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Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 15-16 JUNE 2016

CHAIRPERSON: MS ESTHER PEH

Note by the Secretariat¹

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1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in WTO/AIR/TBT/5.

2 ELECTION OF THE CHAIRPERSON

2.1. The Committee elected Ms Esther Peh (Singapore) as the Chairperson of the Committee for 2016.

3 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

3.1 Statements from Members under Article 15.2

3.1. The <u>Chairperson</u> 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 March 2016, Ukraine and South Africa had submitted revisions to their original statements. She further informed the Committee that since 1995, 132 Members had submitted at least one statement of implementation. Information on the list of statements is available at http://tbtims.wto.org.

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.

3.2 Specific Trade Concerns (STCs)

3.2.1 Withdrawn concerns

- 3.2. The <u>Chairperson</u> reported that the following STCs had been withdrawn from the agenda at the request of the concerned Member:
 - a. Chile Proposed Regulation on antimicrobial products
 - b. United States Energy Conservation Program: Certification and Enforcement Import Data Collection
 - c. European Union Proposal for a Regulation of the European Parliament and of the Council setting a framework for energy efficiency labelling and repealing Directive 2010/30/EU.
 - d. Saudi Arabia Draft for update of the Technical Regulation No. SASO 2857:2014 "Vehicle Tires Rolling Resistance and Wet Grip Requirements"

3.2.2 New concerns

3.2.2.1 Russian Federation - Measure affecting import of Ukrainian products

- 3.3. The representative of <u>Ukraine</u> stated that, as reiterated in the Committee since 2013, the Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor) had banned imports into Russia of Ukrainian confectionary, dairy products, beer, juice, salt and wallpaper, justifying such actions on sanitary and safety grounds. He said, however, that these bans were discriminatory, non-transparent and unjustified, and therefore inconsistent with the TBT Agreement, in particular with Articles 2.1, 5.1.1 and 5.1.2, as the above-mentioned Ukrainian products had been, and continued to be, successfully exported to other countries with well-developed economies and high-quality national infrastructures. He further illustrated this point by referring to two specific Ukrainian products wallpaper and beer which, while banned in Russia, were normally exported to various other countries: Germany, France, Poland, Baltic countries, Romania and Bulgaria (wallpaper) and Germany, Italy, the Czech Republic, Baltic countries, Canada and the US (beer).
- 3.4. He also stated that Ukrainian producers had provided the competent Russian authority (Rospotrebnadzor) with all necessary documents and test results carried out in Russian and Ukrainian laboratories recognized by the Russian Federation accreditation body in both Ukrainian and Russian. Moreover, according to the information provided by the Ukrainian producers to the competent Ukrainian authorities, letters with testing results of Ukrainian producers had been received and registered in the Rospotrebnadzor. In return, he added, Russia still failed to provide the Ukrainian competent authorities and producers with required testing results and justification. More specifically on this point, he said that the Russian competent bodies (namely, the Ministry of Economy, Ministry of Transport, Ministry of Industrial Policy, the Federal Agency on Technical Regulating and Metrology (Rosstandart) and Rospotrebnadzor) had never provided justification for the above-mentioned restrictions, despite repeated requests by Ukrainian manufacturers and various Ukrainian government bodies (the Ministry of Economic Development and Trade, the State Veterinary and Phytosanitary Service as well as the Sanitary Service). His delegation believed that by not responding to such enquiries, Russia had been acting inconsistently with Article 10 of the TBT Agreement.
- 3.5. Finally, he noted that as from 2016 all Ukrainian products that had been banned from being imported into Russia would also be prohibited from transiting through the Russian territory. He said that this concern, which had been raised several times before the TBT and SPS Committees as well as the WTO General Council, still remained unaddressed by Russia.
- 3.6. The representative of the <u>Russian Federation</u> expressed his delegation's view that the issue of transit raised by Ukraine was not covered by the TBT Agreement but that all other actions had been taken in full compliance with Russia's WTO obligations, in particular those under Articles 2.1, 2.2 and 5.1.1 of the TBT Agreement. He explained that the imports of certain Ukrainian goods into

Russia had not been banned as such, rather temporarily suspended for the following reasons: (i) inconsistency with the requirements under the relevant technical regulations; (ii) prevention of deceptive trade practices; and (iii) the need to maintain the appropriate level of human safety and health protection. He explained that at various times the Russian authorities had informed their Ukrainian counterparts, as well as interested enterprises, about the necessary regulatory steps that needed to be followed but that up to now in most cases Ukraine had failed to provide the required documentation. His delegation did, however, welcome the fact that some Ukrainian producers had complied with the relevant Russian requirements; in these cases after follow-up inspection, the introduced measures had been promptly cancelled. With respect to the Ukrainian concerns over the circulation of test results, he underlined that, in accordance with the Russian Law No. 294-FZ, as from 26 December 2008 this information could no longer be delivered to any private person or legal entity other than under the inspection, due to the legislative requirements to protect their commercial interests. He concluded by expressing his delegation's hope that, by working together in a transparent manner and in good faith, Russia and Ukraine would be able to reach a permanent and mutually satisfactory solution to this matter.

3.2.2.2 Egypt - Manufacturer Registration System (Decree No. 43/2016 and Decree No. 992/2015), G/TBT/N/EGY/114, G/TBT/N/EGY/115

- 3.7. The representative of <u>Turkey</u> noted that Decree No. 43/2016 mandated imports for commercial purposes of certain products to only be allowed into Egypt provided they were produced by manufacturing plants or imported from companies owning the respective trademarks for these products or their distribution centres registered in the relevant established register in the General Organization for Export and Import Control (GOEIC) of Egypt. He said that the measure, which was published in Egypt's Official Gazette on 16 January 2016, had entered into force on 16 March 2016, before the end of the 60-day comment period of 1 April 2016.
- 3.8. He also said that the measure covered "registration", which was one of the types of "conformity assessment procedures" (CAP) disciplined by the TBT Agreement, as defined in Annex 1 thereof. He recalled that Article 5.6.2 of the TBT Agreement stated that notifications for CAP should take place at an early appropriate stage, when amendments could still be introduced and comments taken into account. In addition, Article 5.6.4 required Members, without discrimination, to allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into consideration. He noted, in this respect, that Turkey had provided Egypt with written comments and had very recently received a written reply from Egypt, but remained disappointed that its comments and concerns had not been fully taken into account. In addition, Turkey reminded that Article 5.9 of the TBT Agreement stipulated that Members should allow a reasonable interval between the publication of requirements concerning CAP and their entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products or methods of production to the requirements of the importing Member. Turkey considered that the measure's registration requirements constituted CAP that imposed further burdens on producers and/or companies in the export market. Turkey believed that Article 5.9 was valid and applicable for Egypt's manufacturer registration system as well. However, despite its broad product scope and burdensome new requirements, no meaningful transition period had been provided to producers to adapt to the new registration system.
- 3.9. Turkey also considered that the requirements of Egypt's new registration system were burdensome and created unnecessary obstacles to international trade, and thus inconsistent with Article 5.1.2 of the TBT Agreement. This TBT provision, recalled Turkey, stated that CAP should not be prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade. This means, *inter alia*, that 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. It was Turkey's understanding that the objective behind Egypt's registration system was not well defined. For instance, under this system: (i) products selected for registration purposes neither shared common characteristics nor belonged to certain clusters; (ii) required documentation did not provide information or ensure the quality and safety of the products; and (iii) it remained unclear whether the same documents, including quality certificates, were also required internally for the Egyptian companies. Furthermore, he said that the practical process of application for the registration had not been clarified in the decree. The

companies had been unable to obtain concrete information on the way to carry out the application process.

- 3.10. Turkey also noted that the Decree had been changed twice before entry into force. Furthermore, there had been changes even after the commencement of the registration process. This situation caused confusion, complication and thus uncertainty for the applicants. This uncertainty, said Turkey, was compounded by the difficulty that applicants encountered in accessing the Egyptian authorities to get exact information. Moreover, the preparation process of the documents required long and various approval procedures. After providing the documents listed in the decree, these were to be approved first by the Chamber of Commerce, or equivalent bodies, followed by the governorships. Certified Arabic translations of all documents were required to be submitted along with the original versions. Both the local and Arabic versions of all documents were also required to be approved, one by one, by the Egyptian consulates. For Turkey, all these steps and procedures increased the cost and time for completing the registration procedures, in turn damaging applicants' competitiveness on the Egyptian market. Additionally, the registration form, along with other required documents, had to be submitted to GOEIC registration offices in Egypt by the legal representative (their delegates, agents, or counterparts) of the factory. This further complicated and prolonged the process by putting a significant burden on producers and companies with trademarks. He also noted that Article 2, paragraph 3, of the measure introduced the question of the validity of the submitted documents. In this respect, Turkey asked Egypt: (i) how would a document be considered as invalid? (ii) what kind of company or factory inspection would be carried out? and (iii) what would the process be in case a company or producer was rejected?
- 3.11. Turkey also noted that, in addition to the formulation of the registration system, its implementation also seemed problematic. Turkey recalled that, according to Egypt, there had been over a thousand registrations. However, according to Turkish industry, most of the companies had faced serious problems during this process and as a result had not been able to get registered. The companies which had already completed the application procedure had been waiting for a long time and had not received any response on the current situation regarding their application. The procedure was neither well-conceived nor well-designed and did not appear to address the objective of safety or quality of the products. Moreover, since the measure's implementation process was not transparent, Turkey also had no available information on the data regarding the registration system. Turkey therefore requested Egypt to share the list of companies registered and the average time required for their registration.
- 3.12. As a result of all the foregoing concerns, Turkey believed that Egypt's manufacturer registration system constituted a genuine hindrance to market access and therefore requested Egypt to reconsider its current approach and explore less trade-restrictive alternatives. With the aim of overcoming the problem faced by many companies trading with Egypt, Turkey also asked Egypt to bring its legislation and implementation into compliance with the principles and rules of the WTO, including the TBT Agreement, by not creating unnecessary obstacles to trade.
- 3.13. The representative of <u>Switzerland</u> expressed his delegation's concern regarding the two measures at issue, notified by Egypt to this Committee on 1 February 2016, namely: (i) Decree No. 991/2015, which entered into force on 31 December 2015 and provided for the registration of producers and pre-shipment inspections; and (ii) Decree No. 43/2016, which entered into force on 16 March 2016, and which provided for a second registration procedure relating, *inter alia*, to manufacturing sites and quality control certification. Switzerland asked Egypt why the latter decree, which applied to 25 categories of products, had entered into force before the end of the period established by Egypt for the submission of comments pertaining to its notification. He recalled, in this respect, that the TBT Agreement required notifications to take place at an appropriate stage, when amendments could still be introduced and comments be taken into account. Furthermore, according to Article 2.12 of the Agreement, a reasonable interval should be allowed between the publication and entry into force of a TBT measure (except in urgent circumstances) in order to allow producers to adapt to the new requirements.
- 3.14. In terms of substance, he expressed his delegation's belief that, by providing for two overlapping registration procedures, these two decrees were more trade restrictive than necessary because they created unnecessary costs and obstacles. Switzerland thus encouraged Egypt to consider a less trade-restrictive approach. He also noted that Decree No. 43/2016 provided for the registration of foreign factories and trademark owners of products imported into Egypt. It included

a list of documents, such as a list of products manufactured by a given factory and, in particular, a certificate establishing that the quality control system had been reviewed by a third party. In this respect, he asked Egypt to explain why it had decided that 25 very diverse product sectors should be subject to third-party assessment. He said that, while Switzerland shared Egypt's objectives of protecting public health and the environment, it was nonetheless unclear how Decree No. 43/2016 would contribute to these objectives. In Switzerland, third-party quality assurance was required for certain products presenting risks, and was linked to essential requirements based on public interests that were identified by legislators and dealt with in international standards. The extent to which third-party certification had been generalized on the basis of vague requirements continued to be a source of concern for his delegation. Switzerland, therefore, asked Egypt for how long had third-party assessment of quality control systems been in place at national level and verified by the authorities, and if any benefits had been observed. In this respect, he noted that in most markets, including in Switzerland, several of the products covered by the measures at issue, which posed few risks to consumers, were not subject to third-party quality control. The absence of third-party production certification did not mean that a product was unsafe. It was difficult for enterprises that had not implemented a quality management programme or had chosen to ensure quality management independently, to adapt quickly to, and to understand, the requirements established by Egypt. A pragmatic approach in implementation would help manage current obstacles that hindered trade.

- 3.15. The representative of the <u>European Union</u> expressed the same concerns made by Switzerland with respect to the earlier-than-expected entry into force of the two decrees and asked Egypt to suspend their implementation and re-notify them. The EU also asked the Egyptian authorities to consider withdrawing the measures and reviewing them in light of the principles and obligations laid down in WTO law. In addition, the EU was also concerned by the possible duplication of procedures and the lack of clarity of the requirements to be fulfilled by European economic operators. The application of the Egyptian decrees was already creating unnecessary obstacles to trade.
- 3.16. The representative of the United States remained concerned over Egypt's level of transparency during the adoption and enforcement of these measures. For example, Egypt had yet to inform Members why it had not allowed an adequate period of time to consider stakeholders' comments submitted in response to its WTO notifications. The date of implementation was 16 March 2016, yet the comment period ended two weeks later. Under normal circumstances, Egypt would have notified the first draft of the measure for a 60-day comment period. At the end of the comment period, Egypt would have reflected on the comments received and made any necessary changes to the draft to account for stakeholder comments. Upon publication of the final draft, Egypt would have allowed an adequate time for stakeholders to become accustomed to the new requirements, normally at least six months after publication. However, noted the US, Egypt had not done so, and yet the WTO notifications did not indicate that Egypt was responding to any circumstances that required it to deviate from the normal course. Since these were measures specifically targeting imports, the US asked Egypt how it had ensured that they were consistent with its national treatment commitments. US industry feedback from the measures' immediate implementation indicated that these companies might have to give up on the Egyptian market altogether. Others indicated great confusion about the specificity of what documents and which certifications would be accepted to demonstrate compliance. Therefore, the US made the following priority requests: (i) that Egypt suspend implementation of the measures until all stakeholder comments had been taken into account and were given a real chance of being reflected in the final measure; (ii) that an adequate implementation period be provided once the measures were again implemented: 6 months from the date of publication was normally considered sufficient, although this amount of time might not necessarily be adequate for all industries; (iii) that Egypt change its approach from a horizontal one - imposing the same requirements across all industries - to one taking into account the various global norms, risk factors, and practices across different industries.
- 3.17. Regarding the requirement for a Quality Management System certification, the US asked that Egypt recognize the quality control requirements relied on by other Member countries that met the objectives of Egypt's requirements. In this respect, she asked whether Egypt could confirm that ISO 9000 certification was deemed sufficient to demonstrate compliance with the Quality Management System certificate requirement. With respect to the requirement that imports should be accompanied by the product's trademark and product licence, she asked Egypt to clarify who bore responsibility when a trademark had been leased. She also asked Egypt to confirm that it would accept documents that companies already possess on trademarks.

