes would not be similarly affected. Article 2.2 of the TBT Agreement provided that technical regulations not be more trade restrictive than necessary to fulfil a legitimate objective and that they must take into account the risks of non-fulfilment. This provision also stated that in evaluating these important elements, the following elements should be relevant when assessing such risks: available scientific and technical information; related processing technology; and intended end use of products. Brazil had been unable to explain how its legislation would fulfil such requirements. In particular, it seemed that the Brazilian measure was not based on scientific evidence or any impact assessment.

117. Article 2.8 of the TBT Agreement stated that, wherever appropriate, Members shall specify technical regulations based on product requirements in terms of performance

rather than design or descriptive characteristics. Other WTO Members had adopted a standard based on performance that only prohibited those cigarettes that truly had a fruity or sweet characteristic flavour. Brazil was seeking to regulate the design of the product and the components of cigarettes without taking into account how such components affected the performance; in other words the characteristic flavour of the product. The focus based on characteristic flavour was a lot more specific and targeted than an approach prohibiting a list of additives in any amount, regardless of their effect on the end product. Article 12.3 of the TBT Agreement required Members to ensure that their technical regulations would not create unnecessary barriers to exports from developing country Members. By affecting tobacco leaf markets, Brazil's measure may be creating a barrier in violation of this provision.

118. The representative of Guatemala supported previous comments and expressed concern that the measure might have an impact on the trade of US blends cigarettes using burley tobacco. As the Resolution was recently published, Guatemala was still looking at its possible impact on the marketing of tobacco products. Guatemala was concerned that banning certain kinds of additives that were necessary to make the US blend may result in a de facto ban on the marketing of this kind of cigarettes. Because of the way it was cured, burley tobacco had to use certain additives in order for the cigarette to retain moisture and recover the sugars that were lost during the curing process. This measure would therefore have an impact on the growing of burley tobacco and would seriously affect small countries like Guatemala where the production of this type of tobacco accounted for approximately 98per cent of its domestic tobacco production, generating 1,000 direct jobs and some 4,000 related jobs. Guatemala's tobacco exports in 2011 reached $54 million US. While Guatemala recognized Members' right to adopt standards for the protection of human health and safety, in so doing the criteria established in Article 2.2 of the TBT Agreement, in particular the obligation that technical regulations shall not be more trade restrictive than necessary in order to fulfil theirlegitimate objectives, must be respected. She requested Brazil to explain how it took into account Members' concerns raised in this Committee and to indicate whether Brazil felt that its resolution would allow for production and consumption of American blend tobacco. In particular, how would each of the ingredients of American blend be covered by Article 7 of the Resolution?

119. The representative of Dominican Republic supported the concerns raised by other Members and reiterated its previously stated concerns.

120. The representative of Indonesia reiterated its request that Brazil reply in writing to the letters from the Indonesian Minister of Trade, sent in March and April 2011, related to this draft resolution.

121. The representative of Nigeria associated herself with the previous speakers and asked for an update on the public health consultation process. Given that the resolution would ban the use of additives with no reasonable justification, Nigeria encouraged Brazil to ensure that any final decision be based on scientific and technical evidence.

122. The representative of Zimbabwe stated that his delegation was still waiting for Brazil's written responses to the written comments it had sent before the November TBT meeting.

123. The representative of Australia welcomed Brazil's decision to implement tobacco control policies and preventive measures aimed at reducing the attractiveness of certain tobacco products, particularly to children and youth. Each Member had the right to implement necessary measures to protect public health. Australia would follow Brazil's implementation of these measures with interest and was prepared to continue to defend the right of members to protect public health while complying with relevant international treaty obligations.

124. The representative of Chile asked about the resolution's status. At the last meeting, Brazil said that it was reviewing all comments received and would respond to these before the resolutions' adoption. Chile sought these responses as the resolution would affect developing countries which export tobacco products.

