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G/TBT/M/70

17 February 2017

(17-0977) Page: 1/77

Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 10-11 NOVEMBER 2016

CHAIRPERSON: MS ESTHER PEH

Note by the Secretariat[1]

1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in WTO/AIR/TBT/6.

2 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

2.1 Statements from Members under Article 15.2

2.1. The Chairperson reminded the Committee of Members' notification obligation under Article 15.2 of the TBT Agreement and further informed the Committee that the latest list of statements on implementation submitted under this provision was contained in document G/TBT/GEN/1/Rev.15, issued on 29 February 2016. She informed the Committee that since the last meeting in June 2016, Vanuatu, Burundi and Brunei Darussalam had submitted statements. Japan had also submitted a revision to its original statement. She further informed the Committee that since 1995, 135 Members had submitted at least one statement of implementation. Information on the list of statements is available at http://tbtims.wto.org.

2.2 Specific Trade Concerns (STCs)

2.2.1 Withdrawn concerns

2.2. The Chairperson reported that the following STCs had been withdrawn from the agenda at the request of the concerned Member:

[1] 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.

a. Peru — Draft Regulations implementing Legislative Decree No. 1222 on the optimization of administrative procedures and strengthening of sanitary control over processed foods and fishery and aquaculture products

2.2.2 New concerns

2.2.2.1 Kazakhstan, Russian Federation — The amendments No. 2 to the Technical Regulation of the Customs Union on Safety of Toys (TP MC 008/2011) G/TBT/N/KAZ/7, G/TBT/N/RUS/73 (IMS ID 514)

2.3. The representative of Ukraine expressed appreciation for the previous day's bilateral discussions with Kazakhstan, as a result of which certain agreements had been reached on their notification. She nonetheless voiced concern that the conformity assessment procedure foreseen in the Customs Union Technical Regulations "On safety of toys" (TR CU 008/2011) differed significantly from international practice on declaration of conformity. The regulation indicated that stricter conformity assessment procedures were envisaged for all toys. Her delegation considered that Kazakhstan and the Russian Federation should justify such strict requirements for conformity assessment procedures with a scientifically substantiated clarification and urged them to align with international practice and avoid causing unnecessary technical barriers to trade.

2.4. The representative of the United States expressed support for the legitimate desire of the Eurasian Economic Commission (EEC) to protect the emotional well-being of children and looked forward to discussions with EEC members to find a solution that did not unnecessarily restrict trade. She flagged that her delegation would provide comments if Armenia, Belarus, and the Kyrgyz Republic intended to adopt this technical regulation. The US asked Russia and Kazakhstan to explain what criteria would determine if toys were likely to result in the Article 4 risks to children, whether these criteria would be made public and how long it would take to make this determination. Were domestic toys subject to the same evaluation? In addition, Russia was asked to clarify the age grading of toys subject to this measure.

2.5. The representative of the European Union thanked Russia for their bilateral meeting on the matter and associated his delegation with the concerns of Ukraine and the US on the proposed requirement for the prevention of negative impact of toys on the development and health of children. Whilst fully supporting the objective pursued by the Eurasian Economic Union (EAEU) of enhancing the safety of toys, the EU believed that the requirement had no scientific basis, bore no relation to toy safety, nor was there any global precedent on the matter. He formally registered his delegation's concerns and willingness to engage in future dialogue between the competent authorities of the EAEU, WTO Members and the toy industry.

2.6. The representative of Kazakhstan emphasized that the questions regarding certification requirements and standards related to the provisions of Technical Regulation "On Safety of Toys" currently in force and which were not being reviewed by the present draft amendments. The Technical Regulation "On Safety of Toys" had been adopted in September 2011, entering into force on 1 July 2012. To date, the competent authorities had not received any information regarding problems in the application of the technical regulation. She added that her delegation would be ready to answer all questions and comments upon receipt from Ukraine and other interested parties in writing.

2.7. In response to questions from the US, she recalled that the draft amendments envisaged the establishment of requirements aimed at ensuring the protection of children from possible negative impact on their development and mental health, preventing aggressive behavior, fear and anxiety. Public consultation on the draft amendment had been announced on 16 June 2016 with completion planned for 31 August 2016. Whilst the draft amendments were under active discussion, the public consultation had been prolonged until 30 November 2016, upon request of interested parties. She elaborated that the rationale behind the amendments was that the domestic market had been flooded by toys, predominantly dolls, inducing children to aggressive behavior, instilling fear, and misconstruing the true anatomical structure of the human body. Such toys, psychologists warned, might negatively affect children's mental health and development. Qualified psychological and pedagogical expertise of certain types of toys, taking into account a possible psychological role in child development, had become increasingly important in Kazakhstan. She clarified that a working group was in the process of discussing the types of toys to be subject to the expertise, as well as

the relevant criteria and methodology. Her delegation assured Members that all comments and constructive proposals could be sent either to its TBT Enquiry Point or to the EEC and would be taken into account as provided for by Article 2.9.4 of the TBT Agreement.

2.8. The representative of the Russian Federation thanked the EU and the US for their bilateral engagement on this issue. He expressed his delegation's support for the substance of the statement made by Kazakhstan and reiterated that the period of public consultations on the draft amendments had been extended until the end of November 2016.

2.2.2.2 India — E-waste (Management) Rules, 2016 (IMS ID 515)

2.9. The representative of the Republic of Korea expressed concern that whilst E-waste rule (2016), revision of E-waste rule (2011), had been implemented from 1 October 2016, it had not been notified to WTO Members, preventing the submission of comments at an appropriate stage, and causing Korean stakeholders to suffer from an insufficient period to adapt to the regulation. In light of Article 2.9.2 of the TBT Agreement, his delegation therefore requested a 24-month grace period for implementation. He further referred to the fact that the E-waste rule (2016) obliged manufacturers to collect 30% of e-waste as of 1 May 2017. However, waste electrical and electronic equipment (WEEE) was frequently sold on the Indian second-hand market. Moreover, 95% of total e-waste in India was distributed via informal routes, according to a MAIT-GTZ report. Besides, it was generally accepted that electrical and electronic equipment was used in India for more than 20 years according to the custom of using second-hand articles, while the average lifespan for electric equipment such as refrigerators and air-conditioners described in implementation guidelines was below ten years. All these factors made it difficult to accomplish the target collection rate of 2017 owing to the lack of WEEE collection. In regard to Article 2.2 of the TBT Agreement which provides that Members shall avoid technical regulations creating unnecessary obstacles to trade, Korea suggested that India modify the estimation method for "expected e-waste generation" in consideration of the average lifespan of electrical and electronic equipment.

2.10. The representative of Japan voiced support for the concerns raised by Korea and urged India to provide a sufficient grace period and to review the target collection rate based on actual market distribution and lifecycle of electrical and electronic equipment in India.

2.11. The representative of United States reported that US industry had provided comments on several iterations of the regulation but that in the face of continued concern her delegation would shortly be following up with India.

2.12. The representative of India stated that the Ministry of Environment, Forest and Climate Change had issued the E-waste Management Rules, 2016, in exercise of powers conferred by the Environment (Protection) Act, 1986. The rules laid down, *inter alia*, responsibilities of manufacturers, producers, dealers, re-furbishers, bulk consumers, dismantlers, recyclers, etc. in the matter of e-waste management in India. For example, the rules asked a manufacturer in India to collect e-waste generated during the manufacture of any electrical and electronic equipment and channel it for recycling or disposal. Likewise, bulk consumers were obliged to collect the items and hand them over to authorized recyclers. Various producers could have a separate Producer Responsibility Organisation (PRO) and ensure collection of e-waste, as well as its disposal. Thus, the measure in question was primarily focused on collection and disposal of electronic waste in the country in an environmentally sound manner. In this light, India considered that the concern raised by the delegation of Korea and supported by others did not seem to relate to any technical regulation, standard or conformity assessment procedures as defined under the TBT Agreement. India requested those delegations to reflect on whether the TBT committee was the appropriate forum for discussion. His delegation would nevertheless communicate the concerns raised to capital authorities for consideration.

2.2.2.3 Ireland — Public Health (Alcohol) Bill 2015 G/TBT/N/IRL/2 (IMS ID 516)

2.13. The representative of Mexico expressed her delegation's concern with regard to the Public Health (Alcohol) Bill 2015, notified to Members in document G/TBT/N/IRL/2, the objective of which was "to reduce consumption to 9.1 litres of pure alcohol per capita and the harm caused by alcohol". Mexico had submitted formal comments on this bill during the public consultation

process, based on the following considerations raised by domestic industry. Firstly the bill made it illegal to sell or advertise alcohol products at a price below a set minimum price of 10 cents per gram of alcohol. Mexico considered that imposing a minimum price per gram on the sale of alcohol was in violation of Article 2.2 of the TBT Agreement, since a less trade-restrictive measure could have been adopted to fulfil the legitimate objective. Moreover, there was no internationally recognized justification which argued that reducing the harmful consumption of alcohol could be achieved by increasing market prices.

2.14. Secondly, the bill stated that labels on alcohol products must contain warnings about the health risks of consuming alcohol, in particular during pregnancy. She added that the labels must indicate the alcohol content per gram and give details of the Ministry of Public Health website, to be provided by Ireland's National Health Service, where information would be available on the health risks of alcohol consumption. Her delegation sought the scientific or technical justification for incorporating these items in the labelling of alcohol products, since Mexican industry argued that the labels called for by the Irish bill differed from the requirements commonly imposed on the entry of these goods into the EU, and as such could be regarded as unnecessarily restrictive.

2.15. Thirdly, she pointed out that the bill also provided for alcohol to be displayed in separate areas in supermarkets and smaller outlets, to make it less visible to consumers in general. It was not clear whether there would be a limit on the space available for off-the-shelf sale or what the conditions would be in the areas in which alcohol products would have to be displayed on the shelves of these points of sale, in accordance with the measure. It was Mexico's view that the bill in this sense imposed discriminatory treatment on the sale of alcohol products and sought to fulfil the legitimate objective pursued by means of a measure more trade-restrictive than necessary, again in contravention of Article 2.2.

2.16. Mexico therefore requested an update on the present status of the bill, in particular whether it had already been adopted and, if so, when it was expected to enter into force, and whether there was provision for a sufficient transition period to comply with the provisions of the law.

2.17. The representative of Guatemala, in expressing systemic concern about the measure, in particular with harmonization, reiterated that his delegation recognized the legitimate objective of protecting the health of the population but remained concerned about potential barriers the measure could establish.

2.18. The representative of the European Union noted that in parallel with the WTO notification, Ireland had also notified the measure to the European Commission in accordance with internal EU requirements for notification of draft national technical regulations under Article 5(1) of Directive (EU) 2015/1535. Ireland had received comments from the Commission and detailed opinions and comments from some EU member States on the draft measure within the framework of the internal notification procedure. These reactions were currently being analysed and considered by the Irish authorities. As regards comments that may be received under the WTO TBT notification procedure, he assured Members that these would be equally examined and written replies provided in due course by the EU.

2.2.2.4 Bolivia — Technical regulations on the labelling of foods and products destined for human consumption that consist of, contain or derive from genetically modified organisms, G/TBT/N/BOL/3, G/TBT/N/BOL/3/Add.2 (IMS ID 517)

2.19. The representative of Mexico expressed support for Bolivia's objectives of guaranteeing the right of users and consumers to information, for the purpose of protecting human health, via provisions establishing a definition of Genetically Modified Organisms (GMOs) and providing for product labelling by means of the use of words and symbols. Nevertheless, her delegation considered that the measure could contravene Article 2.2 of the TBT Agreement, since it could prove to be more burdensome than necessary to achieve this legitimate objective. Moreover, further clarification was requested with regard to the use of relevant international standards to support the technical content of the Bolivian measure, as domestic industry had stated that it was not based on the Codex Alimentarius, since the latter did not suggest distinguishing food that contained GMOs or using words or symbols to indicate such content. In this regard, no internationally recognized scientific evidence existed to suggest that genetically modified food posed a risk to health. Mexican industry maintained that there was no difference between

genetically modified and conventional products with respect to their protein, nutritional, toxicological or allergenic composition, and as such should not receive different treatment.

2.20. Finally, with respect to the implementation of the regulations, Mexican industry noted the technical and economic impracticability of establishing the system of segregation and traceability in the supply channels for basic agricultural products and in the subsequent stages of food manufacturing and marketing that would be necessary in order to comply with the proposed labelling. Industry further pointed out that compliance with the provisions of the draft regulations would require radical, expensive and unjustified restructuring of the supply and manufacturing systems. This would apply more particularly to the supply chains and the basic agri-food industry, which would have an adverse effect on end consumer prices and ultimately on the basic food basket and a wide range of consumer products.

2.21. Mexico therefore requested Bolivia: (i) to consider eliminating the requirement of a labelling scheme for food entering Bolivia that included wording indicating the GMO content, in the absence of scientific basis for discriminating between conventional and genetically modified products; (ii) to explain the grounds for this measure; and (iii) to arrange a video conference or meeting with the technical services responsible for drawing up the measure.

2.22. The representative of Guatemala reiterated that his delegation recognized the legitimate objective of protecting public health, but remained concerned that these measures could hinder trade. He expressed renewed concern over the lack of harmonization being generated across the region with regard to food labelling as a result of the introduction of different measures in each country.

2.23. The representative of the Plurinational State of Bolivia underlined that as an independent sovereign state his country had the right to decide upon regulations according to the needs of its population. Article 13 of the General Law of Consumer Rights stated that reliable, comprehensive, relevant, easily accessible and timely product information should be available to consumers. As such, the objective of the Bolivian standards was to guarantee those rights to consumers and therefore needed no further scientific or technical justification. Bolivia maintained that there was no global precedent in the field of requirements for food for human consumption, whereby labelling which indicated GMO content would be a technical barrier to trade. To illustrate the point, he added that more than 60 Members currently used different mechanisms to identify and label GMOs and their derivatives in order to safeguard public health. The thematic session on food labelling had highlighted that countries introducing such requirements were doing so with the objective of improving consumer information.

2.24. Regarding international standards he emphasized that Bolivia was a signatory to many international agreements besides Codex, each with equal legal and constitutional value, in particular to the Cartagena Protocol on Biosafety, Article 18.2 of which stated that each party was to take measures to require the documentation and labelling of GMOs for human and animal consumption, for intentional introduction into the environment, and for contained use. To conclude, he stated that whilst Codex did not prescribe GMO labelling, neither did it deny the possibility of using it. Moreover, Codex document CAC/66/2011 recognized the use of different approaches for labelling of foods derived from modern biotechnology.

2.2.2.5 Korea — Amendment of the Notifications on Warning Messages on Smoking and Drinking, G/TBT/N/KOR/664 (IMS ID 518)

2.25. The representative of Mexico expressed concern raised by domestic industry about two of the warning messages to be included in the labelling of alcoholic beverages, which pointed to a causal relationship between alcohol consumption and cancer by stating that: "alcohol is carcinogenic, so that excessive drinking causes cancer of the liver and the stomach" and "excessive drinking is the cause of cancer". Mexican industry maintained that there was no scientific evidence establishing such a causal link, since epidemiological studies pointed to a wide range of cancer risk factors, including family history, genetics, lifestyle and environmental factors. Moreover, existing scientific literature (studies carried out by the US Centers for Disease Control and Prevention in 2011 and the National Institute for Alcohol Abuse and Alcoholism in 2013) stressed that moderate consumption of alcohol was also regarded as an important part of a healthy lifestyle. Accordingly, Mexico considered that the messages required by the Korean

measure constituted an unnecessarily burdensome mechanism for ensuring the fulfilment of the legitimate objective of the measure, i.e. the protection of human health, in breach of Article 2.2, and that moreover they might not provide clear information for the consumer. Her delegation also believed that the measure did not afford a sufficiently long comment period during the international public consultation stemming from notification G/TBT/N/KOR/664, or an adequate transition period for the regulated sector to comply with the new labelling provisions, based on the provisions of Article 2.9 of the TBT Agreement.

2.26. Mexico therefore requested Korea: (i) to take into account existing scientific literature with respect to the correlation between alcohol consumption and cancer and to consider eliminating or amending the above-mentioned warnings to avoid conveying unclear messages to consumers; (ii) to hold a video conference with the Korean authorities responsible for the measure, in order to clarify the nature of the scientific and technical information considered in connection with its implementation and to examine industry's arguments concerning existing scientific literature; and (iii) to further extend the period for comments on the measure and to grant an additional period for its entry into force, according to relevant Committee recommendations.

2.27. The representative of the United States voiced support for Korea's efforts to protect public health by informing consumers of the risks of excessive alcohol consumption. Although Korea had notified the regulation to the WTO, the US was troubled that Korea had finalized and adopted it prior to the end of the comment period. She asked how Korea would take into account comments received from Members and stakeholders after 31 August 2016 but before the end of the 28 September 2016 comment period. A delay was requested in the adoption and implementation of the warning label requirements to allow for significant dialogue with Members which had not been provided under the norms of the Committee. She asked when Korea would respond to their comments and those of US industry. If the regulation was already finalized, how would Korea respond? The US was disappointed that Korea had not allowed for sufficient stakeholder input on a measure which would increase costs and resources for US exporters to such a close trading partner. Her delegation looked forward to further engagement with Korea on the measure and, in the future, sufficient opportunities for input on regulations which would impact their trade.

2.28. The representative of New Zealand expressed support for Korea's right to introduce new regulations to address specific public health concerns, specifically the harmful use of alcohol, in order to fulfil the legitimate public health objective in the notification and appreciated that, in seeking to address the harmful use of alcohol, the notification was directed towards achieving a legitimate public health objective. Her delegation looked forward to a prompt response to written comments submitted on 6 October 2016. She asked whether Korea had considered less trade-restrictive alternatives when drafting this regulation, in accordance with the principles of the TBT Agreement and if so, what these alternatives were and the reasons for not selecting them. An official English translation of the regulation was also requested, to ensure that Members could be certain as to the intent of the language in the regulation.

2.29. The representative of Australia recognized Korea's right to take measures to protect consumer health and that health warning labels for alcoholic beverages could address a legitimate public health concern. Her delegation, nevertheless, sought further information from Korea about a number of aspects to the changes to the National Health Promotion Act related to alcohol and wine labelling. She requested that Korea provide an official English translation of the proposed health warning statements, in view of the number of different translations available. Some available translations, she added, seemed to establish a direct link between alcohol consumption and certain diseases. Australia asked if this was the intent of the proposed warning statement and suggested that the label be drafted in a way that would reflect scientific consensus on the issue. Her delegation additionally requested confirmation that the regulation did not require a rotation in the use of the three health warnings and whether producers could choose between the three labels. She further asked Korea to confirm if the regulation had entered into force on 3 September 2016. Finally, Australia requested deferral of implementation of the measure in order to allow for a proper consultation period in accordance with Korea's obligations under the TBT Agreement as well as an extension of the post-consultation transition period to allow sufficient time for business to adjust.

2.30. The representative of Canada, whilst recognizing Korea's efforts to minimize the negative health impacts associated with excessive alcohol consumption, echoed the concerns raised by

other Members, in particular the fact that the measure came into force before the end of the comment period and without providing an adequate time for exporter to adapt.

2.31. The representative of Japan noted that it had submitted comments on the notification, requesting that appropriate measures be taken, including the provision of a sufficient transition period to avoid creating unnecessary obstacles to foreign liquor exporters.

2.32. The representative of the Republic of Korea recalled that it had received comments from Members on the notification, and on consideration thereof had granted a grace period of 12 months, as specified in Article 4 of the Regulations of the National Health Promotion Act. With regard to specific points such as the scientific basis for the regulation and the English translation of warning messages, his delegation was ready to consult bilaterally with concerned parties. He concluded by recalling Korea's conviction that controlling health hazards stemming from the excessive consumption of alcohol was a matter of utmost importance in his government's duty to protect the health of the population and therefore sought Members' understanding and support for the new regulation.

2.2.2.6 Uganda — Alcoholic beverages specifications, G/TBT/N/UGA/434; G/TBT/N/UGA/435, G/TBT/N/UGA/437, G/TBT/N/UGA/438, G/TBT/N/UGA/439, G/TBT/N/UGA/440, G/TBT/N/UGA/441 (IMS ID 519)

2.33. The representative of the European Union thanked Uganda for the replies it had provided to their comments on the notified drafts. His delegation nevertheless wished to highlight some unresolved issues. Firstly, the drafts required the date of manufacture to be indicated on some of the products. In this regard, he reiterated that Codex Standard, Labelling of Prepackaged Foods (CODEX STAN 1-1985) did not require such a compulsory labelling indication. In addition, the EU considered that for alcoholic beverages the date of manufacture would have no added value since they were not perishable products and this could therefore mislead the consumer. Secondly, according to the notified drafts, imported products would have to indicate the name and address of the manufacturer. The EU noted that Codex Standard, Labelling of Prepackaged Foods (CODEX STAN 1-1985) recommended indicating the name and address of the importer as a contact point for consumers for any product-related question or issue and considered the approach of consumers contacting a person in the marketing country and in their own language easier than in the country of export.

2.34. Thirdly, his delegation requested clarification of the meaning of some of the analytical requirements set out in some of the notified drafts such as, for example, those for total solids, volatile acids such as acetic acids, higher alcohols and furfural. He further asked for information on the rationale of the need to fix such limits and on what basis those parameters had been fixed. Lastly, he reiterated that Codex Standard, Labelling of Prepackaged Foods (CODEX STAN 1-1985) did not provide for the compulsory labelling of indications like "blending" for blended products and "white rum" for rum that is not aged. The indication "blended" was required exclusively for some high quality products (e.g. some geographical indications) but not for basic whisky or wine spirits. On the basis of the above-mentioned issues, the EU recalled the provisions of Article 2.4 of the TBT Agreement on the use of relevant existing international standards. In summing up, the EU requested an update on the revision process of these technical standards. It was his delegation's understanding that the next meeting of the responsible technical committee of the East African Community would take place from 28 November to 2 December 2016; Uganda was therefore invited to ensure that the issues raised in the Committee would be transmitted to this technical committee and be taken into account in the revision process.

2.35. The representative of the United States voiced support for the EU's comments which resembled their own concerns to be raised on the STC 41[2] relating to Kenya — East African Community (EAC) alcoholic beverage standards. She urged Tanzania and Burundi to provide notifications if they planned adopting similar measures.

2.36. The representative of Uganda noted that comments received from the EU and other Members on these alcoholic beverages standards had been answered. As the standards were, however, slated for review, he assured the EU that any remaining concerns would be considered at that time.

[2] See paras. 2.299. - 2.301. page 59.

2.2.2.7 Russian Federation — Medical devices, G/TBT/N/RUS/51, G/TBT/N/RUS/52, G/TBT/N/RUS/53, G/TBT/N/RUS/55 (IMS ID 520)

2.37. The representative of the European Union noted that, while the four drafts had been notified on 10 and 11 May 2016, the proposed date of adoption was 5 July 2016 and final date for comments was 5 June 2016. He asked why the normal comment period for notifications of at least 60 days had not been provided. In relation to G/TBT/N/RUS/51, the EU considered that the draft established an unduly long timeline for the review of dossiers presented in the framework of technical testing for medical devices as part of their "expert evaluation", and believed that this would prevent the market from adequately keeping up with the pace of innovation. He questioned why the Russian authorities considered such a long review time as satisfactory and necessary, pointing out that the timeline for expert evaluations in the EU was normally between 30 and 60 days, compared with what seemed to be over 300 days in the notified draft. Concerning G/TBT/N/RUS/52, the EU noted the proposed date of adoption of the notified draft rules of 5 July and the proposed date of entry into force of 1 January 2017 and recalled that adequate transition times, in particular for registration procedures, were necessary to avoid disruption of market access. He stated that generally a transition period of three to five years was provided for such measures, ensuring a viable transition for the medical device sector, both because of the technical complexity involved in regulating the sector and the large number of medical devices involved. Furthermore, the use and recognition of international standards (especially those of ISO) and best practices (notably for the recognition of clinical information) were essential to ensure market access for medical technologies around the world and in this regard he recalled obligations under Article 2.4 of the TBT Agreement. The EU therefore urged Russia to consider a longer transition period as well as the use and recognition of international standards and best practices.

2.38. On G/TBT/N/RUS/53, the EU understood that all relevant information regarding "safety and efficiency" of a medical device had to appear on its label and sought clarification regarding the scope of "labelling" information and "operational documentation" information. Finally, turning to G/TBT/N/RUS/55, the EU recognized that, in addition to EAEU registration procedures for medical devices, "recognition by expert reports" was required for each individual EAEU member. The EU requested clarification as to whether such decisions of the Board of the EAEU regarding medical devices registered under the new rules could be fully and directly applicable (and enforceable) in all members of the EAEU without such additional "recognition by expert reports".

2.39. The representative of the United States supported the comments made by the EU and said her delegation would follow up in writing directly with the Russian Federation.

2.40. The representative of the Russian Federation recalled that the Agreement on Common Principles and Rules of Medical Devices Circulation in the EAEU had been signed in December 2014, for the implementation of which a package of documents had been developed. To date, all of these documents had been adopted by the EEC but would only enter into force once all EAEU Members had ratified the Agreement. He reassured Members that overall the entry into force of this package of documents would not imply dramatic changes in requirements or conformity assessment procedures, as the transitional period would last until 31 December 2021. In particular, previously issued certificates of registration of medical devices would be valid during the transitional period.

2.2.2.8 Russian Federation — Pharmaceutical products - Resolution 1314 of the Government of the Russian Federation on determining compliance of medicinal products' manufacturers with the requirements of Good Manufacturing Practice (non-notified); draft decisions of the Board of the Eurasian Economic Union G/TBT/N/RUS/54,/TBT/N/RUS/58, G/TBT/N/RUS/63 (IMS ID 521)

2.41. The representative of the European Union raised concern regarding measures adopted by the Russian Federation introducing certification requirements for medicinal products, for both human and animal use. Of most significant concern to his delegation was Resolution 1314 of the Government of the Russian Federation on determining compliance of medicinal products' manufacturers with the requirements of Good Manufacturing Practice (GMP), dated 3 December 2015. He expressed concern that this resolution had apparently not been notified to the WTO as it introduced a requirement of inspection and certification of production sites of medicines with regard to GMP, including foreign manufacturing sites, a pre-condition for obtaining a marketing authorization in the Russian Federation. As the resolution therefore had a significant effect on

trade, his delegation considered that it should be subject to the obligation laid down in the TBT Agreement to notify draft measures for review by WTO Members. Regarding entry into force, the EU was of the understanding that the measure, adopted on 3 December 2015, had started to apply to foreign manufacturing sites since 1 January 2016 with two concrete consequences: the GMP certification requirement already applied to new products without a previously accepted market authorization; and the renewal of marketing authorization would require GMP certificates as of 1 January 2017.

2.42. The EU considered that the interval of one month between the adoption of the measure and its entry into force fell short of the obligation under the TBT Agreement to provide sufficient time to allow manufacturers to adapt to new requirements. Moreover, it appeared that the measure foresaw a timeline for the examination of foreign manufacturing sites of up to 160 business days, much longer than the transition period. In addition, the number of foreign manufacturing sites supplying medicines to the Russian Federation was very high. For each site manufacturing a new imported product without a currently existing marketing authorization, or whenever currently accepted marketing authorizations expired, an inspection by the Russian authorities was necessary as a condition for the requisite GMP certification. Therefore, to ensure smooth and least-trade-disruptive entry into force of the measure, substantial resources would need to be allocated by the Russian Federation. It was his delegation's understanding, however, that the inspection capacity made available by the Russian Federation would be far from the level required for such a smooth entry into force, especially when the measure had already been in force for almost one year. Moreover, for veterinary products, it appeared that not only sites manufacturing final products need to be inspected, but also those manufacturing Active Pharmaceutical Ingredients (APIs), which would increase the burden for industry and the requirements in terms of inspection capacity for the Russian Federation.

2.43. He reiterated that the lack of notification and therefore of transparency towards WTO Members, the absence of an appropriate transition period and the mismatch between requisite inspection capacity and the resources allocated by the Russian Government, resulted in a very difficult situation for industry which particularly affected foreign sites, due to the additional difficulties of the inspection process abroad. This situation was already restricting imports of medicines into the Russian Federation and, unless additional measures were taken, his delegation believed that the negative impact could become much more severe once currently accepted marketing authorizations expired. The EU therefore requested that (i) the measure be notified to the WTO, to allow for review by Members with a view to taking into consideration their comments for the finalization of the measure; (ii) appropriate transition time and additional accompanying measures be taken, including in the area of organization of inspections, so as to ensure that the GMP certification requirement could be complied with by foreign manufacturers in a timely fashion with no negative impact on their exports to the Russian Federation; and (iii) the specific issue for veterinary products of double inspection of sites manufacturing APIs and final products be reconsidered by the Russian Federation.

2.44. He ended by expressing his delegation's hope that the development, adoption and entry into application of the measures contained in notifications G/TBT/N/RUS/54, 58 and 63 would be fully compliant with the obligations laid down in the TBT Agreement, in particular with regard to the need to provide sufficient delay between the adoption of the measure and its entry into application so that manufacturers could adapt to the requirements of the measure.

2.45. The representative of the United States acknowledged that Russia had circulated the "Draft Agreement on Common Principles and Rules of Medicinal Products Circulation in the Eurasian Economic Union (EAEU)" and its implementing acts to WTO Members in May 2016, providing stakeholders with less than a 60-day comment period. Regarding the implementing act dealing with GMP requirements, her delegation supported Russia's objective to ensure that human and veterinary medicines on their domestic market were safe and effective, but had been informed by industry that the implementing acts might result in trade disruptions, for example in the case of insufficient officials in Russia to conduct GMP inspections of all the proposed sites. A status report of such inspections was requested. Further, industry and local stakeholders in Russia had reported that they were concerned that the GMP requirement had caused significant delays in the registration of new medicines. On the agricultural side, this requirement could lead to a shortage of veterinary medicines for livestock, which could in turn negatively impact Russia's goal of increasing its food production. The US urged Russia to provide a transition period so that Russian citizens would not lose access to innovative lifesaving medicines and so that Russian livestock and

pets would not be exposed to the risk of infectious diseases. Confirmation was also sought that Russia would no longer require that clinical trials for orphan drugs be conducted in Russia. The US encouraged Russia to discuss potential solutions to this issue with stakeholders such as patients, hospitals, and industry, and assured that US industry stakeholders stood ready to help facilitate these discussions.

2.46. The representative of the Russian Federation stated that Federal Law No. 429-FZ of 22 December 2014 amended Federal Law No. 61-FZ of 12 April 2010 "On the Circulation of Medicines" by introducing a compulsory requirement whereby the manufacture of pharmaceutical products should comply with GMP provisions in order to adequately protect human life, health and safety. Resolution No. 1314 of the Government of the Russian Federation of 3 December 2015 approved the rules of inspections for manufacturers of pharmaceutical products in order to implement Federal Law No. 61-FZ. This resolution set out the fee for this service, and was equal for domestic and foreign manufacturers. The rules of said inspections did not contain provisions discriminating against foreign operators. Moreover, the schedule of inspections of foreign manufacturers was publically available on the official website of the Ministry of Industry and Trade of the Russian Federation, listing almost one hundred inspections in the second half of 2016. According to the resolution, the Ministry of Industry and Trade (in respect of pharmaceutical products for humans) and the Federal Service for Veterinary and Phytosanitary Supervision ("Rosselkhoznadzor") (in respect of pharmaceutical products for animals) were authorized to control and monitor the application of the GMP conformity certification system to pharmaceutical products. The quantity and frequency of inspections depended on the number of requests thereof. He reported that work on the Draft decisions of The Board of the Eurasian Economic Union was still on-going and that their adoption would require changes in legislation of the EAEU members. He nevertheless guaranteed that previously issued certificates would remain valid for a certain transitional period.

2.2.2.9 Mexico — Official Standard PROY-NOM-199-SCFI-2015: Alcoholic beverages - Designations, physicochemical specifications, commercial information and test methods G/TBT/N/MEX/302 (IMS ID 522)

2.47. The representative of the European Union asked Mexico how the comments the EU had submitted on 29 April 2016 relating to the notification were being taken into account. The concerns on Mexico's draft technical regulation raised in these comments related to the definition of several products, to some analytical parameters, to the definition of ethyl alcohol and to the existing maximum alcoholic strength for spirit drinks. In particular, the EU requested Mexico to align its technical regulation to the Recommendations of the International Organisation of Vine and Wine (OIV), including the International Code of Oenological Practices, as well as to widely accepted international practices, in view of the provisions contained in Article 2.4 of the TBT Agreement. She recalled the TBT Committee Decision on the Timing of Entry into Force of Technical Regulations which determined that a "reasonable interval" should normally constitute a period of not less than six months, except when ineffective in fulfilling the legitimate objectives pursued and urged Mexico to respect a minimum period of six months between entry into force and implementation of the measure. Lastly, she requested an update on the state of play in the process of modification of this technical regulation.