- 3.18. The representative of <u>South Africa</u> said that her delegation shared similar concerns as expressed by the delegations of Turkey, Switzerland, the EU and the US. South Africa thanked Egypt for the bilateral exchanges between them and for the comments Egypt had already sent to some of its questions, which were currently under consideration by her authorities.
- 3.19. The representative of <u>Australia</u> shared the concerns raised by other Members about the trade impact of the measures. Australian businesses were already feeling the effects of the regulations and had raised concerns to the Australian Government that the new registration and certification requirements created unnecessary barriers to trade. The registration and certification requirements did not appear to be in line with international best practices. Australia encouraged Egypt to take a risk-based approach to certification and conformity assessment requirements.
- 3.20. The representative of <u>Canada</u> echoed the concerns raised by other Members and said that his government would contact Egypt's Enquiry Point shortly to convey concerns in writing regarding GOEIC.
- 3.21. The representative of <u>China</u> said that her delegation was also interested in this Egyptian registration system and would continue monitoring its development.
- 3.22. The representative of <u>Norway</u> supported the statements of other delegations and said that Norway was interested in following this discussion for systemic reasons.
- 3.23. The representative of <u>Ukraine</u> joined the concerns raised by other delegations. Ukraine drew Members' attention to some inconsistencies of the measures at issue with the TBT Agreement, including the obligations under Articles 2.12 and 5.1. Given the short period of time (in the case of Decree No. 43/2016), and the complete absence of time (in the case of Decree No. 991/2015), between the dates of adoption and entry into force of these measures, Ukrainian companies exporting relevant products to Egypt had not been given the opportunity to adapt themselves to the application of requirements of the above-mentioned regulations. This, as a result, led to the creation of certain barriers to trade between Ukraine and Egypt. Article 5.1 of the TBT Agreement was not respected because Resolution No. 991/2015 stipulated that customs processing of supplies of certain types of imported products was made under certain conditions, including, for instance: (i) registration before GOEIC; and (ii) inspection and verification of certificate's conformity with Egyptian standards. In any case, he said, customs processing was subject to random checks by GOEIC. Ukraine thus considered that these provisions put domestic and foreign suppliers in unequal conditions.
- 3.24. The representative of <u>Chile</u> said that his delegation joined the concerns raised by preceding delegations with respect to the registration system for manufacturers established by the measures at issue.
- 3.25. The representative of Egypt explained that the two decrees at issue were mutually independent. He explained that Decree No. 991/2015 dealt with pre-shipment inspection to ensure conformity of the products with relevant accredited Egyptian standards, which had already been notified to the TBT Committee over the past years. Decree No. 43/2016, on the other hand, only concerned the registration of the manufacturing plants and companies owning trademarks qualified to export their products to Egypt. The latter measure, therefore, did not deal with product compliance related with specific technical regulations.
- 3.26. He remarked that Decree No. 992/2015 had in fact never entered into force. This measure had been cancelled and replaced before its entry into force by Decree No. 43/2016. Decree No. 43/2016, issued by the Ministry of Trade and Industry, amended the rules governing the registration of the factories eligible for export to Egypt. This measure's objective was to ensure that entities exporting to Egypt maintained a quality control system. Given its administrative nature, this decree did not impose further burdens on producers or companies in the exporting markets. He further said that, despite the fact that the imports of products listed in the said decree presented only a minimal share of the total Egyptian imports, in the last few years the Egyptian market had witnessed a sharp increase of imports of such products as a result of illegal manufacturing practices. Such increase of illegal products had, in turn, a negative impact on consumer's health and safety. All required information regarding the registration process and samples of the required documents and applications had been made available at the following

website of the General Authority for Export and Import Control (GOEIC).² Egypt strongly believed that the registration requirements under Decree No. 43/2016 were not more trade restrictive than necessary. Nonetheless, with a view to facilitating the process, Egypt had adopted a number of measures aimed at ensuring that registration requirements would not impose excessive burdens on producers or companies in the exporting markets.

- 3.27. In reference to the quality control system certificate, he explained that there was no specific standard against which the certificate needed to be issued. It was intentional not to require any specific certificate in order to ensure that the requirement would not create any unnecessary burden on credible manufacturing plants and trademark owning companies that already maintained a quality control system. The only requirement was that this certificate state that the producer or the trademark owner company maintained a quality control system, to be issued by entities accredited by national or regional accreditation bodies such as the International Laboratory Accreditation Cooperation (ILAC), or the International Accreditation Forum (IAF), or an Egyptian or foreign governmental entity approved by the Ministry of Trade and Industry. A copy of the certificates stating that the producer or the trademark owner company maintained a quality control system would thus be accepted, provided that it was available on the electronic database of the accredited certification service providers and that GOEIC would be able to verify it online. The registration of the manufacturing plants, or the company owning the trademark, allowed any intermediary or trading house to import the relevant products to Egypt. The registered companies in GOEIC, according to Article 94 of the Ministerial Decree No. 770/2005, and its amendments issuing the Executive Regulation to Implement the Import and Export Law "WHITE LIST", were considered in compliance with the requirements of the Ministerial Decree No. 43/2016 until they had completed their registration process. The following were excluded: products that had been shipped or had arrived before the entry into force of the decree; shipments for which credit was opened before the entry into force of the decree; contracts concluded, legalized and accredited from Egyptian consulates abroad in case of transfer of at least 10% of its value before the date of entry into force of the decree, provided they were implemented in a time period of no longer than a year; and manufacturing plants and companies owning trademarks that had completed and submitted the required documents and administrative service fees to GOEIC and pending the issuance of the Ministerial Decree concerning their registration. This facilitating measure had been made available for shipments that had arrived at Egyptian ports prior to 30 May 2016.
- 3.28. He concluded by drawing Members' attention to that fact that Egypt had conducted a number of bilateral meetings with interested delegations, during which they had the opportunity to receive all clarifications needed with respect to their comments. The detailed replies had also been provided both through Egypt's Enquiry Point, and directly to missions in Geneva. Egypt nonetheless took note of all points raised at the present meeting, which would be conveyed to capital for consideration and response in due course. Egypt, he said, respected its commitments under the TBT Agreement and was in full compliance with its articles.
- 3.2.2.3 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, G/TBT/N/COL/214/Add.1
- 3.29. The representative of Mexico said that her delegation was concerned with certain aspects of the Colombian measure. She noted that both Articles 8 and 10 of the draft resolution required the submission of a first-party conformity declaration before importing detergents and soaps. In this regard, unlike the Colombian measure, the corresponding Mexican regulation the draft Mexican regulation on the biodegradability of domestic detergents: specifications and test methods which had been awaiting publication in the Official Journal of the Federation, did not require certification to verify the biodegradability of this type of product. Therefore, the party subject to the regulations must ensure the certification of these products in order to import them into Colombia, resulting in procedures which, in Mexico's view, were more costly and lengthy than necessary, and which restricted trade. She also noted that Article 7 of the measure required the laboratory testing of surfactants contained in detergents and soaps, which could only be carried out in laboratories accredited by Colombia, or by those recognized through a mutual recognition agreement (MRA). Mexico considered that these tests were not designed to be conducted on finished products, as

² www.goeic.gov.eg

they may produce a biased result indicating that the product was biodegradable. 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 indicate failure to fulfil the conditions of the conformity assessment. In comparison, the Mexican regulation on surfactants only provided a non-exhaustive list of surfactants that had already undergone such tests therefore no conformity certificate was required by Mexico. This contrast supported Mexico's view that the Colombian regulation may create an unnecessarily burdensome obligation for the party subject to the regulations, and thus may be inconsistent with Article 2.2 of the TBT Agreement.

- 3.30. 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 suggested that the regulation could contain an annex listing the surfactants that had already undergone such tests and therefore met the standards required, which would be sufficient to fulfil the legitimate objective pursued by the measure. As a result, it would no longer be necessary to submit conformity certificates for each shipment imported into Colombia.
- 3.31. The representative of <u>Colombia</u> clarified that its government did not require certification with regard to this technical regulation, rather a third-party declaration of conformity in line with ISO/IEC 17050, Part 2. Therefore, he said, the Mexican arguments with regard to the costs of certification were not valid as they related to a declaration of conformity submitted by Colombian manufacturers or importers relating to this technical regulation. With regard to testing that would be carried out on detergents with the support of a declaration of conformity, he said that it could be carried out in laboratories accredited by Colombia's national body or laboratories with prior evaluation by manufacturers and importers. With regard to the requirement on certification, he said that this was a procedure that was applied in Colombia in the same manner as other WTO Members with regard to certification of technical regulations and the verification of conformity with requirements. In fact, he said, here Colombia had been even more open in its domestic legislation by establishing the possibility of accepting third-party certification by foreigners in Colombia wherever there was an agreement between the parties (e.g. with Canada and Mexico).

3.2.2.4 China - Draft Standardization Law

- 3.32. The representative of the <u>Republic of Korea</u> expressed his delegation's concern with the fact that, while the Chinese government gathered comments within the country with respect to this Draft Standardization Law, WTO Members could not submit comments at an appropriate stage since the regulation had not been notified to the Committee as per Article 2.9.2 of TBT Agreement, and urged China to notify the draft accordingly. He also noted that Article 24 of the draft measure required enterprises to unveil their corporate standards, such as functional criteria, performance criteria, and testing methods of product services. Korea was concerned that this may cause damage to those enterprises by revealing confidential information and may infringe on intellectual property rights, which would not be in accordance with Article 5.2.4 of the TBT Agreement. Korea therefore requested China to withdraw this specific provision from the draft measure.
- 3.33. The representative of <u>China</u> informed that his capital was analysing the comments received from Members and would take reasonable comments into consideration when finalizing the standardization law. With regard to the transparency request from Korea, she said that China would make an evaluation of whether, consistent with the TBT Agreement, a notification to the WTO would indeed be necessary.

3.2.2.5 China - Chinese Standards of Exhaust Emissions (China 6, BEIJING VI)

3.34. The representative of the <u>Republic of Korea</u> said that his delegation had been informed that domestic processes were under way to adopt the China 6 and BEIJING VI standards, which would be enforced on 1 December 2017 and 1 January 2020, respectively. However, as these standards had not been notified to WTO Members, Korea requested China to do so, as per their obligation under Article 2.9.2 of the TBT Agreement. He went on to express concern that, even with the same objective, these two standards took a different approach with regard to test cycles, standardization methods, etc. These standards were deemed to be burdensome because manufacturers would have to develop two vehicle models in order to meet the two standards.

Korea asked China to unify the methodology of the two standards, like the current China V and BEIJING 5, in accordance with Articles 2.2 and 2.3 of the TBT Agreement.

3.35. The representative of <u>China</u> explained that the Chinese Standards of Exhaust Emissions (China 6, BEIJING VI) were drafted in order to ease the severe air pollution in China, especially in Beijing. China committed to conveying all comments back to its capital, since Korea's detailed concerns on this issue had only been brought to her delegation's attention during the bilateral meeting.

3.2.2.6 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

- 3.36. The representative of the <u>European Union</u> first thanked China for having notified the three standards at issue which, intended to become mandatory, were therefore akin to technical regulations. The EU considered, however, that these proposed mandatory measures included unnecessary deviations from relevant international standards. In case such standards would become mandatory, products which were currently assessed on the basis of well-known international ISO standards would have to be assessed for the Chinese market on the basis of specific tests. Some of these specific tests required a complex and costly assessment (e.g. requiring multiple test chambers for "volume factor loading" in accordance with G/TBT/N/CHN/1094 for wood-based furniture, and a rare mattress test chamber for mattresses). In addition, due to the novelty of the proposed test methods, and lack of experience thereof, 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) as well as about the replicability of the tests. He therefore underscored the potential of those deviations not only to make trade more costly, but also to disrupt trade in a non-negligible manner.
- 3.37. He also said that the EU understood that China was modifying the notified standards, and in particular that the TVOC requirements would be applied on a voluntary rather than mandatory basis. The EU thus asked China to confirm this understanding and requested further clarification of which parts of the standard would remain voluntary and which would be mandatory. In particular, the EU asked China to inform whether either the TVOC limits set out in the standards, or the testing method set out in the standards and their annexes, would be considered as voluntary; or, instead, whether both aspects would be considered as voluntary. The EU also asked whether this differentiation would apply to all three notified draft standards. Similarly, the EU asked China to provide information regarding the intended status - voluntary or mandatory - of the other limits and requirements included in the notified drafts (e.g. formaldehyde emissions). In this respect, the EU encouraged the Chinese authorities to accept equivalent international standards, in particular ISO standards, for the product categories covered by the notified drafts. He said that, should China consider that the relevant ISO standards could be improved, the EU would invite China to bring its proposals for discussion to the ISO. This would enable improvements to be considered without creating differences between Chinese and international standards, thus avoiding unnecessary barriers to trade. Finally, the EU asked China to indicate the timeline foreseen for the adoption of the notified drafts.
- 3.38. The representative of <u>China</u> noted that the EU's concerns, such as testing methods, were mainly of a technical nature. She said that China's experts had prepared technical details on the process for the determination of the testing methods. During the recent bilateral meeting, China had provided the expert report to the EU delegation. She clarified that the Chinese standards adopted testing methods mainly based on international standards. While several aspects thereof differed from international standards, they were all designed to simulate realistic usage conditions to ensure that the test results would be more scientific.

3.2.2.7 Kenya - East African Community (EAC) alcoholic beverage standards

3.39. The representative of the <u>European Union</u>, whilst expressing his delegation's support for efforts to fight the consumption of adulterated alcoholic beverages, asked Kenya, and other Members of the East African Community (EAC), to notify this and any other applicable technical regulations so as to give Members the opportunity to provide comments in order to find a solution that properly addressed their concerns without creating unnecessary barriers to trade. In the

meantime, the EU asked Kenya and other EAC members to suspend the application of these measures. The EU believed that widely accepted international standards and practices correctly addressed this type of health concern and would therefore welcome discussions with EAC members in order to analyse how their technical regulations could be better aligned with them.

