



Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 30-31 OCTOBER 2013

CHAIRPERSON: MR. JINGO KIKUKAWA

*Note by the Secretariat<sup>1</sup>*

Contents

<b>1</b>	<b>ADOPTION OF THE AGENDA .....</b>	<b>2</b>
<b>2</b>	<b>IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT .....</b>	<b>2</b>
2.1	Statements from Members under Article 15.2 .....	2
2.2	Specific Trade Concerns.....	2
2.2.1	New Concerns .....	2
2.2.2	Previously Raised Concerns .....	12
2.3	Exchange of Experiences .....	45
2.3.1	Special and Differential Treatment and Technical Assistance (Thematic Session on 29 October 2013) .....	45
2.3.2	Conformity Assessment Procedures (Thematic Session held on 29 October 2013).....	48
2.3.3	Transparency .....	48
2.3.4	Good Regulatory Practice (JOB/TBT/44/Rev.2) .....	49
2.3.5	Standards.....	49
2.3.6	Other Matters.....	49
<b>3</b>	<b>TECHNICAL ASSISTANCE.....</b>	<b>50</b>
<b>4</b>	<b>UPDATING BY OBSERVERS .....</b>	<b>50</b>
<b>5</b>	<b>REPORT (2013) OF THE COMMITTEE ON TECHNICAL BARRIERS TO TRADE .....</b>	<b>50</b>
<b>6</b>	<b>DATE OF NEXT MEETING .....</b>	<b>50</b>

<sup>1</sup> This document has been prepared under the Secretariat's own responsibility and is without prejudice to the positions of Members or to their rights and obligations under the WTO.

## 1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in WTO/AIR/4198.

## 2 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

### 2.1 Statements from Members under Article 15.2

2.1. The Chairman said that the list of statements submitted under Article 15.2 of the TBT Agreement was contained in document G/TBT/GEN/1/Rev.12, dated 18 February 2013. He stressed that while 126 Members had submitted at least one Statement on Implementation under Article 15.2, 23 Members had not yet fulfilled this obligation and he urged them to do so in a timely manner. He recalled that this information was available, and regularly updated, on the TBT Information Management System (the "TBT IMS"<sup>2</sup>).

### 2.2 Specific Trade Concerns

#### 2.2.1 New Concerns

##### 2.2.1.1 Ecuador - Resolution No. SENAE-DGN-2013-0300-RE relating to post entry control of imported alcoholic beverages

2.2. The representative of Mexico expressed her delegation's view that the measure was a technical regulation and should therefore have been notified to the Committee. Further, the measure, the objective of which was unclear, was designed to create unnecessary obstacles to trade in discordance with Article 2.2 of the TBT Agreement. Ecuador should therefore consider less trade-restrictive alternative measures. Mexico also asked for the opportunity to comment and hold consultations with Ecuador on this matter.

2.3. The representative of the European Union associated herself with Mexico's concerns. She asked Ecuador to suspend the application of the measure and notify it to the TBT Committee so as to provide Members a minimum 60-day comment period, and to duly take any comments into account. She asked Ecuador to confirm whether the measure only applied to some types of spirits and did not cover domestic products. She observed that Article 3 of the Resolution required some imported spirits to bear a country-specific front label to be applied at origin - rather than within customs warehouses in Ecuador - detailing the Ecuadorean importer, and that the use of stickers was not permitted. She asked Ecuador for the rationale behind these requirements as they would create significant burden on foreign companies and were against international practice. Finally, the EU expressed its concern with the entry into force of the measure, as it allowed just 30 days before beverages shipped to Ecuador would be required to comply with the labelling obligation, and just four months until beverages already present in the Ecuadorean market would be prohibited from being sold or displayed unless they met the labelling requirements. She therefore asked Ecuador to provide an adequate time, not less than 6 months for the entry into force of the measure, in line with Articles 2.9 and 2.12 of the TBT Agreement.

2.4. The representative of Canada expressed her delegation's view that by not notifying the measure to the WTO and not allowing for a comment period, Ecuador was in violation of Article 2.9.1 and 2.9.2 of the TBT Agreement. Additionally, Ecuador had not yet published the measure in its official register and was not allowing a sufficient time-period between its publication and entry into force. Canada thus asked Ecuador to notify the measure to the WTO and allow for a comment period, as well as to reschedule the entry into force to allow for a full 6-month period after notification of the final technical regulation as stipulated in Article 2.12 of the TBT Agreement. Canada also expressed concerns with Article 3 of the measure, which required improperly labelled liquor to be returned to the country of export. Canada asked Ecuador to explain how the measure, in particular its application only to imports, was in compliance with Article 2.1 of the TBT Agreement, as well as how the measure was in compliance with Article 2.2 of the TBT Agreement by being no more trade restrictive than necessary to accomplish its legitimate objectives. Canada concluded by inquiring whether Ecuador had considered other less trade restrictive alternatives.

---

<sup>2</sup> <http://tbtims.wto.org>.

2.5. The representative of Ecuador explained that in G/TBT/N/ECU/19 of 30 June 2007 Ecuador notified "Technical Regulation of the Ecuadorian Standardization Institute RTE INEN n. 022 on the Labelling of Processed and Packaged Food Products"). This regulation established that the labelling of these products must meet the requirements set out in Ecuadorian Technical Standards NTE INEN 1334-1, 1334-2 and 2074 and in the "Organic Law on Consumer Protection". Members were given 60 days to make comments on this measure. One of these standards, Ecuadorian Technical Standard NTE INEN 1334-1:2011 (third revision), established minimum requirements for the labelling of packages or bottling of food products intended for human consumption, including alcoholic beverages. Additionally, Ecuador's Customs Regulation on such products has been applied for years. More specifically, Ministerial Agreement 428 (13 July 1995) of the National Secretariat, provided: (i) Article 1 - imports of alcoholic products, including beer, shall only originate from the country of origin and through legally authorized representatives, and be only permitted after the granting of the relevant sanitary registration and other legal requirements; (ii) Article 3 - from their place of origin, imported alcoholic products and beers shall contain a front label with the following information: "imported by" (name of agent or representative), the word "Ecuador", the sanitary registration number, the volume in cubic centimetres, and the statement "Warning: excessive consumption of alcohol can cause serious damage to health and can endanger your family" (to be located either in the main or secondary label, in line with Decree n. 1828 of 10 June 1994); and (iii) Article 4 - alcoholic products and beers imported into Ecuador's internal market without complying with Article 3 shall be presumed to have entered the country illegally.

#### **2.2.1.2 Italy - Testing requirement on import of steel cutlery products**

2.6. The representative of India expressed his country's concern with Italy's requirements for the import of stainless steel utensils (HS code 73.23.93.90) and stainless steel cutlery (HS code 82.15.99.00). He noted that while other EU Members (such as France, Germany and the UK) accepted the import of grade 200 stainless steel, Italy only allowed the import of grades 202 and 204. This was at odds with the fact that the grade 200 stainless steel met the Italian chromium threshold requirement of 13% and was considered adequately food-safe. India considered its internal BIS N1, N2 and N3 tests as adequately fulfilling food safety requirements, and argued that the testing method prescribed by Italy – including the stipulation that a serving tong of the same product must be kept in acid for at least four days – was more trade restrictive than necessary given that serving tongs hold food for a very short time. India concluded by expressing concern over the lack of harmonization among EU Members' standards on this particular aspect.

2.7. The representative of the European Union thanked India for its questions, and stated that the questions would be referred back to Italy and a reply would be provided at the next Committee meeting.

#### **2.2.1.3 European Union - Draft Commission Regulation implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for vacuum cleaners (G/TBT/N/EU/79)**

2.8. The representative of China noted that China had submitted four separate comments on the draft measure following the EU's notification of the measure at the end of 2012. China stated that the EU had accepted two of the four comments at the time of the adoption of Commission Implementing Regulation EU 636/2013 in July 2013. While China was glad to see that two of these comments were taken into account, the concerns expressed in the other two comments persisted. China still believed that the noise tolerance for cleaners proposed in the regulation, 80 dba, could be met by canisters of input power less than 900 watts through technological improvement, but that upright vacuum cleaners with smaller brush sizes would have difficulties meeting the requirements due to restrictions on shape and structure. China noted that the current noise level of upright vacuum cleaners was 85-90 dba, and suggested that the EU revise its noise tolerance level to 85 dba. Second, China expressed concern that the regulation required vacuum cleaners to undergo performance testing on metrics such as dpuc, dpuhf and dust emission rate, but the regulation did not stipulate the specific requirements of relevant reference systems or the main measures necessary for enhancing environmental performance. As a result, vacuum cleaner manufacturers in third-party countries could not carry out their own testing and instead had to send samples to the German laboratory that had drafted the European standard for vacuum cleaner testing, EN60131. China asked the EU to disclose details regarding testing so as to fulfil its WTO non-discrimination and transparency obligations.

2.9. The representative of the European Union thanked China for its interest in the measure. With regard to the sound power level requirement, she stated that vacuum cleaner models on the market did not demonstrate a correlation between energy consumption and sound power level, and the EU had identified both parameters as significant and displaying room for improvement. In response to China's concerns over upright vacuum cleaners, she explained that setting different requirements for products with the same functionality is not the EU's preferred legislative approach. Manufacturers would have sufficient time to adapt upright vacuum cleaner models that did not yet comply with sound power level requirements, given that the sound power level requirements would start to apply four years after adoption of the regulation.

#### **2.2.1.4 Indonesia - Regulation number 84/Permentan/PD.140/2013, on halal food**

2.10. The representative of Brazil asked Indonesia to clarify its regulations on halal foods as no new regulation had been notified to the WTO. Brazil expressed concern regarding lack of clarity in the requirements, particularly a previously existing requirement for poultry exporters seeking access to the Indonesian market to utilize specific slaughterhouses employing halal-compliant slaughter practices. Brazil wished to know whether measures in this area were compliant with the guidelines of the Codex Alimentarius for the use of the term "halal", doc. CAC/GL/24 of 1997. Specifically, Brazil drew attention to Article 2.2.1, allowing for the preparation, processing, or storing of halal food in different sections or lines within the same premises where non-halal foods were produced, as well as Article 2.2.2, allowing for the preparation processing, or storing of halal food using facilities which had previously been used for non-halal foods provided that cleaning procedures compliant with Islamic requirements have been observed. Brazil reminded Indonesia that if its requirements went beyond international guidelines, Indonesia may be required, upon the request of another Member, to explain the justification of the technical regulation in terms of the provisions of paragraphs 2-4 of Article 2.5 of the TBT Agreement. Brazil also noted that a number of Muslim countries had already taken initiatives under the Organization of Islamic Cooperation, of which Indonesia was a member, to develop common standards for halal foods so as to remove technical barriers to trade. A specific affiliate body – the Standards and Metrology Institute of Islamic Countries – was cited by Brazil as leading work in this area for the OIC and as having published two additional guidelines for certification and accreditation in the area of halal food. Brazil inquired as to whether Indonesia's halal food requirements follow these guidelines, and concluded by noting its openness to conducting bilateral discussions with Indonesia for the resolution of the matter.

2.11. The representative of Indonesia thanked Brazil for its comments, and noted that the concern was also raised in the SPS Committee. Note of Brazil's concerns was taken and the issue would be brought to capital for discussions with the Ministry of Agriculture.

#### **2.2.1.5 Ecuador - Resolution establishing the "General conformity assessment framework for Ecuador" and the "Handbook of procedures to be observed prior to all stages of the customs clearance, marketing and market surveillance of manufactured, imported and marketed goods subject to Ecuadorian technical regulations (G/TBT/N/ECU/44, G/TBT/N/ECU/44/Add.1, G/TBT/N/ECU/44/Add.2, G/TBT/N/ECU/44/Add.3)**

2.12. The representative of Colombia stated<sup>3</sup> that the resolution at issue was not notified and that no period for comments from Members had been provided. Given that it was not notified as an urgent measure, it also omitted the consultation process. Additionally, the resolution did not indicate what were the legitimate objectives justifying the measure. Further, the measure did not provide for a transitional period before its entry into effect. Given the foregoing, Colombia argued that this measure was not compliant with the main principles of the TBT Agreement, particularly those relating to transparency, and requested that Ecuador suspend its implementation until these deficiencies have been addressed.

2.13. The representative of Chile supported the concern expressed by Colombia. While Chile understood Ecuador's desire to ensure product quality, it stated that the measure at issue was more restrictive than necessary, particularly with regard to the recognition of Ecuadorian, bilateral or multilateral certification agreements. Chile noted that because Ecuador was not a signatory to

<sup>3</sup> See also Colombia's communication in G/TBT/W/373.

the IAF, certificates obtained through the accreditation organization were not being recognized by Ecuador, despite a previous understanding that mutual recognition would indeed take place. Recalling the positive economic relationship between the Ecuador and Chile as well as the close ties between standardization institutions in both countries, Chile called for a quick solution to its concerns.

2.14. The representative of Peru began by aligning her delegation with the concerns expressed by Colombia and Chile. She recounted the basic structure and functioning of the Ecuadorian general conformity assessment framework, including the issuance of conformity certificates by certification organizations for products whose accreditation was recognized by the Ecuadorean accreditation organization, as designated by the Ecuadorean Ministry for Industry. She also recalled that Peruvian exporters with valid certificates of conformity with technical regulations had seen their exports restricted after the entry into force of the Ecuadorean measure. This was not because the exporters did not comply with the specifications of the standard, but instead because no accredited organizations existed in Ecuador that were both recognized by the Ministry of Industry, and thus in a position to certify exporters' products as required under the Ecuadorean measure. Peru argued that the Ecuadorean measure represented an unnecessary trade barrier in violation of the TBT Agreement's principles, as it established a standard without enacting measures necessary to comply with this standard. Peru also noted that the resolution was notified without giving either 90 days for comments, as required by the Andean Community, nor six months between publication and entry into force, as required by the TBT Agreement. Peru asked Ecuador not to apply the measure until the principles of the TBT Agreement had been complied with.

2.15. The representative of Ecuador stated that the measure was compliant with the applicable non-discrimination provisions of the TBT Agreement, which was published in the official registry no. 4 on 30 May 2013.<sup>4</sup> In this respect, Ecuador recalled that Article 2 of the measure established that the general framework for conformity assessment was applicable to any goods – national or imported – subject to Ecuadorean technical regulations for trade, as well as Article 4, establishing the means of demonstrating compliance with the conformity assessment requirements. Ecuador stated that in neither of these provisions was there discrimination in the process of introducing a product into Ecuador or commercializing it within the Ecuadorean market. Ecuador added that Chapter 2, Sections 1-2, Articles 9 and 16 of the measure instructed national manufacturers to register the conformity or inspection certificate in a sub-secretariat of quality in the Ministry of Industry and Production. Ecuador said that these examples underscored the consistency of the measure with applicable non-discrimination provisions of the TBT Agreement as imported products were given no less favourable treatment than locally-manufactured products. A number of additional legal provisions of the measure were cited by Ecuador, including the second general legal provision in Chapter 3, referencing compliance "without discrimination to imported goods subject to local regulations", as well as text from the third legal provision specifying that civil, penal and fiscal responsibility for non-compliance would be found in existing legal provisions and would impact manufacturers, importers, and traders alike. Ecuador summarized these various examples as demonstrating that its regulations were based on the principle of national treatment. The Ecuadorean representative added that any omissions made in terms of procedure could be attributed to the substantial task of consolidating the entire institutional conformity assessment structure. With regard to concerns over mutual recognition agreements (MRAs), Ecuador stated that it had clarified in the March 2013 TBT Committee meeting that with regard to its 5 March 1997 MRA with Colombia, terms refer to WTO rules and not to those of the Andean Community. Ecuador concluded by addressing a Colombian request to hold bilateral consultations in the bi-national "Committee of Standardization, Technical Regulations, Certification, and Metrology", and stated that although it felt that the TBT Committee was the proper forum for addressing these issues, it was also happy to carry out the work necessary to hold meetings in the bi-national Committee.

#### **2.2.1.6 Russian Federation – Measure affecting import of Ukrainian confectionary products**

2.16. The representative of Ukraine expressed concern with the measure's consistency with a number of provisions of the TBT Agreement. Ukraine's full statement is contained in G/TBT/W/377.

---

<sup>4</sup> Notified in G/TBT/N/ECU/44/Add.2 of 5 June 2013 and G/TBT/N/ECU/44/Add.3 of 30 August 2013.

2.17. The representative of the Russian Federation recalled that the technical regulations in question were adopted in 2011 and established obligatory requirements for food products, particularly in terms of labelling. He added that a number of discrepancies were recorded in the indication of product categories, which did not correspond to the definitions laid out in the Russian technical regulations. The decision to suspend the import of Ukrainian "Roshen" confectionary products did not introduce new requirements and thus WTO notification was not required. The Russian Federation was maintaining bilateral consultations with Ukraine, and the Federal Service for Supervision of Consumer Rights Protection and Human Welfare ("*Rospotrebnadzor*") was monitoring agreements reached during a meeting between competent authorities in August 2013. The Russian representative stated that information regarding labelling violations in "Roshen" confectionary products, related bilateral negotiations and implementation of the agreements was available on the official website of *Rospotrebnadzor*. He emphasized that there was not a ban of all confectionaries from Ukraine, but instead the suspension of imports from a single producer, Roshen. He added that the decision reached by *Rospotrebnadzor* could be reviewed when full compliance of Roshen with the Customs Union requirements was achieved.

#### **2.2.1.7 Indonesia - Mandatory Indonesia National Standard (SNI) for Glazed Ceramics (G/TBT/N/IDN/37, G/TBT/N/IDN/37/Add.1, G/TBT/N/IDN/37/Add.2)**

2.18. The representative of the European Union expressed concern with the measure, which required mandatory third-party certification of compliance with the SNI for all glazed ceramic tableware, closets and ceramic tiles imported, distributed and marketed in the country. The EU asked Indonesia to explain why this "mandatory standard" was necessary for products that already complied with relevant ISO standards for glazed ceramic. The EU also reiterated comments sent to Indonesia in relation to the original notification of the Decree in G/TBT/N/IDN/37, asking Indonesia to clarify why release limits for lead and cadmium in the SNI 7275:2008 diverged from international standards and whether it would consider accepting tests from ILAC-accredited EU laboratories. The EU recounted that EU industry had been experiencing difficulties since the decree had begun implementation, largely due to excessively burdensome and costly certification requirements. Companies were asked to disclose large amounts of detailed information, including confidential data on raw materials and products, and were also required to accommodate factory visits by Indonesian inspectors. The EU asked Indonesia to reconsider the need for these requirements and explain how certification costs were calculated. The EU also inquired as to the duration of the certification of products using the SNI mark (SSPT-SNI) and the products covered by the certificate. It was concerned that SNI markings were required to be put on each product and not the packaging, which it said was not in line with ISO standards and would imply significant costs. Recalling Article 5.1.2 of the TBT Agreement, the EU asked Indonesia to consider less burdensome conformity assessment procedures.

2.19. The representative of Indonesia recalled that notification G/TBT/N/IDN/37 pertained to the Ministry of Industry's regulation no. 82/MIND/TER/2012 on mandatory implementation of the SNI for Glazed Ceramic. Indonesia took note of the EU concerns, which would be relayed to the capital for discussion with the related ministry.

#### **2.2.1.8 Thailand - Draft Thai Industrial Standard for Ceramic Tiles (TIS 2508-2555) (G/TBT/N/THA/407)**

2.20. The representative of the European Union raised a number of concerns regarding the Thai measure, recalling that it would enter into force as a "mandatory standard" on 15 January 2014. It first asked Thailand why a Thai Industrial Standard was needed for products that already complied with relevant ISO standards for ceramic tiles such as ISO 13006:2012. It also noted discrepancies with certain ISO 13006:2012 elements, such as water absorption thresholds, and asked Thailand to provide further rationale for these discrepancies. The EU also expressed concern with the prescribed conformity assessment procedure for the Thai Industrial Standard, which required product testing and onsite audits by the Thai Industrial Standards Institute (TISI) in order to inspect manufacturers' quality control systems. TISI required "TISI Standard Mark" and "TIS 2508-2555", along with the manufacturer and registered trademark, to be marked on every tile, rather than allowing such marks be placed on the packaging. The EU stated that these marking requirements were not consistent with ISO 13006:2012 and would lead to significant costs. Additionally, the EU complained that the Thai measure's certification process could only be completed within Thailand; was valid per importer and per product line only and was not granted to third-country manufacturers; required the disclosure of confidential information by

manufacturers, and subjected manufacturers to on-site factory visits by TISI inspectors. The EU said that, overall, the certification process appeared to be unnecessarily burdensome, redundant and costly. Recalling Article 5.1.2 of the TBT Agreement, the EU called on Thailand to consider less burdensome conformity assessment procedures for ceramic tiles, and invited Thailand to consider postponing implementation of the measure so as to provide industry with more time to apply for certification. The EU concluded by asking Thailand whether test results from EU laboratories and certificates from EU conformity assessment bodies would be accepted.

2.21. The representative of Thailand informed the Members that the measure had been notified to the WTO under G/TBT/N/THA/407 on 5 October 2012 with a period of 60 days for comments. Thailand stated that the standard would enter into force on 15 January 2014, or 180 days after its publication in the government's official gazette. The Thai representative stated that she would consult with capital authorities in order to formulate an appropriate response to the concerns voiced by the EU.

#### **2.2.1.9 United Arab Emirates - Control Regulation for Halal Products - Part I - Halal Food (G/TBT/N/ARE/153)**

2.22. The representative of the European Union thanked the UAE for notifying its draft Control Regulation for Halal Products on 15 May 2013 and underlined its support for providing more clarity on halal requirements. The EU nevertheless was concerned that the proposed measure introduced stringent requirements without providing sufficient guidance on their implementation. It thus asked the UAE to provide appropriate detailed guidelines on how the measure would be implemented as well as how it would supersede the existing regulatory framework. In particular, the EU was concerned with the lack of details regarding the requirements for recognition of accreditation bodies and for acceptance of conformity assessment bodies, and noted that the standards mentioned in the draft (UAE.S OIC/SMIIC 1, 2 & 3) had not yet been issued. The EU also requested more clarity regarding mutual recognition of certificates and halal marks, and emphasized the importance of having a well-functioning system of mutual recognition at the time of the measure's entry into force. Citing the potentially significant implications for international trade of the draft measure, the EU suggested that the UAE should further consider the economic and practical implications of implementing the regulation.