2.48. The representative of Mexico reported that the final version of the draft regulation had not yet been published in the Mexican Official Journal, since the Working Party responsible for drafting it was still evaluating the comments received during the public consultation period. The last meeting of the Working Party had been held a month previously, at which point most of the comments received from the various interested parties had been incorporated. She nonetheless assured Members that the health and labelling conditions established in Mexican Official Standard NOM-142-SSA1/SCFI-2014, "Alcoholic beverages. Health specifications. Health and commercial labelling" would remain in force, supplementing the content of Mexican Official Standard NOM 199. Lastly she stated that whilst there was no estimated date for the publication of the final version of NOM 199, it was expected to take place in the first quarter of 2017.

2.2.2.10 European Union – Country of Origin Labelling (IMS ID 523)

2.49. The representative of the United States stated that a number of EU member States (France, Finland, Greece, Italy, Lithuania, Portugal, and Romania) were in the process of developing, and in some cases implementing, country of origin labelling (COOL) schemes for milk and meat, and

certain processed food products containing dairy or meat ingredients. She outlined that each member State's requirements and product coverage varied but that in general the measures appeared to require the labelling of pre-packaged food products containing meat and dairy with the origin of each meat and dairy ingredient. It appeared that in some cases, information on origin relating to place of birth, fattening, slaughter, milking, processing or packaging was required. In some instances, if all activities occurred within the EU, member States could permit a label stating "Origin: EU"; conversely, for activities occurring outside of the EU, the label could read "Origin: Outside EU". It also appeared that in some cases the measures also applied to certain primary products, for example, requiring the labelling of origin of fluid milk. She reported that US industry had raised serious concerns that the new country of origin labelling requirements in various EU member States could act as a non-tariff barrier to trade. Her delegation encouraged the EU to notify the measures shortly as in the absence of notification by the Commission or the member States, US industry had been unable to obtain authoritative versions of the regulations, and not granted the opportunity to comment on them.

2.50. Furthermore, it would seem EU member States would not have time to consider any comments. She recalled recent WTO findings on related issues in which the US was a party which her delegation believed should give EU member States a significant time period before finalizing these proposed measures. In this regard, she suggested that soliciting and taking into account the feedback of trading partners and affected stakeholders would be prudent. Moreover, it appeared that some of the member State measures were expected to enter into force on 1 January 2017, which would not allow for notice and comment or a reasonable interval between publication and entry into force. The US requested clarification on the proposed timeline for moving forward with the COOL measures and questioned whether the EU and the member States were allowing a "reasonable interval" between publication and entry into force.

2.51. More generally, she noted that the member State labelling requirements raised a number of concerns because of differing treatment between EU versus non-EU origin products, as well as the potential amount of recordkeeping required to comply with the proposed measures. Furthermore, she noted that some of the measures included a mutual recognition clause which appeared to favour select countries by exempting processed foods originating in those countries from the requirements, and that the measures could create incentives for local food processers to use locally produced dairy and meat ingredients to the detriment of US exports. She concluded by expressing her delegation's willingness to discuss these issues in detail with member States. Given the importance of these affected sectors in the US, the Commission was urged to intervene to ensure consistency with the relevant WTO obligations so that these regulations would not present barriers to US-EU trade.

2.52. The representative of New Zealand voiced support for the concerns raised by the US, in particular in seeking a time-frame for notification of the draft proposal as well as an update on the forward process.

2.53. The representative of the European Union, whilst recalling that this was the first instance of member State measures requiring country of origin labelling for food products being raised in the Committee, referred to the applicable EU regulatory framework as regards the adoption of member States' national measures in this field. Regulation (EU) 1169/2011 on the provision of Food Information to Consumers allowed member States to introduce measures concerning the mandatory indication of the country of origin or place of provenance for certain category of foods, following the specific notification procedure established for this purpose in the Regulation. Accordingly, member States who deemed it necessary to adopt such national measures had to notify them to the Commission and the other member States, providing justification for them based on grounds specified in the Regulation, including consumer protection. In addition, member States needed to provide evidence supporting their measures, for instance, that the majority of consumers in the member State concerned attached significant value to the provision of the origin indication. He pointed out that certain member States had recently notified draft national measures according to this procedure, some of which were currently under assessment by the Commission. His delegation remained available for further bilateral discussion.

2.2.3 Previously raised concerns

2.2.3.1 European Communities – Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH) (IMS ID 88)

2.54. The representative of Canada reiterated concerns about the significant negative impact of various aspects of REACH on small and medium-sized enterprises (SMEs), including the "Only Representative" (OR) and "Letter of Access" (LoA) provisions, and the 2018 registration deadline for substances manufactured or imported in quantities from 1 to 100 tonnes.

2.55. Canadian SMEs have expressed concerns about the exceedingly high cost for substance LoA relative to their volume of business. In one instance, the LoA cost to register eight substances exceeded EUR 200,000 for an enterprise doing CAD$2.5 million in annual business, and these costs could exceed EUR 500,000 for the remaining substances they would be required to register under REACH. He was particularly concerned that the requirement to register would not exist if substances were purchased in the EU, exported to Canada, and then re-imported to the EU in value-added products.

2.56. While Canada understood that EU manufacturers had already incurred registration compliance costs, he asked the EU to explain why Substance Information Exchange Forums (SIEFs) were permitted to use the LoA process to effectively freeze out non-EU SMEs or late entrants from the EU market. Canada recognized that the European Chemicals Agency did not own the data produced for the registration dossiers, however, it appeared that in practice a certain number of lead registrants and OR consultants were using the LoA and OR processes for economic advantage. Canada strongly urged the EU to ensure that SIEFs were not permitted to use the LoA process to obtain unfair economic advantages. Canada believed that it was not just Canadian SMEs, but SMEs within Europe that were being negatively affected by these prohibitive registration costs.

2.57. Canada requested that the EU explain the process for appealing excessive LoA fees under REACH. He reported that Canadian SMEs had approached REACH helpdesks and would appeal LoA fees in due course. However, Canada was of the view the EU should do more to ensure that SMEs and late entrants to the EU market were not unduly affected by these administrative anti-competitive practices, which in the view of Canada were not contributing to the health, safety or environmental protection objectives of the regulation.

2.58. Canada suggested that the EU consider extending the number of low-risk substances exempt from registration under Annex V of REACH, including substances for which the psycho-chemical properties were extremely well-known and traded in high volumes, such as citric acid and soda ash. Canada asked the EU what the process would be to nominate such substances.

2.59. Finally, Canada was encouraged that the EU had initiated a "fitness check" of REACH, which included a review of support measures for SMEs, registration requirements for low tonnage substances, and the effect of the regulation on competitiveness of SMEs. Canada hoped the EU "fitness check" would focus on burden reduction and simplification to address the disproportionate costs to SMEs.

2.60. The representative of the European Union reaffirmed his delegation's statements in past TBT Committee meetings, and bilateral meetings with Canada, namely that the EU was taking measures to ensure that SMEs were not detrimentally affected by REACH requirements. An evaluation of REACH was ongoing, and a public consultation was open.

2.2.3.2 India - Pneumatic tyres and tubes for automotive vehicles, G/TBT/N/IND/20, G/TBT/N/IND/20/Add.1, G/TBT/N/IND/40, G/TBT/N/IND/40/Rev.1 (IMS ID 133)

2.61. The representative of the European Union reiterated his delegation's concerns with the Indian measure at issue which introduced a certification procedure with a mandatory marking for tyres. The EU referred back to its previous statement at recent Committee meetings concerning the ISI marking fee and the US$10,000 bank guarantee. India was requested to align its procedures to international practices and remove the obligation to pay a marking fee per marked tyre and to eliminate the discriminatory bank guarantee requirement. The EU had asked India to

provide information about the new Schedule of Testing Inspections (STI) 15633/5 of November 2015. The new measure introduced the concept of "control unit", meaning 5,000 tyres of the same family. It required testing of every tenth control unit for load and speed performance, endurance test, bead unseating resistance test and tyre strength test. During the recent bilateral meeting, the EU understood that the control unit was modified to 30,000 types of the same family and his delegation asked for confirmation of this modification. The EU considered that these testing requirements were extremely burdensome and costly and asked what specific safety-related objectives India was pursuing. During the last meeting of the Committee, India had said that the new measure might be further amended following the comments received; the EU asked for an update on state of play in this regard and asked India to notify the measure.

2.62. The representative of Japan voiced support for the position of the EU regarding this issue. Regarding the increase in Conformity of Production (COP) test frequency, Japan expressed its appreciation with the improvement by the revised draft which came into force in July 2016. Japan expressed continued concern in regards of other points. Japan considered that there were misunderstandings on the facts (e.g. the basis for calculation of marking fee) between her delegation and India. Consequently, Japan looked forward to bilateral meetings to reach mutually satisfactory solutions.

2.63. The representative of India said that concerns relating to the bank guarantee requirements were not new and had been responded to several times at previous meetings of the Committee. This was similarly the case for the marking fee. Therefore, the interested delegations were requested to refer to the statement made by India on these matters at previous meetings, particularly in the minutes of the meeting held in March 2015.[3] Regarding the Scheme for Testing and Inspection as per STI/15633/5 November 2015, India refered to its statement of the meeting held in March 2016, in which it indicated that the matter was under further consideration of the authorities. Based on the feedback received, the STI for Pneumatic Tyres for passenger car vehicles had been revised as STI/15633/6 March 2016, which would enter into force in 20 July 2016. In the earlier STI of November 2015, one control unit was defined as 5,000 tyres. However, in this revised STI one control unit had been defined as 30,000 tyres. In both of these STIs, a test had to be carried out on one sample of a family of tyres for every 10 control units. This test would be required to be carried out once for every 300,000 tyres, and not every 50,000 tyres since the control unit in the latest STI was 30,000 tyres instead of 5,000 tyres. Consequently, the testing frequency was reduced six times.

2.64. Regarding the notification of the new STI, he said that Members were required to notify conformity assessment procedures that are not in accordance with the relevant guides and recommendations issued by international standardizing bodies, as per Article 5.6 of the TBT Agreement. He indicated that the Bureau of Indian Standards (BIS) Product Certification Scheme was based on the international standard ISO/IEC 17067 (Type 4). He noted that acceptance and maintenance of the STI was a condition for BIS licence and that it was applied without discrimination to domestic and foreign manufacturers.

2.2.3.3 China - Provisions for the Administration of Cosmetics Application Acceptance, G/TBT/N/CHN/821, G/TBT/N/CHN/937 (IMS ID 296)

2.65. The representative of Japan reiterated its concerns regarding the "Guidance for Application and Evaluation of New Cosmetic Ingredients" in terms of speed of examination, safety evaluation requirements and information disclosure. Japan asked China to share details (schedule, content, etc.) on the planned revision contained in "Regulations concerning Hygiene Supervision over Cosmetics", and to resolve raised concerns. Concerning the latter regulation, Japan asked China to provide a public comments process as foreseen in the TBT rules.

2.66. The representative of the European Union asked China to explain the state of play of the new Chinese draft on Cosmetic Supervision and Administrative regulation and of China's plans to set up a differentiated approach between higher-risk priority cosmetic ingredients, requiring pre-market registration and ordinary ingredients, requiring notification to competent Chinese authorities. The EU, welcoming this approach, also asked China to share the planned timeframe for adoption of this change.

[3] G/TBT/M/65, paras. 2.41-2.43.

2.67. The representative of China thanked the EU and Japan for their continued interest and stated that no updates were available. The importance of the issue of new cosmetic ingredients and of carefully researching it in communication with domestic and foreign business and industry organizations to find an effective resolution was underscored. A new classification system, applauded by the EU, was envisaged in the draft revision of the Regulations Concerning the Hygiene Supervision over Cosmetics, published to the public by the legislation office of state council from 20 July - 20 August 2016 for commenting and opinions. Further comments and suggestions would be welcomed and processed by the competent authority during further revision.

2.2.3.4 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" (IMS ID 274)

2.68. The representative of Canada reiterated his delegation's concerns with respect to India's in-country test requirements for telecoms products, which would hinder or possibly shut Canadian exporters out of the Indian market. Canada disagreed with India's blanket approach to testing in the telecoms sector, questioning why Common Criteria (CC) testing was not appropriate for India's telecoms framework, given that it was internationally accepted. Allowing accredited foreign conformity assessment bodies to test and certify to India's regulatory requirements would reduce testing costs and expedite foreign products entering the Indian market.

2.69. The representative of the European Union requested that the requirements be postponed past the current date of 1 April 2017 pending clarification of the implementation modalities, and that until that time the status quo - meaning continued acceptance of foreign test results and suppliers being allowed to self-certify their products - would continue to apply. Testing modalities under the new requirements was a crucial implementation issue. He asked whether Indian authorities would allow product-type testing rather than the excessively burdensome batch testing, which could cause importation delays and bottlenecks. The EU suggested that India consider a product-type testing based on a prototype of the product being tested once. Concerning the applicable standards for testing purposes, the EU welcomed India's indication that relevant international standards would be relied upon when possible. On the requirement for in-country testing, he failed to see how in this particular case, in-country testing would enhance the security of equipment or the networks. Foreign test results should continue to be accepted and flexibility should be provided for companies with a proven track record and who have consistently demonstrated over time the ability to self-certify products through adequately accredited and competent in-house laboratories. He welcomed India's confirmation that there would be no change to the continued acceptance of results of test results and certificates issued under assessments conducted under the Common Criteria Recognition Agreements (CCRAs), and that Third Generation Partnership Project (3GPP) standards would be used for specific security aspects of telecom network equipment. India was requested to refrain from developing home-grown specific standards, which would just add costs without increasing value in terms of enhanced security Finally, he urged India to continue to conduct the process in a transparent and inclusive manner allowing interested stakeholders to provide input throughout the process.

2.70. The representative of the United States said that while the postponement of the implementation of the in-country testing requirements had been helpful, there remained long-term uncertainty for India's trading partners. Several Members remained concerned that the telecommunications conformity assessment requirements could create an onerous and unnecessary trade barrier on companies, particularly SMEs. She asked that India issue a public notice and notify the Committee of when the new in-country testing requirements would enter into force and the actual date producers would have to comply with them. While recognizing India's need to protect critical telecommunications infrastructure from spyware and malware attacks, other Members faced similar challenges and did not require in-country testing or MRAs. Globally known, innovative, and reputable companies were already developing innovative technology such as anti-spyware, anti-malware, security specialists, and private and international standards so as to secure networks from more and more sophisticated network attacks. What were the specific and unique circumstances in India that rendered such innovations inadequate? What specific incidences could be looked to in order to see India's justification for this regulatory approach? She requested that India provide more specific replies to these questions than had been provided in the past. In a

market where the most secure products were the most competitive, India's approach could discourage innovation and competitive technology development. Another pending request related to India sharing the analysis on which the in-country testing requirement was based. As stated in previous interventions, security testing that would potentially compromise companies' proprietary information such as source code and other intellectual property would potentially discourage companies from exporting high-quality telecommunications equipment to the Indian market, hurting India's trading partners unnecessarily and limiting Indian service providers from having access to the broadest possible range of network products and components. Finally, she encouraged India to accept international testing standards and schemes regardless of whether the tests were performed in India or at accredited labs outside of India.

2.71. The representative of Japan expressed her delegation's support for the positions of the EU, US and Canada. Japan still had interests in the new Unified Access Service License Agreement, and sought assurance that India's telecom regulations would not impede market access for foreign industries. Like other Members, Japan was concerned that the testing modalities had yet to be finalized. She asked that India clarify the details and the development status of the implementation of in-country security testing as this was of interest to foreign industry.

2.72. The representative of India said that telecom networks were part of the Critical Infrastructure on which other critical infrastructures like power, transportation and defence also rode. The licence amendments dated 31 May and 3 June 2011 were mandated under on consideration of national security, and therefore required that the licensee shall induct only those network elements into the network, which had been tested as per relevant contemporary Indian or International Security Standards such as IT and IT-related elements against ISO/IEC 15408 standards, Information Security Management System against ISO 27000 series standards, Telecom and Telecom related elements against 3GPP security standards and 3GPP2 security standards, from any international agency or labs of the standards, for example Common Criteria labs in the case of ISO/IEC 15408 standards, until 31 March 2013. This had been extended up to 31 March 2017. India would rely on the international standards to the extent possible. For IT products, testing carried out against CC Process under CCRA could be leveraged, although additional tests would be conducted if required in the interests of national security. As had been previously clarified, CC was process based and used to certify the claims of the vendor on security features incorporated in the product, without certifying that the product had no vulnerabilities. The Common Criteria certification did not address National Concerns on the Security requirement of Telecom Networks. Telecom equipment was tested against 3GPP standards for operational requirements and did not have security standards per se for telecom equipment. The SA3 sub-group had only been created in 2014 to work out the security standards for telecom equipment. 3GPP, by its own admission, was in the process of developing security assurance requirements for Telecom Network elements and so far had only taken up one network element - MME.

2.73. In-country testing requirements had been incorporated only after wide consultation with various stakeholders such as the Ministry of Home Affairs, security agencies and telecom service providers to address national security concerns. In response to the suggestion that the new requirement should not apply to companies with a proven track record, it was noted that the guidelines were applied regardless of brand/size and geographical location, and were equally applicable to all manufacturers/vendors irrespective of the source of procurement and included domestic manufacturers. In response to the US request that the effective date be made available in a public notice, he said the effective date of 1 April 2017 had been issued and uploaded onto the Department of Telecommunications website[4] on 1 April 2016. Transition times would also be made available there. Finally he said that these guidelines could not be considered a trade barrier as they were equally applicable to both domestic and foreign manufacturers and vendors.

2.2.3.5 China – Requirements for information security products, including, *inter alia*, the Office of State Commercial Cryptography Administration (OSCCA) 1999 Regulation on commercial encryption products and its on-going revision and the Multi-Level Protection Scheme (MLPS) (IMS ID 294)

2.74. The representative of the European Union reiterated his delegation's systemic concerns about the Chinese regulatory framework on information security. This was a general concern – the EU intended to elaborate in more detail on specific sectoral implementation of these general

[4] http://www.dot.gov.in

provisions under the STCs 24 and 28 below[5] concerning specific information security requirements in the banking and insurance sectors. China had developed a number of framework provisions on information security which had restricted the use of encryption products incorporating foreign technology in China. The existence of multiple, overlapping layers of regulation impacting the same sectors created uncertainty about how all the different pieces fitted together. Therefore, industry still had a number of unaddressed questions on how to comply with these system requirements and their future implementation given that many of the requirements expressed in the general laws required further implementation at a later stage. There were different pieces to this complex puzzle: the "old" OSCCA regulation on commercial encryption products which had been under revision for several years (an update of the state of play was requested); The Multi-Level Protection Scheme (MLPS), which introduced the notion of "critical infrastructure" and the classification of IT infrastructure in different levels with the consequence that as soon as a network was classified as critical infrastructure there were certain restrictions as to the type of equipment and technology that could be introduced into the system, with a requirement for the use of products incorporating domestic technologies and whose intellectual property rights were owned by Chinese nationals.

2.75. More recently, the representative of the European Union noted, the National Security Law adopted on 1 July 2015 had introduced the notion of "secure and controllable" which meant that all key cyber infrastructure within China had to be secure and controllable. While this clarification was welcome (in the specific context of the STC dealing with information security in the insurance sector), questions remained about how this notion was going to be rolled out in practice and what its implications were in terms of hardware and software requirements in IT network equipment.

2.76. The most recent development concerned the adoption by the National Peoples' Congress – on 7 November 2016 – of the new China Cyber Security Law which had a very broad scope of application and contained cross-references to the MLPS and the National Security Law, including to the concept of "secure and controllable". It applied to construction, operation, maintenance and use of networks and aimed *inter alia* at protecting critical infrastructure from cyberattacks. It contained some key provisions, for instance: regarding the introduction of a MLPS for cyber security; on the need for products used in networks qualified as critical infrastructure to comply with mandatory requirements of relevant national standards; and, the need for critical equipment for cyber security to be certified by a qualified institution in China, with an indication that a catalogue of such critical equipment would be developed at a later stage. There were provisions for network operators of critical information infrastructure to be subject to direct government supervision and to obtain clearance from government for the products they used through a process which was qualified as a national security review to be conducted by the State-level Cyberspace Administration and there was provision for spot checks to be carried out by state level cyberspace administration for security risks of critical information and infrastructure. The cyber security law was intended for application from 1 June 2017.

2.77. The EU understood, based on bilateral consultations, that this law would require specific implementation and be a benchmark for future regulations in this area. Thus there could be implications for the on-going revision of the specific provisions in the insurance and banking sector and there was a need to understand how all the different pieces mentioned above (the OSCCA regulation, the MLPS, the National Security Law, the Cyber Security Law) would be applied in conjunction.

2.78. The EU had already mentioned several times the need for a transparent process and continued to urge China to notify under the TBT Agreement all relevant rules in this area. A good precedent had been set with the specific rules impacting the insurance sector and China was asked to extend this to any measure in this area. The EU regretted that neither the Cyber Security Law nor the National Security law had been notified in draft form under the TBT notification procedure.

2.79. Concerning standardization activities, China was urged to take into account relevant international standards and to allow for meaningful opportunities for foreign companies to participate in Chinese standardization, notably through Technical Committee 260 which was of strategical importance in this area. This technical committee had recently showed increased

[5] China — Banking IT Equipment Security Regulation (IMS ID 457) and China - Insurance Regulatory Commission (CIRC) Information and Communication Technology Regulation (IMS ID 489), paras 2.178. 2.184. and 2.196. - 2.211. respectively, below.

openness by allowing the participation of certain foreign stakeholders. The EU would welcome continued movement towards more inclusive participation of European stakeholders. Finally, the European Union could not emphasize enough the importance of international co-operation in this area. All countries faced global challenges in this field and it was in the general interest that regulations allowed the best technology available to be used globally in critical infrastructure for the purpose of enhancing security without, however, hindering trade in commercial encryption products.

2.80. The representative of Japan supported the EU position. At the last meeting of the Committee, China had said that "the regulation on commercial encryption products had been listed in the 2016 legislation plan of the State Council of China and the draft was currently being prepared." In this regard, Japan asked China to explain the current situation and the future schedule of the revision. In addition, some cryptography-related regulations were stipulated in "Banking IT Equipment Security Regulation" and "Insurance Regulatory Commission (CIRC) Information and Communication Technology Regulation" which had been notified to WTO. Japan asked if China could confirm whether or not IT Security Regulations such as OSCCA would be applied to these regulations. Moreover, with regard to the cybersecurity law adopted on 7 November 2016, Japan had submitted opinions during the public comment period of the first draft which had been published in July 2015 and for the second draft which had been published in July 2016.

2.81. The United States supported the statements made by the EU and Japan.

2.82. The representative of China noted that the new Cybersecurity Law had been notified on 7 November 2016 and would enter into force on 1 June 2017. This new law comprehensively and systematically defined the obligations and liabilities of various parts and bodies that constituted basic institutions in relation to equipment security, network operation security, network data security and network information security. This was a comprehensive, fundamental law in governing cyber security in China. Regarding specific measures, both the Regulation on Commercial Encryption Products and the MLPS would be revised and adjusted appropriately in line with the principles of cyber security newly published. In this process of revision, China would take into account its trading partners concerns and learn from their good practices so as to coordinate and advance work in both cyber security as well as trade development.

2.2.3.6 Russian Federation – Draft Technical Regulation on Alcoholic Drinks Safety, G/TBT/N/RUS/2 (IMS ID 332)

2.83. The representative of the European Union recalled the explanations provided by the Russian Federation at the previous meeting of the Committee on the procedure for adoption of technical regulations by the EAEU, in particular with regard to consultations within its member States, and invited Russia to update the Committee on the status and timeline for adoption and implementation of the draft technical regulation on alcohol products safety, which had been notified in 2012. Referring to the detailed comments submitted by the EU in writing to Russia in 2013 and the discussions in subsequent meetings of the TBT Committee, the EU representative recalled Russia's explanation that most of the EU comments regarding wine, spirit drinks and beer would be taken into account in the revised draft technical regulation. However, a revised text had neither been notified under the TBT Agreement nor published. The EU requested Russia to re-notify the revised text to the TBT Committee as it would likely include substantial changes as compared to the original text notified in 2012. The EU also requested that sufficient time be provided for manufacturers to adapt their products to the requirements of the technical regulation.

2.84. The representative of Guatemala reiterated his delegation's interest in closely following the discussions on this measure.

2.85. The representative of the United States indicated concern regarding several other provisions contained in the original draft notified to the Committee in December 2012, specifically by the proposed definition of whiskies, in particular the requirement that they had to be aged for no less than three years. She remained concerned that alcoholic beverages were required to have an expiration date. Additional concerns regarded the standards for production facilities and several conformity assessment procedures and their applicability to foreign manufactures. She requested that Russia clarify that these requirements did not apply to producers already subject to controls

by US authorities. She noted Russia's statement that the 2012 draft had been substantially modified in December 2013. She requested that Russia re-notify the latest draft of this technical regulation and provide an additional comment period for stakeholder input prior to the effective date of the measure. She stated that this would enhance transparency and mitigate any undue burden for exporters of alcoholic beverages to Russia. She sought clarification on whether voluntary standards for distilled spirits were to be applied as mandatory standards as well as the mode of application once finalized and implemented.

2.86. The representative of Ukraine joined the concerns raised by the EU and US regarding the draft regulation. She reiterated that the costs on conformity assessment procedures should be equitable in relation to any fees chargeable for assessing the conformity of like products of national origin as producers from other countries had to bear the costs associated with registration of legal entities on the territory of the Customs Union or enter into contracts with existing legal entities registered in the territory of the Customs Union. She explained that the costs on conformity assessment procedures for those producers could be higher than the costs for producers from member States of the Customs Union. She requested that these concerns be taken into consideration to ensure that the requirements of the technical regulation were in line with the requirements of international practice.[6]

2.87. The representative of the Russian Federation emphasized that the draft technical regulation had been elaborated in order to establish unified requirements for commercial circulation of both imported and domestically produced alcoholic products. He informed the Committee that the draft was still in development and that the Members of the EAEU had not agreed on a volume of consumer packaging for soft alcoholic drinks; restriction of the use of sugar-containing products in the production of beer; use of restorative components, such as caffeine and taurine, in alcoholic beverages; prohibition on adding rectified ethyl alcohol in wine; and form of confirmation of conformity of alcoholic beverages.

2.88. He said that Russia could not provide detailed comments on the points made by the US, but expressed interest in resuming bilateral discussions on those concerns. He reassured delegations that all concerns had been taken into account as provided for under Article 2.9.4 of the TBT Agreement, and would continue to inform interested Members on further steps taken in this matter.

2.2.3.7 Indonesia - Technical Guidelines for the Implementation of the Adoption and Supervision of Indonesian National Standards for Obligatory Toy Safety, G/TBT/N/IDN/64 (IMS ID 328)

2.89. The representative of the European Union reiterated the EU request for a substantive revision of the Toy Safety Decree No. 24. Given that the two-year implementation period had now passed (which was considered a pre-requisite to initiate such review), he urged the Ministry of Industry to proceed with a revision in an expeditious manner and asked what the timeline would be. There were some issues of continued concern that the EU hoped could be addressed in the revision such as the removal of the discriminatory conformity assessment procedures for imported products compared to domestic products. The current practice was that imported products were subject to batch testing whereas domestic products were subject to production line sampling every six months. On testing, he asked that relevant tests be carried out outside Indonesia in an adequately accredited foreign laboratory. The two-year grace period that had been previously granted expired in April 2016 and industry was now experiencing delays and bottlenecks at the test facilities within Indonesia. He invited Indonesia to consider a more flexible arrangement, one that required evidence of the competence of foreign labs to test toys while still providing the necessary flexibility for manufacturers to have tests carried out closer to their manufacturing facilities outside Indonesia. This could be achieved either by requiring adequate accreditation by a body which was an ILAC MRA signatory applying directly to the Indonesia authorities to be listed, or to allow subcontracting arrangements between Indonesian certification bodes and foreign labs. Neither of these suggestions required a government-to-government MRA. The participation of the KAN in the ILAC MRA established trust between KAN and the other signatories and should therefore be a sufficient basis for the Ministry of Industry to accept test results from labs accredited by ILAC MRA signatories. He also urged Indonesia to ensure that the mandatory national standard for toy safety be fully aligned with the ISO standard on toy safety ISO 8124 of

[6] G/TBT/M/69, para.3.74

2014 so as to eliminate any possible discrepancies regarding testing methods and certain limits that applied with regard to the content of certain substances present in toys, in particular formaldehyde. The current limits of formaldehyde seemed to be based much stricter for infant clothing than for toys.

2.90. The representative of Japan expressed her delegation's continued support for the position of the EU. There were serious delays in exports caused by a sequence of events such as sampling, testing, SNI certification and pre-shipment inspection. She invited Indonesia to revise the requirements as they appeared to be more trade-restrictive than necessary. Like the EU, Japan had concerns regarding discrimination in testing frequency. Each and every imported shipment of toys was tested whereas domestic products were only tested once every six months. Regarding accreditation requirements whereby only overseas laboratories in countries with an MRA with Indonesia were recognized, she said it appeared Indonesia had no such arrangements and therefore operators could not in fact use any foreign laboratories. Domestic laboratories may not have the testing capacity to run smoothly and accurately. Therefore, Japan strongly requested that Indonesia reconsider the requirements and accept testing results from foreign laboratories. She asked that Indonesia update the Committee on the current state of play.

2.91. The representative of the United States said that despite years of bilateral discussions involving multiple government agencies and technical staff meetings with major US toy companies, no substantive progress had been made despite commitments to find a way to address US concerns. Were there further amendments envisaged and if so, what was the timeline and would this revision include recognition of ILAC-accredited laboratories? Would the revised regulation address the concerns on testing frequency, sampling documentation and substance restrictions? She affirmed US interest in working with Indonesia as it continued to revise this regulation and urged notification of the next draft at an early enough stage so that all stakeholders could provide comments and for those comments to be taken into account.

2.92. The representative of Indonesia noted that this concern had been raised in the Committee for some time. The national standard and conformity assessment procedures in question were still being reviewed. As had been stated previously, all conformity assessment procedure schemes and parameters of chemical substances in toy safety were in line with international standards. She assured Members that Indonesia's policy was in alignment with the TBT Agreement, and that it placed utmost importance on consumer protection. She reiterated her delegation's openness to further discussion, including through bilateral mechanisms.

2.2.3.8 Korea — Regulation on Registration and Evaluation of Chemical Material, G/TBT/N/KOR/305, G/TBT/N/KOR/305/Add.1, G/TBT/N/KOR/478, G/TBT/N/KOR/547, G/TBT/N/KOR/592 (IMS ID 305)

2.93. The representative of the United States thanked the Republic of Korea for its stakeholder engagement and receptiveness to input and expressed her delegation's hope for an ongoing, open and transparent dialogue, with Korea continuing to educate stakeholders on how to comply. She nonetheless reported that due to the significant burden of compliance, many US chemical companies were considering withdrawing from the Korean market, which would negatively impact Korea's manufacturing sectors. The US remained very concerned about the lack of transparency and regulatory consistency throughout the implementation, for example in light of regular complaints about frequently changing guidance documents, many of which are not in English, which caused difficulty given the large number of measures to be complied with. Moreover, significant confusion and uncertainty existed with respect to specific requirements and acceptance of notifications and registrations, especially for those using trace amounts as inputs for production. To help increase transparency and compliance, her delegation suggested the setting up of a single portal or "window" with a FAQ, which would provide a single location to access all relevant guidance/measures/amendments/regulations and which could clarify any questions for industry. Recalling that Korea had flagged in the previous two TBT meetings that it was preparing brochures in English, she welcomed the news from their bilateral meeting that they would be ready by the end of the current year.

2.94. With respect to confidential business information (CBI) and more specifically the plan of the Chemical Control Act (CCA) to disclose company-confidential chemical information on the internet on 1 July 2016, the US asked for confirmation that the Ministry of the Environment (MOE) had issued a public notice on 30 May 2016 excluding non-hazardous substances. Her delegation further

suggested that CBI protection of composition and volume under the CCA should be automatic, in other words that manufacturers should not have to submit a request. Moreover, there could be limited scenarios where CBI was released to a requestor, but it should be based on agreed processes. With respect to K-REACH, she reiterated her delegation's support for strong CBI protection of specific chemical identities, uses, and compositions, and repeated its request that the MOE allow such protection for more substances qualifying as hazardous. Concerning K-REACH joint registration, her delegation considered that the consortium formation process had not been transparent and that there had been a lack of guidance, resulting, for example, in some companies being intentionally excluded from consortia.