- 3.40. The representative of the <u>United States</u> said that her delegation strongly supported the EAC's desire to protect its citizens and reduce the consumption of adulterated alcoholic beverages. She also noted that many of the notifications submitted by Uganda and Rwanda over the past few years on alcoholic beverage labelling and analytical production limits deviated from widely accepted international standards and practices. It was unclear why such deviations were necessary in fulfilling the objectives of the measure. The US would welcome discussions with EAC members to find a solution that would not unnecessarily restrict trade, such as greater alignment with standard international practices. She added that if Tanzania, Kenya, and Burundi indeed intended to adopt EAC standards on alcoholic beverages, the US would then request an opportunity to provide comments. She recalled that the US had previously submitted comments to Uganda and Rwanda expressing concern with the implementation of the standard.
- 3.41. The representative of <u>Chile</u> said that his delegation supported the US request that Kenya notify the measure, which would enable them to make comments.
- 3.42. The representative of South Africa said that his delegation was also very interested in the EAC alcoholic beverage regulations. South Africa fully supported the regulation of alcoholic beverages for health protection, the prevention of deceptive practices, as well as for reasons of quality. However, in South Africa's view, the pursuance of such objectives should be done in a transparent manner, taking into consideration international standards and best practices. The South African wine industry was particularly concerned with the measure's 14% alcohol percentage with no actual alcohol percentage tolerance allowed from what was printed on the label. This tolerance exclusion and the 14% limit would in practice exclude many of South African red wines from the Kenyan Market. It should be noted that for exporting to other countries, a label alcohol tolerance from 0.5% up to 1.5% was normally permitted, allowing for differences in analyses between laboratories and different sets of samples. As no tolerance was allowed under the Kenyan measure, this meant that if the actual alcohol percentage on the clearance documentation and the labelled alcohol percentage of the wine concerned were not exactly the same, the wine would not be granted entry into Kenya. Therefore, this exclusion of a label tolerance was not in line with international best practice. South Africa thus asked Kenya to consider that a label and actual alcohol tolerance of between 0.5 and 1.0% be allowed for the importation of wine.
- 3.43. The representative of <u>Kenya</u> said that his country, together with other EAC Partner States, had been working on the harmonization of standards to facilitate both regional and international trade. The EAC alcoholic beverage standards were among others to have been harmonized in this process. Kenya was committed to the principle of transparency and would therefore ensure that the concerns raised by the EU and shared by the US, Chile and South Africa would be addressed as soon as possible.

3.2.2.8 Chinese Taipei - Draft of the Organic Agriculture Act, G/TBT/N/TPKM/225, G/TBT/N/TPKM/225/Add.1, G/TBT/N/TPKM/225/Add.2

3.44. The representative of the <u>European Union</u> considered that clarity was needed on the scope of the proposed measure with respect to both its product coverage (such as food, feed, processed products and plant reproductive material) and process stage coverage (such as primary, processing, distribution and retail). The EU also considered that the draft measure needed to include production and control rules on organic farming, which would help to understand possible differences in legislative frameworks that could adversely impact operators trading in organic products on Chinese Taipei's market. The EU representative also said that, 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. Such a draft measure, if implemented, would be more trade restrictive than necessary. The EU therefore requested Chinese Taipei to consider the possibility of a reasonable extension of the timeframe to re-apply for equivalence. For reference, the EU representative said, in similar circumstances the EU granted a period of five years.

3.45. The representative of <u>Chinese Taipei</u> said that since the draft measure was still undergoing its legislative process, the EU's suggestions regarding the scope of application and extension of the grace period for unilateral recognitions would be thoughtfully considered. Comments from Australia, India, and the US would also serve as guidance for this legislation.

3.2.2.9 European Union – Quality Schemes for Agricultural Products and Foodstuffs, G/TBT/N/EU/139, G/TBT/N/EU/139/Add.1

- 3.46. The representative of the <u>United States</u> said that on 12 February 2012 and 23 January 2014, respectively, the EU had published two applications from Denmark for the registration of the terms "danbo" and "havarti" as protected geographic indications for cheese. The US noted that the EU had published these two GI applications made by Denmark under Regulation 1151/2012 of the European Parliament and of the Council on the quality schemes for agricultural products and foodstuffs, notified to this Committee in 2013 although the Codex Alimentarius had adopted production standards for these two cheeses years ago: 50 years ago, in the case of "danbo" and 30 in the case of "havarti". These Codex standards had been adopted in order to ensure the quality and uniformity of these cheeses in the various countries producing them.
- 3.47. While both applications were still pending, the US explained that it had decided to raise the concern at this juncture because it had been informed by its producers of "some movement" on these applications. The US said that, if granted, these GI registrations would result in the prohibition within the EU of the two names for any cheese produced outside of Denmark. She therefore posed a series of questions to the EU. First, if the pending EU-level applications by Denmark to seek restricting the use of these Codex-standardized, common name terms solely to Danish producers were approved, would the EU prohibit imported cheeses from using the Codexstandardized terms on the products' labels, even if those cheeses conformed to their respective Codex standards? Second, if the applications related to these two names were approved within the EU, would the EU 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? Third, had the EU considered less trade-restrictive means of implementing regulations pertaining to "danbo" and "havarti"? For instance, had the US envisaged an alternative that would instead require the applications to be amended so as to cover only "Danish danbo" or "Danish havarti", and that would also allow accompanying clear statements so that products produced and labelled in accordance with the Codex standards for "danbo" and "havarti" would be able to continue to be sold in the EU market?
- 3.48. The representative of <u>Uruguay</u> said that, as one of the world's main producers of "danbo", Uruguay followed global developments on these products with close interest. He said that, like the US, his delegation would like the EU to provide Members with an update on the GI applications referred above.
- 3.49. The representative of the <u>European Union</u> said that the original measure had been notified under G/TBT/N/EU/139 and G/TBT/N/EU/139/Add.1. The EU was not in a position to provide a detailed reply with regard to an update on the pending applications, due to the short notice of the request. The EU remained open to discuss this issue bilaterally.
- 3.2.2.10 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
- 3.50. The representative of <u>Indonesia</u>, supported by <u>Guatemala</u>, noted that EU member States were required to implement the EU Tobacco Directive into their local laws by 20 May 2016, Article 7(1) of which prohibited member States from placing tobacco products with a

"characterizing flavour" on the market. In relation to this specific obligation, the European Commission Implementing Decision 2016/786 of 18 May 2016 (the "Implementing Decision") had been adopted to lay down the procedure for the establishment and operation of an independent advisory panel tasked with assisting EU member States and the European Commission in determining whether tobacco products have a "characterizing flavour". Indonesia said that some EU member States had already prohibited the importation into their territories of "Kretek" (a tobacco product containing clove) on the basis that it was a tobacco product with a "characterizing flavour", as a result of which, as of May 2016 all importation of Kretek to the EU had ceased. While Indonesia appreciated and respected the intention of the EU to pursue a public health policy to protect its people from the negative effects of consuming tobacco products, Indonesia nonetheless drew Members' attention to the following facts related to this product: Kretek was a traditional tobacco product originally created in Indonesia and an important export product for this country; the approximate export value of Indonesian Kretek was US\$600 million; and the cultural importance of Kretek to Indonesians all over the world, including EU citizens of Indonesian descent, was significant.

- 3.51. Indonesia also noted that the "advisory panel" mentioned by the Implementing Decision had not yet been established. The Indonesian government therefore requested the EU to explain the basis for the import prohibition of Kretek that had already been implemented by EU member States. Indonesia also noted that Article 7(14) of the EU Tobacco Directive stipulated that tobacco products with a characterizing flavour whose EU-wide sales volumes represented 3% or more in a particular product category would only be subject to application of the Article 7(1) prohibition as from 20 May 2020. Indonesia's interpretation was that, if menthol cigarettes consumed in the EU (the vast majority of which were also produced within the EU) were determined to have a "characterizing flavour", they should also be prohibited under Article 7(1). Instead, however, these products benefit from the delay in prohibition pursuant to Article 7(14). Indonesia thus believed that Article 7(14) of the Tobacco Directive was inconsistent with Article 2.1 of the TBT Agreement because, in practice, it accorded to imported Kretek a treatment less favourable than that accorded to domestic menthol cigarettes. Similarly, Indonesia believed that Article 9 of the Implementing Decision was also inconsistent with Article 2.1 of the TBT Agreement. Indonesia said that this 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 by, as a result, excluding tasting methodology properties, this provision inherently discriminated against Kretek, which used distinctive Indonesia-grown tobacco leaf. Conversely, cigarettes manufactured in the EU were largely made using one or both of the two internationally most commonly used tobacco leaves.
- 3.52. The representative of the <u>European Union</u> informed Members that the Tobacco Products Directive was applicable as of 20 May 2016. This measure was a result of thorough consultations with all stakeholders involved and an in-depth analysis. It provided for measures that were non-discriminatory and proportionate to the legitimate health objectives pursued. During the preparation of the measure, the European Commission had carefully balanced the need to put in place a comprehensive tobacco control policy, including, on the one hand, the implementation of the WHO Framework Convention on Tobacco Control (FCTC) commitments with, on the other hand, various economic and trade considerations. The EU was fully convinced that the Directive was consistent with the EU's international commitments, including its obligations under the TBT Agreement. With regard to Indonesia's specific question concerning *Kretek*, the EU said that it was available for bilateral contacts.

3.2.3 Previously raised concerns

3.2.3.1 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)

3.53. The representative of <u>Japan</u> expressed continued concern with respect to five points: (i) the ISI marking fee requirement; (ii) the cost of the marking fee; (iii) certification; (iv) the bank guarantee fee (only for tyre factories outside India); and (v) the increase of the test frequency. Regarding the marking fee, Japan had repeatedly demonstrated to India calculated evidence that the ISI marking fee was expensive compared to other countries. India was requested to reduce the fee to the same level as other Members. Regarding the increase in Conformity of Production (COP) test frequency, noting other Members' test requirements, Japan considered it possible to

ensure sufficient safety of tyres by implementing the COP test once a year. If the test was implemented based on production volume of tyres, it would impose excessive test frequency on companies, depending on their firm size. Therefore, Japan requested India to delete the production volume-based requirement, to set the frequency only per period and to implement the COP test at most on an annual basis.

- 3.54. The representative of the <u>European Union</u> 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. 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.
- 3.55. The representative of <u>India</u> 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.
- 3.56. Regarding the comparative data analysis presented by the delegation of Japan, the matter had been discussed bilaterally and it had been pointed out that the calculation sheet contained some errors. The cost projected in the calculation was disproportionately high as the volume of production shown was significantly more than the actual figures. As per the records of Indian authorities, most of the Japanese manufacturers did not exceed 100,000 pieces per year, whereas the calculation sheet assumed an annual production of about 800,000 pieces. As the marking fee was linked to the volume of production, the calculation had grossly overstated the actual cost. In the records of the Bureau of Indian Standards (BIS), almost all manufacturers in Japan had actually paid only the minimum marking fee of approximately US\$3,617 (approx.) for the year 2014-15, as against US\$20,475 shown in calculations. Regarding a request made by some Members for further simplification of documents, these were in fact being simplified. On the testing frequency, the STI for pneumatic Tyres for Passengers Car Vehicles had been revised as STI/15633/5 November 2015. In the earlier STIs, the frequency of tests was not linked to the production volume. However, in this revised STI, frequency of test had been linked to the production volume. For example, the earlier STI required that Load Speed Performance test to be carried out on one sample of a family of tyres, every three months, irrespective of whether the manufacturer had produced 100 pieces or 100,000 pieces of the variety in three months. Now, it had been proposed that the above test had to be carried out on one sample of a family of tyres for every 10 control units. One control unit had been defined as 5,000 tyres of the same family manufactured by similar process under similar conditions with similar material composition. Thus, this test would be required to be carried out once for every 50,000 tyres, and not every three months. If the volume of production was up to 100,000 in a year, the testing frequency would not exceed twice a year.

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

3.57. The representative of <u>Japan</u> asked China to clarify how the "Guidance for Application and Evaluation of New Cosmetic Ingredients" would be updated (in particular with respect to the contents and schedule) in accordance with the revision of the "Regulations concerning Hygiene Supervision over Cosmetics". Regarding the current version of the "Guidance", she reiterated Japan's concerns regarding the three following issues: the speed of examination, the safety evaluation requirement, and the information disclosure. She requested that those concerns should be resolved in the revision of the "Regulations concerning Hygiene Supervision over Cosmetics".

- 3.58. The representative of the <u>European Union</u> welcomed the plans of China to set up a differentiated approach between priority ingredients, which were of higher risk, requiring a premarket registration, and ordinary ingredients, which would only need to be notified to the competent Chinese authorities. In this respect, he asked China to indicate the state of play and the planned timeframe for the adoption of this change. He also asked China to explain the current state of play of the new Chinese draft on Cosmetics Supervision and Administration Regulation.
- 3.59. The representative of <u>China</u> informed that there had been no further updates to the measure at issue and invited interested Members to refer to the minutes of the last meeting.³
- 3.2.3.3 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)
- 3.60. The representative of the European Union asked India to confirm the postponement of the entry into force of its security testing requirements until April 2017 and also 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. On the issue of applicable testing requirements, European industry needed greater clarity. As raised previously, the proposed batch testing seemed to be disproportionate and excessively burdensome, creating a bottleneck and disruption of the supply chain. The EU suggested that India consider a product-type testing based on a prototype of the product being placed on the market. Concerning the applicable standards for testing purposes, he reiterated his delegation's past recommendation that India relies on relevant international standards, namely the Common Criteria and Third Generation Partnership Project (3GPP) for EGBB standards on telecom network equipment. His delegation was of the view that India should refrain from developing home-grown specific standards, which added costs without increasing value in terms of in-house security; the same applied to the requirement for in-country testing for which there was no evidence that this would result in enhanced security due also to the lack of adequate laboratory capacity in India. He reiterated the EU's request that even after the entry into force of the new requirements, an adequate notice and transition period should be provided. 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. Finally he asked India to confirm that there would be no change to the continued acceptance of results of certificates issued under assessments conducted under the Common Criteria Recognition Agreements (CCRAs) and related certificates. He concluded by flagging his delegation's upcoming bilateral meeting with India.
- 3.61. The representative of the <u>United States</u>, whilst recalling the numerous times this issue had been raised, asked India to confirm that stakeholders would be informed of the new in-country testing effective date via a public notice and that a notification would be made to the Committee. She also urged India to allow adequate time between the announcement of the entry-into-force date and the actual effective date for producers to comply. Whilst the delayed enforcement of the requirement was helpful to the US in the short-term, the long-term remained uncertain for India's trading partners, inhibiting trade and investment. Once implemented, this in-country testing requirement could create an onerous and unnecessary trade barrier on US companies, particularly small and medium-sized enterprises. The US respected India's desire to protect its critical telecommunications infrastructure from spyware and malware attacks but required specific answers on why this could not be addressed by currently available testing schemes, like the CCRA. India had only identified security concerns and circumstances that exist in most countries, those that did not require in-country testing or an MRA. She reiterated her delegation's concern that the private sector was already securing networks with innovations that were constantly evolving in anticipation of new and more sophisticated types of network attacks. For example, anti-spyware, anti-malware, security specialists, and private and international standards were provided by globally known, innovative, and reputable companies. 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? One of the US's

³ G/TBT/M/68, para. 2.66.

concerns was that in applying inappropriate domestic requirements, India would discourage innovation and competitive technology development. The US asked whether India had prepared a more specific response than the one given in March as to what valid security risks were addressed by this measure that were not being addressed through internationally accepted standards and testing practices in conjunction with other private sector initiatives.