2.23. The representative of New Zealand welcomed the UAE's notification of the draft regulation. Noting its status as a major exporter of high quality halal food products, New Zealand said that it was closely following the development of the regulation and were engaged in direct discussions with UAE officials over aspects of the regulation, and looked forward to receiving further information and a notification of the draft regulation at the next appropriate stage.

2.24. The representative of the United Arab Emirates was not present at this meeting. The Chairman thus asked the Secretariat to convey to the UAE the concerns raised by the EU and New Zealand.

#### **2.2.1.10 Chile - Safety for Printers and Energy Efficiency for Printers (G/TBT/N/CHL/213, G/TBT/N/CHL/214)**

2.25. The representative of the United States raised concerns with two Chilean measures, "Safety for Printers" (CHL 213) and "Energy Efficiency for Printers Labelling" (CHL 214), notified in August 2012. The US also expressed appreciation for its past bilateral engagement with Chile regarding its concerns. The US noted Chile's June 2013 announcement changing implementation deadline from April 2014 to 27 December 2013, thus leaving only 6 months until compliance. The US considered this period to be insufficient to allow companies to adjust inventories and production. Further, it noted that the list of 10 approved testing facilities was only released by Chile in late July 2013, and that many of these facilities were possibly not located in the same geographical area as relevant printer equipment production. The US also expressed dissatisfaction that industry comments had not been taken into account when Chile released its final protocols in December 2012, and that extensive engagement by the US had been necessary to raise awareness of the issues contained in its comments. The US asked Chile to confirm whether the final measures would be liable to revision in the context of Chile's revision of the overarching framework for the measures through Decree 298-2005, as US companies developing compliance plans for the two measures were concerned about future revisions being triggered by changes to the framework.

The US asked Chile to delay the measure's entry into force until the revision of Decree 298-2005 had been finalized and notified.

2.26. The representative of Chile said that her delegation also appreciated the bilateral dialogue both countries have had on this matter. She stated that Chile has been developing the two protocols with the aim of establishing a clear process of certification to promote better consumer information, prevent falsification, and facilitate control processes. Recalling that the protocol was notified to the WTO in August 2012, Chile stated that comments submitted by the US during the consultation process were responded to in a timely manner by Chilean authorities. Based on comments received and consideration of the consequences of the measures, Chile would adopt new measures by means of resolutions of the oversight mechanism. Chile elaborated that the date of entry into force for importing agencies and products manufactured locally by December 2013 would be changed to 30 April 2014. With regard to testing facilities, Chile stated that new laboratories were being considered to facilitate the certification process. Chile also stated that it aimed to ensure that conformity assessment procedures were no more trade restrictive than necessary, and that the Ministry of Economy had stipulated that a review of the decree would take place. Chile reiterated that both protocols had complied with commitments of transparency and notification, and that Chile had maintained constant dialogue with the US so as to arrive at a mutually satisfactory resolution of the issues.

#### **2.2.1.11 China - Regulations of the China Food and Drug Administration on Legislative Procedures (Exposure Draft)**

2.27. The representative of the United States said her delegation was encouraged that CFDA ("China Food and Drug Administration") was proactively working to strengthen its legislative procedures through systematic, formalized stakeholder outreach. She also noted its strong support for provisions of the draft regulations that reflected good regulatory practices discussed in the TBT Committee, such as the required solicitation of public opinion on CFDA drafts of laws, administrative regulations, and rules listed in its legislative plan, through obligatory posting of such drafts on the State Council Legislative Affairs Office (SLCAO) website for no less than 30 days. Recalling the TBT Committee's Sixth Triennial Review and discussions on Good Regulatory Practices, she urged China to consider establishing a "whole-of-government" approach to transparency and stakeholder input that would be applicable to all ministries and agencies involved in regulatory development.

2.28. With regard to the content of the draft regulations, she noted that drafts were to be submitted to the SCLAO website after having been examined and amended by the CFDA's Law Department. She sought clarification on how comments submitted at this late stage would be considered by the Law Department. She proposed that the solicitation of public opinion occurring under Article 17 of the measure specify that "public online solicitation" required posting the draft on the SCLAO website for a 30 day comment period to ensure that online comments could realistically help shape the draft. She also requested that interpretations and opinions as specified under Article 36-37 of the measure should be subject to the same transparency requirements as those affecting draft regulations, and urged the CFDA to amend Article 36-37 to require draft interpretations to be posted on the CFDA's website to solicit public comment for a period of no less than 30 days. She expressed appreciation for the CFDA's proposal in Articles 43-44 to solicit public opinion on normative documents, but sought clarity on the definition of such documents and requested that all draft normative documents of a binding nature were posted on the SCLAO website for a public comment period of at least 30 days. Recalling China's transparency commitments under the TBT Agreement and its WTO Accession Protocol, she recommended that the CFDA specify in the Draft Regulations the process for notifying pertinent measures to the WTO and that the CFDA would answer comments and inquiries in a timely manner. She reiterated the US' support for the CFDA's work on increasing transparency and public participation in the legislative process, and recommended that, in line with Articles 2.4 and 5.4 of the TBT Agreement, the CFDA Law Department's examination under Article 22 specifically include consideration of whether draft measures are based on extant or imminent international standards, guides or recommendations. She also applauded the CFDA's plans to require the evaluation of social and economic impacts of its measure and to report and evaluate those impacts, and suggested that the US FDA's regulatory impact assessment process provided useful guidance. She also praised the CFDA's proposed legislative planning process, along with hopes that it would provide an opportunity for early stakeholder feedback and different perspectives on CFDA legislation. To this point, she highlighted the government's Unified Agenda of Regulatory and Deregulatory Actions as



an example for developing criteria for regulatory planning and execution. She concluded by urging China to continue its exploration and adoption of relevant international regulatory best practices and to take full consideration of comments submitted by US industry and other interested parties in addition to those presented in the TBT Committee.

2.29. The representative of the European Union echoed the concerns of the US and said that while her delegation welcomed the CFDA's efforts to improve transparency in its legislative process, she would still need to ask for clarification on whether the public comment process would take place at a sufficiently early stage and afford equal treatment of foreign and domestic stakeholders. She also asked whether the same transparency would apply to all categories of normative documents published by the CFDA such as guidelines and other implementing rules. She recalled the need for TBT notification to take place at a sufficiently early stage without prejudicing internal public consultation in China, and also stressed the need for greater reliance on international standards in the regulatory process in accordance with China's commitments under the TBT Agreement.

2.30. The representative of China noted her delegation's view that the CFDA's measure was an internal document that regulated legislative procedures and was not related to any specific product or conformity assessment procedures. Accordingly, China argued that the measure was not covered by the TBT Agreement. It welcomed the US to participate in domestic transparency procedures through bilateral communications, but felt that the TBT Committee was not a suitable forum for such discussions.

#### **2.2.1.12 European Union – Fuel Quality Directive**

2.31. The representative of the United States, stated that it shared the goal of the EU Directive, and noted its likely importance to other WTO Members. She understood that this process was nearing conclusion in terms of selecting an implementation option from among the alternatives. She articulated transparency concerns with this impact assessment process, in particular the lack of detailed public information regarding various implementation options under consideration by the Commission, and in light of the potential trade impacts of some of the options understood to be under consideration. In this regard, she noted that public comment on impact assessments was considered to be a good regulatory practice.

2.32. The representative of Canada shared the concerns raised by the US and added Canada's view that the draft Commission proposal for implementation, as written at the time, had the potential to create market access barriers for North American petroleum products in the EU. She emphasized the need for the Directive's implementing measures to be based on the best available science and to encourage transparency. The Canadian representative also stressed the importance of treating all globally-traded petroleum products in an equivalent, non-discriminatory manner. As it seemed that the impact assessment process was nearing finalization, Canada looked forward to learning the results of such assessment. Canada urged the EU's impact assessment to be full, open and transparent, include multiple views, and examine effects on consumers and the European economy.

2.33. The representative of the European Union argued that since the draft Commission proposal for the implementation measures had not yet been adopted, it was premature to discuss the issue in the TBT Committee. The EU had carried out an impact assessment and a series of stakeholder consultations and would ensure that the implementing measures were WTO-compatible.

#### **2.2.1.13 Mexico - Draft Mexican Official Standard PROY-NOM-032-ENER-2013: Maximum electrical power limits for equipment and appliances requiring standby power. Test methods and labelling (G/TBT/N/MEX/263, G/TBT/N/MEX/263/Add.1)**

2.34. The representative of the United States said that while her delegation supported Mexico's efforts to promote energy conservation, it nevertheless had a number of concerns over Mexico's draft standard as well as the related test methods (notified in G/TBT/N/MEX/263) and labelling requirements (notified in G/TBT/N/MEX/214). First, the US was concerned with what it viewed as duplicative labelling and conformity assessment regimes, and asked how they would result in energy efficiency for consumers. It considered that these differing regimes could not be resolved through a single label or test, but would instead require two labels and two tests of many of the same products. Addressing in-country testing provisions in Articles 11.4.3 and 11.6.1 of the draft

standard, the US asked Mexico to confirm whether the Mexican Ministry for Energy (CONUEE) planned to allow non-Mexican labs to provide certification and requested a list of labs approved for certification. The US also noted the lack of identified risk in the risk assessment, and inquired as to how the measures would achieve Mexico's goal of energy conservation. Noting that the final version of NOM-032 would be published in November 2013, the US asked for details on the date of entry into force and whether Mexico planned to take comments into account. It concluded by articulating a belief that further study and analysis could contribute to resolving some of the issues raised, and requested that Mexico take such concerns into account prior to setting an implementation deadline.

2.35. The representative of Mexico recalled that the measure was published on 22 May 2013 in Mexico's Official Gazette and was notified to the WTO on the same day, with distribution by the WTO on 27 May 2013 as G/TBT/N/MEX/263. Mexico received comments from three businesses in the US, which were sent to the appropriate regulatory body, the Ministry of Energy. Mexico also recalled receiving comments from Canada on 23 July 2013, outside of the consultation deadline. Noting that some observations made by Canada coincided with observations made by the US in their respective comments, Mexico stated that the official responses given to the latter also responded to the former's questions. It added that the Mexican Ministry of Energy invited the US Consumer Electronics Association to meetings of the working group tasked with preparing the draft standard. It was at these meetings that multiple amendments were made to the transition articles of the measure in order to minimize the impact of the measure's implementation. The Mexican Government was working to provide responses to various governments' comments as soon as possible, and that these would be taken into consideration before the final publication of the draft standard. There was not yet a scheduled date for this final publication, but it noted Members' comments and would respond publicly through its official gazette.

**2.2.1.14 Turkey - Draft Communiqué on Warning Messages Placed on Containers of Principles Concerning Domestic and Foreign Trading of Alcohol and Alcoholic Beverages (G/TBT/N/TUR/41, G/TBT/N/TUR/41/Add.1, G/TBT/N/TUR/42, G/TBT/N/TUR/42/Add.1)**

2.36. The representative of Canada voiced her delegation's concern that Turkey's proposed measures appeared to violate Articles 2.9.4 and 2.12 of the TBT Agreement. Canada recalled that it had already provided comments to Turkey's TBT Enquiry Point on two occasions. Canada cited a communication from Turkey to Canada, dated 29 August 2013, explaining that these measures were "prepared as secondary legislation to the Law 6487 dated 11 June 2013, which mandated secondary legislation to enter into force within two months after the publication of the Law, that is, as of 11 August 2013". Canada asked how such entry into force period complied with Article 2.12 of the TBT Agreement. Canada also asked whether Turkey had conducted any studies to demonstrate the efficacy of its proposed labelling in achieving its objectives of educating its population on the risks posed by alcohol consumption to those underage, pregnant, or driving, and whether it had considered less trade restrictive measures to achieve these objectives.

2.37. The representative of Mexico expressed her delegation's concern that the proposed measures could be in violation of Article 2.2 of the TBT Agreement as less restrictive measures could be used to achieve the same legitimate objectives. Mexico asked Turkey to explain the scientific basis for the proposed measures on packaging, as it believed that the measures be a violation of intellectual property rights.

2.38. The representative of the European Union noted that although her delegation understood the objective of warning consumers about the risks of alcohol, and particularly those for young people and pregnant women, it found the content, format, and placement of the obligatory warning messages to be affixed on the packaging of alcoholic beverages to be excessive. In particular, she noted that there already existed Turkish legislation forbidding the sale of alcohol to individuals under 18 years of age and on driving under alcoholic influence thus making it unnecessary to require using packaging logos that warned customers about the risks of alcohol. She also raised a concern with the obligation to affix on containers of alcoholic beverages the message "alcohol is not your friend", arguing that it was excessive consumption – not any consumption – that posed a risk to consumer health. The EU thus found the obligatory message to be misleading, as it gave the impression that even a moderate amount of alcohol consumption would be harmful to consumers. The EU considered that the measure's objective could be better achieved through information campaigns and consumer education initiatives stressing the danger

of excessive drinking or putting emphasis on responsible consumption of alcoholic beverages. The EU also noted concerns on the draft regulation on procedures and principles concerning domestic and foreign trading of alcoholic beverages. In particular, the EU was concerned with Article 4, which stipulated that the brand, identification or distinguishing signs used on alcoholic beverages could not be used on non-alcoholic beverages, and vice-versa. This could have the effect of prohibiting an EU brewer using a uniform mark for its entire product range from selling alcohol-free beer in Turkey if its variant containing alcohol was already on the Turkish market and vice-versa.

2.39. The representative of the United States supported the concerns of Canada, Mexico and the EU relating to Turkey's draft regulation. She thanked Turkey for its 30 August 2013 response to US comments, and expressed appreciation for the 60-day comment period afforded by Turkey. She asked Turkey to explain the science behind the required warning statement "Alcohol is not your friend" to be placed on alcoholic beverages.

2.40. The representative of Turkey informed that the proposed measures were prepared as secondary legislation to Law n. 6487 of 11 June 2013, which mandated entry into force of the secondary legislation within two months after the publication of the Law. He stated that due to the 2-month deadline, after the preparation of the secondary legislation by the relevant Tobacco and Alcohol Market Regulatory Authority, the comment period could only be provided until 9 August 2013. Nevertheless, comments provided until and past this date had been accepted. He also noted that in response to requests, Turkey extended the comment period to 6 October 2013 by means of addenda to the original notifications on 29 August 2013, thus allowing Members a total of 60 days to comment. Turkey recalled that also on 29 August 2013, it informed the relevant TBT Enquiry Points of other Members that although the communiqué and regulation had been published in the Official Gazette of Turkey on 11 August 2013 in accordance with Article 2.9.4 of the TBT Agreement, additional comments would be evaluated and taken into account and that secondary legislation would possibly be re-examined and amended if considered necessary. With respect to Article 2.12 of the TBT Agreement, he stated that importers, producers and distributors were provided a 10-month transitional period so as to allow them to adopt their products or methods of production to the new requirements. He clarified that the objective of the relevant measures was to provide better consumer information, as well as the protection of human health and safety, which embodied the protection of especially three internationally accepted target groups - minors, drivers and pregnant women - from the adverse effects of alcohol consumption. Turkey assured the Committee that the measures would not be adopted in a manner that would constitute arbitrary or unjustifiable discrimination or disguised restriction on international trade. Turkey stated that it would provide written replies to the comments it had received from several Members.

#### **2.2.1.15 United States — EPA Palm Oil Biofuels Regulatory Program**

2.41. The representative of Indonesia raised concern over the U.S. Environmental Protection Agency's (EPA) Renewable Fuel Standard (RFS) program. He recounted that the U.S. Energy Independence and Security Act of 2007 established national mandates for biofuel use and established thresholds of greenhouse gas (GHG) emission savings versus traditional fossil fuels that individual biofuels must demonstrate in order to be considered "renewable" and count towards these mandates. To this end, EPA had required that biofuels represent a 20% reduction in GHG emissions over their entire lifecycle, including the consideration of any land-use change associated with the production of the biofuel's feedstock. In 2011 the EPA published a notice of data availability regarding its analysis of the GHG lifecycle emission savings demonstrated by a number of biofuels. Biodiesel produced from palm oil, of which Indonesia was a significant producer and exporter, did not meet the EPA's threshold and thus did not qualify as a renewable fuel for the purposes of the RFS program's mandates. Indonesia argued that both the GHG emission savings threshold and the methodology for calculating a biofuel's lifecycle GHG emission savings were arbitrarily set. Noting that no international standard had been developed for renewable biofuel, the Indonesian representative reminded Members that the TBT Agreement required members to use international standards as the basis for domestic regulation and that such regulation should be as minimally trade-restrictive as possible. He noted that Indonesia was continuing to work with US officials to address its concerns. In March 2012, Indonesia submitted to the EPA the results of its own calculations of the lifecycle GHG emission savings associated with biodiesel derived from palm oil. These results indicated lifecycle savings far above the threshold value of 20%, which would qualify Indonesian palm oil-derived biodiesel as a renewable fuel in the RFS. Indonesia

noted, however, that it did not receive a positive response from the EPA regarding these submitted results. He added that Indonesia had invited EPA officials to come to Indonesia for the purpose of collecting first-hand data. The officials accepted and a visit took place in October 2012. Indonesia also recalled that it had expressed similar concerns during the Trade Policy Review of the US on 18-20 December 2012, and received a response from the US that the EPA's analysis of palm oil-derived biofuels was ongoing. The Indonesian representative concluded by reiterating its invitation to EPA to address its concerns regarding the GHG emission savings values assigned to Indonesian biofuels derived from palm oil, including full consideration of the alternative calculation submitted by Indonesia. The resolution of Indonesia's concerns, he said, would allow Indonesian palm oil intended for biofuel use to revive its position in the US market.

2.42. The representative of Malaysia joined Indonesia in raising concerns over the RFS. Specifically, Malaysia argued that the EPA's calculations of GHG emission savings values for palm oil-derived biofuels were based on erroneous assumptions and projections, including those pertaining to peatland expansion and the development of biogas plants. It added that the EPA's projections failed to take into consideration new policies and regulations that would result in a departure from historical trends. Indonesia noted that it had been engaging the EPA on the matter, but was still waiting for a response to comments and inputs that it had previously submitted.

2.43. The representative of the United States noted that the US had not been informed prior to the meeting that this concern would be raised, so there had been no opportunity to receive instructions or consult with relevant regulators. The US would thus provide a response at the next Committee meeting having consulted with officials in the capital.

## 2.2.2 Previously Raised Concerns

### 2.2.2.1 European Union – Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)<sup>5</sup>

2.44. The representative of India reiterated concerns made at past meetings on: (i) the high cost of compliance for small and medium-sized enterprises (SMEs); (ii) the opaque and arbitrary functioning of the Substance Information Exchange Fora (SIEF), including cost associated; (iii) the definition of micro, small and medium-sized enterprises; (iv) the discrimination of not allowing traders to directly register; and the cost associated with hiring an Only Representative (OR). With the new threshold date coming into effect in 2014, a number of SMEs would be covered under the REACH legislation. As regards Commission Regulation 836/2012, prescribing a threshold concentration of 0.05% for the use of lead in jewellery, India asked whether the EU had issued guidance to parents and enquired for the rationale of exemptions made for vitreous enamels and crystal. He requested the sharing of any scientific studies and risk assessment analysis mentioned in Regulation 836/2012.

2.45. The representative of Indonesia asked for clarification about, and voiced concerns on, a number of issues, including: (i) burdensome and additional cost for Indonesian exporters; (ii) compliance by SMEs; (iii) the use of volume threshold for registration; and (iv) extensive and complex constant revision and frequent amendments to the legislation.

2.46. The representative of the United States reiterated concerns on: (i) the treatment of nanotechnology; (ii) the precise meaning of the term "article"; and (iii) the overall impact on small and medium-sized companies. She also recalled concerns on the rationale of singling out one class of chemicals as regards nanomaterials, or on assessing the potential risk or market barriers for a broad range of products. She asked for any updates regarding an EU-wide central registry, and on the issuing of guidance on accepted measurement methods, implementation, or compliance. She further asked for clarifications as regards expectations on nanomaterials in the REACH Annexes, and for further guidance on the differing interpretation of the term "article". The lack of clarity and consistency across EU Member States led to confusion, higher costs of compliance, and the lack of a harmonized approach on the notification of substances of very high concern (SVHCs). She

---

<sup>5</sup> G/TBT/N/EEC/52 (+Add.1-7) G/TBT/N/EEC/52/Add.3/Rev.1, G/TBT/N/EEC/295, G/TBT/N/EEC/295/Add.1; G/TBT/N/EEC/297, G/TBT/N/EEC/297/Rev.1, G/TBT/N/EEC/297/Rev.1/Add.1; G/TBT/N/EEC/333, G/TBT/N/EEC/333/Add.1, G/TBT/N/EEC/334, G/TBT/N/EEC/334/Add.1; G/TBT/N/EEC/335, G/TBT/N/EEC/335/Add.1; G/TBT/N/EEC/336, G/TBT/N/EEC/336/Add.1; G/TBT/W/208

informed on a survey conducted by the Dutch Ministry of Infrastructure and the Environment regarding the potential impact of registration requirements on its SMEs that had found higher costs of implementation and compliance with REACH than previously foreseen, and lower awareness among SMEs than expected. The survey confirmed concerns voiced in the TBT Committee on insufficient knowledge or available information on compliance with REACH; costs of compliance and for participating in SIEFs, including adverse impacts through the imbalance of power among SIEF participants; as well as downstream users experiencing problems with drafting, interpreting, translating, distributing and updating of Safety Data Sheets (SDSs/eSDSs). She enquired how findings and recommendations of this study would be taken into account.

2.47. The representative of the Philippines reiterated concerns on the impact of REACH on SMEs, specifically with regard to high costs and predictability.

2.48. The representative of the European Union recalled that her delegation's support for SMEs had been analysed in the REACH review of February 2013. She stressed that the Commission was currently working with the European Chemicals Agency (ECHA) on an implementation working plan. As an immediate action, through Commission Implementing Regulation No. 254/2013 of 20 March 2013, the Commission had revised ECHA fees with a further increase in reduction for SMEs. The Commission had also asked ECHA to nominate an SME ambassador to initiate and coordinate ECHA activities, and was considering the need to revise and produce new guidance documents with regard to the operation of SIEF and data sharing. She said that the Commission was launching a technical assistance study to advise Member States on how to assess the impacts of proposed restrictions on SMEs.