2.95. On the issue of Data Acceptance for K-REACH registration and Article 13 of the Final Presidential Decree, the US delegation requested confirmation that quantitative structure activity relationship (QSAR) and computational tools could be accepted in order to reduce duplicative testing. It was suggested that when QSAR or read-across data was submitted, the MOE and the National Institute of Environmental Research (NIER) accept scientific experts' statements and not require additional evidence for the waiving or omission data. An update on this since it was first raised in March 2016 was requested, as well as written reconfirmation that MOE would accept EU REACH datasets to reduce duplicative testing for toxicity and ecotoxicity. Finally, on Only Representatives (ORs), the US acknowledged Korea's efforts to streamline OR requirements, and asked Korea to continue working to make procedures work smoothly.

2.96. The representative of Australia expressed its continued interest in the issue as it continued to monitor the implementation of the regulations, given the importance the registration of chemical substances incurred to Australian industry. Australia encouraged Korea to take a risk-based approach following international best practice to ensure that K-REACH provisions reached Korea's consumer protection objectives while not distorting trade unnecessarily. On a positive note, his delegation welcomed Korea's initiative to release brochures for businesses in English by the end of the year and sought clarification of a date for reception of said brochures. Australia expressed interest in receiving guidance materials or any further information from Korea on the nature of the recent changes to the regulations.

2.97. The representative of the Republic of Korea reported that its website had been updated in order to improve the smooth implementation of K-REACH, and would enable stakeholders, including foreign, to provide comments or questions online. For the benefit of foreign companies, Korea had published some guidelines in English such as "Guidance on compliance procedures of the act on registration and evaluation of chemical substances" and was working on the translation of a guidebook and detailed guidelines of related ordinance which would be distributed within the year. Regarding the issue of CBI, according to the "Revision of regulation for operation and examination result of chemical substances" which had been announced on 8 July 2016, information on the handling condition of chemical substances classified as low hazardous material was not available on the website. However, such information could be made available to selected individuals after deliberation on the necessity thereof, if release of the information was requested under the official information disclosure act. His delegation further confirmed that exporters could register chemical material by simply submitting QSAR results with internationally verified reliability without additional evidence for omission of related test data. In addition, full text or test summaries specified on datasets used for EU REACH registration would be accepted. Korea committed to holding bilateral consultations to resolve any further issues raised in writing.

2.2.3.9 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, G/TBT/N/EU/246, G/TBT/N/EU/246/Add.1 (IMS ID 345)

2.98. The representative of Argentina reiterated concern on the European Union's unjustified delay and the various instances outside the regular procedure that had been used to avoid responding to this STC, which had been raised since 2009. Argentina had repeatedly said that Regulations (EC) 479/08 and 607/09 were in violation of the TBT Agreement and seriously affected the image and prestige of Argentine wines destined for the European market. By restricting or prohibiting the rights to use certain terms on their labels such as traditional expressions "reserva" and "gran reserva" caused unjustified disruption in the trade of Argentine wines. He urged the EU to submit the proposed amendment as soon as possible and to explain how those requests that

had already been approved under the current technical approval process would be treated. He requested the prompt conclusion of formalities under the current regime.

2.99. The representative of the United States again requested more transparency regarding the EU's application process for traditional terms for wine. US wine industry had been waiting patiently for over six years for the EU to act on their applications while the EU had provided no update on the status of their applications. Despite repeated enquiries from stakeholders, there had not even been any justification on why there had been a six-year delay. The US again asked that the EU provide a status update on the applications submitted by US wine industry and to expedite its process and decisions so that this critical trade was no longer blocked. She requested an update on the ongoing revisions to the application review system which she emphasized should not delay or negate any decisions on the pending applications.

2.100. The representative of South Africa joined the concerns expressed by Argentina and the US and requested an update from the EU on the process.

2.101. The representative of the European Union repeated what had been said at the previous TBT Committee meeting, in that an internal assessment on traditional terms had been carried out within the EU involving stakeholders and experts from EU member States (in accordance with Article 114(3) of Regulation (EU) No. 1308/2013 establishing a common organization of the markets in agricultural products). The alignment and simplification of wine labelling provisions and traditional terms rules, as well as the pending applications for traditional terms, were still under consideration in the context of the general reflection on the marketing rules for all agricultural products. Therefore, no proposals on traditional terms were expected shortly and precise deadlines could not be provided. The EU would continue to make all possible and necessary efforts to simplify its current policy on protection of traditional terms and their indication on the labels of wines, taking into account trade partners' concerns. The concerns raised were noted and she said these would be considered when carrying out the complex simplification exercise. The EU remained open to bilateral discussion with trading partners at expert level.

2.2.3.10 Chile - Proposed amendment to the Food Health Regulations, Supreme Decree No. 977/96, G/TBT/N/CHL/219, G/TBT/N/CHL/219/Add.1, G/TBT/N/CHL/221, G/TBT/N/CHL/282 (IMS ID 370)

2.102. The representative of Mexico recalled concerns previously raised on Chile's Food Health Regulations, Supreme Decree No. 977/96, notified to WTO Members on 22 August 2014, and on its amendment, which was circulated to WTO Members on 9 July 2015. Mexico also referred to the Amendment to Article 1 of the Food Health Regulations, notified to WTO Members on 7 January 2016, which had the purpose of taking into account the provisions of Law No. 20.606 and Law No. 20.869 on the nutritional composition of foods and food advertising. These regulations entered into force the 27 June 2016 and mandated the Ministry of Health to issue implementing regulations on food advertising, among others. Mexico expressed appreciation for the recent bilateral meeting and elaborated several specific concerns. First, Mexico considered that Chile may be contravening Article 2.4 of the TBT Agreement, since these provisions were not consistent with the General Guidelines on Claims of the Codex Alimentarius (CAC/GL 1 1979, point 3.5).

2.103. Second, Mexico considered the wording "high in …" to convey a distinction that may cause consumer confusion and to raise labelling costs. Recent amendments proposed the power of the Ministry of Health to determine which foods have high contents of calories, fats, sugars, salt or other ingredients. These foods would be labelled as "high in calories", "high in salt", among others, and it would not be possible to market, promote or advertise them in primary, basic or secondary educational establishments. Mexico highlighted that the Guidelines of the Codex Alimentarius stated that: (i) the labelling should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather convey an understanding of the quantity of nutrients contained in the product; and that (ii) a more exact quantitative delineation for individuals is not valid because there is no meaningful way in which knowledge about individual requirements can be used in labelling.

2.104. Third, she said that the Food Health Regulations prohibition to advertise with elements that attract the attention of minors under the age of 14 of food that contained quantities higher than those specified in Table No. 1 did not apply to foods containing energy, sugars, sodium or

saturated fats in a natural form. Finally, Mexico asked Chile for the scientific or technical evidence to prohibit this advertising and stressed that public policies such as nutritional education could be adopted without employing concepts of "good" or "bad" foods, in accordance with the Codex Alimentarius Guidelines. Mexico also asked Chile: (i) to harmonize the regulation requirements with the General Guidelines on Claims of the Codex Alimentarius; (ii) to provide scientific or technical evidence to support the use of the label "high in"; and (iii) to modify the classification of foods, which made a distinction between solid and liquid foods, so as to take into account international parameters and ensure food would instead be classified according to the category to which it belonged.

2.105. The representative of Guatemala reiterated concerns regarding the measure expressed in past Committee meetings. While Guatemala recognized the legitimate objective of protecting public health, it was concerned that these measures could hinder trade. Also, his delegation renewed concern on the lack of harmonization on food labelling across the region as a result of the introduction of different measures in each country.

2.106. The representative of Costa Rica echoed Mexico's concerns. As expressed in past TBT Committee meetings, Costa Rica questioned the compatibility of this food regulation. His delegation considered it constituted a technical barrier to trade, especially regarding the lack of scientific and technical evidence and the lack of basis on international standards such as those of Codex Alimentarius. He urged Chile to adopt other less restrictive measures in order to safeguard the legitimate objective of protecting its population's health. He also asked for an update on: (i) the current state of this regulation, since his delegation was aware that the measure entered into force at the end of June; (ii) the preliminary results from the implementation; and (iii) the monitoring mechanisms that had been established to ensure compliance.

2.107. The representative of Chile thanked Mexico, Guatemala and Costa Rica for their interest in Supreme Decree No.977/96. He referred to Chile's statements made in previous TBT Committee meetings. He pointed out that this measure was adopted to address the alarming obesity rates in Chile by informing the population on food's nutritional composition. He mentioned that during the thematic session on food labelling, Chile had been able to explain its regulation in detail and clarify Members' doubts. The regulation entered into force on 27 June 2016 and it was being implemented nationally in accordance with the progressive implementation policy contained in it. His delegation affirmed that Chile's measure complied with the TBT Agreement and expressed willingness to continue bilateral discussions to solve any outstanding doubts.

2.2.3.11 India - Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order, 2012, G/TBT/N/IND/47 G/TBT/N/IND/47/Add.1, G/TBT/IND/47/Add.1/Corr.1 (IMS ID 367)

2.108. The representative of the European Union thanked India for their bilateral meeting whilst recalling its two main continued issues of concern with respect to the compulsory registration scheme for electronics. With respect to the streamlining of the registration procedure, the EU recognized that the Ministry of Communication and Information Technology in India was considering possible improvements thereto. His delegation sought an update from India about the state of play of internal reflections on their main request for single product registration by brand owner for multiple factories. Regarding their second main concern, the EU recognized that foreign test reports were accepted for safety-critical components on condition that either the foreign laboratories were participating in the IECEE CB Scheme or they were accredited to international standard ISO/IEC 17025 by an ILAC MRA signatory. He reiterated his delegation's request for India to improve reliance on these two paths for the acceptance of foreign test reports in order to increase their acceptability beyond safety-critical components. Of particular interest to the EU would be the possibility for foreign labs to qualify and his delegation sought information from India on any procedure at the level of the Ministry of Communication and Information Technology or of the BIS which could be explored for that purpose. Finally, the EU reiterated its request for a longer time validity of test reports for registration purposes (currently limited to 90 days), while there did not seem to be any reason for such time limitation.

2.109. The representative of the United States thanked India for their bilateral meeting and informed that it had submitted comments that week on India's Compulsory Registration Order (CRO). Of particular concern was that the CRO's FAQ expanded its scope and that it was extremely burdensome to continually check for potentially contradictory updates, additions, and changes to

existing requirements, creating confusion and a lack of predictability. The US welcomed that the Department of Electronics and Information Technology (DeitY) was now accepting BIS-accredited labs and had requested further information thereto. Her delegation also remained concerned about whether power supplies for servers must be registered as, if so, industry would need more time to adapt. US industry maintained that power supplies and power adaptors were not designed in the same way, did not have the same safety risks, and were therefore not identical in function. US industry also noted that it was an internationally accepted practice to test and certify a "power supply" as a "critical component" of the server, not as a standalone device. Therefore, if the replacement units were already tested and certified as "critical components", why did the standalone devices need to be registered? Her delegation expressed disappointment that their request to add a Highly Specialized Equipment (HSE) exemption had not yet been granted. As a member of the IECEE CB Scheme, the US encouraged India to accept that scheme, which, whilst voluntary, obliged its regulators to accept international conformity assessment systems. India was also urged to reduce the number of product samples from two units to one unit and to increase the required time for sample delivery to between 30 and 60 days. In many cases the product involved was a custom, made-to-order product requiring more time for production than that allowed for sample delivery, preventing companies from guaranteeing prices and delivery times to Indian consumers, in many cases businesses. Her delegation warned that ultimately the CRO may discourage, not promote, business activity in India.

2.110. The representative of the Republic of Korea expressed appreciation for the efforts and cooperation of the Government of Indian to improve this regulation including via the exception by exemption of BIS marking on cells and the provision of an additional grace period for the observation of IS 16046. Nevertheless, following up on an unresolved concern, Korea requested the Indian authorities to accept test reports which had been approved by the IECEE CB Scheme on the basis of Article 5.1 of TBT Agreement, recalling India's obligation, as a member of the scheme, to mutually accept test results of member countries, according to IECEE 02 "Rules of Procedure" Part I. Korea stated that such acceptance of test results would alleviate the unnecessary burden to exporting companies and relieve technical barriers to trade.

2.111. The representative of Canada expressed support for the interventions of Korea, the EU and the US and associated itself with the request for an update on the status of the entry into force of the BIS marking requirement, which was expected to be enforced on 30 June 2016.

2.112. The representative of India began addressing Members' concerns by stating that there was no requirement for in-country testing. Rather, the regulation brought into effect the Compulsory Registration Scheme (CRS) under the BIS Act for notified goods, the sample of which had to be tested in any BIS-recognized laboratory. He added that there was a provision for overseas labs to seek recognition from BIS, based on the qualification criteria. Secondly, his delegation reiterated that the CRO was fully WTO-compliant. The IECEE CB was a scheme of reciprocal acceptance between the National Certification Bodies, and not the regulators. Therefore it did not necessarily find approval amongst all regulators. Nevertheless, the Indian Conformity Assessment process under the CRO still accepted CB test reports on critical components if they were not notified separately.

2.113. On the issue raised regarding the FAQ, India stated that FAQs were being updated and published so as to assist industry and not to expand the scope of CRO. A Technical Advisory Committee had been set up to resolve the technical issues for industry that may arise during implementation of the CRO. This committee issued clarifications in the form of FAQs to avoid repetition of replies to recurring questions. To illustrate this point, in the area of power supplies, FAQs had clarified that the detachable power supplies identical to power adaptors were covered under the CRO. He pointed out that Circular No. 1 of 2016 (dated 8 September 2016) issued in this regard had also been notified to the WTO via document G/TBT/N/IND/47/Add.3 on 7 October 2016, in which the implementation date had been extended to 1 January 2017 in view of difficulties expressed by industry. The Order had separately notified "Power Adaptors for IT Equipment" and "Power Adaptors for Audio, Video and Similar Electronic Apparatus" via gazette notification dated 13 November 2014. Consequent upon this notification of power adaptors for IS 13252 and IS 616, power supplies identical to power adaptors should comply with the Order.

2.114. Regarding HSE, one delegation had made a request that a new criterion be added to the HSE exemption, i.e. if goods were intended for sale to medium-to-large enterprises and not available to normal consumers. Indian authorities believed that the HSE exemption criteria could

not be extended as product safety issues would arise even for the medium-to-large enterprises. Concerning the request that BIS-recognized laboratories should only require a product sample for testing in case a suspected non-compliance issue could not be resolved through exchanges between the Certification Body and the manufacturer, after due consideration India found that it did not qualify under the CRO process. Regarding the question raised on the unique circumstances in India requiring companies to retest to BIS standards, he pointed out a number of typical variations: Use of components for Indian environment like Plugs & Sockets; Tropical country testing; and Different series formation requirements for India.

2.115. India had been asked to reduce the number of product samples from two units to one unit and to increase the required time for sample delivery to between 30 and 60 days. He responded that at least one sample from the range of products covered in the scope of registration was used for testing. In addition to the sample sent for testing, another sample from the same batch or lot was also drawn, sealed and labelled, and left with the registered user as a counter sample, for use in case of any subsequent dispute. A time period of ten days had been allowed for submission of samples for surveillance testing, however more time had been allowed for products which were not available in stock or on the market. On the issue of product registration to be required by brand owner rather than by each factory, India informed the Committee that the matter was under consideration by the authorities. On a question from the June 2016 meeting on the need for prescribing a validity period of 90 days for test reports, India considered that the time period of 90 days was sufficient for filing the test report along with the registration application, once the test report was available. He concluded by informing the Committee that the Orders and their amendments were regularly being notified to the WTO.

2.2.3.12 Peru - Act to Promote Healthy Eating Among Children and Adolescents, G/TBT/N/PER/89 (IMS ID 383)

2.116. The representative of Mexico reiterated the trade concerns previously raised with respect to Law 30021 "Act to Promote Healthy Eating among Children and Adolescents" published on 17 May 2013 in the Official Journal *El Peruano*. She noted that these concerns had first been raised in this Committee in June 2014 and reiterated on subsequent occasions. She indicated that this matter had been the subject of a bilateral dialogue with Peru which was appreciated by Mexico. She elaborated that Supreme Decree No. 007/15/SA – "Regulations establishing the technical parameters for sugar, sodium and saturated fat content in processed foods and non-alcoholic beverages", was published on 18 April 2015 along with the approved technical parameters in respect of the content of certain substances (sugar, salt and saturated fats) in processed foods. She explained that Peru had recently informed Mexico that in September of 2016 it had notified the Regulations of Law No. 30021, on which Mexico will be making pertinent comments. She then expressed the following concerns of her delegation.

2.117. She acknowledged the legitimate objective pursued by the Peruvian measure, namely, to protect its population from chronic non-communicable diseases (NCDs). She enquired as to what was the precise scientific or technical justification for the contention that the Act to Promote Healthy Eating among Children and Adolescents and Supreme Decree No. 007/15/SA did not create unnecessary obstacles to Members' international trade. She stated that it was believed that Peru could be in contravention of the principles of the TBT Agreement, specifically the requirement to base technical regulations on international standards, established in Article 2.4 of the TBT Agreement, since the provisions contained in the act were inconsistent with the General Guidelines on Claims of the Codex Alimentarius (CAC/GL 1 1979, 3.5). As had already been mentioned; Mexico considered that every food had inherent nutritional characteristics, as each person had different nutritional needs, and no food could therefore be characterized as "good" or "bad" in relation to its nutritional content. She explained that the use of the term "HIGH" on food labels could arouse fear in consumers by leading them to assume that non-transmissible diseases such as obesity were caused by the consumption of specific foods.

2.118. She explained that the Guidelines of the Codex Alimentarius stated that labelling "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", since a "more exact quantitative delineation for individuals is not valid because there is no meaningful way in which knowledge about individual requirements can be used in labelling". She requested that Peru provide Mexico with an update on the current status of preparation of the measures that would implement the provisions on labelling contained

in Law No. 30021 and the time-frame for entry into force of the technical parameters for processed foods and non-alcoholic beverages, as set forth in Supreme Decree No. 007 2015 SA. She requested that a time-frame be provided in which to receive and consider comments from the various Members in the preparation of these measures.

2.119. The representative of the United States supported Peru's public health objectives of reducing obesity and related NCDs and expressed appreciation for the extensive bilateral discussions held on Peru's proposed regulations to implement the Healthy Eating Act. She stated that the US would support the objective of improving consumer awareness of nutritional information for food items to encourage healthy eating and informed dietary choices. She highlighted the concern about the trade impacts of the implementing regulation and the development of a list of food products with high content of sugar, salt and saturated fat. She explained that the US was planning to submit comments on the notification G/TBT/N/PER/89 in the near future.

2.120. The representative of Costa Rica reiterated its concern on the issue, requesting an update from Peru on the present status of the planned measure, in particular, the work of the multi-sectoral committee with regard to the implementation of this law 30021.

2.121. The representative of Guatemala reiterated the sentiments made at previous meetings of the Committee. Her delegation recognized the legitimate objective of protecting public health but remained concerned that these measures could hinder trade. She also expressed renewed concern over the lack of harmonization across the region with regard to food labelling as a result of the introduction of different measures in each country.

2.122. The representative of Peru acknowledged the commitment to ensuring public health safety, especially for the more vulnerable population: children and young adults. With regard to international commitments, she explained that this law 30021 sought to reduce problems of obesity and chronic NCDs by promoting the consumption of healthy food for children and teenagers. She explained that Peru, through a multi-sectoral committee, had been working on the regulations that would complement and implement this law and these measures which includes, *inter alia*, advertisements, nutritional education, implementation of a nutritional observatory and a study on weight and obesity. She informed the TBT Committee that on 17 June 2016 the multi-sectoral committee had finished drawing up the regulations for law 30021 and notification G/TBT/N/PER/89 had been sent, with a deadline of 8 December for comments, to WTO and the Andean Community. She requested that all Members examine this regulation and provide their comments by the deadline. She stated that this draft regulation contained a new proposal on technical parameters which replaced those adopted by decree 007/SA which was based on the new recommendations from the Pan-American health organization. The entry into force of this law 30021 would be 180 days after its publication in the official gazette and so law 30021 established 60 days for comments on the law and 120 days for compliance with all the advertisements related to these products which would be counted on the basis of entry into force of the regulation. She expressed firm support for the liberalization of trade without establishing unnecessary obstacles as illustrated in Peru's commitments to the TBT. She concluded by expressing Peru's willingness to hold bilateral discussions on these standards.

2.2.3.13 European Union — Revised Proposal for the Categorization of Compounds as Endocrine Disruptors of 19 February 2013 by DG Environment, G/TBT/N/EU/283 + Add.1, G/TBT/N/EU/384 and G/TBT/N/EU/384/Add.1 (IMS ID 393)

2.123. The representative of Argentina once again raised concerns with the EU's approach to determining the criteria used in identifying substances with endocrine disrupting characteristics, given their broad scope and potential impact on sanitary regulations and trade in agricultural products. He asked if the EU had already completed its analysis of comments received on the modification of Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products notified in G/TBT/N/EU/384. He reiterated that the proposal should have been notified to the SPS Committee, as had been done on the phytosanitary products proposal, given that both proposals and objectives were substantially similar.

2.124. Argentina was also committed to enhancing protection of human health and the environment, but these objectives should be pursued in a manner consistent with WTO

Agreements, and in this case, Article 2.2 of the TBT Agreement. The EU had opted for a proposal that lacked adequate scientific basis that would restrict trade more than necessary. This was despite the Impact Assessment circulated by the EU which indicated the existence of less restrictive alternatives. Despite repeated calls for the adoption of an approach that took into account a full risk analysis, the EU was solely using a hazard-based approach which was inadequate for properly assessing which substances with endocrine disrupting properties posed a real and significant risk to human health and/or the environment. If adopted, this proposal would lead to the probation of safe substances since there was no assessment of hazard characterization, exposure and risk characterization. The adoption of the proposal could mean that active substances contained in biocidal products that had already been approved following a strict risk assessment carried out by the European Food Safety Authority (EFSA) would henceforth be regulated in line with an approach based solely on hazard identification. Their approval could possibly be reviewed and their maximum residue limit be set by default at the detection level of 0.01 parts per million (ppm), without the relevant scientific back up and in a manner that contradicts the maximum residue limits (MRLs) recommended at the CODEX level.

2.125. The proposal was also incomplete as it did not include essential elements of hazard characterization, such as the strength, severity and reversibility of effects. This could lead to disproportionate and unnecessarily trade restrictive measures that were inconsistent with WTO obligations. He noted that the EU had not taken into account the European Commission communication that recognized that "Generally, a risk based approach allows consideration of proportionality when taking regulatory […] decisions". The conclusions of the Impact Assessment were also not taken into account as the EU had selected Option 2. According to this Impact Assessment, the same level of human health protection could be achieved with Options 2 to 4, while Option 4 was identified as that which would register the lowest impact in socio-conomic terms, both in the agricultural sector and in international trade. By choosing Option 4, the EU could have maintained the same level of protection while avoiding unnecessary trade restrictions. Argentina was also concerned that this approach, based exclusively on hazard identification, could also influence other EU policy areas. Should the proposal be approved as it now stood, Argentina hoped that both the repeals and the import tolerances be applied in a transparent and non-discriminatory manner. Finally, he requested the EU to notify any modifications during the course of the adoption process and indicate how comments were taken into account prior to formal adoption. Any additional information related to the proposal would also be appreciated.

2.126. The representative of Canada expressed his delegation's continued concern with the EU's proposed approach for the categorization of compounds as endocrine disruptors, in particular with respect to the EU's implementation of a hazard-based approach for the regulation of plant protection products. While hazard identification was an important first step in the scientific risk assessment framework, it was also imperative that the potential adverse effects be put into context with consideration of potency and the level of likely human and environment exposure based on conditions of use. Using a hazard-based approach in categorizing endocrine disrupting chemicals could unnecessarily restrict trade. Canada urged the EU to recognize the importance of a risk-based approach in its evaluation of biocidal and plant protection products and the setting of MRLs for these products. Finally he asked that the EU respond to comments submitted to the Enquiry Point on 31 August 2016.

2.127. The representative of the United States expressed her delegation's appreciation for the extension of the comment deadline as the proposals involved complex issues with potential significant impacts on international trade. She hoped these comments would be taken into account prior to finalization of the measure. She reiterated her strong support for strengthening public health and environmental protection by properly identifying, understanding, and regulating the use of plant protection products that may have endocrine disrupting properties. However the US remained concerned that the approaches outlined by the EU in identifying endocrine disruptors, the accompanying impact assessment and communication published on 15 June may lead to regulatory outcomes that imposed unnecessary trade restrictions, without improving public health. This could have far-reaching detrimental consequences to global food and agricultural production. She asked the EU to provide the scientific evidence used to justify the regulation as neither Regulation 1107/2009 which mandated the establishment of criteria, nor the EU roadmap published in June 2014, nor the impact assessment published in June 2015, identified the scientific evidence used by the EU in the development and selection of options to establish cut-off criteria for endocrine-disrupting substances. Without this evidence it was difficult to understand the basis on which the EU had drawn its conclusions. According to the report provided to the SPS Committee

in G/SPS/GEN/1448, a policy change to establish definitive criteria to identify endocrine disruptors was required.

2.128. The US believed that the proposal under the biocides regulation should also have been notified to the SPS Committee as biocides were commonly used in medicine, agriculture, forestry and industry. It was puzzling that the notification sent to the SPS Committee disclaimed SPS obligations and indicated that it was done for "transparency purposes". The US presumed the EU knew the rationale behind the measure and trusted that it would recognize in good faith the applicability of the appropriate WTO disciplines prior to its enactment. She welcomed the news that the Commission would soon produce a revised proposal clarifying questions related to the derogation process and the application of the WHO/IPC definition of endocrine disruptors. In particular, the US requested that the EU provide a definition of "negligible risk", include the important aspects of exposure and potency, and follow a risk-based approach under which all substances designated by WHO/IPC as endocrine disruptors be eligible for registration provided they met the "negligible risk" standard. Concerning clarification on the application of the WHO/IPC definition of endocrine disruptors, the US hoped these changes would address previous questions regarding substances that triggered other cut-off criteria such as those classified as carcinogenic, mutagenic or toxic for reproduction. She noted two key questions that had previously been raised that had not yet been responded to by the Commission. Firstly, could the EU clarify whether it was possible to file an application for an import tolerance for a product if a substance was designated as an endocrine disruptor but not authorized for use in the EU? If so, would that tolerance be set on the basis of a risk assessment, as stipulated in Regulation 396/2005? Secondly, she asked that the EU provide a list of substances that would be identified as endocrine disruptors under the WHO/IPCS definition, as well as specific information regarding when and how potency and exposure information would be taken into consideration.

2.129. The representative of Ecuador asked the EU for information on the scientific or technical basis underpinning the parameters for evaluating the list of priorities or whether these would be subject to a new assessment. Given the enormous impact these measures may have on trading partners' imports, there remained a lack of clarity surrounding the scope of the products that might be affected, the scientific basis for the regulatory decisions regarding the measure, the process for renewing authorizations for products that were currently being used safely, and information on substitute products that might be used without causing new risks to health or the environment or posing risks to food safety.

2.130. The representative of Guatemala shared the concerns expressed by other Members. Guatemala was following this matter closely and hoped the EU would take Members' concerns into account prior to approving of the regulation.

2.131. The representative of Chile reiterated concerns on how the measure had generated uncertainty in their domestic industry. He thanked the EU for the presentation made at the SPS Committee meeting which gave a better understanding of the issue. He requested that the EU also inform the TBT Committee on progress being made with regard to the proposal.

2.132. The representative of Colombia shared concerned raised by other Members on the possible negative impact this measure might have on international trade. Colombian stakeholders had indicated that this measure could affect €1.3 billion in exports to the EU. Trade in bananas alone could be affected by over €700 million. This was an unjustified trade barrier. While appreciating the information session at the SPS Committee, he asked that the EU take into account all the concerns raised and looked forward to further clarification.

2.133. The representative of Thailand highlighted that the definition of "negligible risk" remained unclear, and that the criteria for determination of endocrine disrupting properties used a hazard-based approach which may not affect the actual risk. Without sufficient scientific justification, and proper criteria, the regulation would significantly disrupt international trade. The draft regulation should be risk-based with the potential of substances and export assessments taken into account. Thailand encouraged the EU to apply a risk based regulatory approach rather than a hazard-based approach and hoped that the EU would take comments into account so as to resolve the concerns raised.

2.134. The representative of New Zealand echoed concerns raised by others, and hoped that the final shape of the proposal was one which did not unnecessarily restrict trade. She encouraged the EU to take into account comments from trading partners and looked forward to receiving a compiled reply to those comments. Future iterations of the proposal should stress the need for a risk- and science-based approach. New Zealand looked forward to continued constructive engagement and, like Chile, appreciated the exchanges of information, including the useful session held during the SPS week. She asked that the presentation be shared with the TBT Committee delegates.

2.135. The representative of the European Union thanked Members for their very active participation in the information session that had taken place on 26 October 2016 in Geneva, at the occasion of the SPS Committee meeting. The EU was well aware of trading partners concerns and was acting in a very transparent manner. During the impact assessment, the potential impact on trade had been carefully evaluated, together with the impact on agriculture, health, the environment and socio-economy. The new drafts setting the criteria for plant protection products and for biocides were notified under the TBT Agreement, as they concerned approval of substances. The draft act on plant protection products had also been notified under the SPS Agreement, as it was expected to have an impact on the settings of MRLs.

2.136. The original deadlines for comments on the drafts were extended until the end of August 2016 so as to allow Members time to properly consider the notified texts. The EU would reply in writing to comments received. The scientific criteria proposed in the draft acts were based on the widely-agreed WHO definition of an endocrine disruptor and were identical in both legislations (biocides and plant protection). The criteria also specified how the identification of an endocrine disruptor should be carried out using all relevant scientific evidence selected via systematic reviews, and analysed via a weight-of-evidence approach. The proposed criteria would allow the EU to take appropriate and proportionate decisions on endocrine disruptors, while complying with international obligations. To this end, the EU had proposed to adjust the current plant protection products' derogations so as to make best use of available scientific evidence, including information on hazard, exposure and risk. The two draft acts containing the criteria needed to be adopted under the relevant regulatory procedures, taking into account Members' comments. The plant protection measure would need to be voted on by EU member States' delegations in the standing committee. The biocidal measure would need to be adopted by the Commission. Following these steps, the measures would be subject to scrutiny in the European Parliament and the Council before their entry into force. The EU was committed to act in a fully transparent manner and would keep Members informed on further developments.

2.2.3.14 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, G/TBT/N/IDN/84/Add.1 (IMS ID 389)

2.137. The representative of the European Union reiterated its concerns about Regulation 30/2013 of the Indonesian Ministry of Health issued on 16 May 2013, as modified by Regulation 63/2015, introducing a mandatory health warning message on sugar, salt and fat content on labels of all processed foods, whose date of application had been postponed until 2019. The EU asked for information on studies on total diet undertaken by the Indonesian Ministry of Health and the timing of the adoption of implementing provisions and technical guidelines for the regulation. The EU also requested that measures could be notified to the TBT Committee while in draft form, to ensure that comments from Members can be taken into account. In addition, clarifications were requested on (i) the way of placing nutrition information and related health warnings, the testing methods for nutrition levels and the conduct of risk assessment related to NCDs; (ii) whether Indonesia could accept test results issued by laboratories other than those accredited by KAN or by other competent institutions having a Mutual Recognition Arrangement (MRA) with KAN; and (iii) the possibility to place stickers after importation, and before placing the products on the market – e.g. in customs warehouses – as an alternative to labelling in the country of origin. If Indonesia is drafting a new regulation on food labelling and advertising, including general guidelines on health labelling, the EU would be interested in receiving relevant information.

2.138. The representative of Guatemala supported the legitimate objective of informing a population on food products and its ingredients, but shared the concerns raised by other Members.

2.139. The representative of Indonesia repeated that the implementation of the measure was postponed until 2019. Currently, Indonesia was still determining the categories of processed food results which would be mandatory. As for fast food products, the regulation would only be required for food provisions that had more than 250 outlets. The representative stated that testing reports from approved laboratories of other Members, based on a reciprocal approach and in line with an international scheme, will be accepted. In Indonesia, testing mechanisms would be in accordance with Indonesian rules and regulations on standardization and conformity assessments. The labelling modalities related to including sugar, fat and salt content and health messages were covered by government regulation 69/1999 on labelling and food advertisement. This regulation stated that labels should be readable, not separated from the package and not easily removed or damaged. The objective was to give customers better health-related information. The modalities of the implementation of the regulation would be defined by technical guidance currently being discussed. Indonesia said that the regulation would be in line with WTO law and indicated its availability to discuss the regulation bilaterally.