- 3.62. The US further requested a response to a pending query as to whether India had considered options for allowing testing to be conducted in the country of export and, if so, what options had been considered. Another pending request related to India sharing its analysis on which the incountry 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. India was additionally urged to honour its commitment in the Common Criteria Recognition Arrangement to accept the results of Common Criteria (CC) tests conducted internationally and to accept international testing standards and schemes regardless of whether the tests were performed in India or at accredited labs outside of India.
- 3.63. The representative of <u>Canada</u> reiterated his delegation's concerns with respect to India's incountry test requirements for telecoms products, considering they 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 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. He requested an update from India on the status of the entry-into-force date, which, at the previous meeting, India had announced would be extended beyond 1 April 2016.
- 3.64. The representative of <u>Japan</u> expressed her delegation's support for the positions of 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. In addition, with regard to the statement by India at the last meeting that "the requirement of in-country security testing of telecom equipment within India would be extended", Japan requested India to clarify the specific implementation date of this requirement.
- 3.65. The representative of <u>India</u> reiterated that in-country security testing of telecoms equipment had been mandated for "national security reasons" due to its vulnerability to spyware and malware attacks in recent times. He explained that telecom networks were a part of the critical infrastructure on which other important infrastructures (e.g. power, transportation, defence) depend. Accordingly, licences for the provision of telecoms services had been amended on 31 May 2011 and 3 June 2011 in consideration of national security, requiring security certification of network elements before induction into the network. Based on the amended provisions, the processes of security testing and certification by authorized and certified agencies/laboratories within the country were under development and yet to be finalized. Furthermore, at present the authorities were neither considering the suggestion of allowing accredited bodies outside India or MRAs to perform security testing and grant certification, nor that of allowing security testing to be conducted in the country of export. It was India's belief that the Common Criteria was insufficient for the purpose of security testing of telecoms equipment, as it is process based and used for certifying only the security features, excluding vulnerabilities or back doors. Hence, the Common Criteria failed to address national concerns on security requirements for telecoms networks.
- 3.66. The representative of <u>India</u> flagged that international standards would be relied on 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. On 3GPP standards, he said that 3GPP was in the process of developing security assurance requirements for telecom network elements and had taken the Mobility Management Entity (MME) as the first element for which the standards and test suites were still under development. In response to a specific question on whether testing would be product-wise or batch-wise, India reported that the testing modalities were yet to be finalized. On the issue of a WTO notification, he noted that the matter had been under discussion in the WTO TBT Committee

since it had first been raised. All issues raised, comments, and suggestions were in the hands of the authorities and would be kept in mind during the finalization process prior to entry into force. He concluded by informing the Committee that entry into force of in-country security certification had been postponed until 1 April 2017; until that date, such procedures could be carried out in Indian or international standards agencies/labs as per licence conditions.

- 3.2.3.4 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)
- 3.67. The representative of the <u>European Union</u> reiterated his delegation's request for a meaningful update on the state of play of the revision of the OSCCA regulation on commercial encryption products, in particular the current status of the process. If the intention was still to finalize the revision, was it still on the agenda of the State Council legislative office? Was there a timeline to notify the draft to the TBT Committee for comments and to allow a transparent and open process in the finalization of this measure?
- 3.68. He reverted to more systemic points raised at previous meetings, particularly in light of a number of framework measures that had been developed over the years, creating a lot of uncertainty about the notion of critical infrastructure in China. The first such measure was the multi-level protection scheme (MLPS). More recently, the national security law had been passed which provided that all key cyber infrastructure within China had to be "secure and controllable", without however defining the notion or its implications in terms of hardware and software requirements in IT networking equipment. Reference to "secure and controllable" was also made in the draft implementing guidelines concerning the banking and insurance sectors and in the draft cyber security law, on which the EU requested an update, urging due notification to the Committee. He reiterated the need to better understand the criteria for defining an IT system as a critical infrastructure and how the concept of secure and controllable would affect this assessment.
- 3.69. The EU also reiterated its request for standardization activities in the field of information security in China to fully take into account relevant international standards and also allow for meaningful participation of foreign companies. He recalled that the TC260, the relevant technical committee for information security standardization within the China standardization administration, had showed increased openness by allowing the participation of certain foreign stakeholders and indicated that the EU would welcome continued movement towards more inclusive participation. Finally, he stressed the importance of enhanced international cooperation in this field as cyber security was a global issue, needing commitment to develop compatible regimes capable of enhancing security without hindering trade in commercial encryption products.
- 3.70. The representative of <u>Japan</u> voiced support for the position of EU regarding this issue. Her delegation remained particularly attentive to how the various schemes and regulations within China could negatively affect the trade of information security products. She recalled that in the March 2015 meeting, China had made a statement that "the revision of OSCCA is listed in the legislation plan and opportunity for public comment is also going to be arranged". In this regard, Japan asked China to explain the current situation and future schedule of the revision. Flagging some cryptography-related regulations which had been stipulated in "Banking IT Equipment Security Regulation" and "Insurance Regulatory Commission (CIRC) Information and Communication Technology Regulation" and which had been notified to WTO, her delegation asked for confirmation as to whether or not IT security measures such as OSCCA would be applied to these regulations. Japan, moreover, expressed concern and interest with respect to the Draft Cybersecurity Law.
- 3.71. The representative of <u>China</u> reported that the regulation on commercial encryption products had been listed in the 2016 legislation plan of the State Council of China and was currently being drafted in line with legislation law and rules on the formulation of administrative laws of China. Further, she confirmed that OSCCA would undertake scientific evaluation and public consultations

to ensure openness in the legislation process. She said that there were no further updates to be made and referred Members to the minutes of previous Committee meetings.⁴

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

- 3.72. The representative of the <u>European Union</u> 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 Eurasian Economic Union, 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.
- 3.73. The representative of <u>Ukraine</u>, joining the concerns expressed by the EU, noted that Item 4 of Article 7 of the Draft Technical Regulations provided that "upon conformity (verification) assessment of products, the applicant may only be either a legal entity, either an individual as a sole proprietor, or as a producer or seller, or as the agent of a foreign producer on the basis of a contract with said producer, which is registered pursuant to the legislation of a Customs Union member state on its territory". He stated that the requirements of the Draft Technical Regulations relating to the applicants' mandatory registration on the territory of member states of the Customs Union put national producers and producers from other Members of the WTO in unequal conditions and thus violated Article 5 of the TBT Agreement.
- 3.74. Ukraine furthermore recalled that Article 5 provided that any fees imposed for assessing the conformity of products originating in the territories of other Members should be equitable in relation to any fees chargeable for assessing the conformity of like products of national origin. Since the producers from other countries had to bear the costs associated with registration of legal entities on the territory of the Customs Union or contracting with existing legal entities registered in the territory of the Customs Union, the costs on conformity assessment procedures for those producers could be higher than the costs for producers from member States of the Customs Union.
- 3.75. The representative of <u>Guatemala</u> indicated her delegation's interest in following discussions on this issue.
- 3.76. The representative of the <u>Russian Federation</u> emphasized that the draft of the technical regulation on Alcoholic Drinks Safety had been elaborated in order to establish unified requirements for commercial circulation of alcoholic products for both imported and those produced domestically. He informed the Committee that the draft was still in development and that no substantial amendments had been made since the last Committee meeting. He reassured delegations that all concerns had been taken into account as provided for under Article 2.9.2 of the TBT Agreement, and would continue to inform interested Members on further steps taken in this matter.

3.2.3.6 Korea - Regulation on Registration and Evaluation of Chemical Material (IMS ID 305)

3.77. The representative of the <u>United States</u> thanked Korea for its receptiveness to stakeholder input, expressing hope for an ongoing, constructive dialogue that was open and transparent, with Korea continuing to consult with stakeholders and educating them on how to comply. She appreciated the Ministry of the Environment (MOE) opening the Ministerial Decree for amendments and public comments in 2015 and expressed willingness to discuss the comments submitted to

⁴ G/TBT/M/68, para. 2.80; G/TBT/M/67, para 2.85; G/TBT/M/66, para.3.83; and G/TBT/M/65/Rev.1, para. 2.68.

ensure full understanding of what the US was seeking. The US remained concerned about the issue of implementation challenges for stakeholders. Firstly, the Help Desk and Authorities seemed to be difficult to reach and lacked responsiveness to stakeholder enquiries. Secondly, notifications seemed to be taking much longer than the legal targets. Thirdly, there was also significant confusion over specific requirements and acceptance of notifications and registrations.

3.78. On the issue of Confidential Business Information (CBI) and the Chemical Controls Act (CCA), despite the assurances Korea provided in March, the United States was especially concerned about CBI and the announcement that information submitted via the Statistical Survey under the CCA would be published on the Internet. The US asked Korea to reconsider MOE's plan to disclose company-confidential chemical information on the internet on 1 July 2016, as the submission deadlines for companies had been too short and insufficient guidance had been provided by MOE. The US also requested that protection of CBI related to composition and volume under the CCA should be automatic, and that manufacturers should not have to submit a request for it. There could be limited scenarios where CBI was released to a requestor, but it should be based on agreed conditions, protocols and processes (e.g. for the purpose of medical emergencies). With respect to CBI in general, the US once again reiterated its support for strong protection of CBI that recognized specific chemical identities, specific uses, and compositions as information that should be protected and requested that the MOE extend the scope of such protection to more substances that qualified as hazardous under K-REACH. Korea was requested to confirm the impression given in its March 2016 intervention that specific uses would be protected and to elaborate further. As noted in the past, making CBI public or easily accessible could allow competitors to freely acquire information that chemical companies had paid for through years of innovation, research, investment, and experience. Competitors could then use leaked information at little cost to them, which could stifle innovation and create a clear disadvantage for US companies. Korean companies who also relied on these innovative US products for inputs of production would then be at a disadvantage if US companies decided to stop exporting due to these concerns.

3.79. Turning to the issue of guidance documents, his delegation hoped that Korea would continue best efforts to publish much-needed clarification and detailed guidance for use by US industry and that this would not present new challenges (i.e., changes in requirements or forms), as it had consistently done in the past. Such guidance was essential to assist manufactures, importers and suppliers in ensuring accurate and consistent compliance with K-REACH. His delegation would welcome an outline of the guidance documents that MOE planned to publish or update, along with timelines thereof, including brochures in English, as flagged during the March 2016 meeting. He reiterated that more specific guidance was needed on all products that would be classified under the biocides group as the availability of existing guidance documents had not been clearly communicated to all stakeholders; moreover, the guidance documents themselves had also changed frequently. Chemicals continued to be added or removed from the toxic substances list without proper notice, opportunity for comment, or reasoning for the changes, causing uncertainty for chemical manufacturers and manufacturers using trace amounts of chemicals as inputs for production. K-REACH affected a wide range of products from chemicals to consumer products. The US also noted its concern that guidance documents had only been published in Korean which forced stakeholders to have them translated, decreasing time available to come into compliance. To address this challenge, in March, it was suggested that these significant documents should be allowed more time for public comment. In this respect, there was also a lot of confusion about the respective requirements of K-REACH and the CCA, especially since there was no English translation of the CCA implementing regulations. Finally, even though the CCA was only meant to apply to Korean manufacturers, many foreign suppliers were receiving requests for 100% composition and additional information for chemical products. Explanation was sought as to whether Korea had considered US industry's request to translate the CCA.

3.80. On the issue of Data Acceptance for K-REACH registration and Article 13 of the Final Presidential Decree, the US delegation asked Korea to reconfirm the indication it had provided in March 2016 that computational toxicology techniques could be accepted in order to reduce duplicative testing. When such data was submitted, it was suggested that MOE accept the scientific expert's statement and not require additional evidence for the use of such data. During the March 2016 TBT meeting, the US had asked whether scientific expert statements could be accepted. An update on this was requested, as well as the acceptance by MOE of the EU REACH datasets to reduce duplicative testing for toxicity and ecotoxicity studies.

- 3.81. The representative of <u>Australia</u> continued to express its interest in this issue and was monitoring the implementation of the regulations, which was of significant importance to Australian industry. While Australia supported the reporting of products containing hazardous substances so as to protect consumers and the environment, it considered that the current definition of "hazardous substance" was very broad. Australia thanked Korea for the notification dated 26 May 2016 on revised enforcement rules for chemical substances and stated that it was reviewing the proposed amendments. Australia would welcome guidance material or any further information from Korea on the nature of the recent changes to regulations. Korea was encouraged to take a risk-based approach following international best practice, to ensure that the K-REACH provisions met Korea's consumer protection objectives whilst not unnecessarily distorting trade.
- 3.82. The representative of the Republic of Korea assured the US and Australia that information regarded as CBI according to the "Unfair Competition Prevention and Trade Secret Protection Act" would be fully protected. Secondly, he announced that to help foreign companies, Korea planned to make brochures in English available in the second half of the year. It also planned to notify relevant information whenever "Guidance on products and toxic agents" was revised. Thirdly, he noted that exporters could register chemical materials simply by submitting quantitative structure activity relationship (QSAR) results which had internationally verified reliability, without additional evidence for omission of related test data. In addition, full text or test summaries specified on datasets which were used for EU REACH registration would be accepted. Fourthly, Korea recognized that even small amounts of a chemical substance could pose a huge threat to public health, as proven by a recent incident involving humidifier disinfectant, justifying the obligation to register and report all new substances under K-REACH regardless of the amount. However, chemical substances for the purpose of, inter alia, research and study were exempt from the reporting obligation. Lastly, Korea stated that it would continue to strengthen support for the smooth implementation of K-REACH and CCA through the "Task Force on Support for Industry in Complying with Chemical Safety Rules".

3.2.3.7 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)

- 3.83. The representative of the <u>European Union</u> sought confirmation that two parallel revision processes were ongoing and requested an update on both. He said the two revision processes concerned: (i) Toy Safety Decree No. 24, which dealt with conformity assessment procedures for toys; and (ii) the revision of the applicable Indonesian national standard on toy safety for the purpose of aligning it with the latest edition of the ISO standard on toy safety (ISO 8124 of 2014). With respect to the Decree No. 24, the EU expected that the revision would align the conformity assessment procedures between domestic and foreign products and remove the current discriminatory element for foreign products. He explained that under the current system, for domestic products, samples were taken from the production line every six months, while for foreign products there was a requirement to take samples from every imported batch. In the margins of the last TBT Committee meeting, the EU heard from the Indonesian delegation that consideration was given to allowing sampling from the production line also for foreign toy manufacturers, and to allow testing frequency of one year; he sought confirmation of this.
- 3.84. Another important aspect for the conformity assessment procedure was the possibility for foreign test results to be used as a basis for any certificate that would be issued in Indonesia for compliance with the mandatory toy safety standards. The EU noted with serious concern that the two-year grace period for the acceptance of foreign test results expired on 17 April 2016. This grace period had not been extended further, and he reiterated the serious risk of trade disruption and the creation of bottlenecks at importation if foreign test results were not accepted given the lack of adequate capacity of Indonesian labs. To address this issue, his delegation considered that Indonesia should allow test results issued by adequately accredited foreign labs, namely accredited by ILAC MRA signatories, as the basis for any certificate issued by certification bodies approved by the Indonesian Ministry of Industry. Furthermore, the EU said Indonesian authorities should consider explicitly allowing subcontracting arrangements between Indonesian conformity assessment bodies and foreign bodies, without insisting on impracticable government-to-government MRAs to achieve that purpose.
- 3.85. Concerning the alignment of the Indonesian standard with the ISO standard, the EU expected that this would also address the current concerns about testing methods for

formaldehyde, which it deemed were erroneously based on limits that applied to infant clothing rather than toys. The EU was confident that this issue would be addressed because alignment with the ISO standard for toys would allow the necessary rectification to the Indonesian standard. He welcomed the opportunity for future bilateral exchanges with Indonesia in order to advance discussions.