#### **2.2.2.2 India - Pneumatic tyres and tubes for automotive vehicles**

2.49. The representative of Japan expressed concern on Article 10.2 of the revised "Agreement for the Granting of BIS licence", under which only foreign tyre manufacturers were required to provide a bank guarantee of USD 10,000. Japan requested India to amend this clause and to improve the ISI Marking fee calculation method. The ISI Marking Fee was charged for all tyres manufactured in India, as well as those imported into, or exported outside, the Indian Market. Japan considered that tyres exported outside India should be exempted from the ISI Marking Fee, and asked for clarification on the total payment for the ISI Marking Fee.

2.50. The representative of the European Union reiterated longstanding concerns with regard to the Order's certification procedure and mandatory marking for tyres. First, the EU requested removing the bank guarantee of USD 10,000 for the payment of royalty fees, which only applied to foreign manufacturers. Secondly, of particular concern were the royalty fees to be paid on the total production of tyres produced and marked with ISI marking. She urged India to remove the royalty fees or to modify their calculation with a view to limiting them to tyres *de facto* exported to India. Finally, she requested India to accelerate the rather slow certification process and to consider extending the validity of the licences for more than only two years.

2.51. The representative of Korea reiterated previous concerns regarding marking fees that appeared significantly unjustifiable and unreasonable and were imposed only on tyres imported to India. Compared to similar marks issued by other countries, these fees were considerably higher for the ISI system. He said that most countries in general did not charge marking fees for tyres. Korea urged the Indian authorities to revoke or amend the requirement and to provide evidence that marking fees were comparable or even lower than those by other Members. He also requested India to repeal the USD 10,000 performance bank guarantee required for foreign tyre manufacturers outside India and to achieve objectives in a non-discriminatory manner.

2.52. The representative of India replied that the bank guarantee fee was intended to protect the Bureau of Indian Standards (BIS) from breach on behalf of the licensee during the tenure of the licence, and covered a civil liability that might arise during the period of the licence or thereafter. He said that bank guarantees were prevalent in international trade, specifically with regard to performance of contracts. He also explained that once a tyre was marked with an ISI mark, the liability fell on the agency providing the particular mark, while the possibility of the particular tyre being re-exported back to India could not be excluded. India believed that its overall fee structure was comparable to, if not lower than, those applied by other Members. On the speed of the

certification process, he had been informed that BIS labs were managing their workload adequately.

### **2.2.2.3 India – Mandatory certification for steel products**

2.53. The representative of the European Union welcomed India's biennial exemption on imports of steel and steel products and enquired how this would work in practice. Nevertheless, the EU considered third party certification to be inappropriate and too burdensome for intermediate steel products. She noted that European industry continued to report difficulties during the certification procedure, including long delays for issuing certificates, extensive and detailed information to be provided, mandatory factory inspections, the lack of feedback on reasons for refusal of applications, and the lack of recognition of test results carried out by foreign laboratories. She asked India to institute a more expeditious procedure with clear deadlines and the possibility to challenge the refusal of the application.

2.54. The representative of Japan considered that there was no need to impose mandatory standards on intermediate goods such as steel products, as the protection of human health or safety could be achieved by safety regulations for final products. He said that the scope of the standards would have to be specified clearly, and that mandatory standards should be implemented in a manner that did neither obstruct customs and other importation procedures, nor disrupt Japanese supply of high-quality steel products. He also asked for clarification on the rules of exemptions with regard to the standard on structural steel (IS2062) that applied to steel used in the construction sector, but not to steel used in the manufacturing sector, such as automobiles.

2.55. The representative of India reiterated that, subject to certain conditions, exemptions had been provided to projects in infrastructure, petroleum and to manufacturing products involving high end technologies, nuclear reactors, defence chemicals and petrochemicals and fertilizer sectors. As regards implementation of notified goals, he said that certain conditions were applicable to all projects. India informed that one of the Orders of the Ministry of Steel, issued on 1 October, had extended the date of application for certain products to 1 April 2014. Hence, he considered that most of the industry concerned in terms of adaptability to this Order had been addressed. The regulation applied to all sectors with not specific exemption in place.

### **2.2.2.4 Brazil – Health Products Good Manufacturing Practices (GMP) Requirements for Health Products**

2.56. The representative of the European Union welcomed the bilateral meeting held with Brazil on its procedures for the registration of medical devices as well as its efforts to accelerate inspections. She requested an update on further steps to be taken, in particular on whether Brazil intended to rely on or accept Good Manufacturing Practices (GMP) inspections reports issued by foreign authorities.

2.57. The representative of Brazil reiterated that Decree n. 8077 was published in the Brazilian Official Gazette on 14 August 2013, revoking Decree n. 79094 of 1977. With this new Decree, the National Health Surveillance Agency (ANVISA) had autonomy to define products that would require GMP certification for registration, and those cases in which other health authorities or accredited bodies' inspection reports could be accepted to issue the GMP certification. He said that Brazil was moving towards more flexibility with respect to the requirement to issue GMP certificates. ANVISA would soon publish a draft technical regulation defining the requirements to obtain GMP certification so as to make the whole process faster and friendlier. He said that the draft text would be notified to the Committee for comments. The new technical regulation revoking Resolution n. 25/09 was intended to enter into force at the beginning of 2014. The Brazilian delegation recalled the importance of setting up confidentiality agreements between ANVISA and health authorities of other Members to enable data exchange related to inspection reports.

**2.2.2.5 India - New Telecommunications related Rules (Department of Telecommunications, No. 842-725/2005-VAS/Vol.III (3 December 2009); No. 10-15/2009-AS-III/193 (18 March 2010); and Nos. 10-15/2009-AS.III/Vol.II/(Pt.)/(25-29) (28 July 2010); Department of Telecommunications, No. 10-15/2009-AS.III/Vol.II/(Pt.)/(30) (28 July 2010) and accompanying template, "Security and Business Continuity Agreement")**

2.58. The representative of the European Union requested an update on recent developments regarding security clearance requirements for equipment to be used in telecommunication networks as laid down in the Uniform Access Licence Agreement. It posed the following questions: Would India continue to accept self-certification by equipment vendors in light of postponement of implementation until 1 April 2014? Would a "Telecom Testing and Security Certification Centre" be only set up in Bangalore? Would this Centre have the capacity to process all expected applications for testing and certification? Could India confirm the possibility for foreign labs to be approved by Indian authorities, and to supply test reports which will constitute a sufficient basis for the issuance of required certification? India had recently been recognized as "authorising member" under the Common Criteria Recognition Arrangement (CCRA) and would thus be able to test electronics and IT products and to issue certificates with respect to information security accepted in all other 25 CCRA Members. Could India therefore confirm that it will accept test results of labs appointed by CCRA Members for the purposes of the required security clearance assurance? The competence of labs operating under the CCRA is established through a very rigorous process and, hence, they should be allowed to perform any of the tests required by the Indian authorities. Finally, India's Department of Telecommunications had issued final guidelines for the granting of Unified Licence on 19 August 2013, which contained a template for the licence agreement laying down in its chapter 6 the required security conditions and prescribing compliance with a number of security standards, including the CCRA standards. Could India clarify whether this document is the final technical guidelines for the implementation of security clearance requirements, or whether a more detailed guideline would still need to be issued. In this regard, the EU stressed the need for greater clarity and predictability in the implementation of the scheme and the avoidance of market disruptions.

2.59. The representative of the United States welcomed India's extension for compliance to January 2014. She also expressed her delegation's continuing disagreement with India's premise that domestic testing was necessary or sufficient to meet its legitimate security concerns. While the US welcomed India's acceptance to the CCRA as a certifier, it was concerned with the process of recurring three-month extensions, causing the industry to be continuously preoccupied with the imminent implementation of the requirement, and with implications for the broader investment climate. Finally, she noted the practical challenges posed for the implementation of telecom requirements, including India's lack of testing capacity and infrastructure. She urged India to consider postponing the implementation date with a view to testing requirements and the needs of industry to comply with the tests.

2.60. The representative of Japan supported the concerns expressed by the EU and the US. Japan had an interest in the Unified Access Service License Agreement and asked India to ensure that its telecommunications regulations would not impede market access for foreign companies.

2.61. The representative of India clarified that the relevant notification had specified an extension of time for security certification of telecom equipment within the country in respect of licence amendment, dated 3 June 2011, for security related concerns for expansion of telecom services in various zones of the country. While the specific date for internet service providers was 30 June 2014, he would enquire for the exact end date on the unified licence agreement certification. Due to its upgrading under the CCRA, India's guideline had referenced the Common Criteria Labs as being able to certify until 30 June 2014, with certification being conducted by authorised certified agency labs in India from 1 July 2014 onwards. He said that he would revert back on the certification centre in Bangalore. In terms of in-country testing, he clarified that India was addressing the problem of spyware and malware attacks on telecom equipment.

#### **2.2.2.6 Korea – KS C IEC61646:2007 Standard for Thin-film Solar Panel**

2.62. The representative of the United States continued to have serious concerns regarding methodologies and scientific flaws employed in Korea's environmental study, which had led to the exclusion of a certain type of solar panel manufactured in the US from its certification programme.

The results of this study would hence *de facto* determine access to the Korean market, leading to market access issues for US producers.

2.63. The representative of Korea referred to bilateral meetings and Korea's suggestion of holding an expert-level dialogue. He informed that, following last June TBT Committee meeting, certification for CIGS modules had started in July 2013 on a pilot basis with the certification system scheduled to officially start at the beginning of 2014 when preparation for certification of the CIGS module, including test criteria and relevant facilities, was completed. Korea would refer other points raised to their competent authorities.

#### **2.2.2.7 China – Requirements for information security products (including, inter alia, the OSCCA 1999 Regulation on commercial encryption products and its on-going revision and the Multi-Level Protection Scheme (MLPS))**

2.64. The representative of Brazil said that the proliferation of independent standardization activities for security products might create uncertainty and unnecessary technical obstacles to trade, contrary to Article 2.2 of the TBT Agreement. According to best practices, cryptography standards for civil goods should be based on multilateral standardization rules in accordance with the "Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the TBT Agreement" (G/TBT/9, 13 November 2000, para. 20 and Annex 4). In line with Article 2.4 of the TBT Agreement, he stressed that ITU standards and recommendations on cryptography to privacy and data confidentiality had to aim exclusively at the protection of the transactions performed.

2.65. The representative of the European Union supported Brazil's comments and reiterated some systemic concerns about the Chinese regulatory landscape on ICT security, including on transparency, opportunities for foreign stakeholders to participate in the regulatory and standardisation process, and predictability of the regulatory regime. As framework conditions continued to be not very conducive to a predictable business environment, he requested specific updates on several issues. First, he enquired on an update on process and substance of the revision of the 1999 Regulation on commercial encryption products by the Office of State Commercial Cryptography Administration (OSCCA). The representative reiterated the need for transparency in the process, domestically (i.e. public consultation) and in the WTO (i.e. TBT notification). On substance, he welcomed an indication of elements being considered to remove current discriminatory aspects, which failed to allow foreign companies to apply for certification. Second, on the Multi-Level Protection Scheme (MLPS), he welcomed the launch of a revision of this scheme and requested that a clear distinction be made between IT systems for commercial use and those relevant for national security. He said that more stringent national security requirements should be limited to areas where national security was genuinely at stake and stressed the lack of a clear definition of "critical infrastructure". The development of such a definition as well as of a catalogue of systems that would fall under this definition were necessary to increase predictability in the application of the scheme. He further reiterated the need for all interested parties (including non-Chinese companies or nationals) to participate in the standards process and asked China to consider ways to open the process of developing and releasing algorithms to be used in commercial encryption products to all interested parties (consistent with international practice providing for peer review of algorithms in global consortia or international standard-setting bodies), and to publish the license conditions for acceding to these. Lack of transparency and inclusiveness in the process was potentially detrimental to the reliability of algorithms to ensure the level of protection required. As an example, the national standard for mobile payments did not define the actual algorithms, but only included a generic reference to an Algorithm E, to be determined at a later stage by OSCCA. No further details on the algorithm development process, and licensing conditions to interested users were available. Finally, he requested that standards developed by standardisation organisations under the direct control of central governmental bodies comply with the TBT Agreement's Code of Good Practice.

2.66. The representative of the United States and Japan reiterated support for Brazil and the EU. The representative of Japan paid particular attention to the various schemes and regulations within China with regard to how these could negatively affect trade of information security products.

2.67. The representative of China informed that a revision process had started with regard to the MLPS. For further concerns, she referred to minutes of the previous meeting.



### 2.2.2.8 China - Provisions for the Administration of Cosmetics Application Acceptance Cosmetics Label Instructions Regulations and Guidance for the Cosmetics Label Instructions.

2.68. The representative of Japan requested China to accelerate the examination of new ingredients as only three new ingredients had been registered since the implementation of the Guidance in May 2011. Japan also considered requirements with regard to safety data on isolated components of plant extracts and fermented solutions as excessive and trade-restrictive. Japan requested China to revise the Guidance, taking into account the practices of safety evaluation of cosmetic ingredients currently taken in many countries, including Japan, the US and the EU, with a view to cosmetic manufacturers being able to register new ingredients without additional processes. In addition, Japan asked China for an explanation on (i) scientific grounds for evaluating a complex ingredient with a single component; and (ii) the assumed risk on the product safety.

2.69. The representative of the European Union considered that there was still a lack of sufficient progress in the approval of new ingredients and of cosmetic products with new ingredients. She recalled that since 2010 only four new ingredients (and one product containing a new ingredient) had been approved, although 120 applications had been made and several hundred new ingredients introduced safely outside China. Further improvements were therefore needed with regard to the burdensome registration process and the speed, efficiency and predictability for this fast-moving and innovative sector. The EU believed that significant further efforts were necessary to ensure that the registration of ingredients and of products with new ingredients increased to levels comparable with those prior to the introduction of these requirements. She asked for an update from China on the steps taken to solve the situation. The EU was also concerned about China's State Food and Drug Administration's (CFDA) intention to pursue a systematic positive list approach for cosmetics ingredients, and the definitions of "new" and "existing" ingredients. Given that an important number of ingredients and cosmetics products currently sold in China might be subject to the above-mentioned onerous registration procedure, China should reconsider its approach. Finally, she recalled previous concerns on the new cosmetics labelling requirements (notified as G/TBT/N/CHN/937) possibly introducing duplication of, or even conflict between with, the CFDA and the Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). She asked for an update from China on the state of play of this notification.

2.70. The representative of the United States associated herself with points made by previous speakers. The reclassification of special function cosmetics in June 2011 had resulted in a virtual standstill in approvals for cosmetics containing new ingredients causing a serious impact on US cosmetics companies. She asked for an update on China's efforts to expedite approval and expressed concern about the CFDA's creation of a "positive list" of ingredients, requesting China to instead allow companies to demonstrate that ingredients were "existing" by means other than appearance on a positive list. She asked for clarification on the CFDA's stated intention to devolve responsibility for managing "normal cosmetic" registrations to provincial-level authorities, and inquired whether these would have adequate training and resources. She asked China to provide assurance that provincial-level authorities would be treating imported "normal cosmetics" in the same manner as they had treated locally manufactured products. With respect to the notification in G/TBT/N/CHN/937, she noted an overlap of requirements with existing AQSIQ regulations. She also requested that the CFDA address existing concerns on the failure to provide alternative means of labelling small packages that lacked enough surface area to carry all the information as required.

2.71. The representative of Canada and the representative of Korea shared the concerns raised by previous Members.

2.72. The representative of China said that her delegation had been cooperating closely with their trading partners in the implementation of the regulation. China had formed a working group on this issue with the EU, Japan and Korea to keep continuous communication and discussion at both administrative and technical levels. China believed that the specific technical issues as well as the smooth implementation of the regulation could be solved by bilateral open and transparent communications between technical experts. She reiterated that the cosmetic label instruction regulations and guidance had been notified on 21 December 2012 as G/TBT/N/CHN/937, but that an adjustment in the CFDA's legislation plan had taken place that might lead to the possible introduction of new regulations administering cosmetics labels in the future.

---

#### **2.2.2.9 France - Loi No. 2010-788: The National Commitment for the Environment (Grenelle 2 Law)**

2.73. The representative of India thanked France for the presentation made in the WTO Committee on Trade and Environment (CTE) on 16 October, which provided details regarding the national commitment for the environment contained in the Grenelle 2 Law. He said that the Grenelle 2 Law used a simplified lifecycle analysis and was currently based on voluntary participation. He also understood that a report of the results of the experimental phase of the Grenelle 2 Law had been submitted to the French Parliament for review and that next steps would be determined after the review had taken place. He requested an update regarding the status of such assessment report and the next steps, and raised concerns regarding the benchmarking of the Grenelle 2 Law against the ISO carbon footprint standard and the limitations of the lifecycle analysis throughout the experiment.

2.74. The representative of Brazil thanked the EU for their bilateral discussions. He also raised concerns over the lack of transparency of the Grenelle 2 Law, and encouraged the EU to notify the relevant measures to the Committee. Additionally, he inquired about the meaning of the word "generalisation" employed in Article 2.28 of the Grenelle 2 Law, indicating that "this text will be subjected to the parliament and will evaluate the opportunity for generalisation of this provision". Finally, he requested an update regarding the review by the French Parliament, and clarification over whether the emissions resulting from the international transport of the products would be included in the computation of the carbon footprints.

2.75. The representative of Argentina reiterated previously raised concerns and recalled that at the March 2012 Committee meeting the EU said that the results of the experiment would be made available at the beginning of 2013. He asked for an update on this aspect and also whether the results had already been submitted to the French Parliament, and how they could be accessed.

2.76. The representative of the European Union reiterated that the Grenelle 2 Law did not contain technical regulations and provided only for an experiment concerning environmental labelling. She invited Members to refer to minutes of past meetings with respect to the objective and scope of the experiment. The results of the experimental phase were evaluated by the French Government in autumn 2013, and her delegations was prepared to share information about the results of the experiment and future developments as soon as the information became public.

#### **2.2.2.10 Peru - Draft Supreme Decree Approving the Regulations Governing the Labelling of Genetically Modified Foods**

2.77. The representative of the United States thanked Peru for their bilateral discussions. She requested an update on the status of the proposed labelling requirements, and recalled concerns raised by several Members about potential impacts on trade. She suggested that mandatory labelling requirements for genetically engineered foods that were substantially equivalent to conventional foods could give the false impression that the labelled food or feed was substantively different from, or less safe than, the conventional equivalent. She also said that mandatory labelling requirements were likely to increase costs to industry, consumers and government authorities. Her delegation believed that voluntary labelling would allow for consumer choice at a lower cost and with less trade disruption. She sought clarification as to how Peru was taking the comments of other Members into consideration when finalizing the measure, and encouraged Peru to continue to work with stakeholders so that any final measure would be practical and implementable within standard industry practices. She also noted that any revision to the draft regulations should be notified to the WTO. Should Peru decide to move forward with the implementation of the regulation, she requested further clarity on the scope of the requirements as well as the implementing mechanism for monitoring, supervision, verification and compliance.

2.78. The representative of Peru explained that there had been no progress regarding the draft of the regulation since the June 2013 Committee meeting, and that the expected date of publication of the technical regulation was not yet established.

### 2.2.2.11 Russian Federation – Draft Technical Regulation of the Customs Union on Alcoholic Products Safety

2.79. The representative of Australia reiterated that Australia and the Russia Federation shared a commitment to adopting international standards for alcoholic products as set out by the International Organisation of Vine and Wine (OIV), and to avoid the creation of unnecessary obstacles to trade in wine. He recalled that his delegation had submitted comments on Russia's notification in February 2013, which focused on commonly used additives and processing aids, identified by the OIV, which did not affect the safety of alcoholic products. Australia noted that several Members were concerned about the regulation, and recalled his delegation's suggestion that Russia consider adopting the OIV list of approved additives and processing aids, as set out in the International Oenological Codex and the International Code of Oenological Practices. He continued to seek clarification about the legal status of wines which conformed to the health warning statement under the previous legislation, and were in circulation at the time the draft regulation entered into force. Once more, he suggested that Russia introduce a six month transition period for those products so as to enable industry sufficient time to implement the new labelling requirements. He asked Russia to confirm whether wines labelled with an Australian "geographical indication" (GI) would be considered as a protected GI under the new technical regulation, and whether the relevant exemptions from the regulations for protect GIs would apply to them. He also requested clarification about requirements relating to the bottling location of wines that include a GI in their description and presentation. He asked whether the Eurasian Customs Union regulations required such wines to be bottled within the boundary of the GI stated in the description and presentation of the wine.

2.80. In addition, the representative of Australia raised a number of new issues. He expressed concerns about the proposed notification process for the declaration of conformity requirements contained in Resolution No. 474 "On Submission of Notifications about the Beginning of Turnover (sale) of Alcoholic Products in the Territory of the Russian Federation", which may present an undue administrative burden for wine exporters. The requirement that exporters ensure that all information relating to their product on the Federal Register be up to date would require exporters to re-notify the Russian authorities of, for example, a new vintage date on the label of a wine that was exported, or a packaging size change, in response to customer requirements. Australia believed a robust regulatory system could be maintained within the Eurasian Customs Union without requiring such detailed information from exporters. Finally, Australia sought clarification on issues pertaining to the enforcement of the Eurasian Customs Union requirements. For example, further information on the sanctions that would be put in place if an exporter failed to meet the notification requirements.

2.81. The representative of the European Union inquired about the status and timeline for adoption of the regulation, and summarized previously raised concerns. Regarding wines, she reiterated that enrichment with "concentrated must", "rectified concentrated must" or "sucrose" should be allowed under the measure for all types of wines, since these were oenological practices widely accepted at internationally level. She said bottling in the country of destination should also be allowed for all types of drinks with protected GI or designation of origin. Regarding beers, the limit on sugar content should be eliminated and the use of fruits and additives should not trigger the obligation to label beers containing such components as "beer beverages". She also asked for assurances that EU GIs were duly protected and that some missing definitions of alcoholic drinks were added to the regulation. She requested confirmation that the production control procedures and conformity assessment procedures would not be applicable to production sites that had been already controlled by EU national authorities. Finally, she suggested that Russia reconsider the ban on PET packaging and to notify such measures to the Committee.