2.2.3.15 Ecuador – Resolution No. 116 of the Foreign Trade Committee of Ecuador of 19 November 2013 and Technical Regulation of the Ecuadorian Standardization Institute RTE INEN 022 on the labelling of processed and packaged food products, G/TBT/N/ECU/19, G/TBT/N/ECU/19/Add.1–Add.11 (IMS ID 411)

2.140. The representative of Mexico reiterated the concern with respect to the labelling of pre-packaged foods under Ecuadoran Technical Regulation RTE INEN 022 on the labelling of processed and packaged food products. The objective of the regulations was "to regulate and control the labelling of processed foods for human consumption, in order to guarantee a person's constitutional right to timely, clear, accurate and non-misleading information concerning the content and characteristics of these foods, which enables the consumer to make the correct choice when purchasing and consuming them".

2.141. Mexico referred to Ecuador's latest notification G/TBT/N/ECU/19/Add.11 of 18 December 2015, the subject of which had been a recurring feature of the meetings of the TBT Committee since 2014. Mexico appreciated Ecuador's readiness to discuss Mexican industry concerns. However, concerns persisted in a few areas. Firstly, paragraph 5.5.4. of the RTE INEN 022 established a graphic system of colour-coded charts for the labelling of processed foods, for the purpose of indicating the concentration ("high", "medium" or "low") of three components: total fats, sugars and salts. There was no scientific support for this system based on the General Guidelines on Claims of the CODEX Alimentarius (CAC/GL 1-1979, 3.5), which recommended not displaying or using labels or any distinguishing device that employ words, pictures or other graphics capable of arousing fear of consuming the food in the purchaser or consumer. Secondly, the coloured bar system did not take into account Codex recommendations and could mislead the consumer, since it tended to stigmatize food products as "good" or "bad", based on the concentration of their components. This could constitute an infringement of paragraphs 4 and 2 of Article 2 of the TBT Agreement. Thirdly, Article 22 of the Health Regulations stipulated that "as described in the current Ecuadoran Technical Regulation RTE INEN 022 on the labelling of processed and packaged food products, any processed food for human consumption containing transgenic components must display the wording "CONTIENE TRANSGÉNICOS" (Contains transgenics) on its labelling". Industry had indicated that conventional products and GMOs were, in principle, substantially equivalent, since there was no difference in their protein, nutritional, toxicological or allergenic composition. Therefore, the incorporation of this wording could be considered more restrictive than necessary, thereby in contravention of Article 2.2 of the TBT Agreement. Fourthly, Article 3 of the Health Regulations and paragraph 3.1.2. of the RTE INEN 022 (1R) provided for the incorporation of a definition of "Nutritional claim", which differed from the framework definition of the Codex standard (CODEX STAN 1-1985, 2). Mexico highlighted that in keeping with the provisions of Article 2.4 of the TBT Agreement, the application of this term should conform with the provisions of the Guidelines for use of nutrition and health claims of the Codex Alimentarius (CAC/GL 23-1997, 7). Finally, Mexico considered that the measures on advertising, which prohibited the use of images of persons and animals, real or fictitious, in labelling could be inconsistent with the provisions of Article 20 of the WTO TRIPS Agreement, since they might unjustifiably encumber the use of a trademark in the course of trade.

2.142. In view of the above, Mexico requested that Ecuador notify the Health Regulations on the labelling of processed foods for human consumption, in accordance with the transparency provisions of the TBT Agreement. Ecuador should also amend RTE INEN 022 so that concepts such

as "food" and "nutrition claim" would coincide with the definitions established by the Codex Alimentarius and eliminate the difference between "food" and "processed food". An explanation should be provided on the reasoning and the scientific evidence justifying the use of the colour-coded graphic system for indicating the "high", "medium" or "low" concentration of three components: total fats, sugars and salts, respectively. Mexico would also appreciate receiving information about the results of this scheme. Ecuador should also provide justification for or, if appropriate, envisage the elimination of the requirement for the label to include the word "transgenics", where present; and finally, reconsider the restrictions on labelling advertising.

2.143. The representative of Guatemala shared Mexico's concerns. Certain definitions did not match with Codex regarding the lack of scientific grounds for these regulations. Guatemala expressed concern because it seemed that within the region there was not enough harmonization with regard to food labelling as evidenced by the different measures in each country.

2.144. The representative of Costa Rica echoed the concerns shared regarding this STC. In particular Costa Rica remained concerned with the lack of scientific proof. Costa Rica asserted that Ecuador was stepping aside from international standards in their technical regulation INEN 022. Costa Rica invited Ecuador to consider other less trade-restrictive alternatives that were in line with the principles of the TBT Agreement.

2.145. The representative of Ecuador reiterated that Resolution No. 116 neither created nor introduced mandatory technical regulations, but rather incorporated and withdrew subparagraphs subject to the Certificate of Recognition requirement. Ecuador highlighted that this was clearly an administrative measure for the purposes of customs control. In short, this resolution merely provided for the submission of a supporting document with the Customs Declaration as part of an internal administrative procedure and, consequently, was not a technical regulation. Ecuador noted that with regards to the Regulation on Food Labelling and as previously indicated, Ecuador's Ministry of Health had conducted a national survey on health and nutrition in 2012, during which it was discovered that Ecuador's epidemiological profile reflected an upward trend in the number of NCDs affecting all segments of the population, regardless of age, place of residence or socio-economic level. He explained that this had inspired the Ecuadorian Government to develop policies geared towards the prevention of chronic diseases in accordance with international standards. Ecuador further elaborated that the Ecuadorian population had accessed appropriate, clear, accurate and non-misleading information on the content and characteristics of food. He concluded by stating that the Regulation was duly notified pursuant to the TBT Agreement and at present, RTE No. 022 was being implemented, with both domestic industry and importers complying with its provisions without any problems.

2.2.3.16 Russia - Safety of products for children and adolescents, G/TBT/N/RUS/29 (IMS ID 418)

2.146. The representative of the European Union requested further information concerning the timeframe for the adoption and entry into force of the amendments notified under notification G/TBT/N/RUS/29. The EU asked whether the amendments had been adopted since the last meeting of the TBT Committee, and if so, Russia was asked to clarify the date of adoption and the date of entry into force. Finally, the EU requested that Russia provide the final adopted text once available.

2.147. The representative of the Russian Federation appreciated the comments from the EU on these draft amendments, and referred to his delegation's previous statements on this issue at past Committee meetings. He noted that the regulation "On the development, adoption, amendment and cancellation of technical regulations of the Eurasian Economic Union" did not fix time periods for inter-state discussions amongst EAEU members regarding draft technical regulations. Draft amendments to the technical regulation "On safety of products for children and adolescents" were in the course of discussion amongst EAEU members and the final date of adoption had not been defined. He stated that he hoped that these amendments would be adopted by April 2017, and that the Russian Federation would continue to inform WTO Members on this ongoing process.

2.2.3.17 Thailand – Draft Notification of the Alcoholic Beverages Control, Re: Rules, Procedure and condition for Labels of Alcoholic Beverages, issued under B.E. G/TBT/N/THA/437 (IMS ID 427)

2.148. The representative of the United States reiterated its concerns about the continued lack of clarity regarding certain aspects of Thailand's measure dealing with alcoholic beverages control. The US stated that the measure should be suspended until clearer justification and guidance could be shared, and asked for clarifications on the matter. The representative also requested relevant information on the scientific and technical information on which the measure had been based. Thailand was asked to evaluate the impact of the measure after 18 months of implementation and to share results with trading partners. The US suggested working together with Thailand to identify unclear elements and improve and clarify guidance during the suspension. Finally the US asked that concerns of all Members be included in the minutes.

2.149. The representative of Canada welcomed new developments regarding Thailand's regulations on alcohol, including interdepartmental working groups. He expressed hope that any new regulation would be developed in consultation with stakeholders including importers. Results should be in line with the TBT Agreement, and any new regulations be clear and reduce uncertainty for wine and spirits exporters. Canada asked for the opportunity to review and comment on this process. Canadian wine labels were not intended to appeal to children or promote irresponsible consumption of alcohol. Canada emphasized the importance of informing consumers of the dangers of excessive consumption or abuse of alcohol.

2.150. The representative of the European Union repeated its concern regarding the Regulation on Criteria, Procedures and Conditions for Labels of Alcoholic Beverages (B.E 2558/2015), applicable since 19 October 2015. As had been stated in previous meetings and in - unanswered - written comments submitted in December 2015, concerns dealt with the strict labelling requirements and lack of clarity of both the regulation and the technical guidelines on implementation. In particular, the EU had concerns with the lack of clarity of provisions relating to messages permitted on the label, which could lead to inconsistent interpretations by economic operators; and the impact the regulation could have on specific terms commonly used in the EU linked to the ageing or maturation process and to the conditions, quality or characteristics of the product.

2.151. The EU asked whether a working group had been set up to review and amend the regulation and technical guidelines and whether stakeholders would be consulted on modifications. The EU invited Thailand to give an update of the revision process as well as clarification on whether the measure was currently being enforced. In addition, the EU asked Thailand to share information on the results of the consideration on graphic health warnings, and to notify the WTO of draft proposals on labelling of alcoholic beverages or graphic health warnings to allow for comments of Members to be taken into consideration.

2.152. The representative of Australia noted that 15 April 2015 was the date of entry into force of the discussed regulation, and that manufacturers and importers had been required to comply since 18 October 2015. Australian exporters, while keen on working together with the Thai Government to comply with the regulation, required clear guidance to make this possible. Thailand was encouraged to create clear guidance material for industry and trading partners, allowing stakeholders to use compliant labels rather than submitting labels for approval on a case-by-case basis, and to create implementation arrangements that did not require products currently on the market to be removed.

2.153. The representative of New Zealand expressed support for Thailand's right to introduce new regulations to address specific public health concerns. New Zealand appreciated that in seeking to address the harmful use of alcohol, the technical regulation was directed towards achieving a legitimate public health objective. New Zealand restated its concern that the labelling requirements were unnecessarily trade restrictive and that the regulation was unclear and unworkable. New Zealand asked Thailand to update Members on the meetings in Bangkok during which officials would draft amendments to the regulation and technical guidance. Could Thailand provide further information on these amendments and give an indication of when the updated draft would be notified to the Committee. Thailand was also asked to confirm whether amendments were being considered to both the regulation and the implementing guidance, and that the regulation would not be enforced until new amendments were made. She requested an

update on the proposal to implement a graphic health warning label system for alcoholic beverages, and in particular when the draft regulation would be notified to the WTO.

2.154. The representative of Japan shared concerns raised and asked Thailand to provide an update on the discussion on the revision of the measure.

2.155. The representative of Guatemala was not convinced that the discussed measure, establishing criteria for labelling of alcoholic beverages, would be effective in reducing consumption. She asked that Thailand give a precise and detailed explanation of scientific evidence, or consideration that led to the conclusion that the measure actually reduced consumption of alcoholic beverages without being more restrictive than necessary. Guatemala stated that the information, currently being banned, was not intended to stimulate consumption but to inform the costumers on the type of product in terms of quality-related characteristics. Additional information from Thailand on the measure would be most welcome. Guatemala remained available for bilateral discussions if necessary.

2.156. The representative of Thailand indicated that it had included stakeholders in the development of the measure and would continue to do so, and that it would share the scientific evidence on which the measure was based. The representative also stated that the measure did not address alcohol labelling in general, but rather prohibited certain practices also prohibited in many other countries. Thailand provided clarification on several issues raised. She said the measure applied equally to both locally produced and imported products. Effective communication channels between the Office of Alcoholic Beverages Control Committee and the industry have been established to provide advice on implementation. The measure allowed the inclusion of information on quality and characteristics if sufficient evidence indicated that the information is genuine. The measure did not overrule any intellectual property rights, whether copyright, trademark, or geographical. Thailand welcomed suggestions and deeper technical involvement from Members on how to improve public protection from alcohol harm while preserving free and fair trade. The current measure did not obstruct international trade in alcohol and was in line with Article 2.2 of the TBT Agreement. The measure was fully enforced by October 2015. Cases had been brought to court and no temporary protection had thus far been granted. Whilst suspension was not possible, an implementation evaluation was foreseen in due time and results would be shared with Members. Thailand reiterated that it complied with the principles of free trade while adhering to its responsibilities to protect citizens from harm. The measure conformed to international practices, laws and regulations on alcoholic beverages control. If a regulation on pictorial warnings was to be drafted, the WTO would be notified at an appropriate stage.

2.2.3.18 China – Regulations for the Supervision and Administration of Medical Devices (Order No. 650 of the State Council), G/TBT/N/CHN/1022, G/TBT/N/CHN/1023, G/TBT/N/CHN/1024, G/TBT/N/CHN/1025, G/TBT/N/CHN/1026, G/TBT/N/CHN/1029 (IMS ID 428)

2.157. The representative of the Republic of Korea reiterated concerns raised on the Regulations for the Supervision and Administration of Medical Devices in previous TBT Committee meetings. China had not taken these concerns onboard, leading to unnecessary duplication of testing for imported medical devices that had already been tested, thus causing additional expenses and export delays. Korea reiterated its requests for China to recognize test reports issued by internationally accredited laboratories. According to the written responses from China to Korea's questions with regard to the WTO Trade Policy Review, Article 57 of the Regulations stipulated that test reports issued by inspection institutes jointly accredited by the CNCA and the CFDA were recognized. Korea requested that China accredit international testing institutes including laboratories recognized by foreign regulating authorities and Accreditation Bodies of the ILAC, and laboratories that complied with the OECD principles of Good Laboratory Practice for biological tests to avoid duplication of testing, additional cost and inspection delay.

2.158. The representative of Canada drew the Committee's attention to the concerns raised in the last meeting.[7] Canada requested an update from China on the progress of the regulation and restated its commitment to work with a view to addressing these and other aspects of the regulation in a constructive manner.

[7] G/TBT/M/69 paras 3.183-3.185

2.159. The representative of the European Union acknowledged the bilateral meeting held with China in order to clarify certain matters. The EU reiterated concerns on the Chinese regulations notified under G/TBT/N/CHN/1022-1026 and G/TBT/N/CHN/1029. The comments had been sent to the Chinese authorities on 23 June 2014 and raised subsequently in the TBT Committee meetings. The EU referred to its concerns raised during the last meeting of the TBT Committee in relation to the issue of the clinical trials required for the registration in China for Class II or Class III medical devices. China had clarified that Class I medical devices did not require this registration. The EU reiterated the concerns regarding the delays with this registration procedure, and the requirement to register the medical devices in the country of origin. He highlighted the repeatedly raised concern with regard to the unnecessary duplicative clinical trials to be conducted in China. In the last meeting of the TBT Committee, the EU had requested confirmation from China that during the marketing approval of medical devices, manufacturers may present data obtained in clinical trials carried out abroad. The EU had also asked whether clinical trials would have to be performed for Class II and III in-vitro diagnostic medical devices on Chinese populations living in a Chinese mainland environment and whether results of testing on Chinese populations living abroad or on non-Chinese population would not be accepted. As China was not in a position to fully answer these questions at that time, the EU again requested further clarification on this issue, in particular, on whether data from clinical trials abroad were sufficient for the registration certificate. In the bilateral meeting with China, the EU learnt that a new catalogue with 359 exempted products had been published in September 2016. Furthermore, the EU requested that China accept test reports from foreign laboratories accredited by accreditation bodies that are members of ILAC, as an alternative to in-country electromagnetic compatibility testing in China. The EU further requested the exclusion from the registration certificate of the documentation on product technical requirements considered to be confidential. Finally, the EU reiterated its request that China grant a transitional period of three years. Further guidelines detailing the relevant processes would be also welcome.

2.160. The representative of China provided updates on two matters. Firstly, the initial update had occurred in August 2014 when CFDA published the second and third catalogue on medical devices which could be exempted from clinical trials – this had been reported in previous meetings. In September 2016 CFDA published more medical devices under both catalogues, including 267 items under the second catalogue and 92 items under the third catalogue so that the total number of medical devices exempted from clinical trials stood at 359. China considered these developments to be progress.

2.161. Secondly, in October 2016, CFDA published The Priority Approval Procedure for Medical Devices which was a regime similar to a fast-track procedure for 13 types of medical devices. He stated that this document established a priority approval procedure for those medical devices in Important National Science and Technology Projects and Important National Research and Development Plans. Those medical devices alleviating rare diseases, malignant tumors, ageing diseases, and child diseases which satisfied the urgent need of clinical treatment were also applicable.

2.2.3.19 Ecuador – Proposed Motor Vehicle Safety Regulatory Requirements (RTE INEN 034), G/TBT/N/ECU/32, G/TBT/N/ECU/32/Add.1-11 (IMS ID 409)

2.162. The representative of Mexico expressed concerns raised by domestic industry with regard to the Fourth Revision of the Ecuadoran Technical Regulation RTE INEN 034 "Minimum safety requirements for motor vehicle parts", circulated on 31 October 2016 as document G/TBT/N/ECU/32/Add.11, despite having been published on the INEN website on 15 September of this year. Mexico welcomed Ecuador's efforts in heeding the request of Mexican industry to consider foreign standards as equivalent and to permit the submission of a manufacturer's own declaration as an import requirement. Nevertheless, she underlined her delegation's continued concern, in particular with respect to its request that the transition period for the new regulation be extended to two years, with an entry into force in April 2017, in order to allow full compliance with the new specifications contained in the measure, in accordance with Article 2.12 of the TBT Agreement. In spite of this request, she noted that it appeared that the measure had already entered into force and requested further clarifications from Ecuador. Mexico further sought clarification with regard to what would be the standard or valid certification scheme for complying with the requirement to submit "an implemented comprehensive quality management system certificate". She specifically asked whether it would be ISO Standard 9001.

2.163. The representative of Ecuador stated that the Fourth Revision provided for acceptance of the standards of other countries as well as Blue Ribbon standards. Moreover, RTE INEN 034 was in force and applied to domestic producers and importers alike. Concerns raised during the present meeting would be addressed bilaterally in due course.

2.2.3.20 Kingdom of Saudi Arabia – Decree of the Saudi Arabian Ministerial Council on the sale and marketing of energy drinks of 4 March 2014, (IMS ID 442)

2.164. The representative of the European Union shared concerns regarding the impact the measures being applied by the Kingdom of Saudi Arabia and other GCC countries were having on trade in energy drinks. These largely discretionary restrictions could be imposed by lower level authorities, such as at a regional or local level making it possible to create barriers on the ground, thereby creating regulatory uncertainty. As stated in comments submitted to Qatar and other GCC Members on 8 June 2016, the EU was also concerned about the lack of clear scientific substantiation of the statement to be included on energy drinks. The EU proposed that GCC authorities engage bilaterally on this matter and requested that Saudi Arabia provide an update on the measure.

2.165. The representative of the United States supported Saudi Arabia and GCC members in their efforts to develop a public health measure addressing caffeinated beverages. However the US shared concerns raised by other Members and requested a status update on the regulatory process. The US had submitted comments in April 2016 highlighting concerns with the required warning label on the product that must be larger than the ingredient statement; the 250 ml size requirement for energy drinks; and the limit of the recommended daily consumption amount. There was also concern that the regional regulation would include national deviations on the look and placement of the label which could dilute the benefit of a regional measure.

2.166. The representative of Switzerland remained concerned with the mandatory statements that had to be placed on energy drink labels, as well as the restrictions on marketing. These measures appeared to be more trade restrictive than necessary. While sharing the objective of protecting public health and consumer information, Switzerland questioned to what extent these measures would achieve those objectives. He looked forward to further engagement so as to ensure the proposed draft standard was in line with international standards. He asked that the questions submitted to the enquiry point be answered prior to the entry into force of the measure.

2.167. The representative of the Kingdom of Saudi Arabia, on behalf of GCC members, reiterated that the purpose of the measure was not to impede trade but rather to protect public health. There had been positive bilateral discussion with interested trading partners so as to ensure the requirements did not create unnecessary obstacles and they looked forward to further bilateral engagement.

2.2.3.21 Brazil — Draft Technical Resolution nº 69, 9 September 2014, Regarding the Requirement of Describing the Chemical Composition, in Portuguese, in the Label of Personal Hygiene Products, Cosmetics and Perfumes G/TBT/N/BRA/608 (IMS ID 443)

2.168. The representative of Mexico reiterated concerns with respect to Brazil's Draft Technical Resolution No. 69 of 9 September 2014. Her delegation considered that by disregarding the existence of a widely accepted International Nomenclature for Cosmetic Ingredients (INCI nomenclature), the Draft Technical Resolution could contravene the principles of the TBT Agreement and the Article 2.4 requirement to use international standards as a basis. She added that INCI classification could be regarded as equivalent to the requirements of the Brazilian regulations for the purpose of identifying the chemical composition of cosmetics and personal hygiene products, without the need for translation into Portuguese, since such translation would result in a measure more burdensome than necessary to fulfil the legitimate objective, in contravention of Article 2.2.

2.169. Further, Mexico was concerned that the distinction made between products from the European Union and those imported from other trading partners (specifically the Latin American region), was in violation of the principle of non-discrimination contained in Article 2.1 of the TBT Agreement. Mexico therefore requested that Brazil share information on the status of the regulations in question and that their comments submitted on 19 January 2015 during the public

consultation requesting the acceptance of the INCI nomenclature system as equivalent to the requirements of the Brazilian measure, be taken into consideration.

2.170. The representative of Brazil, whilst stressing that there were no updates to be provided since the last meeting, recalled that the measure in question was not yet in force and that comments received during the public consultation phase were still being reviewed by the Brazilian Health Regulatory Agency (ANVISA). He also recalled that the draft resolution had been developed in order to comply with a judicial decision establishing that labels of cosmetic products had to display information on the chemical composition of said products in Portuguese, in accordance with Brazil's code of consumer rights. However, this decision had been appealed, and its effects suspended until further decision by the Superior Court of Justice. He stressed that the draft measure did not prevent the use of the INCI; on the contrary, it created an additional requirement, applicable to all products and regardless of their origin, that the chemical composition of cosmetics also be expressed in Portuguese. Brazil maintained that their position was justified and that the regulation was in full compliance with WTO rules.

2.2.3.22 European Union – Common Criteria for Information Technology Security Evaluation (Common Criteria) Certification in the EU (IMS ID 448)

2.171. The representative of China said constructive dialogue on this matter had taken place during a bilateral meeting with the EU. China continued to remind the EU that the CC regimes were within the scope of the TBT Agreement and in particular, Article 8. China referred to the following obligations for Members in this regard: national treatment, avoidance of unnecessary obstacle to international trade, prompt acceptance of applications, expeditious undertaking and completion of conformity assessment procedures. China expressed concern with the refusal of EU member States' CC certification bodies to accept and process Chinese producers' applications, and about the lack of opportunity for Chinese companies to join CC-related standard organizations such as JIL Hardware Attack Subgroup. The EU was urged to comply with its obligations under the TBT Agreement and to address the raised concerns in a timely manner.

2.172. The representative of the European Union indicated that during the bilateral discussion his delegation clarified that, while remaining available for bilateral discussions, it did not consider the matter relevant under the TBT Agreement. As explained bilaterally, China, according to the EU, failed to identify concrete measures, technical regulations or conformity assessment procedures, falling within the scope of the TBT Agreement. In the EU, there was no general mandatory requirement for certification of commercial encryption products, contrary to the situation in China which had led to several STCs being raised in the Committee. Also, in the EU, companies were responsible for the secure transmission of data over system networks. The EU was of the view that regulatory approaches should not prevent authorities and IT system operators to use the best technology available, regardless of ownership of technology or location of equipment manufacturers. He clarified that while in China no foreign company had ever been granted a license by OSCCA, some Chinese companies had obtained certification up to Evaluation Assurance Level (EAL) 4, which was high in the evaluation scale under the common criteria in international standards. He said that the JIL Hardware Attack Subgroup was not a standards body, but a subgroup composed of EU member State experts set up under the Senior Official Group on Information Systems Security (SOG-IS). The SOG-IS comprised only nine member States along with Norway and dealt with information security issues - those member States who were fully participating in the Common Criteria Recognition Agreement. While Chinese stakeholders could participate in the activities of European standardization bodies in information security, some European companies had difficulties in participating in the activities of Chinese standardization bodies, such as the Technical Committee 260 (TC260). The EU noted the shared interest in aiming for interoperable solutions using the best technology to increase information security and reiterated its willingness to discuss this further with China and any other interested parties. As cyber-attacks that threaten national security were a common challenge, the EU considered strengthening international cooperation in this area to be of utmost importance and mutually beneficial. The EU invited China to continue to discuss these issues with the EU during existing bilateral dialogues on this matter as well as to engage more in cooperation and discussions with its main trading partners in the field.

2.2.3.23 China - Administrative Measure on Cosmetics Labelling (AMCL), G/TBT/N/CHN/1064 (IMS ID 456)

2.173. The representative of Japan acknowledged the while the clarification provided by China that this measure would allow "over-labelling" on imported cosmetic products was a positive step, there remained three concerns. Firstly, on manufacturer labelling, Articles 14 and 15 of the draft measures required, *inter alia*, labelling of the names and addresses of manufacturing subcontractors. This could actually cause consumer misunderstandings and market confusion. The manufacturer labelling should only present the name and address of the company with final legal responsibility for the quality and safety of the products concerned. Secondly, regarding the promotional advertising of cosmetics efficacy claims, according to Article 19 and 20 of the draft measures, testing results issued by an "efficacy assessment testing organization" had to be disclosed. It was Japan's view, however, that since testing results could include companies' know-how, they should not be disclosed and that in addition, the "efficacy assessment testing organization" should not be limited to institutions inside China. Thirdly, Japan stated that in order to promote appropriate operation, it was indispensable that China provide clear guidance - detailed regulations - in addition to the draft measures themselves. Furthermore, as significant changes to existing labelling would be required to meet the conditions of the draft measures, and taking into consideration the negative influence on entry into the Chinese market, Japan requested that China provide a sufficient transition period for the smooth implementation of the new labelling regulation. Japan asked China when the new implementation date would be. Finally, Japan recalled that at the meeting in June, China mentioned that this draft AMCL would be revised according to the contents of "Regulations concerning Hygiene Supervision over Cosmetics" which was the superior regulation to the draft measures. Japan requested that a public comment process be provided for the revision of "Regulations concerning Hygiene Supervision over Cosmetics" in accordance with TBT rules. In addition, Japan requested an explanation from China regarding the details of discussion on manufacturer labelling and efficacy assessment testing in the studies of the reviewing process.

2.174. The representative of the European Union reiterated the concerns raised during recent meetings of the TBT Committee, also sent to the Chinese authorities on 12 January 2015. In its written reply of 18 March 2015, China indicated that it would consider the comments received. The EU welcomed the possibility of labelling cosmetic products by means of stickers, but reiterated a number of issues included in the notified draft. Firstly, the requirement for products to display the name and address of the manufacturer and of the subcontractors when part of the production was done by subcontractors. Secondly, the need to confirm that the efficacy assessment and the cosmetic claim verification could be conducted by any verifying organization scientifically and technically competent to do so according to the criteria and guidance established by the China Food and Drug Administration (CFDA). The EU believed that any requirement for third party verification by a Chinese organization would be more trade restrictive than necessary. Thirdly, the need to align the requirements regarding cosmetic claim substantiation with international best practices. The EU understood that the process for the revision of the general legal framework for the placing on the market of cosmetics in China, i.e. the future Cosmetics Supervision and Administration Regulation, was on-going, and requested confirmation that the Administrative Measures for Cosmetic Labelling be developed in parallel with this general framework and not enter into force prior to the Regulation. Furthermore, the EU reiterated a request for information on the implementation of the guidelines on the verification of efficiency of claims related to cosmetic products presented by CFDA at the technical meeting with their EU counterparts in March 2015.

2.175. The representative of Australia reiterated its interest in this issue and supported the comments from Japan and the EU on labelling requirements. Australia agreed that any requirements for third party verification by a Chinese organization would be more trade restrictive than necessary. Australia would welcome clearer guidance and longer implementation timeframes in order to allow time for industry to adjust to the significant changes. Australia emphasized the importance that domestic and foreign cosmetic manufacturers be treated equally with respect to product registration and approval. Australia noted that the regulations were still being drafted and welcomed clarification on these issues once finalized.

2.176. The representative of New Zealand acknowledged the notification provided to the TBT Committee on this measure. New Zealand requested clarification on whether animal testing for the safety of cosmetic products would continue to be required for imported cosmetic products if widely

accepted alternatives became available and if all domestic and foreign manufacturers would be treated equally with respect to product registration and approval. Finally, New Zealand joined the others in welcoming any updates on the timeline of adoption for these measures.

2.177. The representative of China reiterated that cosmetic labelling was essential for consumers to understand basic information of cosmetic products. China stated that labelling was one of the most important aspects of cosmetic supervision for most Members and indicated that the AMCL was still being drafted. China stated that CFDA would follow international rules and give full consideration to valuable inputs from interested parties to finalize AMCL, moreso, there was no timeline for this work thus far but the work was on-going. China concluded by stating that the CFDA actually followed up any reasonable comments from stakeholders. China explained that the original draft prohibited the modification or amendment of product(s) labelling where CFDA received a lot of comments and opinions on this requirement. China went on to state that after careful evaluation, CFDA improved this requirement and considered to permit, to amend or end any Chinese language labelling for this imported product. China considered this to be an improvement.

2.2.3.24 China - Banking IT Equipment Security Regulation (IMS ID 457)

2.178. The representative of Japan remained concerned about the Chinese banking IT equipment security regulation. He asked China to provide updated information about the revision of "the Guideline for promoting the Application of Secure and Controllable Information Technology in Banking Sector" as China had stated at the June 2016 Committee meeting that this was being reviewed. Japan noted, in addition, that China had said that "opportunity to hear the comments of stakeholders is going to be arranged to issue the final draft" and asked for further clarification on this point. Regarding the requirement for source codes submission for risk assessment, Japan was concerned that, without clarifying the scope of data affected, it would be more trade restrictive than necessary in the light of the guideline's purpose. Therefore, Japan asked China to revise the guideline not to be more trade restrictive than necessary in accordance with international common standards, ensuring transparency during the review process.

2.179. While the representative of Canada understood China's desire to minimize threats to its ICT infrastructure, Canada was of the view that China's approach to "secure and controllable" ICT would decrease, not increase cyber security for China's network and banking ICT infrastructure. Canada agreed with the concerns raised by Japan in this regard and emphasized that, as drafted, China's national cyber security regime and guidelines were far more trade restrictive than necessary to achieve their national security objectives.

2.180. The representative of the United States had similar concerns to those expressed above. Although China had suspended adoption of the ICT banking measures, China appeared to be taking steps on adopting other measures for "secure and controllable" technology that raised concerns over China's commitments on national treatment toward sectors that depended on ICT products. For example, China was taking steps to impose "secure and controllable" guidelines for ICT products in the insurance sector. The draft China Insurance Regulatory Commission's ICT rules, which had been notified to the TBT Committee in April 2016, replicated much of the troubling language from the suspended ICT banking measure. China was requested to inform the Committee of the status of the ICT banking measures. The United States hoped that any draft measures that China adopted and implemented would be transparent and consistent with China's obligations under the TBT Agreement.

2.181. The representative of the European Union joined other delegations in raising concerns on this matter. While the European Union appreciated the suspension of the implementation of the banking guidelines, it was noted that there were other worrying developments on a system level in China, namely the adoption of the new Cyber Security Law raised under STC No. 5[8] – the EU hoped that the on-going revision would address the concerns that had been raised by several delegations and their respective industries so far. To recall the EU's main concerns with respect to the earlier version of the banking guidelines: the disclosure of the source code, the use of

[8] China – Requirements for information security products, including, inter alia, the Office of State Commercial Cryptography Administration (OSCCA) 1999 Regulation on commercial encryption products and its on-going revision and the Multi-Level Protection Scheme (MLPS) (IMS ID 294), 2.74. - 2.82. above.

indigenous technology, the reliance on home-grown standards and domestic algorithms to meet encryption requirements and the uncertainty surrounding the concept of "secure and controllable".

2.182. The European Union understood that the adoption of the Cyber Security Law would also have an impact on the content of, for example, the sectoral implementation of China's information security policies. China was requested to elaborate on the relationship between the sectoral developments and the framework laws, including the latest Cyber Security Law. In terms of the process, the EU – like others – requested that the next phases of the revision be done in a transparent and inclusive way and that the revised draft be notified to the TBT Committee, following the example of the insurance measures.

2.183. The representative of Australia echoed the concerns of other Members. Australian businesses had expressed an interest in the measure and the potential for the regulations to be more trade restrictive than necessary. Australia asked for further information from China on the status of the regulations, including whether they would be permanently withdrawn.