- 3.86. The representative of the <u>United States</u> reiterated her delegation's concerns with this regulation, and hoped that given the positive constructive bilateral discussions with Indonesia that these concerns were understood. However, the US expressed disappointment with several developments on this issue over recent months namely that Indonesia had begun enforcing the government-to-government MRA requirement despite commitments to work with the US to find a way to address ongoing concerns. The US understood that Indonesia had moved forward with enforcement despite an indication that further amendments to the regulation were being considered, and that the Ministry of Industry would resume that revision process as of June 2016. She reiterated the US request that the next revision of the regulation include permanent recognition of ILAC accreditation. Furthermore, the US remained hopeful that the revised regulation would also address remaining concerns as related to testing frequency, sampling, documentation, and substance restrictions. Despite recent events, the US reaffirmed its interest in working with Indonesia as it continued to revise this regulation. Once again, she urged Indonesia to notify the next draft of the regulation to the WTO at an early stage so that all stakeholders could have an opportunity to provide comments, and for those comments to be taken into account.
- 3.87. The representative of <u>Canada</u> recognized the importance of enhancing toy safety to ensure appropriate protection of consumers. However, his delegation considered certain aspects of Indonesia's toy regulatory regime considerably more restrictive than necessary and at odds with internationally recognized practices in the sector. More specifically, Canada was concerned with the provisions relating to in-country testing, sampling and testing frequency, and formaldehyde testing levels. These concerns had not been adequately addressed by Indonesia despite repeated interventions from Members. Canada understood that the 2-year grace period had expired and that as of 17 April 2016, toy products had to be tested at a laboratory located in Indonesia. Canada urged Indonesia to adhere to international best practices by allowing ILAC signatories and properly accredited ISO 17025 laboratories to test without requiring additional approval by the Ministry of Industry.
- 3.88. The differences in sampling criteria for domestic products (every 6 months) and imported products (every shipment) adopted by Indonesia were deemed discriminatory towards imported products. Whilst Canada recognized the difference in the volume of products to be tested, it was considered to be at odds with Indonesia's national treatment and MFN obligations. Canada requested that Indonesia confirm that the new formaldehyde test method had been implemented. Canada was also concerned that the 20ppm requirement was very close to existing feasible detection limits, making it difficult to conduct accurate tests, and in this light suggested that existing international standards and limits be used.
- 3.89. The representative of <u>Japan</u> expressed her delegation's continued support for the positions of Canada, the US and the EU. She reported that serious delays in exports had been caused by a sequence of events such as sampling, testing, SNI certification and pre-shipment inspection and in this light invited Indonesia to revise the requirements that her delegation considered to be more trade-restrictive than necessary. In addition, with respect to accreditation requirements for overseas laboratories, Japan expressed its strong concern about the expiration of the "Stay of Application for 2 years" on 30 April 2016.
- 3.90. Japan understood that most toys imported to Indonesia had been tested by foreign laboratories. Regarding these toys, Japan considered that only using foreign laboratories located in countries with which Indonesia had an MRA and domestic laboratories would not ensure smooth and accurate testing. Japan strongly urged Indonesia to continue to accredit foreign laboratories located in countries not having an MRA with Indonesia, and revise the requests on overseas laboratories in order to secure full capability of laboratories for testing. Finally, could Indonesia confirm whether or not there were any countries with which Indonesia had an MRA at this stage?
- 3.91. The representative of <u>Mexico</u> supported the concerns expressed by other delegations, and hoped to maintain an open dialogue with Indonesia with a view to being informed of developments with respect to this measure.

3.92. The representative of <u>Indonesia</u> referred interested Members to his delegation's previous comments made at the last March TBT Committee meeting.⁵ Indonesia was planning to conduct a review on the implementation of the regulation to ensure that its application was effective and efficient. Indonesia assured Members that its policy was in alignment with the TBT Agreement, and that it placed utmost importance on consumer protection. He reiterated his delegation's openness to further discussion, including through bilateral mechanisms.

3.2.3.8 India – Food Safety and Standards Regulation – Food Labelling Requirements, G/TBT/N/IND/34, G/TBT/N/IND/43, G/TBT/N/IND/46, G/TBT/N/IND/53 (IMS ID 298)

- 3.93. The representative of <u>Switzerland</u> shared technical concerns expressed by several delegations at previous TBT Committee sessions, in the context of the new notification G/TBT/N/IND/53 regarding the Indian food labelling requirements. It was Switzerland's understanding that the latest version of the standards extended its scope without addressing the concerns expressed by Members at several Committee meetings since 2013. The labelling requirements would be less trade restrictive if translations of internationally standardized elements of labels could be rectified by means of supplementary labels, i.e. stickers. Such practice was allowed in India for some non-essential aspects, and was also recommended by Codex standards as an alternative to re-labelling. The latest notified regulations did not allow supplementary stickers for general mandatory information on products. Based on concerns expressed by India in previous meetings, Switzerland proposed that supplementary labelling should be provided or validated by the manufacturers, allowing them to use or approve stickers instead of repacking, thereby fulfilling the objective of consumer information.
- 3.94. The representative of the <u>United States</u> recalled her delegation's intervention from the previous meeting and sought an update on the status of India's efforts to align domestic requirements with international standards. She understood that India had expected to complete those efforts by the end of 2014. The US appreciated the newest measure notified by India: "Draft Food Safety and Standards (Food Import) Regulations, 2016", G/TBT/N/IND/53, to which it had submitted comments on 14 April 2016.
- 3.95. The representative of Australia reiterated his delegation's concern on India's delay in harmonizing India's food standards and associated labelling requirements with Codex standards. He recalled Australia's previously expressed support for the Food Safety and Standards Authority of India (FSSAI's) process of harmonizing India's food standards with those of Codex Alimentarius, which commenced in early 2013. Australia had provided FSSAI with extensive information about Australia's food standards and their enforcement, and would continue to work with India to ensure the progress and completion of the Codex harmonization process. The representative asked India to advise, firstly, on when the process of harmonization with Codex standards would be finalized, and secondly, on whether India was planning another review of its standards and whether it had considered the issues raised by WTO Members. In the affirmative, Australia asked if this process would be carried out through finalization or extension of the Codex harmonisation process, or as a separate review. Australia recalled that India had undertaken to respond to Members' comments from the November 2014 TBT Committee meeting, and sought advice on when a formal reply would be provided. Although India had agreed at the June 2015 TBT Committee meeting to forward queries from WTO Members to New Delhi and to send a response to interested delegations in due course, no response had been received by Australia.
- 3.96. The representative of <u>New Zealand</u> expressed her delegation's interest in the development of India's food safety standards and regulation and commended the steps undertaken by India in this respect. New Zealand welcomed the fact that food labels could be affixed by the importer/customs house agent (CHA) as rectifiable labelling deficiencies upon arrival of imported food consignments in the custom bonded warehouse, ending uncertainty for exporters. New Zealand also welcomed provision 7.3.1 of the regulation that required laboratory analysis to follow Codex or ISO test methods and to fully support the adoption of internationally recognized standards and test methods. New Zealand continued to have concerns with the arbitrary definition of shelf-life and the two separate registration processes, introduced in the regulation.

⁵ G/TBT/M/68, para. 2.98.

- 3.97. The representative of <u>Guatemala</u> expressed her delegation's systemic interest in this topic and its willingness to closely follow the discussion on the measure in question.
- 3.98. The representative of India thanked delegations for their interest in the matter and updated the Committee on certain issues raised in this meeting and in the previous meeting of March 2016. First, on the issue of harmonization with Codex standards, he informed the Committee that FSSAI had recently operationalized 33 Codex standards, and that the direction issued by the authority dated 26 April 2016 was available on its website. The harmonization of standards for olives with Codex was under the process of notification. The standards for pasta were also being revised. Second, he informed that the harmonization of additives with Codex was being finalized based on consideration of comments from stakeholders, such as the International Organisation of Vine and Wine (OIV); further, the revisions proposed in Draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2015 were being processed. The list of additives in the case of wine based on OIV had been approved and was in the draft notification process. Third, he informed that the FSSAI was reviewing the existing regulation on packaging and labelling, where a Draft Food Safety and Standards (Labelling and Claims) Regulation had been framed and was under consideration by the Scientific Panel and Committee. The new draft Regulation took into consideration the United States' concern regarding the labelling requirement for bulk packing but until the regulation was finalized and enforced the existing provisions of Food Safety and Standards (Packaging and Labelling) Regulation, 2011 should be followed. The delegation of India took note of other comments and suggestions and would communicate them to the authorities in capital for consideration.
- 3.2.3.9 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)
- 3.99. 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 specific trade concern, which had been raised since 2009. Argentina had repeatedly said that Regulations (EC) 479/08 and 607/09 would seriously affect the image and prestige of Argentine wines destined for the European market. The EU arbitrarily granted its member States the exclusive rights to use certain traditional expressions in each of their respective languages. Argentina considered this measure to restrict the right of other Members to use these expressions on their labels. Despite Argentina's understanding that this European legislation was inconsistent with the TBT Agreement, it had submitted in 2009 a dossier for approval of the terms "Reserva" and "Gran Reserva". Argentina held that the substantive process of analyzing the dossier had lasted two years and seven months (from July 2009 to March 2012) and the delay in completing the formal administrative steps (inclusion on the agenda of the College of Commissioners for its approval) had lasted for over four years. Argentina made numerous efforts bilaterally, multilaterally and also plurilaterally (in the framework of the World Wine Trade Group), but it had not received any positive response from the EU. This situation affected the entry of high quality and differentially priced Argentine wines and placed wine exports at a disadvantage compared with those of competitors that identified and labelled their wines as high quality.
- 3.100. Argentina further expressed concern regarding the EU's new regime as there was no information on how it would affect the Argentine application for registration. Argentina understood that the registration files that were initiated and processed in accordance with the legislation in force (Regulation (EC) No. 607/2009) must be concluded under the same regulations. Consequently, Argentina believed that the new European registration system should grant recognition to the traditional expressions "Reserva" and "Gran Reserva". Argentina reiterated its request for the EU to include this item on the agenda of the next meeting of the College of Commissioners and to publish the relevant regulatory act in its Official Journal, in order for Argentine wines to enter the European market without discriminatory and unjustified restrictions.
- 3.101. The representative of the <u>United States</u> recalled previous concerns expressed at previous meetings: "...that this measure would severely restrict the ability of non-EC wine to use common or descriptive and commercially valuable terms, on the grounds that those terms are traditional to European wines." This was a particular concern because some of these terms did not have a

common definition across EU member States. Furthermore, she recalled her delegation's concerns about the enforcement of the regulation and how the Commission would ensure consistency of interpretation across EU member States, and requested an update from the EU on the status of the application that was submitted by the US wine industry six years ago.

- 3.102. She held that the continued lack of transparency and fulsome response to repeated requests and interventions on behalf of the US was unacceptable and considered this issue as a serious trade concern that had negatively impacted bilateral trade without resolution for years. Indeed, many US suppliers were still unable to ship their products to the EU. The US failed to see why several other Members had already been granted permission to use various traditional terms, while other Members including the US continued to wait on their applications. The ongoing delay by the Commission continued to erode market access for US wines in EU member States, and the US asked the EU to clarify the basis for the delay in approving US applications.
- 3.103. On the question of approving the applications, the US heard at the TBT Committee meeting in March that the EU would imminently make more information available about the status of the traditional terms of applications, as well as changes to the application review process within the EU. She noted that the EU had not responded to the California Wine Institute's proposed changes to the traditional terms legislation, submitted last August. She also said that the consistent delay and lack of information about the process was completely unacceptable. The US requested the EU: (i) to explain the process and how it would work in the future; and (ii) to provide deadlines to decide on the applications submitted by the US industry and for the completion of the internal review process.
- 3.104. The representative of the European Union thanked Members for the interest in the EU's requirements on wine products. As noted at the last TBT Committee meeting, 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 at that stage. 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 by the other Members were noted and he said these would be considered when carrying out the complex simplification exercise. The handling of the pending applications (whether from EU member States or other Members) would be part of this process. The EU representative expressed the EU's openness to hold bilateral discussion with trade partners at expert level.

3.2.3.10 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)

- 3.105. 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. On 27 August 2015, Chile notified the replies to the comments submitted during the public consultation on this technical regulation. Mexico understood that the measure would be enforced from 27 June 2016 and elaborated several specific concerns. First, the lack of scientific justification or international reference for the definition of the Chilean Ministry of Health on "critical nutrients". Second, Mexico considered the wording "high in ..." to convey a distinction that may cause consumer confusion. Third, Mexico said that the classification of products as high in calories, fat, sugar and sodium was trade-restrictive and unjustified by scientific evidence. Fourth, she highlighted the trade impact of the new packaging of products and the lack of transparency on the process of developing technical regulations. Finally, she stressed the lack of proportionality of the measures in pursuing the legitimate objective. Mexico asked Chile to consider a meeting between their relevant regulatory bodies in order to further discuss the measures and to find less trade-restrictive alternatives.
- 3.106. The representative of the <u>United States</u> strongly supported Chile's public health objectives of reducing obesity and related non-communicable diseases (NCDs), and the extensive bilateral

engagement on Chile's nutrition labelling regulation and its associated WTO notifications. The US appreciated the inclusion of an implementation review mechanism in the final measure, but asked Chile to consider comments received from foreign stakeholders in the context of this mechanism. As raised in past meetings, the US encouraged Chile to evaluate the impact of the "warning" element of the icons, and the use of 100 gram and 100 ml portion sizes. She reiterated the US request for a two-year implementation window from the date that the final regulation was published in order to allow industry time for compliance with the labelling requirements based on nutrient thresholds.