125. The representative of Colombia reiterated previous concerns that this measure would be contrary to the TBT Agreement and would have an impact on Colombian tobacco products by restricting the American blend marketing based on oriental and burley tobacco. Recently Brazil published a new version of the resolution, similar to the previous one, restricting the import and sale of tobacco products containing ingredients that were indispensable for the American blend. The exclusion of sugar in the most recent version of the resolution would not substantially change the situation for American blend cigarettes. Other banned ingredients were required for this blend, and it was likely that sugar would be banned in the future. Colombia was concerned that the resolution would infringe Article 1.2 of the TBT Agreement, establishing less favourable treatment of international products by banning cured tobacco and sugar, of which Brazil was the main producer. He asked for the date of the new resolution, whether it had been notified, and if not, when it would be.

126. The representative of Zambia asked Brazil to confirm that it had enacted a final resolution on tobacco additives and, if so, whether it intended to notify it to the TBT Committee. Did Brazil intend to take into account the special development, financial and trade needs of developing countries in the application of this technical regulation, as provided for in Article 12.3 of the TBT Agreement? Brazil had not provided peer reviewed scientific evidence that the banning of additives would address its stated health objectives and the imposition of such measures could create trade barriers, more so because the legislation would ban additives on a selective basis. This measure would have far reaching implications for countries like Zambia as its implementation would make it impossible to blend tobacco, especially the type produced in Africa. Zambia considered that there were more balanced approaches to meeting Brazil's policy objectives than the current measure. The regulation of ingredients should not be deemed an effective measure to reduce the threat posed by tobacco. Because it was naturally

addictive with or without ingredients. Efforts should focus therefore on measures that had proven effective on the consumers' behaviour.

127. The representative of Turkey supported the concerns expressed. While committed to the protection of human health consistent with the WHO Framework Convention on Tobacco Control and respectful of the measures taken by Members based on that Convention, Turkey was concerned that some Members could use areas of this Convention for commercial interests. The Brazilian regulation containing a list of additives to be prohibited in all tobacco-related products in Brazil, was an issue for Turkey, one of the major Oriental tobacco producers. Some of the prohibited additives were essential components of the blended type of cigarettes, in which both Oriental and Burley tobacco were used. The TBT Agreement prohibited discrimination between "like products". The Brazilian Resolution would ban the production and sales of blended cigarettes, leaving the market to the Virginia type products. He noted that Brazil was one of the main producers of the Virginia type tobacco. Additives did not give any characterizing flavour to tobacco products and this decision was made without considering the effects on final products. Turkey asked Brazil to indicate scientific evidence proving that the prohibited additives would pose increased risk to human health. There was no difference with respect to the "end use" between blended and the Virginia types, and Brazil had not provided a satisfactory explanation for discrimination between these two types. Turkey requested Brazil to respond to its comments and to amend the Resolution in accordance with the TBT Agreement.

128. The representative of Norway informed Members that Norway had implemented measures to combat smoking and would continue to follow the Brazilian tobacco regulation closely. Norway believed that it was within a Member's right to implement necessary measures in order to protect public health and that this was not in contradiction with a Member's trade obligations.

129. The representative of Brazil informed Members that on 16 March 2012, ANVISA, the Brazilian Health Surveillance Agency, published the final regulation on maximum levels of tar, nicotine and carbon monoxide for cigarettes and on the restriction of additives in tobacco products. The measure would be notified to the TBT Committee. A draft regulation had been notified and a four-month period for comments was provided. Further, ANVISA promoted several rounds of public debate all along the process. In December 2011, Brazil held a public hearing on the issue and in February and March 2012, the board of Directors of ANVISA discussed the draft measure in open meetings, with the participation of industry, governments, civil society, academia, etc. Comments received were carefully examined by the Brazilian authorities who were working on a consolidated answer for all Members. Companies now had 18 months to adapt their products to the new requirements; those that did not comply could be sold for 24 months only. The main difference between the draft and the final measure was that sugar had been removed from the list of prohibited additives in tobacco products. The use of sugar as an additive would only be allowed to restore the sugar lost during the drying process of certain tobacco leaves. Arguments about a possible discrimination

against traditional blends produced with burley tobacco did not stand since sugar would be allowed for this process.