2.82. The representative of Mexico supported the comments of Australia and the European Union and expressed her delegation's concerns on the duplication of requirements already found elsewhere, and requested a reasonable period of time for the implementation of the regulation. She also inquired about the status of the regulation and its date of entry into force, and requested a formal response to their comments.

2.83. The representative of the Russian Federation said the draft technical regulation was being developed in order to establish unified requirements for turnover of alcoholic products - both imported and domestically produced. A public hearing on the draft technical regulation was completed in December 2011, prior to Russia's accession to the WTO. In accordance with the TBT

Agreement, all interested parties were given opportunity to provide their comments during a 60-day comment period. At the moment, the draft technical regulation was being modified and the comments of Members were being reviewed. The draft technical regulation had not been approved and Russia was actively engaged in bilateral consultations. The draft provisions on the notification procedure were excluded from the text. He mentioned that in accordance with Resolution No. 474, as of 5 June 2013, a legal entity would have to provide information on the product to the Federal Service of Alcohol Market Regulation in electronic form on a once off basis. Information provided in such notifications would be publicly available at the website of the Federal Service of Alcohol Market Regulation. Given that at all stages of the procedure information would have to be provided by electronic means, his delegation believed that it would not be burdensome for economic operators. The objectives of the notifications procedure were exclusively related to information and greater transparency of the market. Regarding the definitions of various alcoholic products and references to OIV, Russia considered the definitions provided by OIV as relevant international standards and there were intentions to review certain provisions of the draft accordingly. On the issue of GI, the regulation did not contain a list of alcoholic products with protected GI. In addition, the ban on the use of PET bottles was eliminated from the text of the draft and the draft did not set requirements on the use of additives. Finally, he expressed Russia's willingness to continue to engage in bilateral consultations with interested WTO Members.

#### 2.2.2.12 Korea— Registration and Evaluation of Chemical Materials

2.84. The representative of the United States thanked Korea for their bilateral discussions and highlighted three main concerns: (i) that all new chemicals must be registered, which could have far-reaching impacts and particularly seriously disrupt product development for semiconductors, phones, LED TVs, and other household and industrial products; (ii) the sharing of proprietary information within the supply chain; and (iii) the onerous reporting requirements under the measure, which could be expensive. She also requested an update on the status of the implementation of the Act, and asked whether products on the market under TCCA must be re-registered under REACH.

2.85. The representative of Japan supported the statement of the US. He also requested Korea to review the Act taking into account Japanese concerns. The representative of Japan requested an exemption for new chemical substances of small volume similar to the exemption provided for by Japan, the US, Canada, Switzerland, Australia and the Philippines, as the policy objective of the Act was to protect human health and the environment by managing chemical substances according to the results of assessments of the chemicals hazard and risk, but did not provide an exemption for new chemical substances of small volume, making the Act more trade restrictive than necessary to achieve its objective. In order to ensure enhanced transparency, he requested Korea to provide foreign enterprises with opportunities to express their opinions on the designations of permissible, restricted or banned chemicals as results of hazard evaluations and risk assessments. Finally, the representative of Japan asked for clarification regarding the protection of confidential business information and the penalties for its illegal disclosure.

2.86. The representative of Switzerland supported the remarks made by Japan, especially on the issue of the protection of confidential business information.

2.87. The representative of Korea informed that the Presidential Decree and Ministerial Ordinance were being drafted, and that the Act would be finalised by the end of 2013 and shared in early 2014. She explained that a consultative group including industry was consulted and that the Act would reflect these discussions. She also recalled that the purpose of the Act was to protect human health and the environment from the risk of chemicals, by producing and sharing necessary data. Driven by recent chemical accidents, Korea aimed at establishing a precautionary chemicals management system: in April 2011, chemicals contained in humidifier disinfectants caused acute lung injuries and 111 deaths; and in September 2012, leakage of hydrofluoric gases in Gumi caused five fatalities and enormous financial damages. These accidents were mainly attributed to the lack of available information regarding the use and toxicity of chemicals, as well as to the inadequate knowledge on handling practices in workplaces. The Act reflected therefore the need to avoid similar accidents.

2.88. She then addressed certain concerns raised by the US, Japan and Switzerland based on the discussions taking place within the consultative group. Regarding the exemption for new chemical substances of small volume, she said that given that the Act intended to reduce risk arising from

unknown chemicals, new chemicals were a major target. However, from the perspective of effectiveness, she considered that differentiated approaches to new low volume chemicals were appropriate. In this regard, the consultative group was having discussion to seek more reasonable ways to maintain the purpose of the Act, to promote its effective implementation, and to reduce industry burden. These discussions included measures to simplify and shortened registration procedures. Regarding the designation of authorised, restricted or banned chemicals, she said that Korea decided to put in place various measures, including public notice of designation and collecting opinions from stakeholders such as foreign companies, and consultations between relevant ministries and the Chemicals Evaluation Committee. Finally, on the issue of confidential business information, she explained that they would be protected at a similar level to other Members like the EU, the US and Japan, and recalled that the Act stipulated data protection. For instance, Article 45 of the Act stated that, if requested, dossiers submitted for reporting, registration, hazard review and risk assessment should not be opened to the public. Likewise, on information shared between manufacturers/importers and downstream users, the Act excluded information directly related to business secrets such as chemical composition and manufacturing processes.

#### **2.2.2.13 European Union - Directive 2009/28/EC, Renewable Energy Directive (EU - RED)**

2.89. The representative of Indonesia requested information on the calculation method for determining sustainability criteria under Article 17 of the amendment of Directive 2009/28/EC. He also asked whether EU's rapeseed fulfilled the sustainability criteria of 60% of GHG savings and inquired on other sources of renewable energy used by the EU.

2.90. The representative of Malaysia supported the statement of Indonesia and reiterated his delegation's concern over the discriminatory treatment of palm based biofuel under the EU - RED. Palm-based biofuel was given a lower default greenhouse gas emission saving value compared to biodiesel from other competing raw materials, such as rapeseed oil. He explained that this disadvantaged palm-based biodiesel in terms of access to the EU market. Malaysia had conducted research on the greenhouse gas emissions saving of palm-based biodiesel, and the results indicated high emissions savings compared to the EU assessment under the EU - RED. He urged the EU to consider the technical data Malaysia submitted to the Joint Research Centre of the European Commission and the European Commission. A revision of default values for palm-based biodiesel using the data offered by Malaysia would provide further market opportunities for Malaysian biodiesel producers. Finally, he said that the EU - RED significantly reduced the market opportunity for Malaysia's farm-based biofuel and that Malaysia continued to monitor the extent of the negative impacts of the EU - RED.

2.91. The representative of Argentina informed the Committee that a case had been initiated in the DSB against the EU "Certain measures on the Importation and Marketing of Biodiesel and Measures Supporting the Biodiesel Industry" (DS 459). Consultations with the EU and certain Member states had taken place on 26-27 June 2013 regarding directives 2009/28 and 2009/30.

2.92. Argentina reiterated concerns previously expressed regarding what it considered to be an arbitrary threshold of 35% of GHG reductions for biofuel to be considered sustainable. He said that this threshold could not be scientifically justified nor was based on international standards, and that it created an unnecessary obstacle to international trade. The challenged Community regulation established a default value of 31% for soybean biodiesel. Therefore soybean biodiesel could not comply with the GHG reduction threshold. This led to an assessment and approval procedure that imposed additional costs on Argentine industry. Argentina requested this default value to be corrected in the Annex of these Directives.

2.93. Argentina stated that the current European normative framework, its proposed modifications and the different investigations driven by the European industry against biodiesel of non-Community origin, aimed to protect the highly oversized local industry.

2.94. The representative of the European Union considered that the TBT Committee was not an appropriate forum for discussing this issue. She said that the EU remained open to further bilateral exchange in this regard.

#### **2.2.2.14 Indonesia - Technical Guidelines for the Implementation of the Adoption and Supervision of Indonesian National Standards for Obligatory Toy Safety - Draft Decree of the Ministry of Industry on Mandatory Implementation of Indonesia National Standard and Technical Specification for Toys**

2.95. The representative of the European Union thanked Indonesia for their bilateral discussions. He recapitulated the chronology of the measure: on 12 April 2013, the Indonesia Ministry of Industry adopted Decree No. 24, concerning the mandatory application of the Indonesian national standard for toys, with an entry into force foreseen for 12 October 2013; then, on 24 September 2013, technical guidelines supporting the Decree were issued, and on 9 October 2013, the training of customs officers responsible for taking the samples of imported toys for testing purposes started; finally, on 16 October 2013, the Ministry of Industry adopted Regulation No. 52 appointing 8 Certification Bodies and 7 laboratories responsible for the testing and certification under Decree No. 24, with entry into force with immediate effect. The representative of the EU inquired whether his delegation's understanding of the chronology of the measure was correct and highlighted that an immediate entry into force was likely to disrupt the importation of toys, as customs officers were not yet trained and the laboratories and certification bodies had just been appointed. He therefore requested Indonesia to consider postponing the entry into force of the measure. He then recalled the following previously raised concerns: (i) that conformity assessment procedures provided for in Decree No. 24 were more burdensome for imported products (i.e. testing of each shipment as compared with samples taken every six months from the production line for domestic products); (ii) whether Indonesian certification bodies would accept test reports from foreign laboratories accredited by signatories to the ILAC MRA, and whether this would be sufficient for the acceptance and usability of foreign conformity assessment results; (iii) the need to exempt companies that held an ISO 9001 certificate issued by a certification body accredited by a signatory to the IAF MRA from the annual factory audit; and (iv) that restrictions for phthalates, azo dyes and formaldehydes were unclear. Finally, he raised a new concern with respect to the requirement for a list of production equipment to accompany a request for certification, and asked what the rationale for that requirement was.

2.96. The representative of the United States supported the statements made by the EU. She expressed disappointment at the implementation of the regulation despite numerous questions and concerns, and repeated requests for a delay. She was also concerned about the different product testing requirements for domestic and imported products. Furthermore, she indicated that bilateral MoUs appeared to be necessary for the results of conformity assessment procedures, and urged Indonesia to use bodies accredited by ILAC. Finally, she requested the suspension of the regulation until the concerns were addressed.

2.97. The representative of Indonesia informed that the Regulation No. 24 entered into force on 12 October 2013, and that Indonesia could not extend the date of entry into force for reasons of safety, health and consumer protection. Regarding technical guidance, she said that they were stipulated in Regulation No. 9 of 23 September 2013, which covered standards coverage, the procedure to obtain a certificate of using an SNI mark, testing methods, and marking requirements. In the context of conformity assessment procedures, she explained that the certification scheme conducted by Indonesia was based on ISO/IEC Guide 67:2004. On the issue of testing, the Ministry of Industry designated several testing laboratories accredited by the National Accreditation Body (KAN) and the designation of conformity assessments bodies was stipulated through Regulation No. 52. Finally, regarding chemical substances, the limit of phthalates was set at  $\leq 0.1\%$ , and the maximum amount of azo dye was set to "non azo dye" while the limit of formaldehyde was set at 20 ppm.

#### **2.2.2.15 China – Testing and Certification Requirements for Medical Devices**

2.98. The representative of Brazil reiterated his delegation's concern about the testing and certification requirements for medical devices in China. Despite bilateral understandings with the Chinese authorities as well as discussion on this matter held in previous Committee meetings, Brazil producers were still facing problems in exporting medical devices to China due to the uncertainty of the requirements in force. In particular, the lack of transparency about the requirements for the certification was making the whole process unclear. Further, the lack of accredited testing facilities and long delays in them being carried out created hindered the certification process. He also recalled the obligation to notify all legislative changes at an early and appropriate stage in line with provisions of Articles 2.9 and 5.6 of the TBT Agreement.

2.99. The representative of the European Union said that her delegation associated itself with the statement of Brazil and recalled its concerns with the ongoing revision of China's Order 276 on Medical Devices, and more generally the regulatory framework applicable to medical devices imported and sold in China. She also asked China for an update on the state of play of the revision of its medical devices legislation, and recalled the need for this revision to address industry concerns – not only on the registration procedure as such, but also divergences between China's mandatory standards and international ones, the insufficient acceptance of foreign clinical trial data and foreign test results, and the need for approval of the products in the country of origin or of manufacture prior to their placement on the Chinese market. She stressed the need for China to notify this comprehensive legislation to the TBT Committee, allowing WTO Members a reasonable time to provide comments and taking their comments into account, and provide a sufficient implementation period, of at least 1 year, between the publication of the Order and its entry into force.

2.100. The representative of China said that the State Council of China has been open to public consultations online since September 2010. During this period, China has received comments from relevant organizations and foreign medical device enterprises. The Legal Affairs Office of the State Council was still revising this regulation while taking into account comments received from stakeholders.

**2.2.2.16 European Union – Draft Implementing Regulations amending Regulation (EC) No. 607/2009 laying down detailed rules for the application of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products**

2.101. The representative of Argentina reiterated his delegation's concern that this legal regime was not consistent with the EU's obligations under the TBT Agreement. Nevertheless, with the objective of finding a constructive solution to overcome the obstacles of the community regulations, and avoid the halting of shipments to the EU, and at the EU's invitation, Argentina submitted in July 2009 its dossier on the terms "Reserva" and "Gran Reserva". Although this dossier had been approved by the European Commission's Management Committee for Wine in March 2012, it had still not been adopted within the Commission and published in the Official Gazette. After more than 19 months of this approval process within the committee, the EU has still not made any progress with regard to finalizing the last procedure, despite it being purely of an administrative nature.

2.102. He reminded the Committee that the EU had given the same reply that "formal adoption of the draft regulation regarding reserve and gran reserve is still pending" at both the November 2012 and March 2013 meetings and said that it did not have any further updates on this issue at the June 2013 meeting. These were, according to Argentina, merely a description of a situation that had happened 19 months ago. Therefore, the EU's replies were unsatisfactory and dilatory. This delay was doubly unjustified as the procedure hadn't concluded within a reasonable time-frame (the last stages had taken more than four years) with no explanation for the delay, which could constitute a barrier to trade in itself. There did not appear to be any will to resolve this issue as the lack of information on the inclusion of the matter on the agenda of the Commission demonstrated. The lack of transparency disadvantaged high quality Argentine wines in the EU market, both from a price and a labelling perspective.

2.103. This STC, he said, was the second one in terms of frequency and quantity of Members that raised the same concern. These facts reflected the protection given by the EU to this sector to the detriment of wines from other regions. He noted that Argentina believed that this legal regime was not consistent with obligations stemming from the TBT Agreement. These traditional expressions only constituted indications of quality that fell within the scope of the TBT Agreement and not the TRIPs, thus neither registration nor the granting of exclusive rights over these terms was appropriate. He was concerned about registration requirement of these terms when there were diverging definitions of those complementary quality mentions at the European Community level, therefore failing to provide clear, objective and transparent quality parameters for the use of said terms. He also expressed concern that the EU had given, through bilateral trade agreements, other countries the use of these terms without a registration requirement which amounted to discrimination against the rest of countries with whom the EU did not have bilateral agreements. Given that this issue remained unresolved, he again requested the EU to eliminate the unjustified

restrictions that harmed the Argentine wine industry by including this topic in the agenda of the relevant authorities and by publishing the relevant regulatory act in the Official Journal.

2.104. The representative of the United States associated herself with Argentina and asked the EU to provide an update on the status of the applications that were submitted by the US wine industry more than three years ago. She recalled that the US had suppliers that used these traditional terms and that were unable now to ship those products to the EU. She expressed concern with the lack of progress on this matter and noted her delegation's discontent with the unilateral recognition of these terms.

2.105. The representative of the European Union informed that her delegation had no updates on this issue. She referred delegations to the minutes of the previous Committee meetings.

#### **2.2.2.17 Israel – Warning Regulations on Alcoholic Beverages**

2.106. The representative of the European Union said that while her delegation welcomed some improvements in the last available draft, it nevertheless regretted that some of its comments had not been taken into account. In particular, the EU was still concerned about the establishment by this draft regulation of two different types of warnings on alcoholic consumption whose use varied depending on the alcohol content of the beverage. In this respect, she stressed that according to scientific studies, it is *excessive* consumption of alcohol that was harmful for health, regardless of the type of alcoholic beverage. The differentiation between strong intoxicating beverages and regular intoxicating beverage as regards the warning message as laid down in the notified draft regulations could mislead consumers who could conclude that some alcoholic beverages were more harmful than others. She therefore invited the Israeli authorities to consider providing only one form of warning statement against excessive consumption of alcohol. Regarding the size and placement of the warning, she considered that the information to the consumer should be provided with less restrictive requirements, limited to the size and legibility of the message. Strict provisions related to the colour of the text or to the inclusion of a black frame did not seem justified. She thus requested clarification regarding the usefulness of such requirements as well as to where the warning had to be placed and if the use of stickers would be allowed.

2.107. The representatives of the United States and Mexico associated themselves with the EU statement. Mexico added that they also considered that it was the excessive consumption, not the type of alcohol that was harmful. This measure was therefore believed to be an unjustified measure, including with respect to its labelling requirements.

2.108. The representative of Israel explained that the regulations were approved by the Economics Committee of the Israeli parliament towards the end of July 2013. During the discussions, the parliament committee took into account the comments received from the party and certain amendments were introduced consequently. One of them, for example, was to eliminate the requirement of putting health warning labels on the front of the bottle.

#### **2.2.2.18 Brazil – Draft ANVISA Resolution on Used, Refurbished, Rented and Lent Medical Devices**

2.109. The representative of the European Union requested an update on the ANVISA draft resolution on used, refurbished, rented and lent medical devices, notably its expected time for adoption. In the EU's opinion, reconditioned equipment, independent of its place of first installation, should be allowed for importation in Brazil as long as it complied with the health and safety performance requirements. The EU would thus welcome a revision of this resolution in this direction.

2.110. The representative of Brazil explained that the rationale for its regulations was to avoid having used or refurbished medical equipment being exported for Brazil for purposes of final disposal and to hold the producers of such goods liable for their appropriate disposal. With respect to the status of the new regulation in question, he said that, at the present moment, the Brazilian national surveillance agency, ANVISA, was merely considering the *possibility* of issuing. In other words, there would not be any legal requirement in force which would impact ongoing commercial transactions, or even those to be performed in the near future. Prior to any final decision, the Brazilian authorities would undertake new public consultations on the matter. Additionally, there



were some critical issues to be settled, especially those relating to definitions about refurbished goods. A regular time-frame for the conclusion of the whole process was not yet established, and any further developments would be properly communicated to Members in order to receive their timely comments.

#### **2.2.2.19 European Union – Tobacco products, nicotine containing products and herbal products for smoking. Packaging for retail sale of any of the aforementioned products**

2.111. The representative of Cuba recalled that in the Committee meetings which took place in June Cuba analysed the implications of the application of this directive for many developing countries, and specifically for Cuba. On that occasion, Cuba also outlined a series of questions directed to the EU that were later circulated to Members in G/TBT/W/371. These questions were still outstanding. She also noted that on 8 October 2013 the plenary of the European Parliament in Strasbourg had voted on the European Directive for tobacco products, according to which member states would have 18 months to adapt to that directive within their national legislation after it enters into effect.

2.112. The representative of Malawi expressed her delegation's concern with the consistency of the proposed EU measure with the TBT Agreement. Her full statement is contained in G/TBT/W/376.

2.113. The representative of the Dominican Republic recalled that at the TBT Committee meeting of June 2013, her delegation voiced its concerns regarding the draft report presented on 10 April 2013 by Mrs. Linda McAvan, spokesperson for the Committee on the Environment, Public Health and Food Safety of the European Parliament. Subsequently, on 8 October 2013 the European Parliament adopted amendments to the notified directive. She asked the EU to provide more information about the next steps in this legislative process: would there be a review of this directive? If yes, when? She also expressed her delegation's view that the present text of the measure lacked critical scientific basis demonstrating: (i) that it would contribute to, rather than undermine, the legitimate objective of health in the EU; and (ii) that it constituted the least trade restrictive measures possible to achieve this objective. For these reasons, the Dominican Republic believed that the packaging requirements under the measure were incompatible with the TBT Agreement and the GATT 1994.

2.114. The representative of Guatemala said that while her delegation shared the policy objective of the EU to improve public health by discouraging people from using tobacco products, it was nevertheless not clear how the proposed regulations would achieve such legitimate objective. Furthermore, according to the preliminary assessment of Guatemala these regulations appear to be more trade restrictive than necessary to achieve such legitimate objective, so less restrictive alternatives should be considered.

2.115. The representative of Honduras supported the positions of the preceding Members and said that while Honduras understood the need to protect human health, it considered that the measure was more trade-restrictive than necessary to attain such objectives.

2.116. Recalling the statements of his delegations at the last Committee meeting, the representative of Nicaragua considered that because the draft directive was more trade-restrictive than necessary and lacked scientific basis, it was not in accordance with Article 2.2 of the TBT Agreement. He encouraged the EU to consider less trade-restrictive alternatives. Nicaragua also believed that the proposal of introducing plain packaging, in particular, could not be justified under the WHO's Framework Convention on Tobacco Control ("WHO FCTC"), as the proposed measure extended beyond the requirements of this Convention. He explained that Nicaragua had about 23 tobacco producers which together generated 35,000 direct jobs and 45,000 indirect jobs. Nicaragua's tobacco exports were valued up to 185 million dollars. He also underlined that the tobacco industry helped to stimulate Nicaragua's tourist sector as the tobacco production sites attracted many visitors. The EU's proposed directive could therefore cause serious economic and social adverse effects to his country.

2.117. The representative of Australia reiterated the comments made by his delegation to this Committee in March and June 2013 in support of the EU's revised Tobacco Product Directive proposal. The significant public health challenge resulting from tobacco use was a global issue

which all WTO Members must face. Australia therefore commended the EU and its member states for the tobacco control measures it had implemented to date, and for its revised Tobacco Products Directive proposal. He noted that one of the objectives of the EU proposal was the implementation of the WHO FCTC. In addition to a range of measures, including mandating increased graphic health warnings, Australia understood that under the proposal, EU member states would be allowed to implement plain packaging of tobacco products as far as compatible with the Directive and EU law. In particular, Australia welcomed the decision by Ireland to take the lead by developing legislation to mandate plain packaging of tobacco products. Australia was of the firm view that Members had the right to implement measures necessary to protect human health, while complying with relevant international treaty obligations, including the TBT Agreement. The proposed EU Directive was a legitimate measure designed to achieve a fundamental objective – the protection of human health, in particular, the protection of young people against smoking initiation and uptake.