- 3.107. In addition, the US emphasized five outstanding issues: first, whether concentrated fruit juice would be considered "sugar". Second, she asked how Chile would verify the addition of sodium, saturated fats, sugar, and honey as this information would help their industry comply with these requirements given that Chile had indicated that, in addition to the ingredient list, it would consider technical specifications of the product or its ingredients, audits of production methods, chemical laboratory analysis, and possible other means. Third, she asked whether foods such as wholegrain breakfast cereals, whole milk, yogurt, cooking oils, and cheese would be exempt from the measure. Fourth, she asked Chile to confirm whether voluntary claims would be allowed when the claim was not related to a nutrient that exceeds the relevant threshold. Fifth, the US requested Chile to develop guidance on these issues and to consult with all stakeholders in doing so.
- 3.108. The representative of <u>Canada</u> reiterated his delegation's concerns with this measure. He appreciated Chile's responses (from August 2015) to the concerns raised by several Members in the previous Committee meetings, and expressed Canada's support for the objective of promoting healthy dietary choices and reducing obesity and related NCDs. Nevertheless, Canada encouraged Chile to consider less trade-restrictive measures. He suggested that nutrient content limits based on actual serving sizes normally consumed at one sitting could provide an effective way of meeting the policy objective.
- 3.109. The representative of <u>Costa Rica</u> reiterated the concerns raised in past meetings regarding this measure. Costa Rica continued to question the compatibility of the measure with the provisions of the TBT Agreement, especially regarding the lack of scientific evidence and the lack of basis on international standards such as those of the Codex Alimentarius. Costa Rica would continue to monitor this matter.
- 3.110. The representative of <u>Guatemala</u> reiterated concerns regarding the measure expressed in past Committee meetings. Her delegation shared Chile's concerns about childhood obesity and expressed deference to Chile's right to adopt appropriate measures to address these issues. Nevertheless, it was not clear to Guatemala how the establishment of nutrient content thresholds and labelling requirements could potentially reduce obesity since the level of a nutrient ingested by an individual depended on the habits of consumers. She said that any foodstuff had inherent nutritional characteristics, every individual had different nutritional needs and that it was impossible to decide what was good or bad solely on the basis of nutritional content.
- 3.111. She considered the requirement on the amendment to the Food Health Regulations related to the "High in" icon to raise the fear of obesity in consumers without considering other causes. This requirement did not take into consideration the Codex Guidelines that recommended labels to indicate the quantity of nutrients contained in the product rather than suggest that there are products to maintain health.
- 3.112. Guatemala understood that the measure would enter into force on 26 June and appreciated that Chile had taken into account some concerns that had been raised by other Members. Nevertheless, she noted that the Chilean delegation did not answer Guatemala's question on how the measure would reduce obesity and why the measure, as designed, did not constitute an unnecessary obstacle to trade. Guatemala said the measure should be based on Codex standards, and on science. The lack of basis on the standards in the Codex General Guidelines on Claims (CAC/GL 1 1979, point 3.5) was at odds with Chile's obligation under Article 2.4 of the TBT Agreement. Guatemala requested consultations with the Chilean Ministry of Health regarding the conditions for labelling and on the time-frame for products that were already on the market with a shelf life extending beyond the established date. She also asked whether an impact assessment was performed in the preparation of the legislation that could be compared with the impact evaluation that the Ministry of Health of Chile would elaborate in December 2016. Finally, her delegation expressed concern about the changes in labelling requirements in the

region, and stressed that Codex guidelines were not being taken into consideration. As a result, a range of different measures were being taken by Members to safeguard the legitimate objective of protecting public health, which was creating obstacles to trade.

3.113. The representative of <u>Chile</u> thanked Canada, US, Mexico, Costa Rica and Guatemala for their interest in Supreme Decree No. 977/96, amendment to the food health regulations of the Ministry of Health, in accordance with Law 20.606 - Nutritional Composition of Food and Advertising. He reiterated what he had said in the TBT Committee meetings of March and November 2015 and affirmed that Chile's measure complied with the TBT Agreement. Chile's Ministry of Health had trained its inspectors and was holding meetings with the private sector on the application of this measure and the methods by which the thresholds would be determined. Industry would start to implement the regulation on 27 June together with a process of changing industrial production processes towards healthier products. The population was increasingly interested in new measures to promote healthy lifestyles and to protect children given that one out of three children under the age of six in Chile was overweight and that there was one death every hour due to obesity. Therefore it was necessary to provide more information that contributed to better food choices. His delegation was willing to discuss further the implementation of the measure.

3.2.3.11 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)

- 3.114. The representative of the <u>Republic of Korea</u> expressed appreciation for the efforts and cooperation of the Government of India to improve the Requirements for Compulsory Registration Order (CRO) including by simplifying procedures for certification renewal and for the positive consideration regarding the grace period for the observation of IS 16046. However, he highlighted that some concerns still remain unresolved particularly in relation to India's acceptance of test reports generated under the IECEE CB Scheme. He requested that India ensure consistency with Article 5.1 of the TBT Agreement⁶ and elaborated that acceptance of test results from laboratories accredited under the IECEE CB Scheme would remove unnecessary burdens on exporters.
- 3.115. The representative of the European Union expressed his gratitude for a productive bilateral meeting on the EU's outstanding concerns regarding the CRO. He noted two unresolved issues regarding the compulsory registration scheme, namely, the streamlining of the registration procedure and the acceptance of foreign test reports. On the former, he reiterated the EU's recommendation regarding the use of a single registration for multiple factories where identical products with the same safety properties are manufactured under the control of the same company which is the brand owner. He recalled that India had informed the Committee that this point was being considered by the Ministry of Communication and Information Technology and he requested an update in this respect. On the issue of the acceptance of foreign test reports, he supported the comments of Korea and explained that under the current requirements, acceptance of foreign test reports generated under the IECEE CB scheme, or issued by laboratories accredited to international standard ISO/IEC 17025 by an ILAC MRA signatory, applied only to safety critical components. The EU urged India to consider improving their reliance on the IECEE CB scheme, and on laboratories accredited under the ILAC MRA, in order to increase acceptability of test reports beyond safety critical components. He further noted that the current rules provide for a maximum validity of test reports of 90 days, while the general international practice was not to attach expiry dates to test reports. According to the EU, the main concern should be that the product covered by the test reports fully matched the product which was submitted for registration and in this regard having a maximum validity date of the test report did not seem to contribute to achieving this objective. He requested that more flexibility be given, and that in justified cases where the product did not change, an older test report should be accepted for the purpose of the registration.
- 3.116. The representative of the <u>United States</u> highlighted new concerns with CRO's Frequently Asked Questions (FAQ), requirements on power supplies for servers, battery packs, and the BIS mark, in addition to her delegation's previously expressed concerns.

 $^{^6}$ Article 5.1 states "Members shall ensure that, in cases where a positive assurance of conformity with technical regulations or standards is required, their central government bodies apply the following provisions to products originating in the territories of other Members."

- 3.117. With respect to the CRO's FAQ, she said US industry was concerned that some of India's explanations in the FAQ actually expanded its scope. Most recently, India had published a revised FAQs dated 23 December 2015, to clarify the CRO expansion of November 2015 (notified in March 2016). She stressed that FAQ interpretations have a major impact, and that the ICT industry was forced to continually check for updates, additions, and changes to existing requirements that sometimes conflicted with one another, which created confusion and a lack of predictability.
- 3.118. By way of example, she highlighted that an interpretation in the FAQ indicated that detachable power supplies for servers must be registered. However, because this requirement was issued in the FAQ, industry was not provided an adequate transition period to adjust. US industry understood 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. She enquired as to need for registering the "power supply" as a standalone product if the replacement units were tested and certified as part of the registration process as a "critical component" of the server registration. Moreover, she pointed out that the Department of Electronics and Information Technology (DeitY) of India had indicated in previous FAQs that these products would be excluded from the CRO. She stated that US industry felt it had been caught by surprise, and in light of the concerns raised, the US asked India to suspend implementation on detachable power supplies for servers and to address industry's concerns.
- 3.119. The US highlighted that India's recent FAQ revision also prohibited mixed-cell batteries from the battery pack. She noted that mixed-cell batteries were addressed by the IECEE Committee on Technical Laboratories, as set out in decision sheet 1087. She said that use of mixed-cell batteries seemed to be globally accepted in that numerous certification bodies offered certifications of said batteries without the restrictions imposed by India. The US therefore asked India to reconsider its prohibition on mixed-cell batteries.
- 3.120. With respect to BIS mark, she recalled that on 10 February 2016 India had issued a CRO revision requiring registered goods to bear the BIS mark beginning 30 June 2016, but notified to the TBT Committee on 18 May 2016.⁷ For the US, it was not clear whether either the previously required certification statement or the mark would be accepted, or only the mark. In this respect, she queried the relevance of the guidance issued on 3 December 2015 by the Central Marks Department. She asked that India provide an update on its guidance in this respect.
- 3.121. She reminded India that US industry had submitted comments on 16 March 2016, which she hoped India would take into account. As a priority, the US requested that India extend the 30 June deadline to 10 February 2017, in order to minimize the waste of current label inventories carrying the BIS registration statement and to avoid negative impacts on consumers and business clients. Regarding the exemption for Highly Specialised Exemptions (HSE), she asked India to provide an update on her delegation's request that India modify FAQ #40 by adding that HSE shall be exempted if it was intended for sale to medium-to-large enterprises and not available to normal consumers.
- 3.122. She reiterated concerns about the need for re-testing of products in India to a BIS standard that was equivalent to the international standard. She recalled that India said it was attempting to align with international standards, but accounted for unique circumstances in India. In this respect, she asked India to elaborate, and in particular explain what necessitated re-testing in India. As a member of the IECEE CB Scheme, India already had an MRA with other signatories and should reciprocate approval of tests performed at IECEE CB accredited laboratories outside of India, and she asked if India intended to fulfil this commitment.
- 3.123. Concerning the acceptance of laboratory test results, she asked for an update on the US request that BIS-recognized laboratories only require a product sample unit to conduct verification testing if they could not resolve a suspected non-compliance issue from information exchanges between the Certification Body issuing a CB test report, the manufacturer, and the BIS-recognized laboratory. With regard to the 90-day expiration of test reports, the US noted that India's response that the time period was "adequate" did not sufficiently answer the question as to why this expiration was necessary. The expiration created an unnecessary time limit, since the product did not change in 90 days, and the US again asked what risk factors or other concern India was trying to address with this requirement. Turning to brand-based certification processes, she

⁷ G/TBT/N/IND/44/Add.5.

enquired as to the status of the US request that India only require a product to be registered once rather than by each factory. Regarding product registration and renewal, she highlighted ongoing concerns about the costly wait times for the registration and renewal processes, and asked how India intended to address this problem. Finally, she asked for an update on the US request for a clear processing time for each step of the registration and renewal process, from application submission to final approval.

- 3.124. The representative of <u>Canada</u> expressed support for the interventions of Korea, the EU and the US. Canada remained concern that the CRO may hinder or possibly exclude Canadian exporters from the Indian market due to delays in registration and testing. He requested that India provide an update on progress in harmonizing its national standards with international standards. He also asked for further information on the proposed date for entry into force, which was expected to be 1 June 2016. Recognition of foreign conformity assessment bodies accredited by signatories to the ILAC and IAF MLAs to test and certify to India's regulatory requirements would minimize the negative impact on companies wishing to export to India, and would also provide assurance to India that the recognized conformity assessment bodies were competent. Moreover, allowing accredited foreign conformity assessment bodies to test and certify to India's regulatory requirements would reduce testing costs and allow exporters to bring their products to the Indian market more quickly.
- 3.125. He recalled that at the last Committee meeting, India noted that BIS required an MRA in order to accept test results from non-BIS labs, even if they were ILAC/IAF accredited and produced test reports under the IECEE CB scheme. Canada queried the rationale for the MRA requirement, and requested further information on the scope of said MRAs. Finally, he noted that the substantive amendments to the Order with respect to the marking and labelling requirements should be notified by India to the TBT Committee, as already requested by Korea, the EU and the US.
- 3.126. The representative of <u>India</u> referred the delegates to the minutes of the previous TBT Committee meeting, as many of the issues raised (e.g. reliance of CB Scheme, recognition of foreign labs and accredited conformity assessment bodies, expiry period of test results and validity period of registration) had already been responded to at previous meetings.⁸ He mentioned that an amendment had been issued on 10 February 2016 which required registered goods to bear the BIS mark, and that a transition period had been provided until 30 June 2016 to comply with this requirement. On harmonization with international standards, he informed the Committee that Indian Standards for which compliance is mandated under the CRO (IS 616 and IS 13252) were identical to the corresponding international standards.
- 3.127. He explained that regarding the validity of test reports, a time period of 90 days had been prescribed for test reports for registration. After registration of the product with BIS, the product could be launched at any time. He elaborated that the 90-day period ensured that the report reflected the current status of the manufactured product.
- 3.128. He stated that the registration renewal process for electronics and IT products was a simple procedure. The process did not involve re-testing of product or inspection or visit to the factory as the registered manufacturer could register online, make payment of the requisite fees and enter the details of the product quantity with other requisite information, and the renewal was granted within 7 days. Regarding the need for a clear processing time, the timeline for the grant of registration was defined as 20 days, and for inclusion was 10 days. He assured Members that these timelines were observed provided there were no discrepancies in the application, test report or other documents submitted by the applicant. Finally he gave his assurances that other issues raised would be communicated to the capital for a response

3.2.3.12 Peru - Act to Promote Healthy Eating Among Children and Adolescents (IMS ID 383)

3.129. The representative of <u>Canada</u> assured his delegation's support to Peru's objective of reducing obesity and other NCDs, but reiterated the concern that this measure potentially deviated from international standards and would be more trade restrictive than necessary to achieve its objective. He suggested that nutrient content limits based on actual serving sizes normally

⁸ G/TBT/M/68, para. 2.128; G/TBT/M/67, paras. 2.123-2.126.

consumed at one sitting would provide an effective way of meeting the policy objective and that such an approach could be implemented in a manner consistent with international standards. Canada requested an update on when these regulations would come into force.