2.184. The representative of China said that the Guideline for Promoting the Application of Secure and Controllable Information Technology in Banking Sector (2014-2015) was currently suspended and under revision. China would take comments from stakeholders into consideration. There was, he said, at the time of the meeting, no timeline for the release of a finalized version.

2.2.3.25 Indonesia - MOI 69/2014 Article 3: LCR Requirements for LTE Devices - Requirement that Domestic Component Level (TKDN) of LTE TDD & FDD broadband services equipment, G/TBT/N/IDN/103 (IMS ID 472)

2.185. The representative of Canada said his delegation continued to have concerns with Indonesia's local content requirements laid out in its rules and procedures for the calculation of local content requirements for handheld devices (regulation no. 65/2016). He thanked Indonesia for the productive bilateral meetings and looked forward to intersessional contact with Indonesian officials in order to resolve remaining concerns.

2.186. The representative of the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu raised concerns about Indonesia's local content requirements for 4G smartphones. Indonesia's Ministry of Communications and Information Technology issued regulation no. 27 in July, requiring LTE smartphones to increase the quantity of locally produced content for mobile phones and packaging and Indonesia's Ministry of Industry had released a domestic calculation method in September 2015. This measure appeared to be in violation with Article 2.1 of the TBT Agreement, since smartphones from other Members were treated less favourably as they had to comply with local content requirements. Smartphone companies had to purchase threshold value of Indonesian produced components and packaging to obtain an import licence. Chinese Taipei requested Indonesia to bring the measure in line with the TBT Agreement.

2.187. The representative of Australia asked Indonesia to explain how local content requirements included in the revised regulation on LTE technologies, notified to the WTO on 17 March 2016, were consistent with national treatment obligations under the TBT Agreement. Australia continued to have an ongoing interest in the issue.

2.188. The representative of Indonesia indicated that the Ministry of Industry decree 68/2015 had already been notified to the WTO. The update of this decree, decree 65/2016, was still under revision. The notification process of the latter decree would start once the revision process was completed. The number of products covered by this decree was reduced, establishing a components calculation for mobile phones, handheld devices and tablet computers. Indonesia believed the decree and its revisions were in line with WTO regulations. Indonesia was willing to discuss concerns bilaterally.

2.2.3.26 China - Registration Fees for Drugs and Medical Device Products (IMS ID 466)

2.189. The representative of Canada repeated its concern about aspects of the regulation, as reflected in the minutes of last meeting.[9] Canada looked forward to an update from China.

2.190. The representative of the Republic of Korea reiterated its concerns regarding fees for medical devices. According to the notice on the measure of the administration of charging standards for drug and medical registration, made public on 27 May 2015, different prices were used for Chinese manufactures and importers for first registration, discriminating against foreign manufactures. At the TBT Committee meeting in November 2015, China explained that fees for imported devices included administration costs. Korea, while understanding the additional cost of on-site inspection, believed that these costs should be separated to secure transparency and once again requested China to separate the inspection cost and registration fee.

2.191. The representative of Australia repeated it shared concerns raised by Canada and Korea regarding the fee structure and process requirements for domestic and imported drug and medical device products. She asked that China explain how the fee structure and process requirements for imported products were proportionate to the testing process requirements including for the costs of transportation accommodation and allowances. Furthermore, Australia asked China to indicate what the provincial price was and how it was determined, as some of the domestic prices were based on this price, and whether the same testing process requirements applied to the provincial price. Another question concerned the waiving of registration fees for SMEs with an innovative medical device the first time registered, and how innovative products were defined: what were the criteria and could both domestic and imported products be considered innovative? While Australia understood that on-site inspections at foreign facilities might be more expensive, the related fees should be transparent, non-discriminatory and include industry consultation prior to implementation. Australia looked forward to hearing China's responses and considerations on all issues raised.

2.192. The representative of China took note of the statements, indicated that no updated information was available and that its position had been made clear at previous meetings and in minutes thereof.

2.2.3.27 Brazil - Draft Ordinance Act No. 374, 27 November 2014 (Portaria SDA/MAPA 374/2014 replaced by Portaria SDA/MAPA No. 43/2016) establishes Quality Requirements for Wine and Derivatives of Grape and Wine, G/TBT/N/BRA/613, G/TBT/N/BRA/675 (IMS ID 470)

2.193. The representative of the European Union thanked Brazil for opening public consultations on Ordinance No 43, 18 May 2016, notified as G/TBT/N/BRA/675 revising draft Ordinance Act no. 374 establishing quality requirements for wine and derivatives of grape and wine which had been notified under G/TBT/N/BRA/613. The EU appreciated the bilateral contact during the revision of the Ordinance. She asked Brazil for an update on the current revision and whether the EU's comments given on 18 July 2016 had been taken into account.

2.194. The representative of the United States raised concerns with Brazil's wine regulation related to proposed minimum and maximum content requirements for alcohol in table and fine wines versus sparkling wine, volatile acidity, chloride sodium and ash content. These requirements had no stated or discernible rationale while presenting challenges for imported wines. The US asked Brazil to provide specific health and safety reasons for these criteria, which were more stringent than most major wine producing nations. The US also restated its concerns about the definition of "cooler", which allowed for the use of sugar but no other sweeteners, and required a minimum of 10% fruit juice by volume. The US found these definitions to be unnecessarily restrictive. Coolers were currently sold freely and safely in the US, as was wine with added flavors from the Brazilian market. She asked that Brazil explain the regulation's objective and provide evidence for this restrictive definition.

2.195. The representative from Brazil said that public consultations had been held from 18 May to 18 July 2016. Neither the previous measure nor its successor changed labelling and quality criteria

[9] G/TBT/M/69, paras. 3.233-3.237.

currently in force and in line with MERCOSUR wine regulations. Brazil did not foresee this measure as causing any impact on trade, but would bring the concerns raised to the attention of officials in capital. The Ministry of Agriculture intended to invite interested parties to a public hearing on the final text. Brazil had given due consideration to all comments received, but the delegate had no information on how and if these had been reflected in the final text. A date had yet to be set for the publication of the final rule.

2.2.3.28 China - Insurance Regulatory Commission (CIRC) Information and Communication Technology Regulation (IMS ID 489)

2.196. The representative of Canada said it shared China's interest in taking measures that were clear and transparent and which conformed to relevant international standards. Canada appreciated that China had revised its October 2015 draft rules on which Canada had previously submitted written comments. However, Canada remained concerned that many of the rules as drafted were unclear and would have a disproportionate effect on non-Chinese suppliers, perhaps effectively shutting these suppliers out of the Chinese market. In this regard Canada had submitted (to China's Enquiry Point on 17 June 2016) a letter detailing concerns on China's Draft Supervision Rules on Insurance Institutions Adopting Digitalized Operations, and looked forward to a response.

2.197. The representative of the European Union said that this was a specific (sectoral) illustration of the general approach to information security; indeed, the same points made with reference to the banking deadlines under the STC No. 24[10] were also relevant in this context, including the need to better understand the relationship between the sectoral implementation and the general framework including the new Cyber Security Law. The European Union had submitted written comments to China on 10 June 2016 reacting to G/TBT/N/CHN/1172 and a detailed statement had been made in June listing all the EU concerns. The main concerns referred to, first, the need to classify information systems in the insurance sector in accordance to the grid provided in the MLPS, which meant that as soon as an insurance IT System was classified as critical infrastructure, this triggered severe restrictions or even the impossibility to use products incorporating foreign technology. According to the notified draft, insurance institutions would have to progressively phase out non-domestic cryptographic products, with the unintended consequence of in fact weakening, rather than strengthening, information and network security. A second concern raised was about the notion of secure and controllable hardware equipment and software products. The third concern was about the need for equipment suppliers to disclose the source code of the equipment to the insurance institutions and for the latter to obtain ownership of the source code. The latter was, however, an essential asset for information security equipment manufacturers and they would not be able to comply with this disclosure requirement without putting at risk the whole viability of their business. The fourth concern was the need for products and technologies to comply with national standards and encryption requirements and thus the mandating of national cryptographic application requirements and the use of domestic algorithms.

2.198. The representative of the United States remained very concerned about China's suite of measures that appeared to discriminate against foreign technologies and firms in the name of information security. Notably the US was concerned about China's cybersecurity law that had recently passed and draft insurance sector informatization rules. The US thanked China for notifying CIRC and noted that the review of the insurance sector rules revealed that some problematic provisions had been improved, including the requirement on indigenous IP and domestic algorithms. However, the United States still found many draft provisions problematic. The recently passed cybersecurity law remained similarly problematic. The United States understood that the implementation date was 1 July 2017 and that this final law did not address US stakeholders' key concerns. The main concerns of US industry with the final law were:

2.199. Critical information infrastructure (CII): As in the third reading draft, the law provided more details than in past drafts on the definition of CII which stated the ultimate scope of CII would be defined by the State Council at a later date.

2.200. Data flows: The final law stipulated that domestic storage of any personal information or important data may only cross borders for business reasons and if it had passed a (currently) undefined security audit.

[10] China - Banking IT Equipment Security Regulation (IMS ID 457) paras 2.178. - 2.184. .

2.201. Security review: The final law maintained a reference to a cyber security review which critical network equipment and products had to meet in order to be sold in China. In addition, network operators had to ensure compliance with a cyber security multi-level protection scheme. This cyber MLPS had to be based upon an existing MLPS framework which prohibited purchase of foreign technology at some risk levels.

2.202. Secure and controllable information: The United States remained concerned over what seemed to be a widespread effort from China to impose secure and controllable requirements on companies using ICT products that unnecessarily disadvantaged foreign ICT firms. Such requirements ran foal of commitments made by their respective presidents and that had been restated in subsequent meetings of the Joint Commission on Commerce and Trade (JCCT) and Strategic Economic Dialogue. While the requirement of indigenous R&D had been removed from the insurance rules, they still seemed to require insurance institutions to give preference to products that were secure and controllable. The draft cyber security law introduced an equally undefined term "secure and trustworthy". The SIRC regulations on secure and controllable stated that these institutions needed to promote gradual implementation of the secure and controllable technologies. This was a major concern for US ICT companies given that "secure and controllable" was not clearly defined. The United States was concerned that since no further clarity had been provided on the meaning of secure and controllable and that it had been known and understood in the past to include references to domestic technology requirements, companies were already interpreting this language conservatively meaning that they were required to procure only domestic goods. This was similar to trends seen in the banking and other industries in China that were deemed critical infrastructure. China was asked to publish a clear definition of secure and controllable; it was noted that some information had indeed been provided in bilateral discussions on the day of the meeting.

2.203. Domestic cryptography: the United States was pleased that China had explicitly removed the mandate for domestic encryption in the draft insurance rules; there was, however, still a reference to the "national implementation requirements on cryptography in the financial sector" without specifying what these requirements were. The United States was concerned that a domestic Chinese encryption standard would be mandated given that China's national requirements on cryptography in the financial sector generally promoted all-around adoption of domestic algorithms. For example, the January 2014 "national work plan for promoting application of cryptography in financial sector" called for complete adoption of Chinese domestic cryptographic standards and related specifications by 2019 for products such as internet browsers, PCs, laptops, mobile phones, and servers. Although items that did not have cryptography as their core function were still able to be sold in China, the guidelines from 2014 covered products including phones, servers, laptops, etc., which overlapped with non-core function items. China was asked to make more clear in Article 54 that domestic encryption was not required by these rules.

2.204. Multi-Level Protection Scheme: It was noted that the draft insurance rules also appeared to continue to discriminate against foreign providers by mandating that all insurance institutions within China follow the MLPS requirements that all products classified as security level 3 and above use domestic intellectual property (IP). The MLPS was inflexibly prescriptive and could restrict the ability for consumers to purchase technologies established as safe everywhere else in the world. Other Members had rules to ensure security of critical infrastructure, but China was now – without explanation – including non-critical infrastructure. Moreover, the draft Cybersecurity Law appeared to expand the scope and applicability of MLPS to cover "critical information infrastructure", without providing a definition of critical information infrastructure. China was urged to ensure that it adopted an approach that was non-discriminatory and which focused on legitimate security concerns within a clearly-defined category of critical information infrastructure.

2.205. Information Security System Certification: The insurance rules also required that information security system certification be accredited by China's National Certification and Accreditation Administration (CNCA), which could unnecessarily raise costs or cause potential threats on their confidential information. It was unclear what the specific requirements for certification would be, whether there were other options for certification, and what kind of information would be requested from a company to ensure that it met licensing requirements. China needed to recognize relevant international certification results to remove unnecessary or duplicative requirements.

2.206. The representative of Japan supported the positions of Canada, US and EU regarding this issue. In Japan's view there were unclear articles regarding terms, definitions, concrete requirements for examination and evaluation, and the scope of regulation. Japan's concern was that market access of foreign companies to China might be hampered depending on implementation. Japan requested China to clarify the terms, definitions, the concrete contents of requirements and the scope of regulation, and to ensure transparency.

2.207. As Japan had previously explained, Article 25 in particular required insurance institutions to use technologies and products complying with national standards and encryption requirements. Those requirements could be implemented in a way which was more trade restrictive than necessary upon import of relevant products. In addition, conformity assessment procedures of those requirements could be regarded as questionable, if they contained requirements of source code disclosure, etc. Japan asked China to clarify in concrete terms which requirements or conformity assessment procedures were to be applied. It could be the case that foreign companies were disadvantaged compared with domestic counterparts, even if those requirements would be equally applied to foreign and domestic companies. Japan requested China not to apply those requirements. Moreover, Japan's view was that the MLPS referred in Article 56 might cause discrimination of foreign companies by requiring Chinese intellectual property in core technologies or by requiring domestic certification in China. Japan asked China to clarify the implementation procedure of MLPS. Japan also requested China to revise the draft regulation so that it would not to be more trade restrictive than necessary in accordance with international standards.

2.208. The representative of Australia reiterated her delegation's concerns and echoed those expressed by other Members regarding the proposed Information Communication Technology Regulation (CIRC) and the Cybersecurity Law. While Australia understood China's desire to protect ICT infrastructure, Australia questioned whether the proposed measures were necessary to achieve this objective. Australian businesses had expressed great interest in these measures and had raised concerns about the potential of the measures to limit their ability to operate in the Chinese market. While Australia appreciated that China had notified the measure and had amended certain aspects of it, there remained concerns about potential discrimination and unnecessary barriers to trade. The representative of Australia sought further information about the objective of the requirement that certification be completed by bodies accredited by the 'CNCA'. Requiring domestic certification could afford less favourable treatment to foreign suppliers, and might not provide sufficient protection to commercial information. It was suggested that China consider recognition of relevant international certification bodies, as outlined in Article 5 of the TBT Agreement.

2.209. In addition, Australia noted that the regulation required data from China to be stored in data centres located within China's borders, and the design of the computing room conform to national standards. Australia was concerned that these country-specific requirements could disproportionately impact international firms that ran their ICT systems as global platforms. It was important to avoid onerous testing and certification requirements that would either be unnecessarily burdensome, discriminatory, include a review of source code, or other sensitive business confidential information. Australia asked for further information from China about the details of the provisions, including the objectives, definitions of key terms in the certification requirements, and current status of the reforms, under both the Insurance Regulatory Commission's ICT Regulation and the Cybersecurity Law. Australia was still awaiting responses to a number of questions raised at previous TBT meetings – as well as to written comments – and suggested that the implementation of the measures be delayed until there was further consultation and greater clarity on different aspects of implementation.

2.210. The representative of Mexico supported delegations that had spoken and asked China to respect the principles enshrined in the TBT Agreement.

2.211. The representative of China said that the regulation was aimed at ensuring information security in the insurance sector which was essential to preserve financial security in China. The rule had been drafted in a very transparent way and would, he said, be applied in a non-discriminatory manner. China was not of the view that it was discriminatory: regarding commercial encryption, the relevant regulations in China applied equally to domestic and foreign products. Dozens of foreign companies had obtained production licences in China and they did their business well. Thus, China's requirements regarding secure and controllable did not discriminate against foreign product services and technologies. In response to concerns about the term "secure and

controllable", it was explained that the criteria for the determination of what constituted "secure and controllable" were the following. First, a user's information system shall not be remotely controlled without their knowledge. Second, a user's data and information should not be obtained without their prior consent. Third, the products of services provided using a user's information system should not stop services without a justifiable reason. It was noted that the term "secure and controllable" had not been created by China, it was used outside of China as well. Finally, some Members' concerns about "data residency" and "cross-border data transfer" seemed problematic to China since these issues went beyond the scope of the TBT Agreement and, therefore, the TBT Committee was not the appropriate forum to discuss them in.

2.2.3.29 Brazil - Toy Certification; Ordinance No. 489, No. 310 and draft Administrative Rule No. 321, G/TBT/N/BRA/612 (IMS ID 478)

2.212. The representative of the United States said that her delegation continued to monitor this measure and expressed concern about the impact of these requirements on trade with Brazil in this sector, particularly INMETRO's Object Registration System which involved high costs without comparable improvements in safety. While recognizing the objective of improving consumer information, she noted that it was unclear how the registration system and labelling requirement increased consumer safety beyond the current system. The US expressed concern that many SMEs and developing country exporters may be forced to abandon the Brazilian toy market, which would reduce consumer choice.

2.213. In particular, the requirements to register toys in a "family of products" appeared to be unnecessarily burdensome. As noted in previous STC interventions, this approach was problematic when implemented for medical devices. Her delegation understood that the final ordinance was still under review despite expectations that final guidance would be made available to exporters by this point in the year. She asked for clarification on certain issues: (i) whether a final measure would be adopted in 2016; (ii) who would supply the sticker labels with the registration number; (iii) whether a company could print the registration number directly on the packaging; (iv) whether the filming requirement would be removed; (v) whether the confidential business information required as part of the certification process requested to ensure inputs' traceability; (vi) whether other methods had been considered that did not require the submission of sensitive information.

2.214. Concerning the specific testing requirements for the migration of certain elements, she expressed the hope that the final ordinance would only require tests which were applicable based on the toy model and age rating. Also, the US was concerned that the certificates of conformity for testing models 2 and 5 would expire in three years, which was insufficient as most toys had a longer market life than that. The US looked forward to working bilaterally with Brazil and remained open to discuss within the U.S.-Brazil Commercial Dialogue.

2.215. The representative of the European Union supported the US intervention. The EU understood the intention behind the registration requirement, which was to improve traceability of toys, to enable a more effective enforcement of product recalls and to provide more information to consumers about the toys. This database would enable consumers to access and search the different toy products by their registration number. The EU invited Brazil to consider less burdensome alternatives, in particular on the narrow family concept of products which would be a determining criteria for registration. This narrow concept of family products was overly burdensome as it could result in unnecessary registrations for toys with substantially identical safety properties without comparable improvements in safety.

2.216. As mentioned previously concerning registration, the EU reiterated its toy industry proposal to use a registration system per each producer or importer combined with a requirement for toys manufacturers to have an internal traceability system capable of tracking relevant data on each toy, such as production line, date and batch number, to enable effective enforcement of any product recalls. The EU understood that INMETRO's regulatory process was reaching its final stage and the final version of Ordinance 489 could be adopted before the end of 2016. The EU urged INMETRO to take into account the comments submitted by regulatory authorities and stakeholders in order to find a balance between the legitimate objectives pursued and the business realities in the toy sector. Furthermore, like the US, the EU requested confirmation that the filming requirement for testing would be removed from Administrative Rule 321 as Brazil had previously indicated.

2.217. The representative of Canada thanked Brazil for its engagement on the toy safety measures. She echoed the concerns raised by the US and the EU and said that in the previous TBT Committee meeting Brazil had indicated that it expected to have a final rule by August 2016. Canada requested an update on the status of Administrative Rule 321 and asked whether the final draft measure would be notified to the WTO.

2.218. The representative of Brazil said that the regulation aimed at safeguarding the legitimate policy objective of protecting children's health and safety, one shared by all Members. He said that the purpose of the measure was to create a direct link between INMETRO and the producers, as well as establishing a registration procedure to facilitate access by consumers to certification information through its website. This would improve the Brazilian framework of conformity assessment in terms of transparency and traceability. Brazil believed that the requirements of the measure conformed to international best practices and were those that better addressed Brazil's needs and circumstances. The registration system was a legal requirement established in Law 12.545/2011 and in CONMETRO Resolution 5 of 2008, which had to be reflected in these regulations. He recalled that this registration system was implemented in other sectors in Brazil without difficulties.

2.219. Concerning the publication of the final rule, he expected to have a final rule by the end of December 2016. Regarding registration numbers, Brazil clarified that INMETRO had a sticker label to assess conformity with the product registration number, which was provided by a conformity assessment body hired by the producer. The sticker label had to be affixed to the packaging if not already on the product and be visible to the consumer buying the product. On confidentiality of information, INMETRO maintained a strict policy which was consistent with ISO/IEC 17065. On the filming and recording requirements, serious consideration had been given to comments made in the Committee and in public consultation, but his delegation could not disclose at this point if the requirement would be excluded from the final regulation. He also stated that the measure would be a less burdensome approach for producers because products from the same family would acquire the same registration number. Finally, Brazil considered that the fast-moving nature of the industry justified the requirement for a periodic renewal of certification.

2.2.3.30 Korea – Standards and Specifications for Wood Products, G/TBT/N/KOR/563, G/TBT/N/KOR/599 (IMS ID 491)

2.220. The representative of the United States thanked Korea for the bilateral discussion and asked whether Korea would reconsider enforcement of the glue and laminated timber and oriented strand board standards until a suitable method was in place to allow conformity assessment to be conducted in the country of origin. The US appreciated that the Korea Forest Service (KFS) had accepted the US Department of Commerce (DOC) PS 1 standard for plywood. However, she highlighted three outstanding issues: (i) the US requested an update on the adoption of the Foreign Quality Inspection Institute (FQII) Law; (ii) the US encouraged KFS to accept certified glulam that used visually graded lumber in its core pursuant to provisions in the Korean glulam standard and test data provided that demonstrates that necessary strength properties have been met; and (iii) the US encouraged KFS to recognize the US DOC PS 2 standard for oriented strand board.

2.221. The representative of Canada appreciated Korea's efforts to work with Canadian trade and forestry officials to resolve issues related to a number of forest-product standards. Canada shared the concerns expressed by the United States, especially regarding oriented strand board. In this respect, Canada requested that KFS recognize CSA standard O325, which was harmonized to the US DOC PS 2 standard for oriented strand board. He appreciated Korea's attention to Canada's concerns about its forest product standards, and looked forward to resolving this issue in the near future.

2.222. The representative of the Republic of Korea, in response to comments regarding the designation of FQII, said that Korean authorities had prepared an "Amendment of law of sustainable use of wood". However, the Korean National Assembly session had ended in May 2016, and the KFS therefore planned to resubmit the amendment draft to the following National Assembly session. As soon as the amendment draft was approved, KFS would initiate the process for FQII designation. With respect to the Korean standard for oriented strand board, he explained that it covered not only uses for structural purposes, but also general purposes such as interior or furniture manufacturing. Also, like the EU, the Korean standard for oriented strand board adopted

the quality standard of the ISO international standard. The performance standard for oriented strand board adopted by the US and Canada was different from the Korean standard. However, he noted that Korea already amended this regulation regarding the plywood standard to reflect comments from the US and Canada for 3-ply structural plywood, since they satisfied Korea's bending strength requirement. Korea was therefore open to discuss outstanding concerns in a transparent manner with interested parties.

2.2.3.31 China - Interim Measures for Quality Management of Commercial Coal, G/TBT/N/CHN/1057 (IMS ID 477)

2.223. The representative of Australia thanked China for bilateral discussions on the coal standards conformity assessment, notified as urgent in September 2014 and entered into force on January 2015. As concerns continued to exist, Australia asked for a formal written response from China on numerous queries raised through the Chinese TBT Enquiry Point and for an indication of the timing on when Australia could expect a response. China being Australia's second largest coal export market, the implementation and application of the measure was thus followed with interest by Australian industry and exporters. Production from Chinese coal mines was estimated to have dropped by 4.5% in 2015, the global drop of imports accounting for about 32%. Australia was committed to being a reliable supplier to China of high quality thermal and metallurgical coal with low levels of impurities, and supported China in its efforts to improve quality of coal used in the energy and industry sectors, but underscored the importance of implementing measures that enhanced trade in coal and international competition.

2.224. The GlobalCoal standard trading agreement, on which China based its standards in the interim measure, was not recognized as a standard for testing coal quality. Australia asked China to explain why it did not use or recognize the relevant internationally recognized and accepted ISO standard, ISO 13909. In addition, she asked China to explain how the GlobalCoal standard coal trading agreement applied to domestic and imported coal.

2.225. On conformity assessment procedures, Australia also urged China to accept test results of internationally accredited facilities based in other countries, enabling tests to be undertaken in a more expeditious way, reducing duplication costs and preventing delays at point of import where test results had to be received prior to unload. Australia requested that China provide an update on any improvements to timeframes in testing imported coal and asked what type of interaction existed for testing authorities to discuss results obtained in China, whether these results differed from results obtained elsewhere, what review or appeal process existed when Chinese test results differed from Australian or other countries' results and, in case of the latter, or when results differed between test at different Chinese ports on the same shipment, whether China had given consideration to an independent review of appeal process. Australia raised concerns on how the 3.6 billion tonnes of Chinese coal were being tested and how China ensured consistency between tests on imported and domestic coal. He asked China to provide details of authorities that undertook domestic testing, to indicate what happened with the results of domestic tests undertaken thus far, to explain what happened with domestic coal not meeting the quality criteria and how China ensured testing across all ports into China by sea, rail and road. Australia looked forward to the continued discussion with China on these issues.

2.226. The representative of China said that his delegation had replied to Members' concern in the Committee many times and emphasized that from January 2015, domestic and imported coal needed to attain the same standards of Interim Measures for Quality Management of Commercial Coal. China took note of Australia's comments raised in the meeting and would study the written comments previously submitted and address them at the next meeting of the Committee.

2.2.3.32 India - The Stainless Steel Products (Quality Control) Order, 2015, G/TBT/N/IND/50 (IMS ID 486)

2.227. The representative of the European Union reiterated his delegation's previous concerns with this measure, and recalled written comments to this notification sent by the EU on 23 October 2015. The notified draft was similar to other certification measures adopted by India for steel products, such as the Steel and Steel Products (Quality Control) Order, 2006 (notified as G/TBT/N/IND/32). The notified draft further extended the scope of the existing BIS mandatory

certification system to three additional steel products, such as stainless steel plates, sheets and strips.

2.228. The EU was concerned that these measures could constitute an unnecessary barrier to trade. He recalled concerns about the necessity and costs related to BIS mandatory certification requirements, and the re-testing by BIS-authorized laboratories of the covered steel products which had already been tested against relevant international standards. The EU again asked India to confirm that the standards referred in the notified draft were equivalent to the relevant international standards, and if so, requested that India refer to those international standards in the text as well. Finally, the EU reiterated that the factory inspections required by the BIS certification system would be of no added value for the EU steel mills which already had put in place quality management systems (QMS) as defined in ISO 9001.

2.229. The representative of India first addressed concerns about the necessity of the measure and the requirement of re-testing. In this regard, he stated that the BIS (Certification) Regulations 1988 required evidence of conformity of the product to the relevant Indian Standard through testing in a BIS or BIS-recognized laboratory, for the purpose of granting a BIS marks certification licence. He explained that samples were drawn for testing in independent laboratories for assessing conformity to the relevant Indian Standard before granting a licence. Indian Standards specified test methods, and the labs recognized by BIS carried out tests as per the test methods and requirements defined in Indian Standards. With respect to concerns about the cost of certification, India stated that testing charges for samples were part of an annual marking fee for operating the licence. He submitted that the cost of BIS certification was reasonable.

2.230. Concerning the question of equivalence with international standards, India informed Members that the standards referred in Stainless Steel (Quality Control) Order 2015 (namely, IS 5522:2014; IS 6911:1992; and IS 15997:2012) were not harmonized with international standards because they had been developed taking into consideration manufacturing practices followed in the Indian market. Moreover, there was no ISO standard equivalent to IS 15997 and IS 5522. However, the formulation of IS 6911:1992 had drawn upon ISO 683/13:1986, BS 1449 (Part 2):1983 and AISI standards. He noted that IS 6911:1992 was currently under revision, and additional international references were being considered in the revision version.

2.231. He expressed doubts as to the EU suggestion that steel mills with ISO 9001 QMS be exempt from the requirement of factory inspections. India was of the view that product certification was different from QMS certification. A visit to the factory premises, and verification and testing in the factory, was a part of the BIS conformity assessment scheme. On the other hand, ISO 9001 certification did not cover factory testing as per Indian Standards.

2.2.3.33 European Union - Restriction on Polycyclic Aromatic Hydrocarbons (PAHs) in Tyres as specified in Annex XVII of REACH, G/TBT/N/EEC/52 (IMS ID 480)

2.232. The representative of China reiterated its concern about test method ISO 21461, referenced in Entry 50 of Annex XVII of REACH (1907/2006/EC) stating that it was not suitable for conformity assessments related to efforts to restrictions of PAHs, as it was an unusual and indirect quantitative method for the determination of PAHs. GC-MS and HPLC, test methods specified in technical regulations and international standards, were more accurate and more developed. According to China, using test method ISO 21461 was unscientific, inappropriate, could cause misleading results and involved significant costs for tyre manufacturers. China requested the EU to provide a scientific rationale for the test method, to conduct a timely review and make revisions accordingly.

2.233. The representative of the European Union reiterated that the measure in question had been notified under the TBT Agreement on 21 January 2004 (G/TBT/N/EEC/52, so-called REACH regulation) and had been extensively discussed with WTO Members, economic operators and other stakeholders. The EU had been applying the contested test method (ISO 21461), which was part of an international standard, since January 2010. The nuclear magnetic resonance spectroscopy, needed for this test, was an instrument typically available in specialized laboratories. The EU repeated its request for more information on validated chromatographic methods to which China referred.

2.2.3.34 India - Draft Food Safety and Standards (Alcoholic Beverages Standards) Regulations, 2015, G/TBT/N/IND/51 (IMS ID 494)

2.234. The representative of the United States, whilst expressing support for India's efforts to develop safe and effective standards for regulating alcoholic beverages, remained concerned that in a number of areas India had proposed standards that fell outside of widely accepted international norms and standards and that consequently may restrict trade more than necessary than required to achieve India's objective. She observed that recently released revisions of the draft measures did not take into account comments submitted by the US in February 2016.

2.235. She reiterated concerns regarding the standards set by India on a number of compositional limits for which standards did not exist in Codex Alimentarius, for example levels for chemical contaminants in alcoholic beverages. In addition, India had set limits with regard to pH, carbon dioxide, and sugar levels that seemed to pertain to the quality of alcoholic beverages rather than the safety thereof. The US requested scientific justification for these limits as well as the specific scientific studies backing them up, as appropriate.

2.236. Her delegation requested an update on whether India would include a number of additives commonly used in distilled spirits manufacturing in the list of permitted additives and in particular requested a response to the specific additives authorization requests included in US comments on G/SPS/N/IND/108 and G/TBT/N/IND/51 (identical to G/SPS/N/IND/119), submitted the previous year. The US was also concerned with the labelling requirements associated with this standard and asked India to clarify whether stickers would be allowed to be placed on alcoholic beverages at port before these items passed through customs. She recalled the many other important issues and concerns noted in her delegation's comments of 1 February, including irregular serving size measurement, limits for alcohol by volume (abv) that would prohibit many ciders, wines, and distilled spirits from being exported to India, and several compositional requirements that were either unclear or concerning, and asked when India would provide a response thereto.

2.237. In conclusion, she stated that the US would welcome the opportunity to discuss the process India had followed in creating this standard and asked whether India had considered existing regulations of other countries and international standards on alcoholic beverages. In this regard, her delegation would welcome dialogue to explain its own regulations and the rationale behind their formation. Asking when India would implement this measure, she urged that an adequate transition period be provided to allow industry to comply with this measure. Finally, she asked whether the revised draft Alcoholic Beverage Standard would be notified to the WTO.

2.238. The representative of Mexico expressed its concerns with respect to India's Proposed Draft Food Safety and Standards – Alcoholic Beverage Standards – Regulations, 2015, notified to Members in document G/TBT/N/IND/51 on 1 December 2015 and published on 29 October 2015 on the website of the Food Safety and Standards Authority (FSSAI) and on which Mexico had formally submitted comments on 18 December 2015, during the public consultation on the measure. Whilst grateful for a recent bilateral meeting, her delegation reiterated its concerns, which centred on the definition of Tequila in section 2.6 "Tequila" of the FSSAI regulations and, in particular, its subsections 2.6.1. to 2.6.6. Mexico considered that both the domestic production of Tequila and all Tequila exports were highly regulated and monitored, on the basis of both the applicable Mexican technical regulations and the provisions of the Designation of Origin of Tequila concerning the regions of production of this distinctive drink. Mexico therefore urged the relevant Indian authority to take into consideration the definition of Tequila contained in NOM-006, since until this definition was aligned on Mexican regulations, her delegation feared there would be obstacles to the entry of this type of product into India. Finally, Mexico requested an update from India on the status of the review of their comments submitted during the public consultation on the measure and the holding of a video-conference with the technical services responsible for drawing up the measure on food safety and alcoholic beverages standards in India, in order to settle on suitable language for the definition of Tequila in the Indian measure, which would make it possible to protect the Designation of Origin Tequila and ensure access to the Indian market for this type of product.