130. In Brazil, 200,000 people died every year due to diseases caused by tobacco consumption. The objective of the measure was to protect public health by reducing tobacco products' attractiveness, especially on children and the youth. Studies showed that the risks of tobacco addiction were significantly higher when people start smoking as children or teenagers; the Brazilian regulation was therefore intended to reduce the incentive for first experimentation since flavoured products had evident appeal to the youth. A recent study conducted by the Oswaldo Cruz Institute in Brazil, surveyed more than 17,000 thousand students in several Brazilian cities. It found that more than 50per cent of young smokers preferred flavoured cigarettes. The Brazilian regulation also prohibited the use of additives used to reduce the harshness of tobacco smoke and to potentiate the effect of nicotine which reduced the natural rejection to tobacco products and increased their addictive characteristics. Brazilian authorities had taken into account the FCTC "partial guidelines" to the implementation of Articles 9 and 10 as a basis for the regulation. Brazilian authorities had also taken into account the extensive scientific literature on the properties and effects of additives in tobacco products and had produced a compilation of the scientific references on this subject, which had been shared with several Member. Brazil is willing to continue to share it with other interested Members. Moreover, in defining the flavouring additives covered by the regulation, Brazil had taken into account the work of the Joint FAO/WHO Expert Committee on Food Additives and of the Flavour and Extract Manufacturers Association. Finally, the measure did not differentiate between national or foreign producers.

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

263. The representative of the European Union reiterated concerns regarding timelines for the registration of medical devices in Brazil. As of May 2010, a Good Manufacturing Practices (GMP) certificate had to be presented with the application for registration. A GMP certificate would be issued after the Brazilian Health Surveillance Agency (ANVISA) inspected the manufacturing premises. In the June 2010 TBT Committee meeting, Brazil indicated that inspections were being carried out in a timely manner with no trade disruptions. However, according to information available to the EU, a significant number of manufacturing sites had submitted an inspection request with no inspection taking place. It appeared that the elapsed period between the request and the inspection was on average 20 months. She asked Brazil to update the Committee on the number of facilities for which ANVISA had completed audits and issued GMP certificates, and those for which audits had been requested but not yet completed.

264. She urged ANVISA to take effective measures to reduce current backlog and guarantee that inspections to foreign manufactures would be carried out within a period of three months, particularly due to the relatively short life span of medical devices. If it

was difficult to comply with reasonable inspection deadlines, ANVISA could take into account Quality Management System audits conducted by accredited auditing bodies (e.g. EU Notified Bodies). Also, Brazil could consider accepting products that had been authorized in the EU or in other major markets, pending the completion of ANVISA inspections, or consider subcontracting overseas inspections to accredited auditing bodies such as the EU Notified Bodies. Finally, to increase transparency and predictability, ANVISA could regularly inform operators waiting of the expected timing for completion of their registration dossier.

265. The representative of Brazil said Brazilian authorities were aware of the situation and ANVISA had been working to increase the number of GMP inspections. Several measures had been adopted or were under consideration to review procedures and use resources more efficiently. The representative announced that in 2009, when the systematic inspections for medical devices began, ANVISA conducted 39 inspections. In 2011, 226 inspections were conducted, an increase of 579 per cent. Some of the measures adopted by ANVISA to improve its inspection capacity included openinga public consultation number 62/2011, notified as TBT/N/BRA/454, to define criteria for improving the efficiency of international inspections. Another was the establishment of new procedures for prioritizing inspections, such as enabling inspection teams sent to a certain region to conduct all of the inspections requested by companies of that region. It also hoped to establish a list of priority products for inspection, considering the risk of lack of supply in the Brazilian market, and ANVISA sought to make the best use of its human resources by reallocating experts and forming new teams of inspectors. Another measure considered was enabling local Brazilian governmental experts to work as international inspectors.

266. Brazil remained open to the possibility of promoting mutual recognition agreements in this area, or other arrangements that could expedite the certification process such as confidentiality agreements between ANVISA and the competent authorities of other Members. Finally, Brazil joined the International Medical Device Regulator's Forum (IMDRF), with Australia, Canada, the USA, Japan, the EU and the WHO among others, to work on regulatory convergence with the participating regulatory authorities in the Forum so as to improve its regulatory framework on medical devices.