- 3.130. The representative of <u>Costa Rica</u> reiterated his delegation's concerns on this measure, and asked for an update on its implementation.
- 3.131. The representative of <u>Mexico</u> expressed her delegation's support for the concerns raised by Canada regarding the act to promote healthy eating among children and adolescents in Peru. She noted that Mexico had referred to this issue at earlier meetings of the TBT Committee, and supported the request for an update on the implementation process.
- 3.132. The representative of <u>Guatemala</u> stated that, despite Peru's right to safeguard its legitimate objective of protecting the health of its population, consideration should be given to the provisions of the TBT Agreement on the need to base technical regulations on international standards. She reiterated her delegation's concerns about the measure and the comments repeatedly expressed in previous meetings of the Committee. She argued that the impact of eating certain foods did not depend on the pre-established values for the products, but on individual's diet and consumption habits. It is Guatemala's belief that the measure at issue was not supported by scientific or technical basis to justify Peru's legitimate objective. Guatemala stated that provisions contained in the Supreme Decree deviated from the Codex General Guidelines on Claims (CAC/GL 1 1979, point 3.5), and therefore were not based on international standards, as provided by the TBT Agreement.
- 3.133. Furthermore, Guatemala recalled that the technical parameters of Supreme Decree 007-2015-SA differed from the previously notified measure. Guatemala reiterated its concerns about the provisions of Article 3, which referred to recommendations of the WHO and the Pan American Health Organization, mainly in view of the publication of the PAHO Nutrient Profile Model on 18 February 2016 containing parameters for measuring foodstuffs and beverages and their content in terms of sodium, saturated fat and sugar. Guatemala requested a thorough and detailed explanation of the practical interpretation of this law, and clarification on the use of the PAHO Nutrient Profile Model at the domestic regulatory level and on the status of comprehensive regulations for entry into force of the Supreme Decree.
- 3.134. Finally, Guatemala expressed concern on the lack of harmonization in labelling regulations across the region, by not taking into account Codex Alimentarius discussions, or the standards in force within that body. The difference between the measures to safeguard legitimate objectives of protection of health hindered trade in food products.
- 3.135. The representative of <u>Peru</u> recalled that the protection of public health was essential to ensuring welfare and improving the quality of life. He emphasized Peru's commitment to achieve this objective by developing and introducing legislation aimed at the effective promotion and protection of public health and development. He said that Law No. 30021 Ley de Promoción de Alimentación Saludable para niños, niñas y adolescentes, (Law to Promote Healthy Eating Among Children and Adolescents) had been enacted with the objective of reducing diseases linked to excess weight or obesity and chronic non-communicable diseases among the most vulnerable segment of its population, namely children and adolescents.
- 3.136. He reported that the Multi-sectoral Commission continued working on the regulatory provisions, in order to complete the implementation of Law No. 30021. The Commission's work included the advertising and precautionary warnings for certain processes food, food products sold in educational institutions, promotion of nutrition education, establishment of an observatory for nutrition and the study of excess weight and obesity. The Multi-sectoral Commission was also revising the Regulation establishing the technical parameters in respect of sugar, sodium and saturated fat content for processed foods and non-alcoholic beverages, approved by Supreme Decree No. 007 2015 SA. Notification and pre-publication of regulations governing Law No. 30021 would follow once the draft was completed, allowing sufficient time for Members to comment.

3.2.3.13 European Union — Revised Proposal for the Categorization of Compounds as Endocrine Disruptors of 19 February 2013 by DG Environment (IMS ID 393)

- 3.137. The representative of Argentina reiterated his delegation's concern with the revision process being carried out by the European Union to define its criteria for identifying substances with endocrine disrupting properties. Argentina supported the need to provide stronger protection for human health and the environment, as long as this was done with due regard for the WTO Agreements, in particular SPS and TBT Agreements. Accordingly, Argentina requested the EU to ensure that the legislative proposal resulting from this process and the authorization criteria established be based on risk assessment, taking into account the actual exposure to risk. His delegation was of the view that the risk-based approach must also continue to be the basis for defining maximum residue limits (MRLs) and import tolerances. A measure based on an approach that considered only the hazard and not the risk of its likelihood and severity may lead to disproportionate and unnecessarily trade restrictive measures, inconsistent with WTO obligations. Argentina expressed surprise that, having received news that the European Commission (EC) had already concluded its impact assessment, information to that effect did not appear on the website recommended by the European Union at the last TBT Committee meeting for consulting developments on the matter. Taking into account that impact assessment was an essential tool to guide the future decision on identifying endocrine disruptors, his delegation was concerned that the impact assessment concluded in an "accelerated" manner by the EC would not accurately reflect the scope of the impact of a future measure. Of particular concern was the fact that such an acceleration of the process could be especially harmful to the analysis of economic and social impact.
- 3.138. Further, Argentina understood that the results of the impact assessment would be discussed in mid-June in the College of Commissioners "together with" the proposal from the EC, with no opportunity for interested third countries and representatives from the scientific community or the private sector to express their opinions on the risk assessment prior to the submission of the EC's proposal. Consequently, Argentina once again urged the European Union to ensure that any measure adopted be based on sound scientific evidence, be applied in a transparent and non-discriminatory manner, and not constitute an unnecessary restriction on international trade. Moreover, his delegation drew specific attention to the fact that the countries producing raw materials were developing countries. Lastly, Argentina looked forward to the disclosure of the aforementioned impact assessment and the EC's legislative proposal, and requested to be kept informed on both matters in due time.
- 3.139. The representative of <u>Canada</u> 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. Canada considered that such an approach could unnecessarily restrict trade, as may be the case with the categorization of endocrine-disrupting chemicals and that it had the potential to unnecessarily impede EU trade in food, feed and agricultural products for both imports and exports, without increasing the safety of consumers. Canada awaited the outcome of the impact assessments and the EC's proposal for endocrine disruptors, and continued to urge the EU to recognize the importance of a risk-based approach in its evaluation of plant protection products and the setting of MRLs and import tolerances.
- 3.140. The representative of <u>New Zealand</u> expressed her delegation's continued interest in the EU's regulatory approach to endocrines and looked forward to the report due in July and its ongoing engagement with the EU on the issue.
- 3.141. The representative of <u>Chile</u> expressed concern over the time periods involved, regretting that his delegation had not been able to provide comments. His delegation felt strongly that this measure should be based on risk analysis rather than hazard identification and would be following developments closely.
- 3.142. The representative of <u>South Africa</u> thanked the EU for sharing information with his delegation in Brussels on the risk assessment carried out thus far and asked when the EU thought a notification would be submitted to the TBT Committee.

- 3.143. The representative of <u>Colombia</u> shared the concerns raised by other Members and looked forward to follow-up on the matter.
- 3.144. The representative of <u>Guatemala</u> expressed concern over this revised proposal, which it considered could adversely affect trade, and flagged that it would continue to monitor the topic closely.
- 3.145. The representative of <u>Thailand</u> registered his delegation's interest in the matter, stating that it would be following developments closely.
- 3.146. The representative of the <u>European Union</u> stated that the European Commission was committed to presenting scientific criteria by the end of the first half of 2016 which would identify endocrine disruptors in the context of the implementation of the EU pesticides and biocides legislations. He announced that on 15 June 2016, the EC had adopted a communication on endocrine disruptors, accompanied by an impact assessment, which endorsed simultaneously: (i) a draft delegated act containing criteria applicable under the EU Biocidal Products Regulation; and (ii) a draft Commission Regulation adopted under the so-called PRAC comitology procedure (Regulatory Procedure with Scrutiny), including the criteria applicable to the chemical substances falling under the EU Plant Protection Products Regulation. He added that these documents would be published on the EC's website to ensure transparency. The two draft measures including the criteria would then need to be adopted by the Commission under the relevant procedures. He assured that both measures would be notified to the WTO to allow any comments by third parties to be duly taken into account.

3.2.3.14 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)

- representative of the <u>European Union</u> reiterated concerns Regulation 30/2013, issued by the Indonesian Ministry of Health on 16 May 2013, which introduced a mandatory health warning message on sugar, salt and fat content on the label of all processed food products. Regulation 30/2013 had been modified by Regulation 63/2015, which postponed the date of application of the measure until 2019. He asked for information on any studies undertaken by the Indonesian Ministry of Health on total diet, as well as on the timing for the adoption of implementing provisions and guidelines for this regulation. He urged Indonesia to notify these measures to the TBT Committee, while still in draft form, so that comments by Members could be taken into consideration. The EU requested clarification on the following issues related to the regulation: (i) how nutrition information and related health warnings would be placed on the label, the testing methods for nutrition levels and the conduct of risk assessment related to NCDs; (ii) the possibility for Indonesia to accept test results issued by laboratories other than the ones accredited by the Indonesian National Accreditation Body (KAN) or by other competent institutions having an MRA with KAN; and (iii) the possibility to place stickers after importation, and before the placement of the products on the Indonesian market, for instance, in customs warehouses, as an alternative to labelling in the country of origin.
- 3.148. The representative of <u>Canada</u> expressed support for Indonesia's objective of reducing the risk of NCDs and appreciated their transparency on the issue. Nevertheless, Canada was concerned about the potential trade impact of Indonesia's regulatory proposal requiring labels of all processed and fast foods to bear a health warning regarding content of sugar, salt and fat. He appreciated that the regulations would now be delayed until 2019 and hoped this delay would give Indonesia further opportunity to take into account Canada's concerns. Canada requested that Indonesia provide, in due course, an update on the acceptance of test results from accredited laboratories that use internationally recognized and appropriate methodologies. Finally, Canada encouraged Indonesia to notify further amendments to this regulation.
- 3.149. The representative of <u>Australia</u> recognized Indonesia's right to implement measures which would provide consumers with information to make appropriate dietary choices and reduce the risk of diet-related NDCs. However, he stressed that such measures should be no more trade restrictive than necessary in order to achieve this objective. Australia sought further clarification from Indonesia as to why it considered a mandatory health message on processed foods was necessary to achieve Indonesia's public health and consumer information objectives. Finally, he

reminded Indonesia of its obligation to notify the WTO of any proposed regulatory changes in a timely manner and to take into account comments received from Members.

- 3.150. The representative of <u>Guatemala</u> expressed support for the legitimate objective of informing the population about foods and their ingredients. However, she said that Guatemala shared the systemic concerns expressed by other Members and would continue to follow discussions closely.
- 3.151. The representative of <u>Indonesia</u> referred back to earlier comments contained in document G/TBT/W/445. She stated that the purpose of Regulation 30/2013 was to ensure public health, particularly by addressing the risk of increasing threat from NCDs. She flagged that Indonesia was currently continuing a study, guided by various international rules, on the volume of total diet which aimed to measure changes in the pattern of salt, sugar and fat consumption within various communities in Indonesia. The implementation of the regulation would be further reflected through technical guidance which was still under discussion, elements of which included, *inter alia*, test results, inclusion of label, and designation of conformity assessment body. As a follow-up process, Indonesia was undertaking steps to increase public awareness on the prevention and control of NCDs, including its risk factors, in particular a reasonable diet of sugar, salt and fat, based on existing research results. She assured Members that the policy was in alignment with WTO regulation and that Indonesia placed utmost importance to consumer protection. Finally, her delegation was open to further discussion, including bilaterally.
- 3.2.3.15 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.10 (IMS ID 411)
- 3.152. The representative of Mexico reiterated concerns raised in previous meetings about the labelling requirements for pre-packaged food products, established in Ecuadorian Technical Regulation RTE INEN No. 022. She appreciated the bilateral dialogue held with Ecuador at the vice-ministerial level, where Mexico reiterated its concerns with regard to the labelling and requested evidence justifying how the measure meets its legitimate objective.
- 3.153. There remained a number of concerns. First, the definition of "food" in Article 3 of the Health Regulations differed from that contained in the Codex Alimentarius (CODEX STAN 1 1985). Second, she asked Ecuador to reconsider the definition of "processed food" also contained in that article as there is no international reference for distinguishing "food" from "processed food" or differences in their provision of nutrients, and to explain the basis for its distinction in the Health Regulations. Third, that the definition of "nutritional claims" of that Article and paragraph 3.1.2. of the draft of the first revision of the Ecuadorian Standardization Institute Technical Regulation PRTE INEN No. 022 (1R) differed from the framework definition contained in Codex Alimentarius (CODEX STAN 1 1985, Section 2). Fourth, Mexico suggested that the term "health claims" defined in the Health Regulations and the PRTE INEN No. 022 (1R) be applied in accordance with the provisions contained in the Codex Alimentarius Guidelines for Use of Nutrition and Health Claims (CAC/GL 23 1997, Section 7), in accordance with Article 2.4 of the TBT Agreement. Fifth, Mexico considered the system of horizontal colour-coded bars that featured on product labels of Article 12 of the Health Regulations and paragraph 5.5.4 of PRTE INEN No. 022 (1R) misled consumers as it stigmatized food products as "good" or "bad", based on the concentration of their components ignoring the Codex Alimentarius General Guidelines on Claims (CAC/GL 1 1979, Section 3.5), which suggested not displaying or using any distinctive sign featuring words, illustrations or other graphical representations that could cause consumers to be afraid of consuming food products. No food product should be classified as "good" or "bad", or as "high" or "low" in nutritional content, as there was no scientific evidence to support such classifications. She stressed that no individual food product was required to have a specific nutritional composition, as food may be very rich in a certain nutrient, but deficient in another. She further noted that balance was important in a person's diet and requested Ecuador to provide the scientific evidence on which it based its definition of the limits of nutritional content ("high", "medium" and "low").
- 3.154. Mexico understood that Article 22 of the Health Regulations established that any processed food for human consumption containing transgenic components had to display the wording "CONTIENE TRANSGÉNICOS" (Contains transgenic components) on its labelling. Also, that paragraph 5.2 of PRTE INEN No. 022 (1R) in accordance to Annex B of Ecuadorian Technical

Standard NTE INEN 1334 1, stated that the phrase "CONTIENE TRANSGÉNICOS" would be included in the main panel of the product label when the transgenic content exceeds 0.9% of the product. She advised caution when treating this type of products differently given the debate on the risk of their consumption. Many international organizations and institutions such as the WHO, the Food and Agriculture Organization of the United Nations, the American Medical Association, the US Environmental Protection Agency, and the US Food and Drug Administration considered biotech products safe. She affirmed that the objective of conveying clear information to consumers could be jeopardized when labels distinguished between identical products without scientific evidence. Mexico had submitted formal comments and requested Ecuador to organize a meeting between their relevant regulatory bodies to discuss in detail the measures adopted and to find alternative ways to minimize their impact on trade.

- 3.155. The representative of <u>Canada</u> expressed concern with regard to the burdensome nature of the conformity assessment procedures for this regulation. Canada had received industry complaints on the requirement to provide a verification checklist to demonstrate compliance on a per shipment basis. Adequate data management, coupled with periodic audits, was a less burdensome method of achieving the same objective. Canada was of the view that the measure was already having a negative impact on trade. The process of providing samples to an Ecuadorian Accreditation Organization accredited laboratory for testing, in addition to self-certification, suggested this conformity assessment was duplicative, redundant and trade restrictive.
- 3.156. He said technical regulation INEN 085 required Canadian frozen french fries industry to document every single parameter line-by-line, its methods of verification and its conformity with (i) quality parameters (e.g. defects), (ii) physical parameters (e.g. cut size) and compositional requirements (e.g. ingredients, additives, etc.). This overly burdensome document was four pages long. He thanked Ecuador for the opportunity to provide comments and welcomed any information on their efforts to improve the product certification process.
- 3.157. The representative of <u>Costa Rica</u> echoed concerns expressed by other delegations, in particular with regard to the lack of scientific evidence and the departure from the international standard. He asked Ecuador to consider less trade-restrictive measures which were aligned with the principles of the TBT Agreement.
- 3.158. The representative of <u>Guatemala</u> reiterated concerns regarding the lack of transparency in complying with TBT Agreement notification obligations and the lack of public consultation. The measure had a negative impact on trade, and was more restrictive than necessary. Although Guatemala did share the legitimate objective of combatting obesity, it was not convinced that the regulation would achieve this objective, but would rather create an unnecessary obstacle to trade. Codex guidelines were not being taken into consideration and the labelling requirements ignored other causes of the problems besides processed food products. Guatemala asked Ecuador to reconsider the design and scope of this measure, and to share the scientific evidence on which the measure was based. Guatemala had concerns that Codex guidelines were not being taken into consideration in labelling requirements in the region. As a result, a range of different measures were being taken by Members to safeguard the legitimate objective of protecting public health, which was creating obstacles to trade.
- 3.159. The representative of Ecuador thanked Members for their concerns and said that Resolution No. 116 was not related to mandatory technical regulations. With regard to RTE INEN No. 022, Ecuador had addressed concerns raised by Members and had made some changes. The graph would be situated on the upper left corner of the main or back panel. She highlighted that the threshold of 0.9% of the GM content for declaration of processed food was based on regulation CE2819 of the European Parliament and Council on GM modified foods. She stressed that the categories for the concentration of nutritional components according to reference points on the content of salt, sugar and fat was based in international references such as the standards developed by the Ministry of Health of the UK and the Food Standards Agency in June 2003 and a study on the quantitative evaluation of alternative food sectors and food labelling sectors. She further stressed that these standards were assessed by the Swedish Nutrition Recommendations Objectified (SNO) in 2005 and that roundtables were held to base the technical criteria on the parameters of international bodies. She also noted that studies from the University of Texas and scientific journals highlighted that colourings and artificial components led to altered properties in some foodstuffs and that this was related to the increase of obesity and chronic NCDs. Finally, she mentioned that the Pan-American Organization for Health's publication "Model of Profile of

Nutrients" (November 2015) established that any amount of artificial sweetener can negatively alter taste from an early age.