2.239. The representative of Canada requested an update from India on a number of items discussed at the previous meeting including the status of the regulation, as well as a timeline for a further list of additives in alignment with OIV standards which had been approved by the Indian food authority and which, according to India, would be notified to the WTO in due course. He also

referred to his delegation's previous comments concerning the draft regulation's maximum alcohol content limits for whiskies and requested an update on this issue.

2.240. The representative of the European Union noted that India had been interested in the EU position during the preparation of the draft measure and thanked India for the bilateral meeting held at the margins of the ongoing TBT Committee. She recalled concerns raised at the June 2016 Committee meeting[11] as well as detailed written comments on the notified draft in January 2016. She expressed concern that India had not notified a new draft to the Official Gazette (Draft Food Safety and Standards, Alcoholic Beverages Standards, 2016), published by the Food Safety and Standards Authority of India (FSSAI) on 6 September 2016 and reminded India of the transparency obligations contained in the TBT Agreement. In addition, the list of food additives permitted in alcoholic beverages had been recently adopted by the competent Indian authorities and notified to the WTO on 22 September 2016, but only via the WTO-SPS notification system, and not TBT. She therefore reminded India of its obligation to notify the new draft regulations under the TBT Agreement and to allow a reasonable time for comments before the entry into force of the regulation.

2.241. Regarding the new draft regulations, the EU underlined that most of its concerns expressed in its comments sent in January 2016 still remained. In particular, her delegation reiterated its concerns regarding a number of inconsistencies between the new text and current international practices (i.e. the oenological practices and definitions as set by the OIV and Codex) and therefore urged India to align itself with them in order to be fully in line with Article 2.4 of the TBT Agreement. Finally, the EU urged India to provide a reasonable transition period for manufacturers to comply with the new provisions and to allow the sale of products already present on the Indian market until exhaustion of stocks.

2.242. The representative of Switzerland asked for an update on the extent of the scope of validity of India's labelling standards. He also reiterated his delegation's view that by accepting elements that were simple translations of internationally standardized labelling elements by means of supplementary labels, i.e. stickers, India could address its issues regarding consumer information.

2.243. The representative of Guatemala reiterated its systemic interest in this issue.

2.244. The representative of Japan voiced support for the concerns raised by the US, Mexico, Canada and the EU. He requested an update on the status of the revision of the regulations and a timeline for adoption in light of India's statement at the previous meeting that the measure would probably be finalized within the year, after due consideration of comments by all Members and stakeholders.

2.245. The representative of South Africa welcomed bilateral discussions held on this trade concern and encouraged India to follow the well-respected Codex and OIV standards in developing their standard.

2.246. The representative of New Zealand reiterated her belief that wine should be seen as a single ingredient product, and noted that numerically-based labelling requirements, such as the numerical definitions of wine categories, failed to take into account seasonal and regional variances in wine production, thereby constituting an unnecessary burden on wine producers. In this light, her delegation looked forward to hearing how India would respond to the concerns of wine producers and importers. She also requested information on how comments made by Members had been taken into account and when an updated version of the regulation would be notified to the TBT Committee.

2.247. The representative of Australia reiterated his delegation's previously-raised concerns, in particular that India had not fulfilled its notifications requirements. Australia also noted India's steps to adopt certain wine additives consistent with OIV, of which both Australia and India were members, as a positive step.

[11] G/TBT/M/69, paras 3.309-3.310.

2.248. The representative of India recalled that the Draft Food Safety and Standards (Alcoholic Beverages Standards) Regulation, 2015 had been notified via G/SPS/N/IND/119 and G/TBT/N/IND/51, both with a 60-day comment period. After consideration of the comments and feedback from Members and other stakeholders, the Food Safety and Standards Authority of India (FSSAI) had published, on 5 September 2016, another draft regulation, namely the Draft Food Safety and Standards (Alcoholic Beverages Standards) Regulation, 2016, which had been uploaded onto the FSSAI website on 9 September 2016. The matter was presently under consideration of the authority, and the comments received from WTO Members as well as domestic stakeholders were being examined. He went on to confirm that a transition period would be provided for industry to comply with these measures once the matter was finalized, in line with suggestions by several delegations.

2.249. On the issue raised that the revised draft regulation of September 2016 should also be notified to the WTO, India stated that it had been published on the website of the Food Authority, seeking comments of stakeholders, in compliance with specific provisions of the FSSAI Act, and that regarding the notification requirements of the TBT Agreement, the draft measure had already been notified once in December 2015. On the issue raised by some Members that the draft regulations may deviate from internationally agreed norms, he said that the Indian authorities believed that there were no Codex standards prescribed for alcoholic beverages, except for the provisions on additives.

2.250. Regarding additives, he recalled that India had notified its draft regulations on food additives in G/SPS/N/IND/108, wherein the provision of additives for the category of wine had been adopted from Codex GSFA (General Standard for Food Additives). Subsequently, another notification had been filed in the SPS Committee (G/SPS/N/IND/157) seeking comments from Members in the matter of additional additives, enzymes and processing aids for use in alcoholic beverages including alcohol-free and low-alcoholic counterparts. Based on the suggestions received from Members, a further list of additives in alignment with OIV standards had been approved by the Food Authority. Accordingly, the Draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2016 had been uploaded on the FSSAI website on 1 November 2016, seeking comments and suggestions of persons likely to be affected

2.2.3.35 China - Formula Registration Regulation for Infant and Follow-up Formula, G/TBT/N/CHN/1165 (IMS ID 493)

2.251. The representative of the European Union shared the objective of China to ensure the highest level of protection in the area of infant and follow-up formula. However, as conveyed in written comments and during the latest TBT Committee meeting, the EU was very concerned about some aspects of the draft measure. In particular, the limitation of each manufacturing company to a maximum of nine registered recipes within three product lines would have serious and unnecessarily negative trade impact on the current exports from the EU to China. Different major brands of infant formula currently relied on a lesser number of production partners for the manufacture of their products. It was estimated that, without modification of this restriction, the number of brands on the Chinese market would be reduced by 80%. The EU did not find a justification to this limitation, neither on the basis of food safety nor on the basis of any other legitimate objective, and therefore the EU kindly requested that it be removed; in any case it needed to be possible for the recipe owner to be the applicant for registration. The EU also considered that the new registration and approval procedure required appropriate time for transition from the current system in order to avoid disruption of trade, such as a period of 18 months. It was noted that at the latest Committee meeting, China had indicated that a slightly revised CFDA measure, without modification of the limitation of the number of recipes for manufacturing companies, would become applicable on 1 October 2016. The EU requested China to confirm the status of the measure and to provide information about any additional transition measures.

2.252. The representative of the United States sought to ensure that trade would not be unnecessarily disrupted as a result of Decree 26, and asked for more clarification of the measure, its basis, and the process China foresaw with respect to its development and implementation. In particular, the United States requested that China explain the basis for limiting the number of infant formula products that companies could place on the market. Had CFDA determined any health or food safety risk that would be mitigated by limiting the registration of infant formula? If so, on what basis and evidence had that determination been made? In particular it would be

helpful if China could address why the limitation was necessary if CFDA determined the specific infant formulas registered with it were determined to be safe and effective. The US representative also noted that US infant formula production facilities already had to comply with CNCA inspection requirements under Decree 145. So, she asked, under what circumstances would additional inspections need to be done by CFDA? Could the Government of China please clarify how this regulation and Decree 145 would operate together?

2.253. The representative of the Republic of Korea expressed his delegation's concerns about China's Registration Regulation for Infant and Follow-up Formula which had been notified to the WTO TBT Committee on 7 July 2016 under G/TBT/N/CHN/1165. CFDA had announced on 6 June 2016 that the Regulation would go into effect 1 October 2016. At the previous Committee meeting, Korea had asked China to provide a grace period and China had decided on 30 September 2016 to give a 15-month grace period on one of the sub-regulations. Korea also appreciated the transition period to allow products manufactured in China or imported to China before 1 January 2018 to be distributed in the Chinese market until production expiration dates.

2.254. While the Korean Government fully understood the need for strict control of infant formula products, concerns remained regarding duplication of site inspection by the CNCA (Certification and Accreditation Administration of the People's Republic of China) and the CFDA. On 12 August 2016, CFDA had published the new draft regulation for formula registration of infant formula milk powder for public comment. The draft regulation had included requirements on registration dossier and on-site inspection. Korea had submitted its opinion and suggestions. However, the requirements on registration dossier and on-site inspection had not yet been notified to the WTO TBT Committee. Korea requested that China notify the draft regulation to the WTO TBT Committee so that stakeholders could provide input in order to reduce business risks associated with the Regulation in a predictable and transparent manner. Korea also asked China not to duplicate registration process for Korean formula recipes and establishments; it was hoped that China would exempt the Korean establishments which had already been assessed by and registered at the CNCA in 2014 from site inspection. China was asked to simplify the process to register products already being exported to China.

2.255. The representative of Japan shared the concern raised by Korea, the US and the EU. As the EU had pointed out in previous meeting, this measure would drastically reduce the number of brands on the Chinese market. Japan did not see any justification for the limitation on the basis of legitimate objectives. China was hence asked to reconsider the measure, also taking into account the concerns raised by other Members.

2.256. The representative of New Zealand noted that China was a major export market for New Zealand, including for infant formula. New Zealand industry had undertaken a lot of work to prepare for the new regulatory environment and, as the application process continued to be developed, New Zealand hoped that this would result in simplification. As applications were not yet being accepted, China was invited to consider extending the transition period. New Zealand would continue to work with CFDA to ensure a smooth transition to the new regulatory environment for imported products.

2.257. The representative of China said that his delegation attached great importance to the safety of infant formula milk powder quality. Infant formula milk powder had always been the most stringently regulated food in China. The situation in China was quite unique: there was great market demand and rapid development, while at the same time there were problems on the market such as consumer confusion caused by too many brands and formulas. The regulation at issue would further regulate China's market to ensure high quality of milk powder and this would be beneficial for relevant enterprises, including foreign companies.

2.258. It was noted that before drafting this regulation, China had carried out research in infant formula milk powder. Theoretically, infant formula milk powder should only be a nutritional supplement to breastfeeding. Therefore, the composition of infant formula milk powder needed to be similar to breast milk and there could not be too many recipes. Data from research showed that large foreign infant formula milk powder manufacturers had, normally, no more than three brands in production and sale. To address Members' concerns regarding on-site inspection, China wished to clarify that the on-site inspection mainly focused on the R&D data of milk powder formulas and manufacturer's capacity to turn formulas into production. The focus of the on-site inspection differed from the past one. China had also taken note of Members' concerns about possible

duplicative inspections; such duplication would be avoided through more internal communication. The representative of China stressed that the regulation applied in a non-discriminatory manner to both domestic and foreign manufactures.

2.2.3.36 Indonesia — Halal Product Assurance Law No. 33 of 2014 (IMS ID 502)

2.259. The representative of the United States thanked Indonesia for the bilateral meetings that had taken place. The US wanted to work with Indonesia to ensure the law was implemented so as to achieve the objective of ensuring that consumers knew whether products were halal without creating unnecessary barriers to trade. The US strongly supported providing consumers with the necessary information to make informed decisions but remained concerned on the requirement that both halal and non-halal products be labelled as such as this could cause confusion for consumers and be costly and challenging to implement. On the new registration requirement for foreign halal certificates, there were concerns that the requirements were cumbersome and duplicative and it was unclear what the registration requirements were for local products. She requested that Indonesia modify the registration requirements to reflect that foreign halal agencies issuing halal certificates for imported goods had already been verified by BPJPH. She further requested an update on the official status of the revision of the September draft that the Ministry of Religious Affairs had prepared, including the timeline regarding the issuance of the final regulations. The US again requested that the draft implementing regulations be notified to the WTO prior to being finalized so as to allow time for comments from stakeholders and for those comments to be taken into account. Finally she requested clarification on where the official draft would be made available and how it would be disseminated.

2.260. The representative of the European Union expressed concern with Law 33 of September 2014 which had a very broad scope, affecting, *inter alia*, food and beverages, pharmaceuticals, chemical and biological products, all consumer goods and cosmetics, as well as related services. It required mandatory halal certification and labelling for the products within its scope in order to be placed on the Indonesian market. In particular, Article 4 of the law provided that products that entered, circulated and traded in the territory of Indonesia must be Halal certified. The law would be implemented gradually in three stages and fully enforced as from 2019. It appeared that, from then on, non-halal products (not certified and labelled in accordance with the law) could not be placed on the Indonesian market. This represented a total ban on the importation of non-Halal products. The EU invited Indonesia to clarify whether non-Halal products could be placed on the Indonesian market and whether they would be subject to mandatory labelling or any other restriction for international trade. The law did not specify the requirements that had to be fulfilled by exporters, and certain halal requirements had already been set out in separate regulations (i.e., for imports of carcasses and meat). The EU considered that the lack of transparency on implementing rules and the fragmented approach created uncertainty as to which requirements were applicable at any point in time.

2.261. According to recent information received by the EU, a draft implementing regulation was being developed, but had not yet been adopted. The EU asked for an update on any developments in this respect and on the time frame for the adoption of the said implementing regulation. She reminded Indonesia that measures should not be more trade restrictive than necessary and that the non-discrimination principle should be taken into account, as well as transparency provisions. She further noted the EU's request that in accordance with Article 2.9 of the TBT Agreement, Indonesia notify the law, and any subsequent implementing rules, while still in draft form, allowing reasonable time for Members' comments to be taken into consideration. Additionally, as laid out in Article 2.12, Indonesia should allow for a reasonable interval of time between the publication and the enforcement of the measure, in order to allow time for producers in exporting Members to adapt their products or methods of production to Indonesian requirements.

2.262. The representative of Australia raised concerns regarding the possible trade restrictiveness of the proposed measures. Australia had on-going discussions with Indonesia and recognized the importance of halal product assurance. She welcomed the delay in introducing the regulations until November 2019 and, like other delegations, reminded Indonesia of their transparency obligations under the TBT Agreement. On the content, status of implementation and the expected consultation process, she put the following questions to Indonesia: what were the standards for halal products that were not subject to certification under the current arrangement, such as leather belts? What were the labelling requirements for non-halal products? Could Indonesia explain the objective it sought to achieve through the labelling of non-halal products? Would the relevant halal registration

authority grant mutual recognition to halal product certificates issued by foreign halal agencies, and what was the process for foreign agencies to be recognized? Finally Australia reiterated their support for measures that achieve legitimate policy objectives but it was important to ensure they were not more burdensome than necessary and could result in cost increases for both producers and consumers.

2.263. The representative of New Zealand said her delegation was closely following this regulation and like others requested that Indonesia provide an update on the development of the draft and that it be notified to the WTO.

2.264. The representative of Indonesia referred the Committee to the minutes of previous meetings[12] where answers had been provided to Members' questions. Indonesia would notify the Committee with any updates of the law.

2.2.3.37 Russian Federation — Rules of cement certification G/TBT/N/RUS/48, G/TBT/N/RUS/49 (IMS ID 497)

2.265. The representative of the European Union informed the Committee that the EU had already raised this issue during previous meetings of the TBT Committee and that following those meetings the Russian Federation had notified, on 8 March 2016, the Government Resolution No. 930 of 3 September 2015 "On Amendments of the Single List of Goods Subject to Mandatory Certification" adding cement to the list of goods subject to mandatory certification (G/TBT/N/RUS/48). Russia had also notified the Order of Federal Agency for Technical Regulation (Rosstandart) No. 1-st of 11 January 2016 "Conformity assessment. Rules of cement certification" (GOST standard 56836-2016), on 12 April 2016 (G/TBT/N/RUS/49), setting out the relevant rules for cement certification. However, both measures had already been adopted and were in force at the time of their notification. The EU therefore reiterated its request to Russia to suspend the measures and re-notify them to the WTO at a draft stage, allowing Members' comments to be taken into account. On the content of the measures, the EU raised several concerns.

2.266. Section 8.2 of the notified GOST standard provided that for imports from third countries the certification body should conduct additional inspection controls of each batch of cement. This included sampling at the border, as well as the testing and control of all characteristics set out in the standard according to which the certificate of conformity had been granted. On the basis of the results, the certification body had to make a decision as to whether to confirm, suspend or terminate the certificate of conformity. It was the EU's understanding that this provision set a requirement for "additional inspection control" of each cement batch arriving in Russia from third countries, including sampling at the border, testing and checking according to the standard. The EU asked Russia for the reasons and justification for such a requirement and underlined that the presence of additional requirements for conformity assessment affecting only imported products might contravene both Articles 5.1.1 and 5.1.2 of the TBT Agreement.

2.267. In relation to the additional inspection controls, the EU raised further questions: (i) what was the meaning of shipment (whether it would mean each wagon, whole train or yearly production); (ii) by whom and how would these samples be taken from imported cement; (iii) how would the tests be performed, their length and whether after sampling and testing the imported cement would be allowed to proceed further to the unloading point and/or to the end consumer, or whether the imported cement would be held at the border until the results of the testing were known and a decision on the certificate of conformity was taken (which the EU understood to take on average 28 days).

2.268. The EU again requested clarification on the following issues. Firstly, confirmation that the certificates issued by a certification body had to be registered with Rossacreditation. If this was the case, Russia should clarify why such a registration might be refused or delayed. Secondly, the EU asked Russia to clarify whether the certification bodies had to be registered with, and empowered by, Rossacreditation to issue certificates of conformity under the notified GOST standard. The EU understood that many EU manufacturers were granted certificates during the summer, which were withdrawn after an audit by Rossaccreditation. What were the reasons for such withdrawals?

[12] G/TBT/W/443 and G/TBT/M/69 paras 3.325-3.327.

2.269. The representative of Ukraine echoed the position of the European Union. Her delegation considered that the provisions of cement certification placed on domestic and foreign suppliers to be unequal. She asked Russia to take into consideration these concerns so as to ensure that the notified measures were in line with the requirements of international practice and did not create unnecessary barriers to trade.

2.270. The representative of the Russian Federation recalled that the Government Resolution No. 930 of 9 September "On Amendments to the Single List of Goods Subject to Mandatory Certification" had added cement to the above-mentioned list. He further stated that the resolution had been notified to the WTO. The relevant new standard GOST-R was adopted by the Federal Agency for Technical Regulation and Metrology and was also notified to the WTO. The necessity for inclusion of cement in the list of goods subject to mandatory certification had been determined by a sharp decrease in cement quality in Russia and urgent problems of safety, health and environmental protection. In particular, state supervision at construction sites revealed serious problems caused by low-quality cement, with four main issues: (i) hazardous content in cement of carcinogenic hexavalent chromium (CrVI); (ii) high alkali content in cement leading to early-age cracking in concrete and negative impact on the metal support structure; (iii) low compressive strength; and (iv) insufficient frost resistance. These urgent problems constituted a danger to life and health directly because of the content of a carcinogen and indirectly due to the quality and reliability deterioration in construction. The lists of certification bodies and of issued certificates were available on the website of the Federal Accreditation Body. He noted that since 8 March 2016 294 certificates for different types of cement had so far been issued, including 51 certificates for cement imported to Russia from WTO Members. He said that the list of documents and tests required to obtain a certificate for cement and the GOST-R requirements were equal for all manufacturers. Regarding inspection control for cement, the GOST-R provided for two forms: (i) inspection control at a production site; and (ii) inspection control of the products on the border. While inspection control at a production site presumed a complex control of production conducted once every six months and with additional unscheduled inspections, the control of products was a simpler and less costly procedure. Russia had taken note of concerns raised and would continue to work with interested Members on this matter.

2.2.3.38 United Arab Emirates — Control scheme to restrict the use of hazardous materials in electronic and electrical devices (IMS ID 496)

2.271. The representative of the European Union thanked the United Arab Emirates (UAE) for notification of this measure, and said that her delegation shared the UAE's objective of protecting human health and the environment. Nonetheless, she raised a number of issues of concern with the measure. First, regarding the lists of exemptions in Annexes 3 and 4 of the notified draft, the EU noted that they did not include many relevant exemptions included in similar regulations on the restriction of the use of certain hazardous substances in electrical and electronic equipment, as was the case in the EU's own legislation on the matter. In particular, exemptions for the use of mercury and other substances currently used for the production of light sources, such as bis (2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP), would be forbidden without appropriate transition, which would certainly disrupt trade in this area.

2.272. Second, regarding the enforcement of the restrictions laid down by the notified draft, the EU noted that Article 4.1 was unclear and did not specify whether the restrictions listed in Annex 2 only applied when the electrical and electronic devices were placed on the market for the first time or also to the following marketing stages. Therefore, the EU requested the UAE authorities to clarify whether and how the restrictions listed in Annex 2 applied to electrical and electronic equipment already on the market. Third, she stated that re-use, refurbishment and extension of lifetime of products already on the market were beneficial for the protection of the environment. Spare parts therefore needed to be available. In this respect, the EU asked the UAE authorities whether exceptions for the repair of products placed on the market before the application of the notified draft could be considered. Fourth, the EU highlighted that in Article 9.4 of the notified draft the list of exemptions in Annexes 3 and 4 related to "products", instead of "applications in a product", whereas the headings of Annexes 3 and 4 referred to "applications". In this respect, the EU asked the Emirati authorities to explain the exact scope of application of the exemptions at hand. Fifth, regarding the procedure for conformity assessment, the notified draft referred in Article 5 to "Model A" and to a submission to the Emirates Authority for Standardization and Metrology (ESMA); in Article 6 to registration; and in Article 8 to an application. Clarification was

sought on the exact procedure for the placing on the market of products following the assessment by the manufacturer and the drawing up of a Declaration of Conformity, and in particular on whether a prior authorization by the UAE authorities was required.

2.273. The EU representative noted that it was not possible for the UAE to provide a response to EU comments at the two previous TBT Committee meetings. In the course of bilateral contacts, the UAE indicated that EU comments would be given full consideration. However, to date no amended draft measure had been made available. The EU sincerely hoped that the UAE could provide a response to its comments, and kindly requested an update on the status of the measure.

2.274. The Chairperson took note of the EU's statement and asked that their concerns be brought to the attention of the UAE.

2.2.3.39 Thailand — Milk Code - Draft Act on Controlling to the Marketing Promotion on Food for Infant and Young Children and Other Related Products BE (IMS ID 503)

2.275. The representative of the United States, whilst strongly supporting the public health objective of promoting breast feeding, expressed continued concern regarding Thailand's proposed measure. Her delegation was of the understanding that a new draft of the measure would be notified and requested a timeframe for this notification. She asked how the revised draft, "Marketing Control on Food for Infants and Young Children Act", would interact with the Thai Food Law and the Thai Food Labelling Regulation and whether either of these measures would need to be revised in order to enforce the Marketing Control Act. Recalling the various Codex standards relevant to this measure, including the Standard on Infant Formula and Formulas for Special Medical Purposes Intended for Infants, Standard on Follow-up Formula, Canned Baby Foods, and Processed Cereal-based Foods for Infants and Young Children, as well as the Codex Guidelines for Nutrition and Health Claims, her delegation asked Thailand how it had considered these standards and any deviations therefrom in certain areas.

2.276. Regarding the un-notified draft entitled "Draft Marketing Control on Food for Infants and Young Children Act BE", the US asked Thailand to clarify if they were defining supplementary or complementary foods. She noted that Section 15.2 in the un-notified draft stated that importers must provide warnings against inappropriate preparation or use of the Food for Infants and Young Children and in this regard asked what inappropriate use was, and what types of warnings would be required. In particular, the US was concerned that the new draft did not appear to take into account the Codex Guidelines for Nutrition and Health Claims, although resolution WHA 63.23 on Infant and Young Child Nutrition, noted in the draft Thai Code, referenced the Codex. Thailand was asked to explain how the provisions regarding nutrition and health claims reflected the Codex Guidelines.

2.277. The US reiterated that the WHO's Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children was not an international standard according to the criteria established by this Committee and asked whether Thailand also recognized this fact. She reminded Members that in the US, adherence to the application of the WHO's International Code of Marketing of Breast-Milk Substitutes was voluntary, and complemented by similar codes developed by leading US medical professional societies on the marketing of those products. Her delegation expressed hope for deeper technical engagement with Thailand on how to achieve its health objectives without unnecessarily impacting trade in products appropriate for infants and young children and requested that a reasonable interval for implementation be provided after notification of this measure to the TBT Committee.

2.278. The representative of the European Union joined the US in its interest in this measure and thanked Thailand for the reply to written comments. She reminded the Thai authorities of the need to ensure that the draft Milk Code was aligned with relevant international standards and therefore the need to take into consideration the ongoing revision taking place within the Codex Alimentarius of the Standard on Follow-up Formula. She also recalled that, as stated in Article 2.2 of the TBT Agreement, the Thai draft Milk Code should not be more trade restrictive than necessary. Further, and in accordance with Article 2.12 of the TBT Agreement, Thailand was urged to allow for a reasonable interval of time between the publication and enforcement of the measure, in order to allow time for producers in exporting Members to adapt their products or methods of production to the Thai requirements. She noted that her delegation would be following closely the developments

on the draft, in order to ensure that its concerns were taken into account, and looked forward to receiving information on the timing for its adoption.

2.279. The representative of Australia, whilst recognizing Thailand's right to take measures to address a legitimate public health concern, said that as a supplier of high quality dairy products to Thailand, his delegation encouraged them to implement standards for the marketing of food for infants and young children in a manner that was as trade facilitating as possible. His delegation supported transparent and flexible implementation of regulations to minimize disruptions to trade and which would provide opportunities to allow traders to comply with new regulations.

2.280. The representative of New Zealand said that her delegation was of the understanding that the draft legislation had been revised and requested that the revised draft be promulgated to give Members adequate opportunity to comment. Recalling New Zealand's continued concerns about the intended application of the draft legislation and its potential impact on trade, she said whilst the draft regulation pertained to infant formula, follow-up formula and growing up milk, her delegation sought clarification on the application of the draft regulation to other food products consumed by young children defined in the act as between 12 months and 3 years. Additionally, clarification was sought on the product labelling restrictions for food products covered by the draft legislation.

2.281. The representative of Thailand reported that comments submitted previously from Members had been taken into account in the revision of the draft by the Ministry of Public Health and ensured continued involvement of stakeholders, the provision of Members with sufficient opportunity to comment on the draft as well as a sufficient transition period before implementation. In response to specific concerns, he confirmed that Thailand stood by Codex for relevant products. However, for sales promotion not covered by Codex, Thailand used other international standards and relevant documents. Secondly, he explained that the draft Milk Code Act had been developed with strict observance of Articles 2.2-2.6 of the TBT Agreement and in line with the international code of marketing of breast milk substitutes and relevant documents. Thirdly, he explained that it was necessary to regulate marketing promotion of breast-milk substitutes for children up to the age of three years given evidence showing that marketing promotion of milk products for children of 12 months and above was erroneously used for children of a younger age. Fourthly, he stated that the revised draft of the Milk Code did not contain a section on labelling, as suggested by Members. Lastly, he welcomed the deeper technical involvement of experts from Members in order to improve their practices.

2.2.3.40 Egypt — Manufacturer Registration System (Decree No. 43/2016 and Decree No. 992/2015) G/TBT/N/EGY/114 and G/TBT/N/EGY/115 (IMS ID 505)

2.282. The representative of Turkey reiterated its concerns on Egypt's Decree No. 43/2016 regarding the amendment of the rules organizing the Registration of the Factories Qualified to Export Products to Egypt. Turkey considered that the requirements of Egypt's registration system were burdensome and created unnecessary obstacles to international trade and were thus inconsistent with Article 5.1.2 of the TBT Agreement which stated that conformity assessment procedures (CAP) should not be more strict, or be applied more strictly, than necessary to give the importing Member adequate confidence that products conformed with the applicable technical regulations or standards, taking account of the risks non-conformity would create. Turkey remained of the view that the objective behind the registration system was not well defined, that products selected for registration purposes did not share common characteristics or belong to certain clusters, and above all that required documentation did not provide information or ensure the quality and safety of the products. It was also unclear whether equivalent documents, notably quality certificates, were required for Egyptian companies.

2.283. She recalled that during the previous Committee meeting Egypt had explained that it had provided a number of facilitating measures including the consideration of registered companies in GOEIC, according to Article 94 of Ministerial Decree No. 770/2005, and its amendments issuing the Executive Regulation to Implement the Import and Export Law "White List", as meeting the requirements of Ministerial Decree No. 43/2016. Her delegation expressed disappointment that apparently even this measure was no longer in place. Turkey understood that Annex 3 of Ministerial Decree No. 770/2005 had been enlarged by Ministerial Decree No. 961/2012. Moreover, the scope of the product list had been widened with the Ministerial Decree No. 991/2015. Decrees 961/2012 and 991/2015 conveyed alternatives for importing the products listed therein, one of

which was the registration of economic operators to GOEIC to be included in the Visual Inspection-White List, meaning that most products subject to White List overlapped with products in Decree No. 43/2016. Turkey deemed this to be a duplication of product implementation since there was already a registration system or pre-shipment inspection in place and questioned the purpose and necessity behind establishing a second registration system that would be costly for economic operators. Notwithstanding Egypt's statement that White List required producers to provide documentation proving that production was carried out according to one of the relevant Egyptian standards, Turkey urged Egypt to find a less trade-restrictive measure than duplication of an already established registration system.

2.284. Turkey considered that the implementation process also resulted in obstacles to trade as the preparation of the large number of documents necessitated long and varying legalizing, translating and approval procedures, some of which at significant cost and loss of time which would impact negatively on the competitiveness in the Egyptian market. Moreover, she highlighted that the practicalities of application for registration had not been clarified. It was challenging to obtain information about the companies that had completed the registration procedure, since the list of applicant companies was not provided by the Egyptian authorities or made publicly available. Companies who had already completed the application procedure had been waiting a long time without receiving feedback on the status of their application. These difficulties made the system much more burdensome for economic operators in terms of time and high costs and led Turkey to deem that implementation was not transparent.

2.285. In response to an invitation from Egypt in the margins of the previous Committee meeting, Turkey had transferred the list of companies still awaiting news of their registration applications to the Egyptian authorities through various official channels. However, despite Egypt's assurance that manufacturing plants and companies owning trademarks were duly informed of their registration, all formal requests by Turkish authorities on the status of registrations had remained for over four months. It was Turkey's view that the registration process, claimed as simple by Egypt, took at least five to six months and was therefore a burden on economic operators. On the issue of validity of submitted documents contained in Article 2, paragraph 3, of Decree No. 43/2016, Egypt had stated that the validity of documents was subject to objective visual and material evidence. In this regard, as most of the required documents were subject to Turkish Commercial Law, Turkey requested further information as to what kind of company or factory inspection would be carried out.

2.286. In conclusion, Turkey remained of the view that the manufacturer registration system constituted a genuine hindrance to market access and therefore requested Egypt to explore less trade-restrictive alternatives and to bring its legislation and implementation in compliance with the principles and rules of the WTO and TBT Agreement.

2.287. The representative of the European Union thanked Egypt for the bilateral meeting held in the margins of the TBT Committee. She reiterated its concerns expressed in written comments to Egypt, to which it had already received replies, in particular with regard to the entry into force of the legislation. The EU urged Egypt to suspend the application of the measures, to review them in light of the principles and obligations laid down in WTO law, and to re-notify them under the TBT Agreement. In addition, the EU was concerned by the possible duplication of procedures and the lack of clarity of the requirements to be fulfilled by European economic operators. She noted that the application of the Egyptian decrees was currently creating unnecessary obstacles to trade. Industry had reported serious difficulties resulting from the two measures, in particular, companies were facing long delays in the registration process, in some cases extending for months before a confirmation of registration was issued by the Ministry of Trade. Moreover, she said, the registration process lacked transparency, as the list of registered companies had not been made available to the public, and not even to the companies involved.