2.118. The representative of New Zealand registered his delegation's support for the European Union for its move to introduce further controls on the packaging of tobacco products, including by allowing individual EU members to take plain packaging measures. The negative effects of smoking could be not be overstated for it constituted the single largest cause of preventable death and disease in New Zealand.

2.119. The representative of Canada recalled that Canada was a pioneer in package labelling requirements for tobacco products, a core component of the right to regulate in the interest of the Canadian public. She noted that the EU proposal could impose labelling requirements for cigarettes similar to those already in force in Canada where pictorial health warnings occupied 75% of the front and back of packages.

2.120. The representative of Norway stressed that public health and tobacco control were topics of particular interest to his delegation and thanked the EU for notifying the proposal at such an early stage in the process. In Norway's view, it was within the rights of each WTO Member to adopt measures which were necessary to protect public health as long as they would be consistent with WTO obligations. Norway had a long history in tobacco control. In 1933, the Norwegian parliament adopted the first tobacco control act banning advertising, setting up an age limit for sale of tobacco, and mandating health warnings. However, he said, smoking continued to be the single factor with the greatest negative impact on public health in Norway, with about 5,100 people dying each year from smoking-related diseases (13% of all deaths). On average, each of them losing 11 years of their lives. Smoking was also a major cause of social inequality and health. The Norwegian Government therefore strongly supported the EU in its effort to combatting tobacco epidemic.

2.121. The representative of the European Union referred to the statements her delegation made at the last Committee meeting and then provided a brief update on the state of play of the Directive proposal's draft. The proposal was put forward by the Commission on 19 December 2012, and was currently going through the EU's legislative process, in which both the Council of the European Union and the Parliament had to give their approval in order for it to be adopted. The Council reached a position on the proposal on 21 June 2013. On 8 October 2013, the European Parliament also voted on the draft proposal, paving the way for inter-institutional negotiations with the Council and the European Commission on the draft. These discussions were currently ongoing, with a view to concluding an agreement on the draft Directive as soon as possible and, in any case, no later than the end of the mandate of the current European Parliament in May 2014.

#### **2.2.2.20 Chile - Proposed amendment to the Food Health Regulations, Supreme Decree No. 977/96**

2.122. The representative of Mexico said that, as stated in the previous sessions of the Committee in March and June 2013 and set forth, respectively, in documents G/TBT/W/361 and G/TBT/W/372, Mexico considered that Chile had violated basic WTO principles relating to the preparation of technical regulations, such as transparency, proportionality, scientific basis and conformity with international standards. It also believed that these measures could constitute violations of the TRIPS Agreement. Mexico also asked Chile: (i) to provide an update on the status of this measure; (ii) to consider Mexico's comments in light of Article 2.9 of the TBT Agreement; (iii) to comply with the TBT Agreement and its provisions that trade should not be restricted more

than was necessary, by promoting public policies that helped the population to obtain accurate information on food nutrients, so that they could make food choices based on their particular needs; (iv) to modify its measure so as to base it on relevant international standards (Article 2.4 of the TBT Agreement), such as the Codex Alimentarius; (v) to consider other public policy instruments that could be less trade restrictive, such as launching outreach campaigns to encourage the population to eat healthily and promoting physical activity programmes; (vi) to take into account other instruments that could form part of the Chilean regulatory framework for the marketing of foods, such as the "*Código de Autorregulación y Ética Publicitaria*" (Code of Self-Regulation and Advertisement Ethics).

2.123. The representative of Guatemala reiterated her delegation's comments made at the last two meetings in March and June 2013, including its concern that the measure could be more trade restrictive than necessary to fulfil its legitimate objective and that Chile should therefore consider alternative less trade-restrictive measures.

2.124. The representative of Argentina said that his delegation continued to be concerned with the provisions of the law 20.606 and the draft regulations - decrees number 12 and 28 - elaborated to implement this law. They were considered to be excessive to the legitimate objective they sought to pursue, by not being in accordance with Article 2.2 of the TBT Agreement. Argentina asked Chile to notify the decrees numbers 12 and 28 of 2013 before their publication and asked for confirmation on whether Argentina's comments had been taken in consideration.

2.125. The representative of Brazil expressed his delegation's support to any measure taken by any Member with the purpose of protecting human health, including those relating to food labelling, provided they complied with WTO rules. However, Brazil believed that such objective could be addressed in a more effective and less restrictive manner than currently established in the proposed measure, which therefore seemed to conflict with Articles 2.2 and 2.4 of the TBT Agreement. Brazil considered that a good departing point to address these shortcomings in the measure could be to establish different labelling requirements for different types of food. It would thus be important to distinguish between, on one hand, products that contained ingredients or substances that might cause allergies or that are related to food decolourants (like gluten and lactose) and, on the other hand, products with common ingredients that were not harmful per se (like sugar or salt). In the specific case of the proposed measure at issue, Brazil's concerns related to the grounds for the threshold determining whether or not products were unhealthy. In this respect, he noted that the proposed measure was not based on the WHO's dietary guidelines that took into account the suggested daily intake of nutrition. He also noted that the new Chilean draft contained an even harsher approach prohibiting the commercialization of products considered unhealthy in school shops and requiring all products to observe the regulation irrespectively if they had already been registered with the Chilean authorities or not. Finally, the way that Chile's measure pursued its legitimate public health objective seemed to be incompatible with the list of prohibited claims under Section 3 of the *Codex General Guidelines on Claims*. For example, Section 3.5 of these guidelines prohibits "claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer."

2.126. The representative of the European Union associated herself with the statements made by the preceding delegations and expressed concern that the measure was never notified to the Committee. She also recalled the EU's concerns regarding the lack of scientific basis for the definition of the maximum levels for the relevant nutrients, noting the absence of international guidelines backing up this measure. The EU was also not convinced about the proportionality and effectiveness of the measure. Regarding the labelling technical specifications, the EU asked Chile the following questions: (i) the technical graphical specifications only established that the stamp had to cover 7.5% of the total surface of the package. Has Chile considered that for small products (e.g. candy bars, mints, and candies) the stamp would cover substantially more than 7.5% of the surface, taking into account the requirements on the fonts to be used? Was there any exemption foreseen for these products, considering that it would not be possible to comply with the 7.5% of the surface requirement? (ii) the specifications provided examples in which it seemed that the stamp shall cover 7.5% of one of the main surfaces of the products. However, the 7.5% of the surface requirement was to be calculated based on the entire surface of the package. If this was the intention of the legislator, it would entail a significantly larger stamp as compared to a stamp covering 7.5% of one of the main surfaces of the products. Could Chile clarify this point?; (iii) the specifications did not require that the stamp be placed on the front of the package. Could Chile clarify that indeed the stamp can be placed on the back of the package? (iv) all pictures in the

technical specifications showed the stamp on the low left corner of the package, but there was no explicit indication that this placing was a formal requirement. Could Chile clarify if the stamp could be placed anywhere on the package or on a specific location of one of the main surfaces of the package? and (v) could Chile also clarify why the label must refer to "high in fat" when the regulation actually referred to "saturated fats"?

2.127. Finally, after noting that the measure's implementation deadlines for labelling obligations would now be at least 6 months from the final date of publication, she expressed the EU's view that this period was too short for economic operators to be able to comply with such comprehensive legislation. In this context, she noted that the EU's own legislation on nutritional labelling was adopted in 2011 but would only come into force in 2014. Given that adaptation to new labelling requirements required significant investment for manufacturers and a redesign of the packaging and given the uncertainties previously exposed, the EU asked Chile to consider providing an even longer deadline.

2.128. The representative of the United States associated herself with the previous speakers on Chile's regulation, including their view that Chile's proposed regulation could impose unnecessary barriers to trade. She also noted the existence of alternate approaches, grounded in international standards, which could provide similar information to consumers in a less trade restrictive manner. Chile's regulation was not based on science and its labelling requirements could be misleading and stigmatize foods that could be part of a healthy diet. Under the measure, imported foods would need to be labelled specifically for the Chilean market, raising their costs for Chilean consumers and making them less attractive than similar domestically produced goods. In this respect, she recalled that on 4 October 2013 the Chilean Ministry of Health's proposed regulation, currently under consideration by *Contraloría General de la República*, only marginally altered the requirements under the original proposal, ignoring alternative voluntary approaches and thus did not address WTO Members' underlying trade concerns. For instance, the regulation still required: (i) the use of "STOP sign" shaped icons that would account for a significant portion of the package (7.5%); (ii) nutrient limits by food category that lacked a clear explanation of the scientific basis; (iii) category nutrient thresholds that required many "healthy" imported foods to bears icons while Chile's traditional foods that were "higher in fat, sugar and sodium" were exempted; (iv) front of pack icons that could mislead consumers or create fear about consuming food, even in moderation, as part of a healthy diet; and (v) insufficient time for implementation. The US asked Chile to delay finalisation of its regulation until these concerns were addressed.

2.129. The representative of Canada said that her delegation associated itself with the previous speakers. While Canada supported Chile's policy objectives, it however remained concerned that the updated draft regulations deviated from international standards, was not based on science, and were likely to be more trade restrictive than necessary. Canada had raised this issue with Chile in several fora including the WTO TBT Committee and on the margins of APEC in Indonesia, as well as bilaterally via the Canadian Embassy in Chile. Canada has been assured that Chile was reconsidering its regulations with a view to making them WTO compliant.

2.130. The representative of Costa Rica said that his delegation shared the same concerns voiced by previous delegations.

2.131. The representative of Chile stated that obesity was becoming epidemic in Chile, particularly among those aged under 14. This law was one of the first measures which Chile has adopted to address this problem and was based on the understanding that the public needed to be able to make informed decisions about their food consumption and avoid excessive consumption of substances which lead to obesity. Regarding the decree at issue, he explained that the on 3 July 2012 the President of the Republic finalized the proposal, taking into consideration the comments received. Two days later, the final proposed decree was then submitted to the general controller's office, one of the final steps in Chile's internal legislative procedure. On the 27 September 2013, the controller issued an opinion making a series of comments that should be included into the Ministry of Health's proposal. These were incorporated into the decree and would be submitted back to the controller. Once the controller issued a new decision the decree would be published in the official journal. Regarding the content of the decree, Chile informed that the final version signed by the President contained the following: (i) a timeframe for entering into force at least 6 months from the final date of publication; (ii) the fact that only a small number of products would be affected (24% of products); (iii) the warning label would no longer take the form of an octagonal "STOP sign" but rather a coloured hexagon and its size would be established in relation

into the size of total area of the products (7.5%); and (iv) that it would provide for the possibility of using stickers for the warning label.

#### **2.2.2.21 India - Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order, 2012**

2.132. The representative of Japan requested India to re-postpone the date of full enforcement of the Order until 3 April 2014. According to "Bureau of Indian Standards Rules, 1987" (hereafter "the BIS rules") 16B (3), test reports issued by the testing laboratories designated by BIS were required for equipment registration. However, as of September 2013, only 11 testing laboratories in India had been designated for testing information technology equipment, although thousands of applications from companies inside and outside India have been submitted. According to a survey of Japanese industry, some applicants have been waiting for over 6 months to finish the testing and it often took over 200 days to issue test reports. Therefore, Japan would like to request India to give additional 3 months for transition period and re-postpone the date of full enforcement until 3 April 2014. Also, in order to shorten lead-time of testing, Japan requested that India, as one of IECEE members, utilizes CB certificates and CB test reports issued by National Certificate Body in the other member countries. Japan also requested India to set adequate transitional period for new product categories. On 11 July 2013, India announced that "projectors" were within the scope of new product category. However, according to the Japanese industry, they estimated that more 9 months were needed as a sufficient transitional period to comply with the current registration procedures, including testing, registration, labelling and transport from factories to India. In light of this practical difficulty, Japan needed to request India to set sufficient transitional period of more than 9 months for new product categories when some product categories become newly subject to the Order. Japan further requested India to simplify registration procedures. Since May 2013, many kinds of notifications have been issued to specify various registration forms in addition to Form VI and VII specified by BIS rules, which caused confusion among applicants. Applicants must prepare large number of application documents and BIS also spent a long time checking the documents. Japan therefore requested India to simplify the registration documents in order to shorten the time spent for the registration procedures.

2.133. Japan further requested India to simplify conformity marking requirements. According to the Order, a product or a package must bear conformity mark with a self-declaration of conformity, the technical standard applied and its edition (year) as well as the registration number. However, under this new requirement, a specific size of font was required to be used, which caused a longer preparation time for the industry to adapt to the new conformity making requirement. Japan asked India to simplify the contents of the conformity marking requirement and to provide a sufficient transitional period to inform applicants of all marking requirements broadly and beforehand. Lastly, Japan requested India to set a transitional period for revision of technical standards. According to the BIS rules 16L, when Indian standards (IS) were withdrawn or abolished, any registration granted in respect thereof were deemed to have been cancelled from the date of withdrawal of the standard. If there were no transitional periods, importers and manufacturers must stop supply of products for a certain period of time until they get prepared for re-registration based on the new standards and replace the conformity mark on the products. In this regard, an adequate transitional period would enable smooth re-registration. For example, the EU gave suppliers almost three years as a transitional period when a new European standard replaced an old one. For this reason, Japan requested India to set transitional period of 24 months or longer during which both of old and new standards would be applicable, in order to enable importers and manufacturers to prepare for smooth transition to the new standards.

2.134. The representative of the European Union said that his delegation associated itself with Japan's concerns. He sought confirmation of the current situation of the measure in legal terms. In this respect, he noted the postponement of the entry into force of the new legislation until 3 January 2014 pursuant to a notification by the Ministry of Communications and Information Technology (MoCIT), dated 30 September 2013. He understood that the lack of testing infrastructure to ensure timely processing of all testing applications was the decisive factor in ordering this postponement. He therefore asked India to confirm that, pending the entry into force of the new regime, a supplier's declaration of conformity would be considered sufficient to place products on the market. On a more general point, as observed by Japan, he also noted with some concern the fact that successive amendments, clarifications, interpretations have been issued on a regular basis, and that the recent notification from India in G/TBT/N/IND/44/Add.2 provided a compendium of all these successive amendments, interpretations via Orders, Circulars, Notices

etc. He considered this to be detrimental to the predictability of the regulatory framework as it caused confusion and prevented sound business planning. He thus asked the Indian authorities to consider a more structured process when regulating and that all important elements be consolidated in one single text to put out for stakeholder comments and notified to other WTO Members.

2.135. Besides the specific points made by Japan, he said that the EU had three main general points. First, the EU continued to view this scheme as excessively burdensome in view of the low safety risk associated with the 15 categories of electronics products concerned. These were office equipment, printers, scanners, laptops, answering machines, not really equipment with a serious safety risk. Therefore, the EU continued to have concerns on the overall necessity and proportionality of the scheme. Second, the EU took note of the assurance given at the last meeting by India that, pursuant to a Circular by the Department of Electronics and IT issued on 29 May 2013, safety critical components would be accepted if certified or tested by a certification body that was a signatory to the IECEE CB scheme or accredited to the relevant international standard ISO 17025 by an accreditation body that was a signatory to the ILAC MRA. Despite the EU's general concerns about the scheme in general being too heavy-handed in relation to the product risks involved, the acceptance of foreign testing would alleviate the burden for exporters. Finally, on the mandatory testing frequency of every two years, the EU considered this as excessively burdensome as the testing that should only be repeated if a product was substantially changed in such a way that its safety properties were affected. The EU expressed hope that there would be the possibility to further discuss bilaterally with India these concerns and that workable solutions could be found before the entry into force of the scheme. Like Japan, the EU recommended that consideration be given to further postponement of the measures until all these aspects had been discussed and addressed satisfactorily.

2.136. The representative of the United States associated herself with the comments made by Japan and the EU. While acknowledging the granting of extension until 24 January 2014, the US continued to be at a loss on understanding why in-country testing in the security context was necessary. She stressed that the criterion and systems to assure the competence and independence of testing laboratories were well established in international standards and in the international systems of conformity assessment. Competence and independence of labs was not determined by place of domicile. She then addressed some practical challenges posed with implementing the ICT Product Safety requirements, as they are currently constituted. First, the issuance of test reports by BIS approved labs added an unnecessary stage in the compulsory registration process. Manufacturers already tested their IT products to the international standard (IEC 60950). They must then retest them to an identical Indian standard. While BIS approved labs continued to work through the backlog, there would likely be an on-going bottleneck beyond the January 2014 implementation, as manufacturers submit new products for testing. In addition, under the current registration process, test reports would expire ninety days after issuance. This was an unnecessary burden on the manufacturer that, given the existing backlog of testing and approvals, could result in further delays in getting products on the market, if the manufacturer did not meet the ninety day window for registration application. Second, there were conflicting labelling requirements being issued by BIS and the Department of Electronics and Information Technology (DeitY). BIS stated that products *and* packages must be labelled with location requirements and font size to be at least  $\frac{3}{4}$  of brand name font or 12 points, whichever was larger. DeitY states that it was preferable for products to be labelled, but packaging may instead be labelled due to limited product size or other restrictions. Unlike BIS, DeitY did not indicate any location for labelling nor did it require a specific font size. Third, there were issues with Highly Specialized Equipment (HSE) Circular No. 2, which stated that DeitY "may" issue Exemption Orders for exempted HSE to clear India customs. As a result, manufacturers were forced to react to BIS, DeitY or Customs' interpretation of this policy on a case-by-case basis. Manufacturers were left in need of a routine process that yielded predictable outcomes.

2.137. Another issue of concern to the US related to "Import of Prototypes" under Circular No. 1 of 2013, according to which DeitY would allow for import of up to 5 units of prototype or test samples (devices for demonstration/development/testing) without penalty. This limitation was far too low to support product development in India and it would have an immediate impact on the ability of industry to introduce new products globally. If this limit was not changed or if these prototypes/samples were required to be tested or registered before sample units were shipped to India, manufacturers may be forced to move hardware and software development out of India. Given the foregoing, the US urged India to postpone the implementation date so as to allow for

---

proper notification and comment, and welcomed the opportunity to further discuss this issue with India on a bilateral basis so as to better explore more commercially viable options that would fully meet India's electrical safety needs.

2.138. The representative of Canada said that her delegation was concerned with the excessively burdensome nature of India's Order. Canada believed that India's in-country testing requirements were not needed given the nature of the products in question. Canada asked India to reconsider its Order as it currently stood and to respond to Members' concerns, as had already been enumerated by Japan, the EU and the US.

2.139. The representative of India started by giving Members an update on the status of the measure. He said that as per the notification dated 30 September 2013, the Order had come into effect as from the 3 July 2013 but some manufacturing units with specific conditions have been provided an additional period until the 3 January 2014. The test labs are actually hosted both on the DeitY as well as the BIS websites. There were 11 labs, including of foreign labs, which have been recognized for testing as of the 3 October 2013. In terms of the notifications, he explained that G/TBT/N/IND/44, Addenda 1 and 2 provide clarification on the scope and other aspects. These addenda have emanated from many of the questions that Members have asked in this particular forum as well as bilaterally. Regarding Japan's questions about the delay in the report, he said that India had put up lists of the workload being handled by the 11 laboratories, and it seemed that they were well on track and were adequately addressing demand of testing under this particular order. This fact would also dispel the concern that the procedures were cumbersome. On the question of the time period for amendment or withdrawal, he said that under this particular regulation there had been no amendments or withdrawal at this point of time. He said that nevertheless he would forward this input to BIS because this was a larger generic issue rather than a specific issue to the DeitY Order. Concerning EU points, he expressed surprise about the confusion of the Addenda. The EU, like some of the other delegations, has been an advocate of transparency. He recalled that the EU has made a statement whereby they very categorically said that they wanted transparency database containing all the notifications in one place. The addenda were issued exactly to address this request. The addenda were an output of the clarifications that have been sought out by Members or by the stakeholders on specific issues they came across when this particular Order was issued by DeitY. On the specific issue raised by the US on the prototypes, he said that India had forwarded those questions to both to BIS and DeitY.

2.140. Finally, he addressed two other issues that have been raised in the last meeting as well as in the current meeting. One was about the terminology of further Orders, which was used in a circular dated 29 May 2013. DeitY had confirmed that this terminology had primarily being used to expressed that safety critical components would be accepted if there were either certified or tested by certification body that was a signatory to IECEE CB Scheme or accredited according to the relevant international Standardized IEC 17025 by an accreditation body that was a signatory to ILAC MRA until the circular got amended or modified further. On the US question on the testing labs, he explained that DeitY has clearly said it would be unfair to claim that Indian labs were ill-equipped as most of the labs recognized by the BIS had already been testing under the International Safety Certification programmed for decades. In fact three of the recognized labs were of US origin (e.g. UL India Private Limited, in Bangalore and Inter Tech Private Limited, in New Delhi).

2.141. The representative of the European Union thanked India for the information provided and made a clarification with respect to the EU's position on the Addenda. He said the EU welcomed the submission of the notifications of the two addenda. This has been very useful to recap the long history of successive interpretations, clarifications and amendments to the original measures. Addendum 2 listed not less than seven of such circulars, adopted in the period from 29 May until 11 September 2013. So, in the time span of just three and a half months, seven times the measures were subject to amendments and interpretations, extensions and so on. It was this way of adjusting the original measures and introducing essential implementing elements that, in his view, created problems. It was not the use of addenda per se. Indeed in this particular case, without the addendum it would have been very difficult for the EU to establish a clear chronology of events during the last months. Thus, while the EU would encourage the use of addenda, it would also prefer if these measures would be introduced perhaps in a fewer texts and that these texts would be notified for comments.

### 2.2.2.22 Ireland - Proposal to introduce standardised/plain packaging of tobacco products in Ireland.

2.142. The representatives of the Dominican Republic and Malawi expressed concern with the consistency of the proposed Irish measure with the TRIPS Agreement and/or the TBT Agreement. Their full statements are contained, respectively, in G/TBT/W/374 and G/TBT/W/375.

2.143. The representative of Honduras expressed concern with the fact that the proposed Irish tobacco plain packaging measure was similar to that of Australia, which was currently under five dispute settlement proceedings in the WTO - including one initiated by Honduras - and whose consistency with WTO rules has been challenged in this Committee by a large number of WTO Members. Honduras urged Ireland to reconsider its decision to start the adoption of plain packaging with respect to tobacco products and to, prior to taking such a decision, at least wait for the conclusion of the disputes lodged against Australia.