2.288. The representative of the United States said that whilst Egypt had provided further guidance on its website on how to comply with Decrees 43/2016 and 991/2015, her delegation remained concerned over Egypt's level of transparency during the adoption and enforcement of these measures and the burdensome nature of the requirements. She drew particular attention to Egypt's written response to her delegation's concern about the inadequate period of time to consider stakeholder comments submitted in response to its WTO notification, in which Egypt had responded that the registration requirements were administrative in nature and did not impose further burdens on producers or companies in the exporting markets. She maintained that one of

the key points of stakeholder comments was to understand what burdens might exist and how they could be mitigated in a manner that would still allow the Member to fulfil its objective. Egypt had further stated that a two-month transitional period was enough to carry out the registration process and that there had been over a thousand registrations. The US, however, had received complaints from companies which had submitted all required documentation but had nonetheless experienced serious difficulties registering. Moreover, it appeared that some 18,000 requests were pending approval with the Ministry of Trade and that overall US exports to Egypt for the most products covered by the decree were down 32% for the January–August 2016 period.

2.289. In this context, the US reiterated that had Egypt notified the first draft of the measure for a 60-day comment period, Egypt could have reflected on the comments received and made any necessary changes to the draft accordingly. Additionally, upon publication of the measure, Egypt should have allowed an adequate time – at least six months - for producers to adapt to the new requirements which would have allowed enabled Egypt to process documentation whilst avoiding backlogs and unnecessary disruption in trade for foreign importers already registered with the Trade Ministry and other relevant ministries.

2.290. Recalling that the measure in question specifically targeted imports, the US again asked Egypt how it had ensured that it was consistent with its national treatment commitments. Further, as a result of Egypt's immediate implementation and lack of transparency, whilst some US companies reported total withdrawal from the Egyptian market, others continued to indicate confusion about the documents and certifications which would be accepted to demonstrate compliance, as well as the backlog of applications preventing approvals or serious difficulties registering.

2.291. In light of the above, the US requested the following, as a matter of priority: (i) that Egypt suspend implementation of the measure until all stakeholder comments had been taken into account; (ii) that Egypt change its approach from a horizontal one that imposed the same requirements across many industries to one that takes into account the various global norms, risk factors, and practices across different industries and commodities; (iii) that regarding the requirement for a Quality Management System certification, Egypt recognize that international standards and best practices to control for quality differ by industry; (iv) that Egypt consider how this new requirement which is duplicative of existing requirements for registration and certification, including those implemented by other ministries, may meet the objectives of the proposed quality certificate requirement; (v) that Egypt continue to engage with the US and other trading partners to address these concerns; and (vi) that Egypt continue working with all stakeholders to ensure an approach not more trade restrictive than necessary to accomplish its regulatory objective.

2.292. The representative of Switzerland reiterated concerns raised during the previous Committee meeting regarding Decree No. 43/2016, in particular its entry into force before the end of the notified comment period. He recalled that Decree No. 43/2016 provided for the registration of foreign factories and trademark owners of products imported into Egypt and that this procedure required, *inter alia*, a certificate testifying that a quality control system had been reviewed by a third party. Switzerland encouraged Egypt to consider a less trade-restrictive approach, bearing in mind that in most markets, several products covered by the decree were not subject to third-party quality control. Moreover, in Switzerland, third-party quality control was required for certain products presenting risks even if the absence of third-party production certification did not necessarily mean that a product was unsafe. He reported that Swiss enterprises that had not implemented a quality management programme or had chosen to ensure quality management independently, were finding it difficult to adapt quickly and to understand the requirements established by Egypt. His delegation was concerned about how Decree No. 43/2016 would contribute to the objectives of protecting public health and the environment, and the extent to which third-party certification had been generalized to cover 25 very diverse product sectors. He requested an update on the implementation of procedures and on the future of the "white list" mentioned during the June meeting.

2.293. The representative of Ukraine voiced support for the positions of the EU, US and Turkey. She said that reports from domestic producers indicated that the Egyptian measures created unequal conditions due to the costs incurred by the additional requirements for legalization of product certificates. Ukraine was of the view that the measures might not be in line with WTO commitments and to illustrate their position cited the inspection and verification of certificates' conformity with Egyptian standards, as well as customs processing of products being subject to

random checks by the GOEIC. In addition, Ukrainian businesses had been given very little time to adapt to the requirements of the decrees due to the short timeframe between their adoption and entry into force, leading to the creation of unnecessary trade barriers between Ukraine and Egypt. Ukraine therefore asked Egypt for further explanation as to the grounds for such swift implementation and the choice of measures which appeared to be unnecessarily trade restrictive. Egypt was urged to suspend implementation of the decrees and to re-notify when the effects had been analysed and a revised proposal made.

2.294. The representative of South Africa said that his delegation remained concerned about the measure, and expressed interest in a speedy resolution to the matter that would facilitate trade rather than hampering it, as was currently the case.

2.295. The representative of Australia voiced support for the concerns raised by other Members on Egypt's proposed manufacturing registration system which her delegation deemed more restrictive than necessary to achieve its objectives. Australian businesses were already feeling the effects of the regulations and had raised several concerns to the Australian Government that the new registration and certification requirements created an unnecessary barrier to trade. Her delegation encouraged Egypt to take a risk-based approach to certification and conformity assessment requirements in consideration of international standards for product quality assurance.

2.296. The representative of Canada, echoing the issues raised by other Members, expressed concern with these measures, the development of which they would continue to monitor.

2.297. The representative of Egypt referred to their response from the previous Committee meeting, and highlighted some specific points regarding implementation.[13] First, he reiterated that notification G/TBT/N/EGY/114 referred to a different independent ministerial decree and did not require double registration. Decree No. 43/2016 required registration for the manufacturing plants and trademark owners of products imported into Egypt whilst Decree No. 991/2015 dealt with preshipment inspection to ensure product conformity with relevant Egyptian standards. Second, he assured Members that since the adoption of the new decrees, the Ministry of Trade and Industry had concentrated all its efforts on accelerating the registration process and handling any obstacles faced by individual companies, as reflected in the increasing number of companies registered to date. Third, on quality certification, Egypt confirmed that any certificate issued from an accredited entity would be accepted. He added that a copy of the certificate would equally be accepted if Egyptian authorities could access an electronic version on the database on accredited certification service providers. This flexibility was intended to facilitate registration. Fourth, on the power of the ministers to exempt manufacturing plants and trademark owners from the registration requirement, Egypt confirmed that this exemption would only be applied in emergency situations and to date had not been invoked. Finally, his delegation confirmed that Egyptian manufacturing plants and companies were also subject to registration surveillance and inspection requirements by numerous Egyptian regulatory authorities to ensure compliance with relevant regulations.

2.298. Egypt reiterated its belief that the registration requirement under Decree No. 43/2016 was not more trade restrictive than necessary and confirmed its commitment to being in full compliance with all articles of the TBT Agreement. Nonetheless, he invited delegations to initiate bilateral contact in case of any registration obstacles or delays.

2.2.3.41 Kenya — East African Community (EAC) alcoholic beverage standards (IMS ID 510)

2.299. The representative of the European Union reiterated support for Kenya and other Members of the East African Community in their efforts to achieve their legitimate objectives while respecting their WTO obligations. At the last TBT Committee meeting, the EU asked Kenya to notify a set of new technical regulations that had been adopted without prior notification to the WTO. These were causing significant problems to EU exporters of alcoholic beverages. Following that request, Kenya had notified these measures to the WTO and the EU had submitted comments on some of them. While not going into detail on the content of the nine sets of comments on the different technical regulations, she highlighted a common request that technical regulations for alcoholic drinks be aligned to the Recommendations of the OIV, including the International Code of Oenological Practices, and to the CODEX standard on Labelling of Prepackaged Foods (CODEX

[13] G/TBT/M/69, paras. 3.25-3.28.

STAN 1-1985). The EU believed that widely accepted international standards and practices correctly addressed Kenyan legitimate objectives. Based on the above-mentioned elements, the EU reiterated the provisions contained under Article 2. 4 of the TBT Agreement. The EU requested that Kenya provide an update on the revision process of these technical standards. The EU noted the next meeting of the responsible technical committee of the East African Community would take place on 28 November - 2 December 2016. She requested that Kenya ensure that the comments provided were transmitted to this technical committee so as to be taken into account in the revision process.

2.300. The representatives of the United States strongly supported the EAC's desire to protect its citizens and reduce the consumption of adulterated alcoholic beverages. The US recognized the importance to public health which these measures were intended to address and wished to collaborate with the EAC in the achievement of these goals through its own experience in the US. The US acknowledged the notification of the EAC alcohol standards in response to their request at the last TBT committee meeting in June. She thanked Uganda for the response to their written comments and urged Tanzania and Burundi to also notify these alcohol standards to the WTO. The US welcomed the news that several standards would be considered for possible revision during the next EAC review. However, the US requested continued technical engagement on the remaining standards which Uganda noted they did not intend to adjust. These standards were not in line with international practices. The US requested that the EAC Members provide the scientific rationale on which these regulations were based. Furthermore, the US requested that member countries consider regulatory approaches of other well-established trading partners. The US welcomed discussions with EAC members on finding a solution that could fulfil their legitimate objectives without unnecessarily restricting trade, such as greater alignment with standard international practices. If Tanzania, Kenya, and Burundi intended to adopt EAC standards on alcoholic beverages, the US asked for the opportunity to provide comments prior to finalization of the standards. The US has previously submitted comments to Uganda, Rwanda, and Kenya expressing the unnecessarily trade-restrictive impact of these standards. The US welcomed a response to their comments submitted to Kenya in August. She requested that a date or timeline be provided as to when the EAC would next meet to discuss revisions to the alcohol standards. The US reiterated its interest in the discussions as well as collaboration on standards and conformance through technical exchange and further discussions. The US urged EAC member states to notify new trade restrictive regulations while still under development in the EAC and prior to implementation to allow for meaningful consultation with trading partners in keeping with WTO commitments. She reiterated US interest in discussing Kenya's, Tanzania's and other EAC members' plans to implement alcohol standards.

2.301. The representative of Kenya stated that in July 2016, the Regional Harmonized Alcoholic Beverage Standard was notified the WTO. Subsequently Kenya had received comments from the delegations of the EU and US. Kenya explained that the EAC Alcoholic Beverage Standards were regional harmonized standards. Kenya had brought this STC and the comments provided by the EU and US to the attention of the EAC Secretariat. Kenya continued to explain that the EAC Alcoholic Beverage Standards were due for review. Consequently, the EAC Secretariat would soon be convening a Joint Regional Technical Committee meeting to discuss and share the comments that had been raised on the EAC harmonized Alcoholic Beverages Standards. At the national level, the Technical Committee on Alcoholic Beverage Standards would meet on 16 November 2016 to consider the comments raised by the EU, US and other Members of this Committee. The outcome of this national process would feed into the EAC consultative review process. Kenya was available for further discussions with the delegations of the EU, US and any other interested delegations so as to address their concerns.

2.2.3.42 European Union - Quality Schemes for Agricultural Products and Foodstuffs (IMS ID 512)

2.302. The representative of the United States noted that Denmark had applied for the registration of the name "danbo" and "havarti" as protected Geographical Indications (GIs) for cheese through the EU Quality Schemes for Agricultural Products and Foodstuffs. However, Codex had well-established and long-standing standards for these two cheeses – 50 years ago, in the case of "danbo", and 30 in the case of "havarti". She said these standards recognized these were common types of cheese that were traded internationally. The Codex standards had been adopted to facilitate quality and uniformity of these cheeses in the various countries producing them.

2.303. Although both applications were still pending, the US was concerned that, if granted, these GI registrations would result in the prohibition of the use in the EU of the two names for any cheese produced outside of Denmark. Accordingly, the US was concerned that approval of the applications under the Quality Schemes for Agricultural Products and Foodstuffs would effectively ban from the European market any common-name cheeses using the international compositional standards established by Codex. The US first enquired as to whether the applications related to these two names were approved within the EU. Second, she asked if the EU would seek to use international treaties to prohibit cheeses being sold in other markets from using the Codex-standardized terms on the products' labels, even if those cheeses conformed to their respective Codex standards.

2.304. Finally, her delegation understood the EU had considered and rejected less trade-restrictive means of implementing regulations pertaining to "danbo" and "havarti". For instance, the US said the EU could require the applications to be amended to cover only "Danish Danbo" or "Danish Havarti", while providing accompanying clear statements that products produced and labelled in accordance with the Codex standards for "danbo" and "havarti" could continue to be sold in the EU market. She requested that the EU explain its Quality Schemes for Agricultural Products and Foodstuffs as it related to these products, and clarify why those alternatives did not meet the EU's objective in this case.

2.305. The representative of the European Union explained that the procedure for granting of protection to the terms "Danbo" and "Havarti" as GIs in the European Union had not yet been finalized, as already indicated to the US bilaterally. Therefore, the EU had no further comments on this issue. Furthermore, the EU noted that the elements raised by the US delegation pertained to intellectual property rights, in particular to GIs. The EU believed that any issues concerning intellectual property rights would be more appropriate for discussion in the relevant Committee responsible for intellectual property, notably the TRIPS Council. In any case, the EU remained open to discuss this issue bilaterally with the US.

2.306. The representative of the United States recalled that the EU had notified this measure to the TBT Committee, which was the reason her delegation had raised this issue in the TBT Committee and not the TRIPS Council.

2.307. The representative of the European Union stated that this regulation had been notified to the TBT Committee because it included elements in addition to GIs, elements which were covered by the TBT Agreement.

2.308. The representative of the United States said the measure covered GIs, but also Codex standards which were pertinent to the work of the TBT Committee. The US stressed that Codex standards were relevant for the EU determination of whether to grant these GIs, which was why her delegation had chosen to raise this STC in the TBT Committee.

2.2.3.43 European Union — Directive 2014/40/EU on the approximation of the laws, regulations and administrative provisions of the member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (IMS ID 513)

2.309. The representative of Indonesia requested that the EU respond to its written enquiry sent the EU TBT Enquiry Point on 25 June 2016. EU member States were required to implement the EU Tobacco Directive into their local laws by 20 May 2016, and the majority had notified its national implementation measures to the EU Commission. Article 7(1) prohibited member States from placing tobacco products with a "characterizing flavour" on the market. The European Commission had adopted Implementing Decision 2016/786 on 18 May 2016 (the "Implementing Decision") to lay down the procedure for the establishment and operation of an independent advisory panel tasked with assisting EU member States and the EU Commission in determining whether tobacco products had a "characterizing flavour". Implementing regulation 2016/799 of 18 May 2016, issued by the European Commission, established uniform rules for the procedure to determine whether tobacco products had a characterizing flavour (the "Implementation Regulation").

2.310. Kretek, a traditional tobacco product, was an important Indonesian export product, with an export value of about USD 600 million a year. While Hungary had already taken steps to ban the

sale and import of Kretek into their territory claiming it was a tobacco product with characterizing flavour, the above-mentioned advisory panel had not yet been set up and the procedure to define what should be considered a characterizing flavour, set out in regulation 2016/799, had not been followed. For example, Article 4 requested that member States implementing the directive should inform manufacturers and importers that the concerned tobacco product was considered to have a characterizing flavour, initiating a dialogue on the product. In case of dispute, a referral of the information should be made to an advisory panel (Article 6 and 7). To the Indonesian Government's knowledge, no Indonesian manufacturer importing Kretek in the EU had been contacted by a member State or the EU Commission. The representative requested the EU to explain the legal basis for the ban on Kretek established by some EU member States.

2.311. Indonesia pointed out that Article 7.14 of directive 2014/40/EU stipulated that tobacco products with characterizing flavour whose EU-wide sale volumes represented 3% or more in a particular product category would only be subject to application of the Article 7(1) prohibition as of 20 May 2020. Indonesia believed this measure was tailored to menthol cigarette producers/importers. The vast majority of menthol cigarettes sold in the EU was produced domestically. Based on these facts, Indonesia stated its opinion that Article 2.1 of the TBT Agreement applied to Article 7.14 of directive 2014/40/EU, as the measure, in practice, exempted menthol cigarettes from the prohibition discussed in Article 7.14. Therefore imported Kretek was treated less favourably than domestic menthol cigarettes. Indonesia referred to the dispute DS406, in which the DSB concluded that a similar measure introduced in the US, prohibiting imported clove cigarettes while not prohibiting domestically produced menthol cigarettes, was inconsistent with the no less favourable treatment obligation in Article 2.1 of the TBT Agreement.

2.312. Similarly, Indonesia believed that Article 9 of the Implementing Decision was also inconsistent with Article 2.1 of the TBT Agreement. Article 9 imposed a specific methodology to determine "characterizing flavour", which was to be based on a comparison of the smelling properties of the test product with those of reference products. Indonesia considered that by restricting the methodology to smelling properties, and excluding tasting methodology properties, this provision inherently discriminated against Kretek. Kretek was, according to Indonesia, a different tobacco product category, typically composed of up to 40% clove. Clove was thus a fundamental part of the kretek cigarette. Regular cigarettes consumed in the EU could not be used as reference product to determine whether Kretek had a characterizing flavour.

2.313. The representative of the European Union stated that written comments received from Indonesia on this issue are currently under analysis and a reply on specific concerns on Kretek would be provided. The EU stated it preferred to discuss the Indonesian concerns at bilateral level and remained available for bilateral contacts.

2.2.3.44 Chinese Taipei — Draft of the Organic Agriculture Act, G/TBT/N/TPKM/225, (IMS ID 511)

2.314. The representative of the European Union thanked Chinese Taipei for notifying the Draft of the Agriculture Act on which it had sent comments on 2 February 2016. In these comments, the EU considered that clarity was needed on the scope of the proposed measure with respect to both its product coverage and process stage coverage. The EU also considered that the draft measure needed to include production and control rules on organic farming. In the EU's view, the most critical element of the proposed measure was Article 37, which stated that countries that had been recognized as having equivalence regarding organic imports before the notified draft was implemented would have to re-apply for recognition and that a new bilateral protocol or agreement would then have to be signed within one year of the implementation of the notified draft. If the one-year timeframe for signature was not respected, then the bilateral protocol or agreement with the third country concerned would be revoked by Chinese Taipei. The EU thus considered that the implementation period of one year did not allow trading partners sufficient time to re-apply for recognition and to conclude the required ratification process of the new bilateral protocol or agreement. In addition, the EU considered that the penalty imposed for exceeding the one-year timeframe was too strict. The draft measure in its current form would be more trade restrictive than necessary.

2.315. She noted that at the previous TBT Committee meeting, Chinese Taipei had not referred to a specific time-frame for the adoption of the measure and that at bilateral meetings it indicated that the measure could be adopted in the first half of 2017. The EU understood that the measure

was still under development and therefore renewed its request to Chinese Taipei to consider EU's comments and the possibility of a reasonable extension of the timeframe to re-apply for equivalence. In similar circumstances the EU granted a five-year extension. The EU asked how Chinese Taipei intended to take into account the comments and for an update on the current status and timeline for adoption of the notified measure. She also requested a written response to the submitted comments.

2.316. The representative of Chinese Taipei said that the draft was proposed to establish a specialized law for the management of organic agricultural products and to make the legislative framework clear and easy to understand. The draft was designed to address: (i) challenges arising from rapid changes to the domestic production environment of organic agricultural products; (ii) consumers' heightened expectations; and (iii) cross-border trade problems of Chinese Taipei organic agricultural products. He stated that the draft did not affect the implementation details; these were currently specified in the regulation entitled "management regulations for certifying organic agricultural products and organic agricultural processed products". He indicated that the coverage of products and process stages were prescribed in the regulations and he expressed willingness to provide a copy for EU's reference. He stated that the draft was under administrative review and his delegation currently had no update. The comments on the extension of the timeframe for concluding new bilateral equivalency agreements and others would be carefully considered. Chinese Taipei would continue bilateral discussions and consultations with interested Members on equivalency so that trade in organic agriculture products could benefit from the arrangements immediately after the adoption of the act.

2.2.3.45 Colombia — Draft Resolution of the Ministry of Health and Social Welfare and the Ministry of the Environment and Sustainable Development adopting the Technical Regulation establishing the maximum levels of phosphorus and the biodegradability of surfactants in detergents and soaps, and introducing other provisions, G/TBT/N/COL/214 and G/TBT/N/COL/214/Add.1, (IMD ID 506)

2.317. The representative of Mexico was concerned with certain aspects of the Colombian measure notified on 12 May 2016. She noted that Article 7 of the measure required the laboratory testing of surfactants' biodegradability contained in detergents and soaps, which could only be carried out in laboratories accredited by Colombia. Currently no laboratory had been accredited and this was not a practicable option for Mexico where approved laboratory tests were not designed to be conducted on the finished product. She also indicated that these requirements on testing surfactants' biodegradability of detergents as an end product were more restrictive than necessary to fulfil the measure's legitimate objective. As surfactant agents were the main component of detergents, in addition to an organic compound, this implied that the surfactants were also biodegradable substances and therefore the tests would be a redundant conformity assessment procedure.

2.318. Given the foregoing reasons, Mexico requested that Colombia reconsider the relevance of performing laboratory tests on soaps and detergents to determine the permitted biodegradability limits of surfactants, or allow for the recognition of tests that had been performed in other countries. Mexico also asked for an update on the status of the measure, since a version published in the Colombian Official Journal extended the scope to include cosmetic and hospital soaps and detergents in addition to the domestic and industrial products already covered. Mexico considered this version to be inconsistent with the Addendum 1 notified to the WTO. Finally, Mexico asked Colombia for a bilateral meeting to clarify the incompatibility of their regulations.

2.319. The representative of Colombia noted that Mexico had not informed its TBT contact point that it intended to raise this STC during this meeting. During the public consultation, Colombia had received comments from the Chamber and Association of the Industry of Personal Care and Home Care (CANIPEC), but not from Mexico. As the TBT Committee was an intergovernmental forum, Colombia asked comments to be made directly by Mexico. She noted that these comments had been transmitted to the Ministry of Environment and Sustainable Development and that this authority had published on its website a compendium of the replies to comments from the national and international public consultations.[14] The Administrative Decision had entered into force in

[14] http://www.minambiente.gov.co/index.php/atencion-y-participacion-al-ciudadano/consultas-publicas#comentarios

November and had been notified to the WTO. Colombia therefore asked other delegations to review this document and to submit comments on the measure through official channels.

2.320. This technical regulation had been developed on the basis of the National Quality Subsystem guidelines under which conformity assessment processes differed in complexity and cost depending on the risk they sought to mitigate. The draft standard selected first-party conformity assessment, which did not require a certifier or a third guarantor. Therefore, economic operators could produce evidence in their own laboratories or where they deemed appropriate. She explained that the technical regulation applied in Colombia to prevent the environmental and health impacts of non-biodegradable surfactants in detergents and soaps by ensuring that these products did not exceed the maximum limits of phosphorus and polluting substances that were not easily biodegradable. This measure had been agreed in consultation with producers and importers and she said that it had not been considered to be an unnecessary barrier to trade during consultations at the WTO.

2.321. Soaps only containing surfactants obtained from natural sources through saponification or neutralization of fats, oils, waxes, rosin or their acids of organic or inorganic bases were exempted from the biodegradability requirement, in accordance with the paragraph of Article 6 of Resolution 689 of 2016. With regard to the request to include the test methods listed in NMX Q 901 CNCP of 2015, Colombia could consider this proposal when Members agreed to work on bilateral or harmonization of sub-regional technical regulations. She highlighted that when the notified draft was revised and compared with Resolution 689 of 2016, no substantial differences were found and there was no extension of the scope of application. The tariff headings were the same and referred to all soaps and detergents with surfactants that pollute and exceed the maximum levels of phosphorous, regardless of their use.

2.322. She said that the measure was in harmony with European guidelines and that the Ministry of the Environment and Sustainable Development had received comments from domestic industry. Her delegation considered that these products had a global trend towards standards of hygiene and cleanliness associated with developed regions such as Europe. Also, consumers preferred products of plant origin because of concerns for the preservation of health and the environment. Colombia invited Mexico to review the measure and submit comments through official channels.

2.2.3.46 China — National Standards on Limits of Volatile Organic Compounds for Furniture, G/TBT/N/CHN/1094, G/TBT/N/CHN/1095, G/TBT/N/CHN/1096, (IMS ID 509)

2.323. The representative of the European Union thanked China for having notified these three standards which, because they were intended to become mandatory, were akin to technical regulations. The EU continued to have a number concerns, of which the most important were (i) the proposed "mandatory standards" included unnecessary deviations from well-known, international ISO standards. In case such standards became mandatory, products which were currently assessed on the basis international standards would have to be assessed for the Chinese market on the basis of specific tests; (ii) some of these specific tests required a complex and costly assessment, such as multiple test chambers and a new test chamber for mattresses; and (iii) there were significant doubts among industry about the relevance of the tests with regard to the presence of harmful elements to be measured – Total Volatile Organic Compound (TVOC) measured a sum of harmful and harmless substances - and also about the replicability of the tests.

2.324. It was noted that at the previous Committee meeting, China had indicated that deviations from international standards would be justified by realistic conditions of use. It was the EU understanding that the notified standards were still under development. The EU appreciated the openness of China in engaging with the relevant stakeholders with a view to revise the draft standard.

2.325. The EU understood that TVOC requirements would be applied on a voluntary basis and sought confirmation of this, as well as clarification about which parts of the standard would remain voluntary and which would be mandatory. In particular, the EU wished to know whether either the TVOC limits set out in the standards, or the testing methods and their annexes would be considered as voluntary, or both. Moreover, would this differentiation apply to all three notified draft standards? The EU also asked for information from the Chinese authorities about the

intended status, voluntary or mandatory, of the other limits and requirements included in the notified drafts (e.g. formaldehyde emissions).

2.326. The EU encouraged the Chinese authorities to accept equivalent international standards, in particular ISO standards, for the product categories covered by the notified drafts. Should China consider that the relevant ISO standards could be improved, the EU invited China to bring its proposals for discussion to the ISO as this would enable improvements to be considered without creating differences between Chinese and international standards and would thus avoid unnecessary barriers to trade. The EU also asked for a timeline for the adoption of the notified drafts.

2.327. The representative of China said that the EU's concerns appeared mainly to be on technical aspects, such as testing methods. Chinese experts had prepared the technical details on the procedure for how testing methods were determined, and, in bilateral meetings during the previous day, these had been conveyed to the EU delegation. It was stressed that the Chinese standards adopted the testing methods mainly based on international standards; they did not vary from international standards. There were several points in Chinese testing methods that could differ from international standards, but these were all designed to simulate realistic conditions for use so that the testing results would be more scientific. China had notified the three standards to the WTO in July 2015 and provided 60 days for comment. At the request of the EU, China had extended the comment period for one more month and had studied the EU comments carefully upon receipt. As stated above, answers had been conveyed and further discussions could be undertaken on a bilateral basis.

2.2.3.47 Peru — Implementing Regulations of 14 November 2012 for Moratorium on Planting Genetically Engineered Crops (IMS ID 392)

2.328. The representative of Mexico referred to the Peruvian Law establishing a ten-year moratorium on the entry into and production of living modified organisms on the national territory (Law No. 29811) that had been published in the Official Journal *El Peruano* on 9 December 2011. This law established a moratorium on the introduction into – and production of – Living Modified Organisms (LMOs) for the purposes of cultivation or breeding, including aquatic organisms, for release into the environment. The Regulation implementing this law had been published in the Official Journal *El Peruano* on 14 November 2012. In addition to preventing the entry, production and release of LMOs, the objective of Law No. 29811 included building national capacities, developing infrastructure and generating basic guidelines that allowed for the proper assessment, prevention and management of the potential impact of the release of living modified organisms (LMOs) into the environment. In this respect, the Mexican industry that produced hybrid maize (corn) had a number of concerns.

2.329. First, Article 4 "Accreditation" of the Law stated that "all genetic material that enters the national territory […] must be accredited as not being a LMO. If the material analyzed is shown to be an LMO, the Competent National Authority shall proceed to seize and destroy it and apply the appropriate sanctions". The Mexican seed industry had tested the fitness of seeds by means of production processes based on good management practices, quality assurance, and quality control systems, so as to ensure varietal purity and so as to facilitate the international seed trade. However, because of the very nature of the biological system, low-level unintended genetic impurities, including genetically modified events, could occur. At the same time, existing detection techniques had a certain margin of error that could produce false positives or false negatives.

2.330. The internationally recognized seed quality standards for identity and varietal purity were those established under the OECD and Association of Official Seed Certifying Agencies (AOSCA) seed schemes. Considering that a conventional seed might contain unintended low levels of genetically modified events (less than 2%), Mexico was concerned about the zero tolerance established in the regulations in question and the consequences of the unintended low-level presence of genetically modified events being detected in conventional seed, with the possibility of its being deemed to be an LMO and the shipment seized and destroyed or sanctions – which could amount to several million US dollars – being imposed on the exporter.

2.331. Mexico considered that this could constitute non-compliance with the provisions of Articles 5.1.2 and 5.2 of the TBT Agreement, since the conformity assessment procedure set out in the

Law represented an unnecessarily restrictive obstacle for the Mexican export industry – particularly because of the penalties that did not allow for the taking of corrective measures if the seed shipment was found to contain LMOs. In addition, establishing a zero tolerance for the identification of genetically modified events during the assessments carried out as a prerequisite for entering Peru meant disregarding the existence of less trade-restrictive alternatives which did not affect the fulfilment of the legitimate objective, such as the imposition of a threshold of 2% of genetically modified events. In view of the above, Mexico requested the following: (i) that Peru recognize the OECD and AOSCA purity standards and their certification as equivalent to the requirements imposed by the Law in question, in order to avoid GMO inspections at the border; (ii) where appropriate, consider recognizing non-LMO certificates issued by third–party laboratories that were certified by a recognized authority and accepted, by the standards of the Peruvian authorities, at the port of loading, instead of subjecting shipments to inspections at the border; (iii) promote bilateral dialogue with regulatory bodies that were studying the question of low LMO levels in batches of conventional seed, together with the determination of thresholds and detection technologies; and (iv) take into account the position of the Mexican seed industry and the positions of the other countries affected by the considerations of this conformity assessment procedure.

2.332. The representative of Peru said his country was considered to have a rich biodiversity with wide-ranging ecosystems and genetic resources. With regard to the trade concern expressed, Peru reiterated that the establishment of a moratorium on genetically engineered crops had been for a period of ten years. The regulation at issue was considered to be an environmental measure and therefore it did not need to be notified to the WTO under TBT Agreement's requirements – this was, he said, a law intended to protect biodiversity.

2.2.4 Exchange of Experiences

2.333. The moderators for the thematic sessions made the following reports:

a. Mr. Tim Ward (Australia) on **technical assistance** (G/TBT/GEN/205);

b. Mr. George Opiyo (Uganda), Ms Siti Mariam Mohd Din (Malaysia) and Mrs Jo-Anne Beharry (Trinidad and Tobago) on regulatory cooperation between Members (**Food Labelling**) in G/TBT/GEN/205; and,

c. Ms Esther Peh (Singapore, Chairperson) on the Information Exchange Meeting, including the thematic session on **transparency** (G/TBT/GEN/206).[15]

2.2.4.1 Topic of the next Thematic Session

2.334. The representative of Chinese Taipei suggested that the Committee organize a thematic session on the topic of Risk Assessment. The full proposal is contained in document JOB/TBT/211.

2.335. The representative of Indonesia proposed for following for the March Thematic Sessions:

a. to highlight the implementation of standards by SMEs;

b. a discussion on forestry issues, especially issues related to "timber legality" often used as an unnecessary barrier to trade. These barriers were caused by high standards and technical requirements aimed at reducing illegal logging and protecting the environment; and,

c. regulatory reform under the framework of good regulatory practices.

2.336. The representative of South Africa proposed that the Committee follow the same schedule of topics that had been proposed for the March 2016 meeting, that is: one thematic session on GRP and one on Conformity Assessment. With regard to GRP, South Africa welcomed Chinese Taipei's proposal and supported further discussions on risk assessment.

[15] A full summary report of this meeting is annexed to this report.

2.337. The representative of Canada supported Indonesia both with respect to a discussion on SMEs and standards as well as an examination on national forest management frameworks – the latter could be useful in exploring different ways Members achieve environmental objectives in the forestry sector.

2.338. The representative of China was open to discuss the issues mentioned; however, he noted that the TBT Code of Good Practice had been discussed less in the Committee and proposed more discussions with an emphasis on the Code and its acceptance by non-governmental standardizing bodies, pursuant to para 2.10.c of the Seventh Triennial review and para 7(a) of the Sixth Triennial Review.

2.339. The Chairperson noted that her intention had been to get a sense of the topics Members had an interest in, and not to come to any decision at the current meeting. She took note of the ideas expressed and announced her intention to make herself available for consultation with interested Members.

2.2.4.2 Other

2.340. The representative of South Africa requested that the Secretariat update document G/TBT/1/Rev.12 to include the recent decisions and recommendations.