2.144. The representative of Nicaragua associated his delegation with the statements made by the previous delegations and expressed concern as to whether the measures proposed by the Government of Ireland would achieve the desired result. While not questioning Ireland's sovereign right to introduce measures to protect public health, Nicaragua believed that the Irish measure at issue would not achieve this objective. Like previous speakers, Nicaragua asked Ireland to either reconsider this measure or at least suspend its adoption until the disputes against Australia have resolved.

2.145. The representative of Guatemala stated that while her delegation shared Ireland's policy objectives related to public health and tobacco control, it was nevertheless concerned with the proposed legislation and encouraged Ireland to consider less trade restrictive alternative measures that would effectively achieve its own legitimate objectives.

2.146. The representative of Zimbabwe said that her delegation shared the concerns raised by the previous delegations regarding Ireland's proposal to introduce standardized plain packaging of tobacco products. While Zimbabwe appreciated efforts to protect the health of consumers, the proposed measure would be inconsistent with the TBT Agreement (Articles 2.2 and 2.4) and TRIPS Agreement (Article 20) *inter alia* because there was no scientific evidence that it would meet the intended objectives. Developing countries, such as Zimbabwe, relied on tobacco farming. The proposed measure would therefore negatively affect their employment creation efforts. Tobacco was Zimbabwe's largest single exporting item in the agricultural sector, with over 1,000 tobacco growers. Over 80% of growers were small scale farmers. Zimbabwe therefore urged Ireland to reconsider its measure.

2.147. The representative of Cuba expressed doubts as to whether the Irish plain packaging measure would attain its intended legitimate public health objectives. None of the countries proposing or implementing such a measure had been able to prove its effectiveness, nor did they have scientific evidence on which it could be based. On the contrary, serious doubts existed as to whether plain packaging was appropriate, partly due to its undesirable effects, which did not result in the reduction in the consumption of tobacco products. A measure such as this was therefore more trade restrictive than necessary under the rules of the TBT Agreement, and also undermined the provisions of international legislation on geographical indications, including the TRIPS Agreement.

2.148. The representative of Australia reiterated comments made in previous Committee meetings in support of Ireland's decision to legislate for mandatory plain packaging of tobacco products. Tobacco plain packaging was a legitimate measure, designed to achieve a fundamental objective - the protection of human health. Australia looked forward to supporting Ireland as it underwent the development of its own measure. The tobacco plain packaging measure was endorsed by leading public health experts as well as the World Health Organization (WHO) and was supported by extensive research reports and studies. Tobacco plain packaging was recommended in the guidelines for the implementation of Articles 11 and 13 of the WHO Framework Convention on Tobacco Control, to which Australia and the EU were both Parties. Australia was of the firm view that Members had the right to implement measures necessary to protect public health, while complying with relevant international treaty obligations including the TBT Agreement.



2.149. The representative of New Zealand stated that his delegation supported Ireland's move to consider introducing controls on the packaging of tobacco products. There was an extensive and compelling body of international research and scientific studies that established that plain packaging, as part of a comprehensive tobacco control programme, would contribute to the objective of improving public health. WTO rules, including those in the TBT Agreement, contained appropriate flexibilities to enable WTO Members to regulate for health and other public policy purposes. New Zealand was therefore confident that Ireland would be able to introduce a Plain Packaging regime in a manner consistent with its obligations both under the WTO and WHO FCTC.

2.150. The representative of Norway recalled his delegation's usual stance that it was within the rights of each WTO Member to adopt measures necessary to protect public health as long as they were consistent with WTO Agreements. Norway therefore supported Ireland's intent to introduce this kind of measure.

2.151. The representative of Canada recognized how challenging it was to introduce tobacco control measures that had never been implemented before. Canada was in a similar situation a decade ago when it introduced pictorial health warnings on tobacco packages. Canada took these regulatory and other steps because tobacco use was a significant problem, both in Canada and around the world. In Canada alone, 37,000 people died annually from tobacco use – Canada's leading cause of preventable death and disease. Tobacco products were also the only goods that were the subject of a legally-binding health treaty, the WHO FCTC. As Members move forward in their discussions on this topic, they may want to consider the complete economic picture regarding tobacco control, including whether tobacco may actually be a net economic drain for many countries.

2.152. The representative of Uruguay expressed his delegation's conviction that the Irish plain packaging measure was compatible with WTO rules. In implementing such a measure, Ireland would be simply exercising its sovereign right to protect public health by giving effect to the obligations assumed as a party to the WHO FCTC, in particular its Article 11 and relevant implementing guidelines.

2.153. The representative of the European Union again informed that on 28 May 2013 the Irish government decided to begin the process of developing legislation introducing plain packaging for tobacco products sold in Ireland. It was therefore premature to discuss this issue in the context of the TBT Committee at this stage.

#### **2.2.2.23 Peru - Act to Promote Healthy Eating Among Children and Adolescents.**

2.154. The representative of Mexico expressed her delegation's concern with the fact that this law, which would have an impact on international trade, had not been notified to the WTO. Mexico considered that this measure was not the least trade restrictive alternative available to Peru to address its public health objective. In this regard, Mexico referred to other alternative ways, such as public campaigns promoting healthy eating and physical activities. Mexico also noted that the measure did not mention the technical parameters that were used to select the "foods adequate for each age". Nor did it provide for the scientific basis justifying the list of restricted foods or the prohibition to sell such products in schools or the use of expressions to inform consumers a product was "high in" a given nutrient. Finally, given the existence of relevant international standards in this area, like the Codex, this measure could be also inconsistent with Article 2.4 of the TBT Agreement.

2.155. The representative of Argentina recalled its concern that the law 30.021 was not in accordance with the obligation of Article 2.2 of the TBT Agreement, as this law contained measures that were more trade restrictive than necessary to achieve the legitimate objective. Argentina was also aware that in late May 2013 the Ministry of Health of Peru created a Sectoral Commission (Ministerial Resolution n. 301-2013-MINSA) charged with the drafting of the implementing regulation of Law n. 30.021. In June 2013, the presidency of the Council of Ministry created a parallel Multisectoral Commission for the same purpose (Supreme Resolution n. 210-2013-PCM). Argentina therefore requested Peru to notify any drafts and reports elaborated by the Ministry of Health to the PCM and by the Multisectoral Commission.

2.156. The representative of the European Union associated her delegation with the statements made by Mexico and Argentina. The EU regretted that the law had not been notified and WTO Members have therefore not had the opportunity to comment on it. While sharing Peru's public health concerns, the EU also doubted if the approach taken in the notified draft was the best way to achieve these objectives and whether it was proportional to the aim pursued, which was to empower consumers to make an informed choice in order to foster effective competition and consumer welfare. In this respect, and in relation to the warning labels and implementing provisions which would establish limits for certain nutrients as foreseen in the transitional provisions, the EU recalled the Codex's Guidelines on Nutrition Labelling (CAC/GL 2-1985 CODEX) which stated that the information contained in the nutrient declaration "should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product". The EU noted that no nutrient thresholds have been established by CODEX for the nutrients targeted by the Peruvian legislation. The EU recognised that for certain nutrients there was evidence of a positive association between its intake and the risk of developing a disease or disorder but there was no scientific evidence suggesting an identifiable threshold above which the risk existed. The risk increased rather continuously when the nutrient intake increased above the levels recommended by the nutritionists. The EU also asked Peru to provide information on the foreseen deadlines for the entry into force of this legislation. The EU noted that according to the second transitional disposition, some of its provisions would come into force 120 days after the publication of the implementing regulation. The EU highlighted that adaptation to the new labelling requirements would require significant investment for manufacturers and a redesign of the packaging for some categories of products which were not defined yet. The EU therefore asked Peru to postpone the entry into force of the measure and provide a reasonable implementation period in accordance with Article 2.12 of the TBT Agreement. In this respect, the EU noted its own legislation on nutritional labelling, adopted in 2011 but would only come into force in 2014.

2.157. The representative of the United States stated that her delegation shared Peru's concerns regarding poor nutrition and its link to obesity and other non-communicable disease. The US has been a key supporter of work to implement the recommendations of the 2004 WHO Global Strategy on Diet, Physical Activity and Health through new Codex guidance on nutrition and labelling. The US however still remained concerned that some front-of-pack labelling provided under the measure could stigmatize certain foods as "bad" when any food could be eaten in moderation as part of an overall healthy diet. Alternative approaches could instead provide similar information to consumers, without the cost of mandatory product relabeling. Codex, for example, recommended mandatory nutritional labelling of products and recently expanded the list of nutrients for declaration to include saturated fat, sodium, sugars (and trans fatty acids in countries where this nutrient was a public health concern). The Codex Committee on Nutrition and Foods for Special Dietary Uses had also proposed Nutrient Reference Values for labelling purposes for sodium and saturated fat, which provided another means for consumers to identify foods "low" and "high" in nutrients. In addition, Codex had defined voluntary "low" claims, "no added sugars" claims, and conditions for health claims. The US noted in this regard that Peru had not yet adopted a daily allowance for saturated fats and required this information as part of the Nutrition Facts panel as recommend by Codex. Product labelling was only one element of a larger effort needed to change consumer behaviour in a way that fostered healthier eating. Robust consumer information programs were therefore key to changing patterns in consumer behaviour. Finally, as Peru continued to consider its regulatory approach, the US reiterated the need for an extended period for compliance with the measure. By way of example, she recalled that when the US issued its Final Rule requiring mandatory nutritional labelling in 1993, it allowed for an 18-month period for compliance to reduce the costs associated with relabeling of products. An even longer period, of three years, was allotted for trans-fat labelling when it was adopted in 2003.

2.158. The representative of Canada said that while her delegation supported Peru's objective of reducing obesity and other non-communicable diseases, it was nevertheless concerned that this measure may be more trade restrictive than necessary to achieve this objective. Canada wondered whether Peru had considered less trade restrictive alternatives to pursue its objective. For instance, the Codex Committee on Nutrition for Foods for Special Dietary Uses had also proposed Nutrient Reference Values for labelling purposes for sodium and saturated fat, which provided another means for consumers to identify foods "low" and "high" in nutrients. In addition, Codex had defined voluntary "low" claims, "no added sugars" claims, and conditions for health claims. Canada also shared other WTO Members' concerns that this measure was not properly notified to the WTO for comment and thus recommended that Peru notify this measure, along with a copy of

the full text of the proposed regulation, so as to allow for comments. Canada also understood that some internal review had taken place in Peru with a view to potentially adjusting the proposed regulation. Canada encouraged Peru to provide Members with an update on the scope, purpose and timing of the proposed regulations including proposed dates of notification, deadline for comments, and entry into force. With respect to entry into force, Canada also encouraged Peru to adhere to Article 2.12 of the TBT Agreement, noting that Members shall allow a reasonable interval between the publication of technical regulations and their entry into force.

2.159. The representative of Guatemala stated that her delegation shared the view that healthy eating should be promoted in order to prevent diseases among the population. Nevertheless, Guatemala was concerned that the Peruvian measure might be more trade restrictive than necessary to achieve the stated legitimate objective of reducing obesity in order to fight non-communicable diseases. In this context, it was absolutely essential to know the scientific basis of the measure.

2.160. The representative of Peru informed that the Multisectorial Commission that was drafting the implementing technical regulation of Law n. 30.021 was ready to publish such a draft with respect to the parameters to be used to establish the content in sodium, sugar and saturated fat. This draft would be notified to the WTO with a 90-day period for comments.

#### **2.2.2.24 Indonesia – Ministry of Health Regulation 30/2013 on the inclusion of sugar, salt and fat content information, as well as health messages on the label of processed foods (G/TBT/N/IDN/84).**

2.161. The representative of the European Union recalled that this Regulation required mandatory nutrition labelling for salt, sugar and fat content of processed foods. Such nutrition declarations must be based on tests carried out by accredited labs. Furthermore, a mandatory health warning message would have to be included on the label of all processed food products. Firstly, with regard to procedure, the EU requested Indonesia to notify the regulation to the TBT Committee in accordance with its obligations under the WTO. It also requested that the application of the Regulation be suspended until such notification has been submitted. In this context, the EU also noted that Indonesia had indicated in the last TBT Committee meeting that an implementing Decree for this Regulation would be issued. The EU therefore requested that this Decree be also notified to the TBT Committee while still in draft form, and Members be provided sufficient time to comment. While supporting Indonesia's goals of providing nutritional information to consumers so as to prevent diet-related chronic diseases, the EU wondered whether these objectives could not be achieved with less trade restrictive means, such as, for example, promoting healthy lifestyle and eating habits, rather than through a warning message applicable to all pre-packaged products. The EU was also concerned with the lack of clarity as to how these requirements would apply. For instance, it was not clear where on the label the nutritional information and related health warning should be placed; what methods would be used for the tests verifying the nutrition declarations, and whether tests performed by foreign laboratories, or in-house laboratories of companies would be accepted. It was also unclear how the gradual implementation of the Regulation would take place, in particular how the risk of the products with respect to non-communicable diseases would be assessed. Finally, the EU enquired whether Indonesia would allow stickers placed after importation, and before being placed on the market in Indonesia (for instance, in customs warehouses) as a means to show compliance with the Regulation.

2.162. The representative of the United States associated herself with the comments made by the EU including with respect to notifications and delaying the implementation of the measure. She noted that Indonesia had finalized MOH Regulation 30/2013 and that it would enter into force three years from the date of adoption. The US also sought clarification with respect to the testing provisions set forth in Article 6 of MOH Regulation 30/2013, which seemed to establish a strict testing procedure that would not allow minimum normal variations between batches and would possibly include unnecessary shipment by shipment inspections.

2.163. The representative of Indonesia informed that the regulation had been issued by the Minister of Health, dated on 16 April 2013 and would enter into force three years after promulgation, thus giving an appropriate time for industry and other sectors to comply with it. Within three years, the coverage products obliged to use the label and health messages would be implemented gradually by considering the level of risk of non-communicable diseases. Basically, the inclusion of sugar, salt and fat content as well as health messages for processed food aimed to

protect consumers from certain non-communicable disease such as hypertension, stroke, and diabetes and heart attack (cardiovascular). In addition, the Regulation was also to educate consumers. He further informed that the Ministry of Health would later develop a Technical Guidance to be used as reference of the implementation of this Regulation. Further, the Ministry of Health had conducted certain surveys on public consumption patterns and diet to determine the type of products which would be obliged to use the label and health message. The inclusion of labels and health messages was not intended to prohibit consumer to consume additional nutrition (sugar, salt and fat). Rather, the purpose was to better inform consumers on nutrition in order to prevent certain non-communicable disease. In addition, the inclusion of label and health message was part broader policy in favour of a healthy diet.

2.164. Regarding the affixing of a sticker prior to entering the Indonesia custom area, he clarified that this would be determined by the Ministry of Health and would be discussed with relevant Ministries involved. Regarding alternatives ways to address the health objectives of the measure, Indonesia had conducted several activities to support nutrition awareness, including through video campaign, advertising and video profile. He said that Indonesia appreciated information on the on the Codex's Special Dietary Uses on nutrition claims. In this regard, this Regulation had adopted requirements on nutrition labelling through regulation HK. 03.1.23.11.11. 09909 Year 2011 concerning Claim on label and processed food advertisement, stipulated by NAFDC (BPOM). The said Regulation of NAFDC was based on international references. With regard to testing, as provided in Article 6 of the regulation, he informed that this matter would be discussed further with the competent authority, in particular the NAFDC (BPOM). Finally, with respect to notifications, he said that Indonesia was still in the process of notifying the regulation of Ministry of Health No. 30 Year 2013, which would be sent to the WTO Secretariat at the soon as possible.

#### **2.2.2.25 European Union - Proposal for a Regulation on Fluorinated Greenhouse Gases**

2.165. The representative of Japan raised three concerns with the current version of the Proposal. First, he said that although in its written reply the EU responded that "the ban on the placing on the market of pre-charged equipment applies without discrimination to equipment produced within or outside the EU", there was a lack of clarity in the Proposal as to how Hydrofluorocarbons (HFCs) quota foreseen under Article 14 would be allocated to imported equipment pre-charged outside the EU. A way to allocate this quota in a fair manner, irrespective of whether the equipment was produced within or outside the EU, could be for Article 14 or Annex 5 to specify that the amount of HFCs in pre-charged equipment imported into the EU be included in the reference value of quota allocation specified in Article 14. Another way could be to provide for the Proposal to lay down a concrete method for quota allocation, either in Article 14 or Annex 6. According to the Commission's impact assessment, the amount of HFCs imported in pre-charged equipment to the EU was estimated to be 11% of the total amount of HFCs placed on the EU market. He noted that if the amount of HFCs imported in pre-charged equipment was not included in the reference value, or if included, importers of pre-charged equipment were not allocated quotas for administrative reasons, the importers would be treated as "new entrants". In this situation, he stated that the importers would be allocated a maximum 5% of the reference value, which was the amount to be allocated to new entrants. His delegation believed that this situation unfairly modified conditions of competition between EU and foreign products. The second concern involved Article 12. In this respect, Japan requested that the European Union withdraw the prohibition of pre-charging, which his delegation believed was a trade restrictive measure. As noted at the June 2013 Committee meeting, this requirement lacked technical validity and rationale, because it would lead to increased HFCs emissions through leakage. He said that therefore the EU would not be able to achieve the stated policy objectives of the Proposal. Under the third and last concern, with respect to the "Ban on HFC use", he requested the EU continue to allow the use of HFCs after 2020. He reported that the Environment Committee of the European Parliament had adopted in the Proposal a ban on the use of HFCs in stationary refrigeration and air-conditioners after 2020. He noted the technical difficulties of phasing out HFCs by 2020, since no alternative refrigerants had been developed to date which were both sufficiently safe and had low global warming potential (GWP). Furthermore, he argued that the ban lacked rationale in light of the policy objective of combating global warming; given that over their lifecycle, HFCs refrigerants had a very limited impact on global warming. Until alternative refrigerants were developed, his delegation requested that the EU allow the use of HFCs after 2020.

2.166. The representative of Korea noted with appreciation the fruitful bilateral meeting held with the EU delegation, and that his delegation respected the efforts of the EU to protect the

environment. His delegation understood that Article 12 of this regulation specified that HFCs gas should not be charged into refrigeration, air-conditioning, and heat pump equipment before the equipment was placed on the market or before it was made available to end-users for final installation. The EU had explained that the ban on pre-charging was aimed at reducing the risk of accidental release of HFCs during installation, and at reducing the use of HFCs in products manufactured and charged outside the EU and imported into the EU. Regarding Article 14 on "Quota Allocation", he noted that according to the EU delegation this provision covered both manufacturers and importers of equipment using HFCs. His delegation appreciated this clarification and requested that the EU send an official interpretation of this provision. Nevertheless, he said concerns remained as to how the EU would allocate the quota and whether manufacturers or importers of equipment would still need to charge HFCs after installation within the EU. Furthermore, he emphasized the need to reconsider the prohibition on pre-charging. His delegation believed that during installation and charging, accidental releases were more likely when using bulk HFCs, even if the equipment was installed and filled with HFCs by certified persons. He noted that the amount of released gases in this case could be significant. He recalled that at the last Committee meeting his delegation had stressed that the precise level of refrigerant was a critical factor for the performance and energy efficiency of air-conditioners, and that manufacturers had to test the performance of products filled with refrigerants prior to placing them on the market in order to comply with Directive 2009/125/EC (on eco-design requirements). However, to then comply with the proposed regulation under discussion, manufacturers would have to remove refrigerants after testing, which could affect the performance of the products in the process. He stressed that this would make it difficult for manufactures to guarantee the performance of products which were charged with HFCs after installation.

2.167. The representative of the United States expressed support for global efforts to phase-down the consumption and production of climate-damaging HFCs, but nevertheless raised procedural and participation concerns regarding this proposal. She first requested that the foreseen entry into force deadline of 2015 for refrigerators and freezers be pushed back, so that industry would have time to comply. The representative next noted a pressing concern regarding the exemptions required by both the EU and US semiconductor industries to continue semiconductor production. She noted that semiconductor manufacturers had already eliminated non-critical usage of HFCs, but no alternative existed for certain production processes. As opposed to other sectors, there were no substitutes available for the fluorinated gases used in semiconductor production. She further emphasized that the fluorine atom's stability was critical for precise manufacturing, and had specific chemical properties and functionalities which were critical to the production process for semiconductors. Moreover, she noted that the semiconductor industry was an insignificant contributor to absolute emissions of fluorinated gas, emitting less than 0.05% of total EU HFC emissions in recent years. She finally sought clarification of her delegation's understanding that the EU member states and the Council had agreed to text that would exclude semiconductor processes from the HFCs phase-down, but that the European Parliament was currently debating the issue, and she asked for an update on this aspect.

2.168. The representative of China said that while his delegation supported the environmental protection efforts of the EU, China, as a major exporter of refrigerators and air conditioners, was still concerned that this measure was more trade restrictive than necessary, and that it would have a significant impact on Chinese manufacturers, especially small and medium sized enterprises.

2.169. The representative of the European Union said the proposal was currently under discussion between the Council and the European Parliament. Her delegation was aware of the trading partners' concerns about the ban on the placing on the market of equipment pre-charged with HFCs, and those concerns were being taken into account in ongoing discussions in the EU legislative process. Turning to the US concerns on the availability of HFCs for the manufacturers of semiconductors, she stated that the needs of this industry had been fully taken into account in the drafting of the proposed measure. She noted that only one of the fluorinated compounds used by the semiconductor industry, HFC-23, which had a very high Global Warming Potential (GWP), would be subject to the phase-down, while PFCs, SF<sub>6</sub>, NF<sub>3</sub> and other fluorinated compounds used by this industry were not. The representative explained the proposed phase-down would provide the necessary gas quotas to cover all critical uses up to 2030, of which semiconductors was one. Moreover, since the amounts needed for the semiconductor industry were very small, a shortage of gas was extremely unlikely. With respect to the concerns raised by Japan and Korea on the allocation of quotas for importers of pre-charged equipment, she noted

that the proposal did not require quotas to be held for gases in imported equipment. Finally, on Japan's last query, she said that the proposal did not contain a total ban on HFCs after 2020.

#### **2.2.2.26 European Union - Revised Proposal for the Categorization of Compounds as Endocrine Disruptors of 19 February 2013 by DG Environment**

2.170. The representative of the United States recalled that her delegation provided background on the issue of endocrine disruptors at the last meeting, and reiterated concerns over the EU's proposal for the categorization of compounds as endocrine disruptors. She noted both procedural and substantive concerns with the work underway in the EU, including uncertainty about timing and the process ahead, which could entail significant potential impacts on trade. She welcomed the decision to conduct an impact assessment on the plant and biological side, and mentioned independent impact assessments that suggested significant trade impact from a horizontal approach. However, she highlighted systemic issues on stakeholder participation and transparency, and asked the EU to clarify if this impact assessment would be based on the most recent proposal for categorization, or whether there would be other options considered as well. She sought further clarification as to the relationship between this impact assessment and other legislation and directives, including with regard to the plant biological side, chemicals and cosmetics. She said that US industry was uncertain as to the timing of the process ahead, and opportunities for stakeholder participation and transparency, and requested that the EU clarify those elements.

2.171. The representative of South Africa enquired whether this regulation would be notified and said that his delegation was concerned about impacts on specific products and related regulations.

2.172. The representative of the European Union reiterated that several pieces of EU legislation contain specific provisions regarding endocrine disruptors. However, she explained that scientific criteria for the identification of endocrine disruptor substances at a horizontal level were not yet available. To this end the EU planned to propose horizontal scientific criteria to identify endocrine disruptors in 2013, which were to be implemented in a second phase in sectorial EU legislation, notably by updating the Biocidal Product Regulation and the Plant Protection Products Regulation, which had put in place provisional criteria. The EU decided to carry out a comprehensive impact assessment analysing different options for defining criteria for the identification of endocrine disruptors, and their corresponding health and socio-economic effects once incorporated in different pieces of EU legislation. She noted that this impact assessment would include a public consultation, most likely to be launched at the beginning of 2014 and lasting for 3 months. At this stage, WTO Members would have the opportunity to provide comments. She emphasized that only after the impact assessment was concluded, would the European Commission present proposals for introducing criteria to identify endocrine disruptors in different pieces of EU legislation, which was expected to occur in the second half of 2014. With respect to the questions of the US, she said it was premature to discuss the outline of the impact assessment, its structure and the options that would be assessed, and reported that the Commission would soon publish a roadmap containing this information. The impact assessment would nevertheless follow the European Commission's guidelines for preparing impact assessments, which were publicly available on its website. Finally she specified that the impact assessment would take into account, as a scientific basis, existing studies and reports on this matter such as the recent opinion of the European Food Safety Authority, the report of the EU Joint Research Centre, the reports of the World Health Organisation and the OECD review paper.

#### **2.2.2.27 Indonesia - Ministry of Trade Regulation 82/M-DAG/PER/12/2012 on imported cell phones, handheld and tablet computers (G/TBT/N/IDN/78).**

2.173. The representative of the European Union expressed regret that this regulation was not notified according to the TBT Agreement in a draft stage, denying other WTO Members the possibility to comment on it. EU industry reported that following the entry into force of the regulation, considerably more time was needed to place the products concerned on the Indonesian market. Of particular concern was the burdensome requirement for pre-shipment inspections for every import taking place at the port of loading by appointed representatives of the Indonesian Government. In addition, her delegation was concerned that the type label (SKPLBI) and type approval number label (POSTEL) had to be available at the pre-shipment inspection stage, while the usual practice was for these to be available *after* custom clearance. She requested that

Indonesia consider less time-consuming and burdensome procedures for imports of cell phones, handheld and tablet computers.

2.174. The representative of the United States enquired as to the legitimate objective of the measure, and also noted the importance of Indonesia respecting TBT Agreement transparency obligations. After recalling previous interventions, she noted additional concerns with the Information Technology Postel Notification 5 of 2013. In particular, the 60-day comment period was provided only when the measure was already in force. She further noted concerns with amendments to Ministry of Trade Regulation 82 of 2012 as contained in Ministry of Trade Regulation 38, issued in August 2013, and asked for further information from Indonesia regarding those changes. Finally, her delegation was aware that an amendment to Ministry of Industry Regulation 108 of 2012 was being considered, and she requested additional information on the changes being considered, and urged Indonesia to notify these measures to the TBT Committee.

2.175. The representative of Canada expressed the view that these regulations created unnecessary administrative barriers to trade, echoing the US statement. Her delegation's principal concern was the need for companies to comply with excessive labelling requirements in order to receive importer licenses to sell their products in Indonesia, resulting in significant delays in time to market. In addition, she was concerned that new certification requirements had not been notified and requested Indonesia to do so. Lastly, her delegation recommended that Indonesia delay the implementation of the wireless certification requirements guidance.

2.176. The representative of Indonesia reported that the Indonesian Ministry of Communication and Information Technology had conducted bilateral meetings with the US delegation in Jakarta in September 2013. At this meeting, the US received a comprehensive explanation from Indonesia on the issues of imported cell phones, handheld and tablet computers. Regarding transparency, his delegation had notified the Regulation of the Minister of Communication and Information Technology n. 5 of 2013 concerning Classification of Telecommunication Equipment as G/TBT/N/IDN/78. The regulation had three main objectives: ensuring interconnectivity, interoperability, and security for networking and information; facilitating CAB to determine appropriate technical regulations; and, facilitating completion of the application form with the appropriate HS code. Turning to the certification procedure, he reported that the Ministry of Communication and Information Technology had developed a new Regulation concerning Certification of Telecommunication Equipment, which was a revision of the previous Regulation n. 29 of 2008 (notified in G/TBT/N/IDN/81). He noted that this revision included certain procedural requirements for certification, submission of application, testing requirements and certification license. His delegation was of the view that the requirement for inclusion of International Mobile Equipment Number (IMEI) labels was in line with Article 2.2 of TBT Agreement. The representative explained that the rationale for this IMEI labelling was national security requirements, as well as to protect consumers from stolen and lost phones, and also for prevention of the deceptive practices. The IMEI number could be used by network providers to identify valid devices, and could also be used to prevent certain devices from accessing the network. He explained that if a mobile phone was stolen, the owner could request that his or her network provider "ban" the phone using its IMEI number. In addition, he argued that the requirement for Bahasa Indonesia labels did not create unnecessary obstacle to trade, rather this provision was aimed at conducting surveillance or monitoring of every product to be marketed in Indonesia in order to prevent deceptive practices. Regarding the technical guidelines on registering products for cellular phones, computer and handheld tablets, the representative informed the Committee that the Indonesian Ministry of Industry had issued Guideline 5/IUBTP/PER/1/2013 which regulated the implementation of the Decree of Ministry of Industry 108/MIND/PER/11/2012. The decree was notified under document G/LIC/N/2/IDN/13. He asked delegations to refer to document G/LIC/Q/IDN/27 circulated on 7 October 2013, for answers to other technical questions, in which Indonesian provided written replies to questions from the EU and the US on this aspect, which was. Nevertheless, Indonesia continued to welcome bilateral discussion on these issues with concerned Members.

#### **2.2.2.28 Russia – Safety of light industry products**

2.177. The representative of the European Union said that while her delegation shared the legitimate objectives of protection of human life and health, these objectives could be achieved by means less restrictive than the mandatory requirements laid down in the technical regulation. The technical regulation subjected many textile and clothing, footwear and leather products to detailed

compulsory third party conformity certification, and given that these products were considered as relatively low risk, this created unnecessary barriers to trade. She suggested that Russia's legitimate objectives of consumer health protection be achieved by less strict means, for example, random inspections. The representative recalled Russia's clarification in the last TBT Committee meeting that mandatory third party certification was limited to products that entered into direct contact with human skin, as enumerated in Article 11, paragraph 2 of the technical regulation. However, she said this provision covered a wide range of textile products and footwear, and her delegation believed that a self-declaration of the manufacturer should be sufficient for all products covered by the technical regulation. Furthermore, she contended that the parameters to be tested were in many cases not based on scientific and objective criteria. She asked Russia to clarify the relevant standards for the conformity certification. She further noted that the technical regulation provided for extensive labelling and marking requirements, some of which were of limited use for the customer. In the view of her delegation, mandatory labelling requirements should be limited to essential elements, leaving the remaining information at the discretion of the producer or distributor. At the last TBT Committee meeting, Russia had said that the EU written comments were under consideration by the competent Russian authorities, and she requested information as to the outcome of this consideration, and also to receive a written reply to her delegation's comments.

2.178. The representative of the Russian Federation explained that this technical regulation, developed in accordance with Article 2.2 of the TBT Agreement, was introduced on 3 December 2011 and entered into force in July 2012, prior to the Russian Federation's accession to the WTO. This technical regulation of the Customs Union actually replaced the national legislation and substantially facilitated regulation in this field, in the markets of all the member states of the Customs Union. Under Article 11, paragraph 4 of this measure, mandatory certification was only required for three kinds of textile products that came into direct contact with the skin, for example, underwear, bed linen and socks. His delegation did not share the opinion of the EU that the scope of products subject to mandatory certification was too broad. He noted that other textile products were subject to self-declaration of conformity. Moreover, new draft amendments were notified in document G/TBT/N/RUS/14, which further facilitated the technical regulation. Specifically, he explained that the amendments repealed excessive regulation of raw materials used in manufacturing of final products, by excluding them from the need to undergo conformity assessment procedures. He stated that only final products were subject to conformity assessment procedures. The representative said that EU comments submitted in May 2013 were well received during the public hearing, and would be included in the roster of comments of interested parties. According to the procedures of the Eurasian Economic Commission, all comments included in the roster concerning draft amendments to the technical regulation shall be replied to, and his delegation expected that the roster would be ready in the near future, at which time it would be made publicly available on the website of the Eurasian Economic Commission. The representative expressed his delegation's willingness to continue to engage in bilateral consultations on this matter.

#### **2.2.2.29 China – China Food and Drug Administration (CFDA) EMC Enforcement Notice for medical devices of 19 December 2012.**

2.179. The representative of the European Union said that electro-magnetic compatibility (EMC) test for Classes II and III medical devices was mandated in the context of China's registration procedure for such devices, and was carried out in order to ascertain compliance with Chinese mandatory standard YY0505:2012, which appeared to be equivalent to IEC standard 60601-1-2 (2<sup>nd</sup> edition, 2004). The EU was grateful that the China Food and Drug Administration (CFDA) had constructively engaged with European industry on this issue and other regulatory issues pertaining to medical devices, and also appreciated that the Chinese standard appeared similar to the international IEC standard. In this context, she reiterated her delegation's request that the CFDA accept test reports from foreign laboratories accredited by accreditation bodies who are members of ILAC, as an alternative to in-country testing by a Chinese laboratory. This would avoid unnecessary duplication of testing, as medical devices imported into China were already tested in accordance with the IEC standard. She also stated that it would ensure that there was no disruption in the importation of medical devices into China from 1 January 2014 due to a lack of necessary infrastructure to perform the EMC testing. She noted that the number of laboratories accredited by the CFDA to perform the required EMC testing continued to be quite low, and was insufficient to comply with the likely heavy increase in activity resulting from the enforcement of the CFDA notice. This would likely lead to longer registration timelines and higher compliance costs



for industry, and she therefore asked China to provide information as to steps taken to address this problem, and, in particular, if it would allow foreign test reports proving compliance with the relevant IEC standard as an alternative to in-country testing in China.

2.180. The representative of the United States said that the new requirement to conduct EMC testing in CFDA-approved facilities in China would require medical devices that have already been tested and certified outside of China to be re-tested within China, which would significantly impact trade by increasing both the cost and time-to-market for products exported to China. She mentioned that China previously accepted EMC test reports generated outside of China by qualified international laboratories, including those recognized under the IECEE CB Scheme. Her delegation requested that China reconsider accepting EMC test reports generated by laboratories outside of China that have been internationally accredited under the ILAC or IECEE CB Scheme. If these test reports were not accepted, she requested an explanation why they were considered inappropriate in this case. As noted in past interventions, her delegation believed that the confidence and independence of laboratories should not be determined by place of domicile. Further, the representative noted that the new requirements referenced GB standards that were based on an outdated version of the IEC standard, and she sought clarification from China that it intended to accept the current version of this standard as equivalent. If this was not the case, she asked for an explanation of why the current relevant international standards would be ineffective in meeting China's objective. Finally, she recalled that the US submitted an enquiry on these requirements via China's national enquiry point on 17 October 2013, but to date, her delegation had not received a response. She again requested that China notify this requirement to the WTO Secretariat and allow a reasonable time for Members to comment.

2.181. The representative of China stated that standard YY0505:2012 ("Medical Electrical Equipment Part 1-2: General Requirements for Safety, EMC Standard Requirements and Test Standards for Medical Devices Industry") was an identical transposition of the IEC international medical electrical equipment electromagnetic compatibility test standard IEC 60601-1-2. She said the standard was set to ensure a safe environment for medical devices so as to protect public health. As IEC 60601-1-2 was a recognized international standard in this area and was widely used by WTO Members, it was her delegation's view that the promulgation of YY0505:2012 would not have a significant impact on international trade.

#### **2.2.2.30 European Union - Transformation of still wine into sparkling wine (EC Regulation 479/2008 of 29 April 2008).**

2.182. The representative of Australia expressed ongoing concerns with EC Regulation 479/2008 of 29 April 2008 which did not allow bulk still wine produced outside the EU to be transformed into sparkling wine in the EU. At the same time, the EU permitted still wine from one EU member state to be transformed into sparkling wine in another EU member state. The regulation appeared to be inconsistent with the national treatment principle under Article 2.1 of the TBT Agreement. His delegation understood that the EU only permitted sparkling wine to be made from still wine in limited circumstances and subject to specific conditions and labelling requirements; however, wine sourced from outside the EU was excluded from this possibility under EC Regulation 479/2008. Australian wine exporters were seeking access to the same conditions and regulations applicable to bulk EU wine being transformed into sparkling wine in the EU. His delegation encouraged the EU to amend the regulation as a matter of priority.

2.183. The representative of the European Union reiterated that the transformation of wine from still into sparkling in the EU was subject to strict regulations, regardless the origin of the still wine. As a result, most sparkling wine sold in the EU could not be produced from still wine from another country, regardless of whether this was a third country or a European one. In the exceptional cases where this was allowed by EU legislation, specific labelling rules were in place in order to avoid consumer deception. She explained that her delegation was discussing this issue with Australia bilaterally in the framework of the EU-Australia Agreement on trade in wine.

#### **2.2.2.31 European Union – Implementing Regulation (EU) No 481/2012 of 7 June 2012 laying down rules for the management of a tariff quota for high-quality beef.**

2.184. The representative of Argentina said that despite four years of bilateral negotiations, and having met all the requirements and providing all the information required by the EU, Argentina

was not yet authorized to export high quality meat to Europe under the tariff quota established in August 2009 by Regulation (EC) No. 617/2009. He recalled that the latest version of Control and Certification Protocol was submitted by Argentina in February 2012, , more than 20 months previously, but had not yet received any response. A number of follow-up requests had been made bilaterally, as well as in the TBT Committee context, and on each occasion the EU replied had been vague and dilatory. At the June 2013 meeting, the EU had only said that this request was still under consideration. Given the time elapsed, and the clarifications and supplementary information provided by Argentina in response to EU requests, he stressed that the time had come for a response. As previously stated, this unwarranted postponement was an unnecessary obstacle to trade, and was therefore incompatible with the TBT Agreement. He underscored that the fact that Argentina had not received authorization to export meat under the tariff rate quota was incompatible with the most favoured nation principle, since other countries in a similar position to Argentina, whose production and control systems were similar or equivalent to those of Argentina, had already been authorized to access this quota, sometimes for a period of several years. He therefore once again requested the EU to clarify the reason for the lack of progress since February 2012. He also urged it to promptly take a favourable decision on Argentina's application, publish this decision without delay in the official bulletin of the EU with the name of the Argentine body issuing the certification of authenticity, as established in Article 5 of Regulation 481/2012 concerning the management of the tariff rate quota, so that Argentina could participate on equal terms with other Members.

2.185. The representative of the European Union reiterated her delegation's doubts that this issue, which related to the management of a tariff rate quota, fell under the scope of the TBT Agreement. Nonetheless, her delegation was providing Argentina with regular updates on its application bilaterally, and would continue to do so.

#### **2.2.2.32 Peru — Implementing Regulations of 14 November 2012 for Moratorium on Planting Genetically Engineered Crops**

2.186. The representative of the United States appreciated the productive engagement with Peru on this issue during our bilateral discussion in the context of their Trade Promotion Agreement. Her delegation nevertheless remained concerned about the lack of notification to the TBT Committee of the implementing regulations for the moratorium on GE crops.

2.187. The representative of Peru reiterated that the ten year old moratorium was not a technical regulation within the meaning of the TBT Agreement, and therefore did not need to be notified. She stated that that this was an environmental measure related to the protection of biodiversity. She took note of the comments and pledged to relay them to her capital for due consideration.

#### **2.2.2.33 New Zealand – Proposal to introduce plain packaging of tobacco products in New Zealand**

2.188. The representative of Cuba expressed thanks for the bilateral meeting with New Zealand, but reiterated that her delegation had not yet received replies in writing to their questions of 28 November 2012. She also noted a meeting had taken place on the margins of the March 2013 Committee meeting with experts from capital, who had requested additional time to participate in New Zealand's public consultation on this measure. Her delegation remained concerned with this measure, and considered it to be incompatible with WTO rules. The representative again asked for updated information on New Zealand's domestic legislative process on this aspect.

2.189. The representative of Dominican Republic said that her delegation shared New Zealand's interest in protecting human health, but the proposed plain packaging measures were nevertheless a source of serious concern. She recalled concerns express at past TBT Committee meetings, as well as in the TRIPS Council meeting of 5 March 2013. Her delegation was concerned that this proposed measure ran counter to WTO obligations under WTO Agreements, including the TBT and TRIPS Agreements. She further stated that the proposed requirements were unnecessarily trade restrictive to meet New Zealand's legitimate objective. She urged WTO Members to postpone any implementation of plain packaging requirements until the DSB had dealt with the complaints brought by five WTO Members, including the Dominican Republic, against Australia's plain packaging legislation.

2.190. The representative of Honduras echoed concerns of Cuba and the Dominican Republic. While his delegation fully endorsed New Zealand's public health objective, he reiterated concerns that the measures in question were not in line with New Zealand's obligations under the TBT and TRIPS Agreements. He recalled that the TBT Agreement mandated that technical regulations be no more trade restrictive than necessary to fulfil legitimate objectives. Moreover, Article 12.3 of the Agreement stipulated that Members must ensure that technical regulation do not create unnecessary obstacles to exports from developing country Members. Given the complaints currently before the DSB, his delegation hoped that there would not be a proliferation of similar legislation in other Members, which risked undermining the multilateral trading system. He therefore urged the New Zealand Government to reconsider its decision to introduce plain packaging for tobacco products while awaiting the results of the complaints lodged by Ukraine, Honduras, Dominican Republic, Cuba and Indonesia.

2.191. The representatives of Nicaragua and Malawi endorsed the preceding interventions.

2.192. The representative of Zimbabwe appreciated the efforts of New Zealand in protecting public health, but nonetheless shared the concerns expressed by other delegations with the proposed plain packaging measures. She reiterated her delegation's position that these measures ran counter to the TBT and TRIPS Agreements. She encouraged New Zealand to await the outcome of the Australia case before the DSB, and reconsider its decision to implement these measures, which were unnecessarily trade restrictive, would not achieved their legitimate objectives, and were not based on scientific evidence.

2.193. The representative of Australia reiterated his delegation's previous interventions in support of New Zealand's decision to legislate for mandatory plain packaging of tobacco products. He said tobacco plain packaging was a legitimate measure, designed to achieve a fundamental objective – the protection of human health. His delegation looked forward to supporting New Zealand as it underwent the development of its own measure, and appreciated New Zealand's consistent strong support for Australia's measure, including in meetings of this Committee. Tobacco plain packaging was endorsed by leading public health experts as well as the World Health Organization (WHO), and was supported by extensive research reports and studies. He noted that tobacco plain packaging was recommended in the guidelines for the implementation of Articles 11 and 13 of the WHO Framework Convention on Tobacco Control, to which Australia and New Zealand were both Parties. Australia was of the firm view that Members had the right to implement measures necessary to protect public health, while complying with relevant international treaty obligations, including the TBT Agreement.

2.194. The representative of Canada said that international developments in tobacco product packaging remained of interest to Canada. She noted that Canada had been a pioneer in package labelling requirements for tobacco products, and considered these sorts of requirements a core component of the right to regulate in the interests of the public. In her delegation's view, it was important to recall Article 2.2 of the TBT Agreement, which allowed for the legitimate objective of protection of human health. Her delegation looked forward to further views from other Members on the appropriate balance amongst regulation, international trade and public health.

2.195. The representative of Norway expressed continued support for New Zealand in this regard.

2.196. The representative of Uruguay reiterated his delegation's conviction as to the legitimacy of plain packaging under WTO rules, and support for the proposal of New Zealand. He noted that New Zealand was acting in line with its commitments in the WHO context, which were shared by 176 states, and stated that this plain packaging measure was not more trade restrictive than necessary to protect public health. The objective of protecting public health was within the sovereign right of states, and he said therefore that each state could legislate in the interest of public health as recognised in the WHO FCTC. New Zealand had committed not to undermine international standards in implementation of this public health measure, and Uruguay held this justification.

2.197. The representative of New Zealand welcomed interest in his government's decision to work towards the introduction of a plain packaging regime for tobacco products, and efforts to continually reduce the burden of preventable death and disease caused by tobacco consumption. He recalled that this decision, which was announced in February 2013, was taken to advance

public health objectives and followed a comprehensive public consultation process, which was notified to the TBT Committee. New Zealand had previously reported to the Committee on numerous occasions the outcome of the consultation process, and had repeatedly responded to the points raised by concerned Members at this meeting. He said that since the February decision, officials had commenced the process of preparing draft legislation that would provide for a plain packaging regime, and it was his government's intention to introduce this legislation before the end of 2013. Detailed regulations to implement the regime would be developed subsequently. The representative stated that prior to the plain packaging legislation being introduced to the New Zealand Parliament, his government would allow sufficient time for the public to make submissions on the legislation and for the Parliamentary Select Committee to review the legislation and consider the submissions received. His delegation would also notify the legislation to this Committee, to allow Members the opportunity to comment. In announcing the decision to introduce plain packaging, New Zealand acknowledged the WTO legal challenges to Australia's plain packaging laws. His government noted, if necessary, that enactment of final entry into force of New Zealand's legislation or regulation could be delayed pending conclusion of Australian cases before the DSB. He emphasized New Zealand's willingness to continue to meet bilaterally with concerned Members, including the distinguished delegation of Cuba, to further discuss the proposed measure. Finally, he thanked those Members which expressed supported for New Zealand's introduction of plain packaging.