3 TECHNICAL COOPERATION ACTIVITIES

3.1. The representative of ISO informed the Committee that the Actionplan for Developing Countries 2016-2020 was now being implemented. There were currently over 20 regional activities, to expand to 30 in 2017. There had been significant cooperation with the WTO secretariat and a number of other international organizations. A workshop on the theme of standardization and public policy in Singapore had been very well received. He thanked the WTO Secretariat which had given a very important contribution. The next event would take place in Uruguay where the WTO Secretariat would also contribute. Further details were available on the ISO website.[16] He further informed the Committee that at the September ISO General Assembly, one of the key themes was the SDGs and the role of standards. There was much focus on the cooperation with international organizations in achieving these objectives. For the first time, the World Bank gave the keynote speech in the DevCo meeting where they addressed the role of standards in support of SDGs in developing countries.

3.2. The representative of the IEC informed the Committee that the IEC Regional Centre for Africa had visited a number of IEC members and affiliate countries providing support to the national committees of Cameroon, Benin, Burundi Mali, Mauritania, Niger, Democratic Republic of the Congo, Rwanda, Tanzania, Togo, and Uganda. The Latin American Regional Centre had visited Chile and Peru to offer training to technical experts and government authorities. On Conformity Assessment, the IEC in collaboration with COPANT (the Pan-American standards commission) PTB (the German national metrology institute) and INTECO (the Costa Rican national standards institute) would hold a workshop at the end of November on the topic of IECEE conformity assessment schemes increasing participation in international standardization, and electrical installation codes. This event was targeted towards regulators, standardization and certification bodies in the region.

3.3. The Secretariat made available a document on the TA activities contained in G/TBT/GEN/212.

4 UPDATING BY OBSERVERS

4.1. The representatives of UNECE, OECD, CROSQ, IEC, and OIML updated the Committee on their activities. [17]

4.2. The representative of ISO reminded the Committee of the importance of the role of standards in supporting the SDGs. Some recent developments in this area included ISO TC 268 on Sustainable Cities and ISO TC 282 on water re-use. Recently published standards included those

[16] http://www.iso.org/iso/iso_action_plan_2016-2020_en_ld.pdf
[17] G/TBT/GEN/207, G/TBT/GEN/208, G/TBT/GEN/209, G/TBT/GEN/210, G/TBT/GEN/211

on Evaluation of Energy Savings and Anti-bribery Management Systems. A standard on Sustainable Procurement Guidelines (ISO 20400) would be published in early 2017. He highlighted the Industry Workshop Agreement (IWA) which had proven to be a very important instrument in the early stages of development of a standard. He gave the example of IWA 11 on Clean Cook Stoves which had evolved into the ISO TC 220. A US initiative on next generation toilets in IWA 24 had also evolved into ISO TC 305: Sustainable Non-sewered Sanitation System. Finally he mentioned a document under development in IWA 20 on understanding and applying drip irrigation for sustainable agriculture which was supported by Israel and Sweden.

4.3. The representative of South Africa encouraged Members to review the list of pending observer requests as contained in the document G/TBT/GEN/2/Rev.12.

5 REPORT (2016) OF THE COMMITTEE ON TECHNICAL BARRIERS TO TRADE

5.1. The Committee adopted its 2016 Report to the Council for Trade in Goods (G/L/1167).

6 DATE OF NEXT MEETING

6.1. The next regular meeting of the Committee is scheduled for 29-30 March 2017. The full schedule of meetings is contained in JOB/TBT/212, issued on 25 November 2016.

ANNEX

SUMMARY REPORT OF EIGHTH SPECIAL MEETING

ON PROCEDURES FOR INFORMATION EXCHANGE

Pursuant to its decision to hold, on a biennial basis, "regular meetings of persons responsible for information exchange, including persons responsible for enquiry points and notifications"[1], the TBT Committee held its Eighth Special Meeting on Procedures for Information Exchange on 8 November 2016.[2] The Special Meetings are organized to provide Members with an opportunity to discuss issues relating to information exchange and to review periodically the functioning of notification procedures and the operation of enquiry points. The meetings are also used to follow up on decisions and recommendations agreed by the TBT Committee during its triennial reviews. The Eighth Special Meeting was organized in three panel sessions dealing with (i) online tools; (ii) functioning of enquiry points; and (iii) transparency in standard setting.[3]

These panel sessions were preceded by the official launch of ePing, a new global alert mechanism for TBT and SPS notifications, put together jointly by the WTO, ITC and UNDESA. This notification alert mechanism originated in the mandate given to this Committee in the 7th Triennial Review[4], and responded to a need to facilitate businesses, especially SMEs, in complying with TBT and SPS requirements by enhancing transparency. At the launch, the representative of UNDESA[5] focused on the need to invest in sustaining the ePing initiative and further strengthening the tripartite cooperation. He underscored the importance of ePing in light of the Sustainable Development Goals (SDGs), especially SDG 17 on global partnerships. The representative of the WTO[6] emphasised how enhanced transparency of SPS and TBT regulations could help foster inclusive trade and the contribution that ePing would make to that goal. The representative of the ITC[7] highlighted the significance of ePing in light of the increasing number of SPS and TBT regulations disproportionally affecting SMEs. All three representatives underscored the successful and productive cooperation between the three organizations and the importance to keep working together to make sure that ePing reached its full potential.

1 ONLINE TOOLS

1.1 Tracking, responding and involving stakeholders

1.1. The representative of the Secretariat introduced the newly-launched ePing system by recalling that this online tool facilitated the dissemination of SPS and TBT notifications from the WTO to the public and private sector and provided communication tools, at the domestic and international level. The system aimed to enhance the awareness and understanding of SPS and TBT measures and to foster or increase cooperation among stakeholders, ultimately facilitating market access and avoiding trade disruption. She highlighted the most prominent feature of ePing, notably the email alert service, which enabled stakeholders to subscribe to receive daily or weekly email alerts listing notifications targeting products and/or markets of interest, rather than having to browse all SPS and TBT notifications. Other features of the system were explored, including the easy-to-use search table, the possibility to download word versions of notifications as well as full texts of regulations or translations, export search results to an excel file, and save search filters. The system included both SPS and TBT notifications, and was available in the three official working languages of the WTO. An additional element of ePing was the Enquiry Point Management tool which afforded Enquiry Point officials access to an additional set of functions allowing them to monitor national activity and to customize several features. Features of interest included: access to a list of all domestic subscribers; creation of contact groups; possibility to activate or deactivate domestic fora and the file sharing option at national level. The Secretariat representative then

[1] G/TBT/1/Rev.10, page 35.
[2] The programme for the Special Meeting is contained in JOB/TBT/207/Rev.1.
[3] Presentations made during the sessions are available on the TBT gateway page on the WTO website: https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm
[4] On on-line tools, Members agreed to "request the Secretariat to explore the development of an export alert system for TBT notifications, in cooperation with other organizations" (G/TBT/37, para. 5.12).
[5] Mr. Lenni Montiel, UN Assistant Secretary-General.
[6] Mr. Karl Brauner, WTO Deputy Director-General.
[7] Ms. Arancha González, ITC Executive Director.

underlined that ePing was globally available and free of charge but that training and capacity building should be promoted at the domestic level to ensure that it could reach its full potential. In this context, the three organizations participating in this initiative, the UN, the WTO and ITC, had already committed to including ePing training in existing capacity building activities, and, depending on available funding, additional activities would be set up. She concluded by underlining that the cooperation between the three organizations had been formalized through a Memorandum of Understanding, signed at the highest level, and subject to review within five years.

1.2. She proceeded to introduce the TBT-IMS modernization project currently being undertaken by the Secretariat, the TBT-IMS being a comprehensive database including all TBT notifications and TBT-related documents. The project focused on two objectives: making the system more user-friendly and creating more linkages between different sources of information. Amongst new improved features was the function of searches now being able to retrieve all related notifications, corresponding addenda, corrigenda and STCs. In addition, users could now search STCs by meeting and year; search full documents using keywords; and benefit from improved and more intuitive navigation buttons. She reported that a pilot version of the updated TBT-IMS was currently available and in a testing phase. Members were invited to use the test website and to share comments by the end of November in advance of the replacement of the current system scheduled for December.

1.2 Piloting and ongoing implementation of the WTO TBT/SPS Notification Alert System (ePing) in Uganda

1.3. The representative of Uganda[8] presented his delegation's experience as part of the ePing pilot project. He first recalled the mechanism to disseminate notifications prior to the introduction of the ePing system. He underlined the main challenges of the old notification system, notably the weak communication link between members of national TBT/SPS Committee and stakeholders in relevant sectors, as well as the difficulty of accessing pertinent notifications. He then outlined the phases of transition from the current notification system to implementation of the ePing system. He presented an overview of all the ePing-related events attended by Uganda and emphasized the lessons learnt from piloting and ongoing implementation of ePing, such as the need to address long-term sustainability and the need for more time to cover all ePing-related topics. Finally, he announced Uganda's proposals for promoting ePing, such as the introduction of an agenda item on ePing in regular meetings of national TBT/SPS Committee and the need for more training, promotion and awareness after the launch of the ePing system by the WTO Secretariat.

1.3 The TBT IMS and ePing in Korea

1.4. The representative of the Republic of Korea[9] outlined the structure of its TBT enquiry point, the Korean Agency for Technology and Standards regarding TBT issues ("KATS"), the hub of which is the Korean Information Management System for TBT Notifications known as Korean Network on World TBT ("KNOWTBT"). KNOWTBT mainly acted as a comprehensive channel including support services for stakeholders to track and respond to TBT notifications. She summarized the role of related public and private actors, focusing on the Korean procedure for its response system to TBT issues.

1.4 Enhancing business and government engagement through information exchange in Australia

1.5. The representative of Australia[10] stressed the need to address non-tariff barriers (NTBs) as a matter of priority. She underlined the benefits of ePing in terms of improved transparency, consultation and accountability, all of which facilitated trade and which benefitted public agencies and private stakeholders alike. She described how the Australian Government was promoting ePing via various tools and events during which its benefits were stressed (e.g. enhanced information about product requirements and the contribution to the regulatory development process). Finally, she referred to the Australian multi-stage approach towards NTBs and flagged some ideas to further enhance information exchange among Members.

[8] Mr. George Opiyo, TBT Enquiry Point.
[9] Ms Changin Ha, TBT Unit, Korea Conformity Laboratories.
[10] Ms Sophia Vincent, Department of Foreign Affairs and Trade.

1.5 The EU's experience in relation to involving stakeholders (private and public sector) in the processes of tracking and responding to TBT notifications of other Members

1.6. The representative of the European Union[11] started off by showing the extensive involvement of stakeholders in TBT issues and the increasing number of notifications in the last decade. He outlined how the EU had dealt with this increase, presenting the motives for and the objectives of the ad hoc TBT web platform (EC-TBT website). He explained in detail how the platform works and how the system had been made known to stakeholders. Finally, he focussed on third country notifications, highlighting the comments procedure and the tight cooperation between the European Commission and stakeholders.

1.6 Transparency and the Philippines

1.7. The representative of the Philippines[12] underlined the importance of the "Philippine National Trade Repository" in its government's trade facilitation strategy. This web-based portal contributed to a more transparent trade environment, which would allow businesses easier access to information as well as the facilitation of compliance with prescribed regulations. Underscoring the importance of Good Regulatory Practice (GRP), she outlined ongoing actions engaged by the Philippines, such as the creation of an oversight body that would review regulatory impact assessments. Finally, she took the example of the Philippine food sector to show how the use of technology could facilitate transparency in this area of regulation.

1.7 Experience of the USA TBT Enquiry Point Using a Notification Alert Service to Engage with Domestic Stakeholders

1.8. The representative of the United States[13] outlined the various functions of the US TBT Enquiry Point and spoke about the benefits of the web-platform "Notify US" (i.e. receiving e-mail notifications of drafts or changes to technical regulations from WTO Members). She underlined the extensive use of the alert service throughout the US and concluded by referring to the new ePing alert service and suggested that as usage inevitably increased, challenges to stakeholders could be addressed by, *inter alia*, providing the full texts of new technical regulations when notified.

1.8 Discussion

1.9. The representative of Malaysia asked how long it had taken Australia to fully transition from the old system to ePing.

1.10. The representative of Australia replied that since the inception of the pilot phase, it had taken 12 months before being able to stop using the IMS system in a manual way to alert stakeholders. The relatively long timeframe was attributable to the challenges faced in not leaving anyone behind during this transition phase.

1.11. The representative of Trinidad and Tobago noted that when they submitted notifications, they generally sent a link to the full text but despite this were always then asked to send the full text separately. She asked whether there was an advantage to the latter and whether there were any implications for copyright.

1.12. The representative of the United States remarked that their enquiry point also received numerous requests for full text notifications, which often led them to think that they had forgotten to include the relevant link. She suggested that it would be worthwhile checking that these links did in fact work and pointed out that any documents provided to the Secretariat would then be permanently available. She then noted that sometimes Members cited international standards which were indeed copyright protected and that in such cases, it would be advisable to add a note to that effect, to name the standard, and, where possible, provide a link to where it could be purchased.

[11] Mr. Alessandro Polito, European Commission – Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs.
[12] Ms Ann Claire Cabochan, Director of Bureau of International Trade Relations.
[13] Ms MaryAnn Hogan, U.S. Inquiry Point, National Institute of Standards and Technology.

1.13. The representative of the Secretariat confirmed that two scenarios were current practice: the notification either contained a link to the full text on a server in the Member country, or to a WTO server, when a pdf copy of the full text had been provided.

1.14. The representative of Australia noted with interest how different Members operated their enquiry points. She asked if the US Enquiry Point operated with its trade ministry in matters relating to notifications and comments, as was the case in Australia, or whether these matters were dealt with solely within the enquiry point itself.

1.15. The representative of the United States responded that its enquiry point was essentially a facilitator of communications, ensuring that everything that needed to be notified was notified and that on receipt of a foreign comment, all interested parties were made aware. The US Enquiry Point made information available to both industry and government but did not coordinate with the trade agencies on developing comments unless specific technical questions could be addressed. Based on information received from the US Enquiry Point, USTR was then able to coordinate with industry to develop positions for WTO TBT Committee or for bilateral engagements.

1.16. The representative of Uganda, referring to the need for links to full texts, noted that his enquiry point was in the habit of sending a draft text to the Secretariat, who would provide a link to the text on disseminating the notification. On dissemination, his enquiry point would then check to confirm that the link was working. In spite of this, his enquiry point received frequent requests for the full text. He therefore suggested that domestic stakeholders should be encouraged to check links contained in notifications in order to obtain draft text, in the absence of which an enquiry point or notification authority should then be contacted.

1.17. The representative of Brazil recalled that Uganda's presentation had nicely summed up the definition of a relevant notification: a combination of relevancy of product and of export destination. He therefore asked the Secretariat whether ePing allowed for cross-referencing of HS codes and trade data either from national databases or directly from the WTO.

1.18. The representative of the Secretariat confirmed that upon registration, ePing allowed subscribers to identify HS and ICS codes and free text products, as well as markets of interest. Henceforth, whenever a notification matched either one or both of those criteria, it would be sent to the user via the email alert system.

1.19. The representative of CARICOM Regional Organization for Standards and Quality (CROSQ) asked what challenges SMEs encountered in reacting to notifications and how these challenges were overcome to enable to better participation in the multilateral trading system.

1.20. The representative of Uganda observed, in this respect, that there seemed to be certain gaps in terms of the capacity of SMEs to analyse some of the technical texts referenced in notifications. He suggested helping these SMEs to build capacity in order to be able to perform this sort of analysis, or to bring trade lawyers on board on a needs basis in order to provide comments on notifications.

1.21. The representative of Australia underlined that SMEs constituted a major part of its domestic market – over 95% of all businesses – and were therefore of prime importance in the development of trade policy. To ease the burden that SMEs may face in participating in, and tracking, government and consultation processes, she suggested two adjustments: (i) to start including ePing in training programmes to increase awareness; and (ii) to use industry associations such as the Export Council of Australia to alleviate some of the burden by analysing trade barriers on behalf of SMEs.

1.22. The representative of the ITC voiced support for the positions of Australia and Uganda that access to information was a problem and suggested that in this regard ePing could be beneficial. In addition, understanding the information itself could also prove difficult. He noted that not only was the absence of linguistic translations sometimes a problem, but also the translation of the legal language of notifications into business language that would make sense to SMEs. His suggestion was that SMEs could work with enquiry points in this respect and that business associations should also contribute to such capacity building.

1.23. The representative of Canada acknowledged the positive aspects of ePing, to which it had registered, which included the user-friendly interface, the logical placement of icons, and the rapidity of becoming acquainted with the system. She considered the automatic email alert of utmost use, especially the possibility to customize it by product and export market, as pointed out by Uganda. She also welcomed the very efficient search filters, which she deemed superior to other engines used to search SPS and TBT-related material.

1.24. The representative of Senegal asked whether the US Enquiry Point submitted notifications on behalf of the US or whether it was the Notification Authority. He envisaged a potential problem of coordination and sought information on the situation in the US between the two bodies.

1.25. The representative of the United States replied that the US Enquiry Point and Notification Authority happened to be in the same place and staffed by the same people and therefore coordination was not an issue. In cases of borderline measures, contact was made with the office of USTR to review the measure but no formal coordination was needed.

1.26. The representative of Trinidad and Tobago added to Senegal's query by explaining that its enquiry point was housed at the Bureau of Standards. The enquiry point was charged with preparing notifications, and then sending it through its notification authority, the Ministry of Trade and Industry, who in turn submitted it to the WTO via the Geneva-based mission. This process posed a problem in that once the notification left the enquiry point, it was hard to know when it would be submitted to the WTO and could sometimes take 28 days, in turn hampering the 60-day comment period. In this respect, the newly developed NSS removed such time constraints as notifications were sent directly to the WTO.

1.9 Submission of notifications

1.27. The representative of the Secretariat updated the Committee on the TBT Notification Submission System (TBT NSS), the online platform for Members to prepare and submit TBT notifications to the WTO. He noted with pleasure that Members' use of the TBT NSS had increased every year since the end-2013 launch of the system. To illustrate this point, he reported that in 2014, 35% of all TBT notifications were submitted through the TBT NSS, and from 23 Members; in 2015, figures were up to 52% of notifications, by 26 Members; and in 2016, 61% of notifications for 33 Members. Whilst a total of 38 Members had already signed up to use the system, it was hoped that this number, as well as the share of notifications received via the TBT NSS, would both further increase. The benefits of such an increase would be two-fold: from the Secretariat's point of view, the use of the NSS facilitated the processing of notifications, in terms of speed (four times faster, with obvious implications for respecting the comment period) and accuracy; for Members using the system, feedback had shown that the tool helped towards the organization and tracking of submitted notifications, also facilitating coordination between ministries. He concluded by urging more Members to sign up to this online system.

1.28. The representative of Canada reported that its enquiry point had been using the NSS for three years and recognized the value and reliability of the tool. She outlined the benefits in terms of faster processing of notifications by the Secretariat, which in turn gave Members more time to become informed and for interested parties to submit comments. Canada's specific situation as a bilingual country with two official languages was adequately contemplated by the system. There were, nonetheless, some disadvantages, such as the rejection by the system of certain characters as well as the absence of a mechanism to withdraw a notification in case of errors or omissions. Her delegation looked forward to continued improvements to the system based on feedback from interested parties.

1.29. The representative of the United States highlighted the benefits of the NSS over the old method of emailing word documents to the Secretariat. Responding to concerns raised by Senegal, as well as by Uganda in the past, she addressed the issue of coordination between one or two agencies before notifying. In this respect she noted the possibility of applying for more than one password to allow for coordination between multiple agencies. In effect, templates could be put on hold, allowing another agency to review prior to submission.

1.30. The representative of the European Union, despite a general view that the system worked well, expressed a few reservations. He said that when texts were too long, or contained many

images, they had to be sent in parallel, by email. He also requested that the Secretariat inform Members in advance on which days the WTO would be closed in order to plan ahead and respect 60-day transparency obligations.

1.31. The representative of Kenya welcomed the faster and reliable NSS system. On the issue of coordination, he stated that once the enquiry point had completed the preparation of the notification, their notification authority was alerted that they could notify immediately, thus removing the challenge of delays to processing.

1.32. The Chairperson wrapped up the session on online tools by encouraging Members to: (i) test the modernized TBT-IMS; (ii) start using ePing and the NSS; and (iii) look at the job document overviewing online tools.[14]

2 FUNCTIONING OF ENQUIRY POINTS [15]

2.1 Internal coordination and handling of comments

2.1. In the Seventh Triennial Review, the Committee had recommended continuing discussions on the role of enquiry points in facilitating internal coordination and in the handling of comments and exploring ways to improve their functioning.[16]

2.1.1 The EU's experience in relation to the role of enquiry points in facilitating internal coordination and in the handling of comments

2.2. The representative of the European Union[17] presented the functioning of the TBT notification procedure within the EU. He outlined the internal procedure within the European Commission services for the notification of new EU draft technical regulations, also recalling the obligations of EU member States when notifying new national technical regulations to the Commission. He concluded by pointing out that in case of comments from third countries the reply would come directly from the EU, as per the European common external trade policy.

2.1.2 Chinese Taipei: Building Constructive Working Relationship with Regulators

2.3. The representative of Chinese Taipei[18] outlined the objectives of its national TBT Enquiry Point. She then indicated the various regulatory authorities involved in the notification process, and the ways its Enquiry Point maintained connections between them via preparatory work before WTO TBT Committee Meetings (e.g. overviews of STCs or the review of notifications already submitted) and the delivery of seminars on transparency. Finally, she highlighted how the national Enquiry Point enhanced coordination among regulators.

2.1.3 Discussion

2.4. The representative of Switzerland said that having a unit within its administration screening all legislative projects, assessing relevancy for trade and TBT, and ensuring notification took place, was equally possible in the European Commission and Switzerland. He asked whether other Members had something similar in place to ensure consistency with TBT notification obligations.

2.5. The representative of South Africa said that a list of contact persons in different regulatory departments should be maintained. He asked whether Chinese Taipei maintained a contact list presenting just one contact person, or the contact point of each regulatory division in that department.

2.6. The representative of the United States asked what would happen if ever a regulator did not want to notify a measure, for example if there was low awareness. She asked whether in such a case Chinese Taipei would provide assistance.

[14] JOB/TBT/210.
[15] G/TBT/37, para. 5.12.
[16] G/TBT/37, para. 5.12.a.i.
[17] Mr. Alessandro Polito, European Commission – Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs.
[18] Ms Chuan-Shu Cha, Bureau of Standards, Metrology & Inspection.

2.7. The representative of Uganda added that it was a challenge to empower notification authorities and enquiry points to be able to identify draft regulations that probably met notification requirements.

2.8. The representative of Malaysia asked whether Chinese Taipei had encountered instances of duplication of a regulation, or whether there was ever a "no-man's land" with no regulation regulating that area.

2.9. The representative of Australia asked whether in workshops and seminars, regulators were educated in following, receiving, and making comments on notifications. She was interested in knowing to what extent regulators became involved in the comment-making process and whether most comments came from regulators, stakeholders or from ministries.

2.10. The representative of South Africa explained their system of coordination. A domestic TBT committee brought regulators and technical quality infrastructure bodies together to share experiences, normally just prior to TBT Committee meetings in order to discuss the annotated agenda and STCs. For the notification of draft regulations, regulators always mentioned that their mandate was under a specific act of parliament or legislation. The response of South Africa would always be that a notification authority was a country and therefore a Member of WTO, and as such all regulators were indirectly WTO Members, having to comply with TBT obligations.

2.11. The representative of Canada underlined the importance for trading partners of the work of enquiry points in collecting and disseminating information. This ensured that observations made by Members on notifications were dealt with efficiently. She then outlined the process of dealing with comments within the Canadian authorities.

2.12. The representative of Chinese Taipei in response to South Africa said that they had 15 regulatory authorities and just one contact person for each regulator, the person responsible for internal coordination (so 15 contact persons). On resistance to notify, she said that in such cases they would give assistance by showing the regulator similar notifications made by other Members to help persuade them of the necessity to notify. On possible duplication of notifications, she answered that when regulators notified, they would know if there was any duplication or not and therefore there were no such cases. Nor were there any cases of areas with no regulations in place. On Australia's question, she replied that all regulators participated in seminars during which they would be provided with samples of formats for commenting. She confirmed that most comments came from regulators.

2.2 Capacity Building and Training

2.13. In the Seventh Triennial Review, the Committee had recommended exploring ways to improve the functioning of the Enquiry Points by addressing capacity building needs of developing Members.[19] Members had also requested the Secretariat to prepare a guide on best practices for enquiry points based on experiences shared by Members and for the purposes of training and capacity building.[20]

2.14. The representative of the Secretariat updated the Committee on the status of the Enquiry Points guide, which was being developed in response to the mandate of the Seventh Triennial Review.[21] She recalled that an online survey of enquiry points had been developed, which would be used to gather information to assist in the preparation of the guide, scheduled for conclusion during 2017, and that it was available online for completion by Members' Enquiry Points. Information on how to participate in the survey was available in the room document on TBT Online Tools.[22] She reported that to date, 32 Members had requested their password for the survey, 10 of whom had completed it. The Secretariat looked forward to greater participation from Members, and encouraged those who had not done so to complete the survey.

[19] G/TBT/37, para. 5.12.a.i.
[20] G/TBT/37, para. 5.12.a.ii.
[21] G/TBT/37, para. 5.12(a)(ii).
[22] JOB/TBT/210.

2.2.1 US Technical Assistance to TBT Enquiry Points and Notification Authorities in Africa

2.15. The representative of the United States[23] presented the African countries benefitting from technical assistance provided by Standards Alliance, explaining the main focus as being capacity building for enquiry points and notification authorities. The development of customized action plans was aimed at improving the effectiveness of these bodies, mainly in terms of enhanced communication with stakeholders and promotional events. Finally, she detailed the key elements of subsequent on-site training.

2.2.2 Discussion

2.16. The representative of Australia asked whether capacity building events included SPS enquiry points and how other donors of technical assistance explained the differences between SPS and TBT.

2.17. The representative of Kenya expressed appreciation for the in-depth training received from the Standards Alliance which had enabled them to set up a notification alert system similar to ePing.

2.18. The representative of South Africa pointed out that its TBT enquiry point officials had a wide range of backgrounds, from lawyers to librarians to administrators, and asked the US what they considered an appropriate qualification for such a task. On this point, the representative of Australia shared their experience that attention to detail and document management were critical, as well as knowing who and how to consult so that all relevant experts could provide input.

2.19. The representative of Brazil asked whether capacity building activities only covered assistance in preparing notifications or whether it also helped countries to understand and comment on third party notifications.

2.20. The representative of Senegal commented on the elaborate nature of the action plans described by the US in their presentation and asked what the deadlines and timing were in drawing them up.

2.21. The representative of Malawi, a beneficiary of the Standards Alliance programme, said that the activity had improved awareness of TBT to stakeholders in both private and public sectors. In particular they had realised that an enquiry point could be run by relatively few people, an important point for a smaller economy like Malawi.

2.22. The representative of Canada informed the Committee of its intended capacity building activities with a standards-setting body in Trinidad and Tobago which would consist of representatives visiting the Canadian notification authority and enquiry point to observe operations in order to boost transparency, conformity and good regulatory practices. Other elements of training would examine the national quality infrastructure, the development of technical regulations, and conformity assessment procedures.

2.23. he representative of Canada informed the Committee of its capacity building activities with a standards-setting body in Trinidad and Tobago which would consist of representatives visiting the Canadian notification authority and enquiry point to observe operations in order to boost transparency, conformity and good regulatory practices. Other elements of training would examine, inter alia: legislation, legal documentation required to implement technical regulations, calculation of costs and benefits of technical regulations, and conformity assessment procedures.

2.24. The representative of the United States replied that the scope of their agreement only covered TBT-related assistance but that future events would target SPS enquiry points. On the question related to appropriate qualifications for working in an enquiry point, she said that she was herself a librarian by training and that this served well in dealing with the documents and metadata involved. On the scope of capacity building activities, she replied that the bulk of activities were related to the preparation and submission of notifications but that an equally

[23] Ms Leslie McDermott, Director, International Development, American National Standards Institute.

important element was the discussion of stakeholder engagement and national coordination, as was preparing support for national level committees. During these activities, best practices were shared in order to produce effective comments. On Senegal's question on action plans, she replied that timelines were relatively short as they were developed in one to two months, followed by onsite training as soon as possible after conclusion. This timeline could vary depending on levels of coordination and communication.

2.25. The Chairperson underscored the importance of education and training in raising awareness and in enhancing the functioning of enquiry points.

3 TRANSPARENCY IN STANDARD SETTING[24]

3.1. In the Seventh Triennial Review, consistent with paragraphs J and L of the Code of Good Practice, the Committee had encouraged Members' central government standardizing bodies and non-governmental bodies which had accepted the Code to (i) publish their work programmes on websites and notify the specific website addresses where the work programmes are published to the ISO/IEC Information Centre; and (ii) share information about the publication of a notice announcing the period for commenting on a draft standard.[25] The Committee had also recommended discussing ways of improving Members' access to the information on the above-mentioned points concerning transparency in standard setting.[26]

3.1 Japan's Action following the 7th triennial review -Transparency in standard-setting

3.2. The representative of Japan[27] highlighted some problems encountered in using the "WTO TBT Standards Code Directory". He then recalled some of the outcomes of the 7th triennial review, such as the recommendation to share information about the publication of notices announcing the comment period on a draft standard, or discussion on ways of improving Members' access to relevant information. He then explained how the Japanese Industrial Standards Committee planned to implement those recommendations, in particular the possibility offered by the new system to notify the specific website addresses where the work programmes were published to the ISO/IEC Information Centre.

3.2 WTO-ISO Standards Information Gateway

3.3. The representative of the Secretariat updated the Committee on the WTO's collaboration with the International Standardization Organization (ISO) on the WTO-ISO Standards Information Gateway. He recalled that in pursuance of a recommendation made by Ministers in a 1994 Marrakesh Ministerial Decision, in 1995 the Secretariats of the WTO and ISO had entered into a MoU establishing the "WTO Standards Information Service" to be operated by the ISO Central Secretariat. This service was intended to provide information about: standardizing bodies that had accepted or withdrawn from the Code of Good Practice[28]; and the work programmes these bodies must publish at least every six months.[29] Specific notification templates had been drawn up both for notifications of standards to the ISO directly, but also to the WTO. ISO had since published information annually on this, regularly noted by the Committee at its March meetings.

3.4. He stated that in retrospect, while the notification requirements for technical regulations and CAPs had functioned very well, in general less information about *standards* was available. This could be attributable to the difference between notification requirements for technical regulations (and CAPs) and those for standards. In this respect, he highlighted three recommendations currently before the Committee with respect to transparency on standard-setting contained in its 7th Triennial Review:

a. encourage Members' central government standardizing bodies, and non-governmental bodies that have accepted the Code, to publish their work programmes on websites and

[24] G/TBT/37, para. 4.10.
[25] G/TBT/37, paras. 4.10.b.i and 4.10.b.ii.
[26] G/TBT/37, para. 4.10.b.iii.
[27] Mr. Takatoshi Yamamoto, Office for Economic Partnership for Standards and Conformity Assessment & JISC Secretariat, Ministry of Economy, Trade and Industry.
[28] TBT Agreement, Annex 3, Para. C.
[29] TBT Agreement, Annex 3, Para. J.

notify the specific website addresses where the work programmes are published to the ISO/IEC Information Centre (paragraph J);

b. encourage Members' central government standardizing bodies, and non-governmental bodies that have accepted the Code, to share information about the publication of a notice announcing the period for commenting on a draft standard (e.g. title and volume of publication, website address) (paragraph L);

c. to discuss ways of improving Members' access to the information mentioned in the above paragraphs.

3.5. He announced that as part of this process, and spurred by these recent recommendations, discussions with the ISO Secretariat had been set in motion on how to enhance the service to Members. To this effect, a new gateway for this information had been developed by the ISO[30], setting out information on standardizing bodies that had accepted the Code of Good Practice and, where available, their work programmes. It also contained the WTO forms for the acceptance, withdrawal and notification of work programmes. With respect to hyperlinks to the source of this information, it had become apparent that it was often too general (i.e. link solely to homepage) or outdated (pdf files); moreover, sometimes links were broken. Members' central government standardizing bodies and non-governmental bodies were therefore encouraged to review information about their work programmes and to provide any corrections directly to the ISO.[31]

3.6. The representative of the United States reported issues with ISONET with respect to the working of the website as ANSI had not been able to notify to ISONET for several years due to, inter alia, broken links. She asked if other Members had encountered similar problems, and if so, how they were submitting their work programmes to the information centre.

3.7. The representative of ISO expressed his organization's satisfaction with the collaboration with WTO. He reported on the joint-resource database that had recently been developed to enhance the sharing of information on standards: https://tbtcode.iso.org/. His organization made themselves available to the standardization community for any support necessary in the use of this service.

[30] https://tbtcode.iso.org
[31] tbtcode@iso.org