#### **2.2.2.34 Kenya – Alcohol Labelling: The Alcoholic Drinks Control (Licensing) Regulations, 2010: Legal Notice No. 206: 2010 (G/TBT/N/KEN/282)**

2.198. The representative of the European Union thanked Kenya for its written reply to EU comments on G/TBT/N/KEN/282. While her delegation welcomed the clarifications therein, concerns remained that under current Kenyan requirements the health warning must comprise not less than 30% of the total surface area of the package, an extremely burdensome requirement. Her delegation sought further clarifications about these requirements, and urged Kenya to proceed with the proposed amendments regarding the size of the warning, as established by the Alcoholic Drinks Control Amendment of 2012, in order to provide legal certainty to economic operators. Furthermore, she expressed concern about the rotation requirement for warning labels, which established that: "all the warning labels specified in the Second Schedule shall be randomly displayed in each twelve month period on a rotational basis and in as equal a number of times as is possible, on every successive fifty packages of each brand of the alcoholic drink and shall be randomly distributed in all areas within the Republic". In this context she recalled Article 2.2 of the TBT Agreement, and requested further clarifications on how this requirement would be enforced.

2.199. The representative Kenya took note of the concerns raised, and referred to previous responses provided on this trade concern. Nevertheless, her delegation would consult with capital and regulatory authorities in order to provide an appropriate response.

#### **2.2.2.35 Mexico - Refusal of the National Water Commission to re-certify HDPE pipe products meeting quality/safety standards for piping set out in NOM 001 and NMX 241**

2.200. The representative of the United States reiterated concerns over Mexico's restrictions on sanitation pipes, detailed in the minutes of the previous Committee meeting. Her delegation appreciated Mexico's continuous engagement on this difficult issue, and understood that there had been significant movement. In particular, she confirmed that Mexico intended to grant a three-year certificate, and she awaited written approval to this effect. Her delegation would continue to monitor the situation, and she looked forward to a final resolution of this issue.

2.201. The representative of Mexico said that her delegation had done everything possible to address the concerns of the US on this issue, which had been before the Committee for some time. The Government of Mexico was pleased that this matter could be effectively dealt with as an STC. She said that her government would need to take care of matters officially before a written confirmation could be provided to the companies concerned. Her delegation was happy to deal with these matters, and would continue as necessary to engage in bilateral meetings, as well as in other meetings or fora.

### 2.2.2.36 India – Food Safety and Standards Regulation - Food labelling requirements (G/TBT/N/IND/46)

2.202. The representative of the European Union voiced concerns regarding the implementation of this regulation which was published in the Indian Gazette in August 2011. Her delegation regretted that this text and its subsequent amendments had never been notified to the TBT Committee, despite several requests from the EU Enquiry Point and despite the fact that it contained several aspects which fell under TBT Agreement provisions, such as labelling and packaging requirements. She reminded India that a publication of the Food Safety and Standards Regulation on the Food Safety and Standards Authority of India (FSSAI) website did not constitute a notification to WTO Members in the sense of Article 2.9.2 of the TBT Agreement. She reported that several food containers originating in the EU had been blocked at certain Indian ports allegedly on the grounds that compulsory labelling information was missing and/or compulsory labelling information was provided by means of a sticker instead of being printed on the package. Her delegation was still collecting information on the nature of the problem, and asked India to inform the Committee of the current procedures for the control of food imports as regards labelling provisions. She encouraged Indian food authorities to adopt the least trade restrictive means to achieve their legitimate objectives, which was, in this particular case, consumer information. Further, the Indian regulation of August 2011 defined a food label, and laid out the type of information the food label must contain, further specifying that the label shall be applied in such a manner that it would not become separated from the container. She recalled that in October 2011 India issued ad hoc guidelines specifying that certain information, which was India-specific, such as the vegetarian/non-vegetarian logos and the name and address of the importer, were considered "rectifiable" information and could be affixed by the importer in customs warehouses. The guidelines also detailed that a number of labelling elements were "not rectifiable".

2.203. She said that the EU was of the view that the October 2011 Guidelines, while initially intending to provide some trade facilitation to market operators, were in fact, if implemented *sensu stricto*, not in compliance with Article 2.2 of the TBT Agreement. She therefore requested that India allow all types of food labelling information, and not only India-specific information, to be affixed by the importer by means of a sticker in customs warehouses, if needed. This was a sound alternative to labelling in the country of origin which still attained the objective of duly informing the consumer, while being more convenient for market operators, in particular for products exported to India in small quantities. Finally, her delegation was aware that a new Indian draft technical regulation dedicated to alcoholic drinks was being drafted, and she invited India to inform the Committee of its state of play and the timeline for notification to the Committee.

2.204. The representative of India informed the Committee that his delegation had notified the Draft Food Safety and Standards (Packaging and Labelling) Amendment Regulation, 2013 on 24 October 2013 in G/TBT/N/IND/46. He noted a fruitful bilateral meeting with the EU, and said that all the specific requests raised were sent to his capital, and he was awaiting replies. Regarding the draft technical regulation on alcoholic beverages, he said that it would be notified to the Committee as soon as there was a semblance of a draft regulation.

## 2.3 Exchange of Experiences

2.205. The Secretariat drew Members' attention to the revision of the Committee's compilation of decisions and recommendations contained in document JOB/TBT/67. It was noted that this document would be open for comments from Members until 29 November 2013 and would thereafter be issued as G/TBT/1/Rev.11.<sup>6</sup>

### 2.3.1 Special and Differential Treatment and Technical Assistance (Thematic Session on 29 October 2013)<sup>7</sup>

2.206. The Chairman reported on the thematic session held on 29 October 2014 on both special and differential treatment (SDT) and technical assistance (TA). The full report, provided on the Chairman's own responsibility and with comments from Members taken into account, is contained in G/TBT/GEN/156.

<sup>6</sup> G/TBT/1/Rev.11 was issued on 16 December 2013.

<sup>7</sup> A background document by the Secretariat is contained in JOB/TBT/65.

2.207. The representative of China appreciated the Chairman's report. He said that China had offered, on a preliminary basis, some ideas on possible guidelines for special and differential treatment. He stressed that the proposal for the guidelines was not as such preliminary – this was a proposal that China and other Members were making. China made reference to an earlier submission from Ecuador (JOB/TBT/49). The Chinese delegation reiterated the need for more effective implementation of the SDT provisions of the TBT Agreement. In addition, he proposed that the Committee establish an e-working to bring this work forwards. He congratulated the EU delegation on the pioneering exchange of experience specifically on the subject of SDT – and hoped that other delegations would follow suit using the EU presentation as a role model.

2.208. The representative of El Salvador thanked the Chairman for an accurate and concise report. In general, El Salvador was pleased with the work that was being undertaken in thematic mode – it had enabled a rich exchange of experiences, SDT and TA.

2.209. The representative of Ecuador stressed the importance of moving towards a fully operational Article 12 of the TBT Agreement. He drew the Committee's attention to a working paper contained in JOB/TBT/71 on general guidelines for Article 12 of the TBT Agreement.

2.210. The representative of Cuba thanked the Chairman for an excellent report. She expressed support for the statements from China and Ecuador. It was important to look specifically at measures implemented by developed countries that were harmful to developing countries. The use of plain packaging for tobacco products was an example of a measure that had serious consequences on small subsistence farmers and their families whose livelihood depended on exporting tobacco products. The EU's REACH regulation was another example of a measure that was more trade-restrictive than necessary.

2.211. The representative of India thanked the Chairman for his exhaustive report. In his view the thematic discussions on TA and SDT were particularly important because they had been the least discussed areas in the TBT Committee. The session had been a good start. He supported China's suggestion to frame guidelines on the implementation of both articles and to establish an electronic group to do so. He referred to the SPS Committee as an example in terms of how to do this.

2.212. The representative of the Dominican Republic thanked the Chairman for his excellent report. Like others, she said that the thematic sessions were a concrete outcome of the sixth triennial review that was extremely helpful. She expressed interest in the proposals from China and Ecuador and said that her delegation would consider how best to move forward.

2.213. The representative of Brazil joined others in appreciating the usefulness of the Chairman's report and noted, in particular, the need for a more effective implementation of SDT provisions in the TBT Agreement.

2.214. The representative of Argentina called for more focus on SDT rather than technical assistance, and in particular on how developed countries were complying with Article 12. He noted that with the exception of the presentation from the EU, most presentations had focused on technical assistance.

2.215. The representative of the European Union thanked the Chairman for an accurate report. He was of the view that the exchange of information was both necessary and useful and needed to be continued. He recalled that both the sixth and fifth triennial reviews provided a built-in agenda on how to discuss the development dimension under each of the main cross-cutting topics of the Committee's work, whether under GRP, conformity assessment, international standards, or transparency. There were, therefore, a number of entry points to deepen the debate on how the development dimension was taken into account in the implementation of the TBT Agreement, without necessarily opening a completely new platform on developing new guidelines.

2.216. In terms of methodology, the EU said it might be worth recalling what had been done in other areas before considering guidelines: in the areas of GRP and conformity assessment, for example, there had first been many substantive papers from Members and an in-depth debate. Specific areas had been identified and it was only after a consensus on the main areas had emerged that the Committee could usefully concentrate its work. This was followed by an

agreement to move to a different level of ambition: to develop guidelines, or a set of principles. So the EU was of the view that this level of maturity had not yet been attained with respect to SDT. The Committee still needed to go through the logical and necessary incremental steps using the methodology that had worked in other areas.

2.217. With regard to the obligation in Article 12.3 of the TBT Agreement – this was an obligation to take into account the special needs of developing countries, but it was not as such a derogation from the core obligations in the TBT Agreement; the final benchmark was the test of necessity and proportionality under Articles 2.2 and 5.1.2 of the TBT Agreement with a view to achieving a legitimate objective. One could, for example, consider a mechanism to allow these interests to be "taken into account", expressed or conveyed. It was also necessary to keep in mind the business reality. Providing a two-tier structure that allowed products to fulfil different requirements depending on the origin (developed or developing) might not actually be in the interest of developing countries. Indeed, within the EU there had been a similar debate with regard to the treatment of SMEs, whether it would be justifiable to provide lower requirements for small enterprises. An analysis of the market had revealed that this would not work: if there were certain consumer preferences or perceptions of risk, products that did not comply with certain requirements would simply not have a market.

2.218. The EU considered technical assistance a powerful tool to build capacity that enhanced the ability to comply. By improving quality, and improving the capacity to certify against foreign requirements, new market opportunities were created. It was therefore not constructive to diminish the importance of technical assistance – it could indeed contribute significantly by creating capacity that allowed compliance with technical regulations of developed countries. The EU had mentioned a number of examples, REACH being one of them.

2.219. The representative of the United States appreciated Members' engagement and said that her delegation would look in particular at the ideas put forward by China with a full understanding of the importance of this issue as had been expressed by other Members. As had been noted by the Chairman in his summary, the US was also of the view that the initial exchange of information and experience on SDT and TA had been rich with information; the US would continue to bring their own experiences to the table when possible. The US appreciated the interest in creating an electronic working group and would consider this, including in light of the SPS experience.

2.220. The representative of Egypt joined other delegations in thanking the Chairman for his concise report. Regarding the implementation of Article 12, Egypt supported working forward on guidelines as had been proposed by China and Ecuador.

2.221. The representative of Argentina wished to respond to the EU. He noted that his delegation did not deny the significance of technical assistance. However, it was important not to confuse TA with SDT. In the view of Argentina, TA could help a country to deal with a problem whereas SDT helped to avoid it in the first place.

2.222. The representative of South Africa thanked the Chairman for an accurate report and stated his delegation's interest in participating in clarifying the provisions of Article 12.

2.223. The representative of China emphasized the importance of more work and a concrete outcome on SDT in the TBT Committee. He echoed the statements from both the EU and the US on the benefit of continued information exchange and encouraged other Members to share information and experience on SDT in both detail and depth.

2.224. The Chairman noted the strong appetite among Members for swift and concrete progress. He also recalled that the Committee was facing several issues on which progress needed to be made. There was a need to achieve a good balance between them. He therefore stated his intention to hold an informal meeting in early 2014 to discuss the way forward.<sup>8</sup>

---

<sup>8</sup> This informal meeting has been preliminarily scheduled for 6 February 2014.

### 2.3.2 Conformity Assessment Procedures (Thematic Session held on 29 October 2013)

2.225. The Chairman reported on the thematic session held on 29 October 2014 on conformity assessment procedures. The full report, provided on the Chairman's own responsibility and with comments from Members taken into account, is contained in G/TBT/GEN/155.<sup>9</sup>

2.226. The representative of the United States thanked the Chairman for his excellent summary of the discussions. She stressed the difficulties, as had been explained by South Africa, of negotiating and implementing MRAs – indeed these were often a drain on resources. With respect to the ISO and ILAC IAF presentations, the US emphasized the importance of understanding the role of international standards in conformity assessment – this was, in her view, an important element of the Committee's work. Indeed, both the US' and the EU's presentations had emphasized the importance of risk in evaluating the choice of conformity assessment procedures. This was an enduring idea that had recurred often in the Committee's work and could be an area for more in-depth work: how exactly to apply risk-based tools with respect to conformity assessment and their direct effect on the efficiency and effectiveness of the conformity assessment procedure itself. The presentation by the representative of Chinese Taipei had been valuable in the sense that it had provided useful numbers that gave a sense of the significance that the Committee's work had on facilitating trade and reducing unnecessary burdens on producers and manufacturers.

2.227. The representative of Brazil suggested that the Committee raise the issue of mutual recognition in a thematic session in 2014. He recalled that the representative of ILAC and IAF had reiterated the importance of multilateral systems for conformity assessment as a means of overcoming technical barriers to trade – but this only related to accreditation, largely outside of the regulatory system of governments. Brazil stressed the importance of mutual recognition and suggested that the Committee exchange information in this area. Brazil would provide a submission on this for the next meeting of the Committee.

2.228. The representative of El Salvador noted that all Members had worked very hard on this issue; she recalled the substantive mandate before the Committee for further work and the need to start considering possible concrete outputs for the Seventh Triennial Review in the area of conformity assessment procedures.

### 2.3.3 Transparency

2.229. Two separate matters were discussed by the Committee under transparency: notification formats and the formal launch of the on-line Notification Submission System (TBT NSS).

#### 2.3.3.1 Coherent use of Notification Formats (JOB/TBT/68)

2.230. The Chairman recalled that the European Union had circulated a paper at the June Committee meeting entitled "A Coherent approach to notification formats". The paper was contained in document JOB/TBT/48. At that meeting the Committee had also heard from the SPS Secretariat on their working practices. Since the last meeting, the Committee had received six submissions pertaining to this issue, from: South Africa (JOB/TBT/51); Indonesia (JOB/TBT/59); Uganda (JOB/TBT/60); Ukraine (JOB/TBT/61); India (JOB/TBT/63) and the US (JOB/TBT/64). These submissions had been discussed the Committee's informal meeting on 23 September.

2.231. Building on Members' submissions and comments as well as relevant previous decisions by the Committee and the relevant SPS Committee recommendations, the Secretariat had prepared a draft recommendation for delegations' consideration (JOB/TBT/68). During the informal meeting held back-to-back with the ongoing regular TBT Committee meeting, a number of useful points had been made. In general, the Chairman noted that there was agreement that JOB/TBT/68 provided a good basis for further work. He thus asked Members to provide any further comments in writing before 31 December 2013.<sup>10</sup>

<sup>9</sup> A background document by the Secretariat is contained in JOB/TBT/69.

<sup>10</sup> Submissions were received from Japan (JOB/TBT/74) and Canada (JOB/TBT/75/Rev.1).



### 2.3.3.2 Formal Launch of the TBT on-line Notification Submission System (TBT NSS).

2.232. The Secretariat announced the launch of the TBT NSS – a system that allows Members to submit notifications to the Secretariat through an on-line application. Seven Members were currently using the system (Brazil, Canada, Japan, South Africa, Uganda, Unites States and the European Union), representing about a third of all incoming notifications. Members wishing to use the system could send an e-mail to [Tbttnss@wto.org](mailto:Tbttnss@wto.org) for further instructions.

2.233. The representatives of Brazil, Canada, the European Union and South Africa expressed their appreciation for the Secretariat's commitment and responsiveness to address challenges identified during the testing phase; they were pleased with the reliable final product that had emerged and encouraged other Members to use the system as well.

### 2.3.4 Good Regulatory Practice (JOB/TBT/44/Rev.2)

2.234. The Chairman noted that the Committee had held significant discussions on GRP. For more background, he referred to the minutes of the last TBT Committee meeting (G/TBT/M/60) as the factual reports of the first and second thematic sessions on GRP, held on 5 March 2013 and 17 June 2013 (contained in documents G/TBT/GEN/143 and Add.1). At the informal meeting held on 23 September, the Committee had further addressed the topic. Indeed, significant input had been received on the revision of the Non-Exhaustive List of Voluntary Mechanisms and Related Principles of Good Regulatory Practice, contained in document JOB/TBT/44/Rev.1. Submissions had been received from: Uganda (JOB/TBT/53), Indonesia (JOB/TBT/54); Japan (JOB/TBT/55); Cuba (JOB/TBT/56); India (JOB/TBT/57); and Canada (JOB/TBT/58).

2.235. The Chairman recalled that based on this input, and as agreed at the 23 September informal, the Secretariat had prepared a revision of the Non-Exhaustive in an effort to consolidate the comments received to date. The new revision is contained in JOB/TBT/44/Rev.2. Considering the recent distribution of the document, the Chairman proposed that Members consider this revision and provide comments in writing by 31 December 2013.<sup>11</sup> An informal meeting would be organized ahead of the March formal meeting bring work forward on this. He stressed that the current basis for further comments on GRP was JOB/TBT/44/Rev.2.

### 2.3.5 Standards

2.236. The Chairman recalled that at the first meeting of 2013, the Committee had held a thematic session on standards. The Session had considered the topics of (i) the Code of Good Practice; (ii) the use of the "Six Principles"; and (iii) transparency in standard-setting. The moderator's summary of the session was contained in G/TBT/GEN/144.<sup>12</sup> He recalled that there had been a high level of engagement and interest by Members at the session. There had also been a sense that the information exchange on standards had not been fully exhausted – and that the Committee needed to reflect on how to bring this work forward in a more specific and detailed manner. At the end of the session it had been suggested that future work in the Committee might focus on some specific elements of the standardization process, in order to deepen Members' exchanges.

### 2.3.6 Other Matters

#### 2.3.6.1 A new regulatory framework for federal food inspection in Canada

2.237. The representative of Canada presented a new regulatory framework for federal food inspection. A full description is contained in document G/TBT/GEN/154.<sup>13</sup>

---

<sup>11</sup> Submissions were received from South Africa (JOB/TBT/72), Japan (JOB/TBT/73), Canada (JOB/TBT/76) and Cuba (JOB/TBT/77).

<sup>12</sup> A background document by the Secretariat is contained in JOB/TBT/42 and Corr.1.

<sup>13</sup> More detail is also available at: <http://www.inspection.gc.ca/food/action-plan/food-safety-regulatory-forum/presentations/discussion-document/eng/1370029593829/1370029641557>.

### 2.3.6.2 Topics for discussion at the Committee's next thematic session (18 March 2014)

2.238. The Chairman noted that the Committee had come full circle. Three thematic sessions had been held, covering GRP, standards, transparency, technical assistance and special and differential treatment, and conformity assessment procedures. Clearly, and in view of Members remarks, dedicating one day to discuss cross-cutting topics, as mandated in the sixth triennial review, had been a meaningful exercise and a useful decision by the Committee. The Chairman proposed that, in March 2014, the Committee revert to the topics of GRP and Standards while leaving a window open to also address any other issues, depending submissions provided by Members. It was so agreed.

## 3 TECHNICAL ASSISTANCE

3.1. The Secretariat provided a document containing information on its technical assistance activities.<sup>14</sup>

## 4 UPDATING BY OBSERVERS

4.1. The representative from BIPM reminded the committee that BIPM was the intergovernmental body operating the international system of units ensuring comparability of measurements worldwide. Recent activities included Colombia becoming a Member State, and Mongolia becoming an associate Member, bringing the BIPM membership to 55 Member States and 37 Associate States. Both also signed the CIPM MRA.<sup>15</sup> This MRA had been running for 14 years, and would be subject to a major review over the next two years. The representative also informed the Committee of a workshop in Lusaka, Zambia, organized in conjunction with AFRIMETS - the Regional Metrology Organization for Africa, so as to increase understanding of the MRA in that region.

4.2. The representative from UNECE informed the Committee that the 23<sup>rd</sup> annual session of the Working Party on Regulatory Cooperation and Standardization Policies (WP6) would take place from 18-20 November<sup>16</sup>, and would include an international conference on standards and regulatory frameworks.<sup>17</sup> She also informed the Committee that the Working Party had been developing best practices in the use of risk management tools in regulatory frameworks and a publication was available on Risk Management Regulatory Framework.

4.3. The representatives from OIML; IEC and Codex updated the Committee on their activities relevant to the TBT Committee.<sup>18</sup>

## 5 REPORT (2013) OF THE COMMITTEE ON TECHNICAL BARRIERS TO TRADE

5.1. The Committee adopted its 2013 Report to the Council for Trade in Goods (G/L/1052).

## 6 DATE OF NEXT MEETING

6.1. The next regular meeting of the Committee is scheduled for 19-20 March 2014. It will be preceded by thematic sessions on 18 March 2014.

---

<sup>14</sup> G/TBT/GEN/161.

<sup>15</sup> <http://www.bipm.org/en/cipm-mra/>.

<sup>16</sup> <http://www.unece.org/trade/wp6/welcome.html>

<sup>17</sup> <http://www.unece.org/fileadmin/DAM/trade/wp6/documents/2013/ReportOfTheConference.pdf>

<sup>18</sup> G/TBT/GEN/158, G/TBT/GEN/159 and G/TBT/GEN/160.