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

- 3.160. The representative of the <u>European Union</u> requested information on the dates for adoption and entry into force of the amendments notified under G/TBT/N/RUS/29 and requested that, once adopted, the final text be made available.
- 3.161. The representative of the <u>Russian Federation</u> thanked the EU for comments on the draft amendments to the Customs Union's Technical Regulation on Safety of products for children and adolescents. Recalling Russia's previous statements, she stated that no fixed timeframe applied to the discussion among Eurasian Economic Union (EAEU) members on the Regulation. Discussions were ongoing and a date for adoption had not yet been set. She said Russia would continue to inform WTO Members on this process.

3.2.3.17 India – Labelling regulations for canola oil (IMS ID 413)

- 3.162. The representative of <u>Canada</u> reiterated concerns relating to the FSSAI's advisory reaffirming the position that the product in question must be labelled and marketed as "Imported Rapeseed Low Erucic Acid Oil (Canola Oil)", which directly affected exports, marketing and sales of canola oil in India. Canada was concerned that the regulation was more trade restrictive than necessary to achieve India's legitimate objective. Canada strongly encouraged India to accept "canola oil" as a synonym for "rapeseed low erucic acid oil", consistent with India's past practice, the existing Codex standard for naming of vegetable oils, as well as with India's application of the Codex standard to other vegetable oils (i.e. maize and arachis). Noting that the Supreme Court of India had ruled against the FSSAI's interpretation of the regulation and that the decision had been sent to the Bombay High Court for final ruling, he asked when a ruling on the issue was expected. Canada encouraged India to consider an alternative measure regarding labelling requirements for canola oil that did not unnecessarily create a barrier to trade.
- 3.163. The representative of <u>Australia</u> said that her delegation remained concerned that India's Food Products and Food Additives Regulation only allowed canola oil to be used as a secondary term, which was not consistent with the Codex Standard for named vegetable oils, which permitted the use of synonym descriptors for "rapeseed oil", including canola oil. He said this was an unnecessary labelling requirement affecting all exporters of refined canola oil to India, and Australia called on India to remove it. Australia understood that the term canola oil was often used to describe domestic products that were available for sale in India. Australia called on India, once again, to complete the harmonization of its food standards with Codex as soon as possible.
- 3.164. The representative of $\underline{\text{India}}$ replied that there had been no change in the regulatory status since the previous meeting held in June 2015 and referred interested delegations to India's intervention from that meeting.

3.2.3.18 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)

3.165. The representative of the <u>European Union</u> restated his delegation's concerns, expressed in previous TBT Committee meetings as well as in the still unanswered written comments submitted to Thailand in December 2015, with the strict labelling requirements included in the regulation and with the lack of clarity of both the regulation and its implementing technical guidelines. The EU noted, in particular: (i) the lack of clarity of the provisions relating to the messages permitted on the label, which may lead to inconsistent interpretations by economic operators; and (ii) the impact that the Thai regulation may 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 concerned. The EU also asked Thailand to confirm the information that a working group has been created to review and amend the Thai regulation, and the technical guidelines, so as to clarify

⁹ G/TBT/M/66, para. 3.167.

some of their provisions. According to this information, stakeholders would be consulted and, in the meantime, enforcement would have been delayed. A request for confirmation of the above information had been addressed to Thailand by several Members, including the EU, in March 2016. The EU asked Thailand to provide information on the outcome of considerations on graphic health warnings and invited Thailand to notify any draft proposal to the TBT Committee, so that eventual comments by Members could be taken into consideration.

- 3.166. The representative of the <u>United States</u> expressed her delegation's support to Thailand's efforts against excessive alcohol consumption and its detrimental health effects. She also said that, at the same time, the US hoped that, after further review, Thailand would be able to achieve these goals in a way which would not create unnecessary obstacles to international trade. In this respect, she said that the current regulation remained unclear in a number of ways, making it impossible for companies to comply with it. For instance, the US considered as problematic the following aspects of the measure: (i) that it lacked enforcement procedures; (ii) that it lacked clarity on how labels would be determined to "directly or indirectly persuade consumption or make claims on the benefit or quality of an alcoholic beverage"; and (iii) that it lacked definitions for terms such as "immoral" and "exaggerated statements". The US also posed the following questions: could Thailand please provide the scientific evidence and studies it said had informed the policy at issue? Could Thailand confirm that, under the measure, graphic warning labels would be required to cover more than 25% of the label? Was Thailand considering an evaluation of the regulation after 18 months? If so, could Thailand explain the evaluation process and whether evaluation results would be shared with trading partners? Could Thailand confirm whether it intended to suspend implementation of the measure and set a timeline for when Thailand could provide new clarity on the regulations?
- 3.167. The representative of <u>Canada</u> welcomed any new developments regarding Thailand's regulations on alcohol, including any inter-departmental working groups, and hoped that any new regulations would be developed in consultation with relevant stakeholders, including importers. He hoped, more specifically, that the new regulations would take into account the fact that Canadian wine labels were not intended to appeal to children or promote irresponsible alcohol consumption. Canada understood that Thailand was still considering the use of graphic warning labels and would therefore appreciate an opportunity to comment on this particular aspect. Noting the recent design contest for graphic health warnings, Canada emphasized the importance of informing consumers of the dangers of excessive consumption or abuse of alcohol.
- 3.168. The representative of New Zealand expressed her delegation's support of Thailand's right to introduce new regulations to address specific public health concerns. New Zealand appreciated, in particular, that in seeking to address the harmful use of alcohol, the technical regulation at issue was directed toward achieving a legitimate public health objective. As previously raised in both written form and in this Committee, New Zealand was nonetheless still concerned that the new labelling requirements were unnecessarily trade restrictive, and that the regulation was unclear, and unworkable in practice. She also asked Thailand update Members on any discussions on the revision of the measure, and when updated regulations would be notified to the Committee. Additionally, would the regulations not be enforced until the new amendments were made? Finally, she asked Thailand for an update on the proposal to implement a graphic health warning label system for alcoholic beverages: was Thailand intending to introduce mandatory graphic health warnings on alcohol labels and if so, when did Thailand expect to notify WTO Members of the new draft regulation?
- 3.169. The representative of <u>Australia</u> asked Thailand to confirm whether the Ministry of Public Health was indeed planning to draft amendments to clarify the current alcohol labelling and implementing guidance document. He also requested that the Thai government submit an official translation of the technical guidance to the TBT Committee in one of the WTO languages.
- 3.170. The representative of <u>Chile</u> said that, while his delegation supported the public policy objective Thailand was addressing with this technical regulation, Chile also considered that there should be a less trade-restrictive measure available. He also asked Thailand if there would be a new draft on public health and whether such draft would be notified to the Committee for comment before its implementation. Finally, he noted that a series of questions Chile sent to Thailand on 9 March 2016 remained unanswered.

- 3.171. The representative of <u>Japan</u> said that his delegation shared the concerns raised by the EU, US and Canada. Japan was still concerned with Thailand's guideline dated 30 September 2015 and reiterated its request to Thailand to revise the examples listed therein, taking account of its comments at previous TBT Committee meeting.
- 3.172. The representative of Guatemala said that while her delegation recognized the need and legitimacy of protecting consumer health by reducing levels of alcohol consumption, it was nonetheless still not convinced that the measure in question, which established certain criteria with respect to labelling for alcoholic beverages, was effective in terms of reducing such consumption. In that light, Guatemala asked Thailand for a precise and detailed explanation of the scientific evidence and other considerations which led it to conclude that the measure in question would effectively reduce consumption of alcoholic beverages without being more restrictive than necessary to achieve its legitimate goal. In this respect, she noted that the measure could cover the use of certain expressions on a label that indicate the quality of the alcoholic beverage, such as "premium", "finest", "original", "limited release", and "añejo". Guatemala was concerned that by banning the mentioning of such international terms of recognition, the measure would not only put in danger the recognition and description and the quality of the product, but it could also infringe the legitimate intellectual property rights that persons and companies have over the brands they own. Guatemala therefore considered that the terms that Thailand prohibited were not intended to stimulate consumption of alcoholic beverages. On the contrary, such terms provided objective and clear information to the consumer on the type and quality of the product being bought.
- 3.173. The representative of <u>South Africa</u> associated himself with the concerns by previous delegations and reiterated the concerns expressed by his delegations in previous meetings.
- 3.174. The representative of <u>Thailand</u> explained that the objective of this regulation was to fulfill the goal of addressing alcoholic-related problems and served the purpose of consumer protection, especially with respect to children and young people. The regulation did not intend to create any unnecessary obstacles to trade, and was therefore not contrary to Article 2.2 of the TBT Agreement. Following the notification of this regulation, the relevant Thai authorities had conducted numerous meetings with both private and public sectors of concerned Members. Explanations and technical clarifications were provided in respect of how to comply with the regulation. He also clarified that the regulation has been uninterruptedly implemented and enforced since April 2015. He also said that any additional technical concerns and repeated questions (including comments raised during this meeting) should be sent to, and would be further considered by, the Thai TBT national enquiry point and the Office of Alcohol Control Committee under Department of Disease Control. Finally, as already indicated in previous meeting, Thailand explained that, in the case of any doubt, exporters were welcome to send the example of alcoholic beverage labels to the Thai Department of Disease Control, Ministry of Public Health, for advice or consultation.

3.2.3.19 Ecuador – Draft Technical Regulation of the Ecuadorian Standardization Institute (PRTE INEN) No. 189: "Labelling of Alcoholic Beverages", G/TBT/N/ECU/243 (IMS ID 433)

3.175. The representative of the <u>European Union</u> recalled his delegation's concerns about Ecuador's Technical Regulation 189 on the labelling of alcoholic beverages, already expressed in previous Committee meetings, in particular on (i) the obligation to state the name of the importer in the front label. In this regard the EU referred to the Codex standard CODEX STAN 1-1985 (Rev. 1-1991), which did not establish any obligation regarding the information to be put on the front label; (ii) the requirement that the labelling of alcoholic products be done in the country of origin, not allowing labelling or relabeling in a primary customs area. In this respect the EU referred to CODEX STAN 1-1985 (Rev. 1-1991), which allowed for the use of supplementary labels; (iii) the need to undergo certification by a conformity assessment body in order to verify compliance with labelling requirements. Here the EU recalled the Codex Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995), which established that inspection and certification systems should be fit for purpose, based on risk assessment and be efficient. Ecuador had previously informed the Committee that they were still in the process of analyzing the comments received from Members and the EU asked at what stage this process was. The EU looked forward to receiving a reply to their comments submitted on 1 July 2014.

- 3.176. The representative of the <u>United States</u> supported other Members' interventions and raised concerns, particularly with Ecuador's requirement that the name of the importer of alcoholic beverages be placed on the exported product in the country of origin, with no flexibility for placement in customs bonded warehouses via the use of supplementary labels (stickers). At the previous TBT Committee meeting, Ecuador had noted that it was suspending this regulation and the US requested that Ecuador confirm this suspension through a notification to the WTO. She asked for an update on Ecuador's efforts to align the suspension with customs regulations.
- 3.177. The representative of <u>Canada</u> asked Ecuador to confirm the suspension of the regulation that required that labelling of alcoholic products be done in the country of origin. He indicated that the standard practice in the internationally traded spirits industry was to apply, in the country of production, generic front labels providing mandatory information. All country-specific information was then affixed on the back or secondary label in customs-bonded warehouses located in the importing country. Ecuador had indicated at previous TBT Committee meetings that the competent authorities were looking at revising the measure in view of the comments received. He invited Ecuador to provide an update on whether the comments had been taken into account and whether Ecuador would be notifying any amendments to the regulation.
- 3.178. The representative of <u>Chile</u>, echoing the concerns expressed by the EU, US and Canada, indicated that Chile had received a positive response to its written comments submitted to the Ecuadorian Enquiry Point where Ecuador confirmed that the suspension of the measure was under consideration. Chile asked Ecuador that they notify this suspension as an addendum to the original notification.
- 3.179. The representative of <u>Guatemala</u> questioned whether this measure was based on evidence showing that the measure sought to reduce consumption without being more restrictive than necessary to achieve that legitimate objective. Guatemala asked for information on the current situation of the measure and the various time periods involved.
- 3.180. The representative of <u>Ecuador</u> confirmed that No. 189 Labelling of Alcoholic Beverages was currently suspended and stressed that its national authorities were still assessing the concerns and comments made by Members.
- 3.2.3.20 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)
- 3.181. The representative of the <u>Republic of Korea</u> recalled that his delegation had asked China to accept test reports issued by internationally accredited laboratories in previous TBT Committee meetings. China, however, had not taken on board this request, leading to unnecessary duplication of testing for imported medical devices that had already been tested, thus causing additional expenses and export delays. Korea therefore reiterated its request for China to accept internationally accredited laboratories' test reports and internationally recognized test reports if they were based on the same criteria that China was adopting under its regulations. Korea expressed willingness to continue to work together with China on this matter, and hoped to find a reasonable solution as soon as possible.
- 3.182. The representative of the <u>European Union</u> referred back to its concerns raised during the last meetings of the Committee in relation to the issue of the clinical trials required for the registration in China for Class II or Class III medical devices, the delays in this registration procedure, and the requirement to register the medical devices in the country of origin. On the issue of duplicative clinical trials, during the March 2016 meeting the EU had asked for confirmation from China that during the marketing approval of medical devices, manufacturers might 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 populations would not be accepted. As China had not been in a position to answer these questions at that stage, the EU reiterated its request for further clarification on this issue. Furthermore, the EU requested China to accept test reports from foreign laboratories accredited by accreditation bodies that were members of ILAC, as an

alternative to in-country electromagnetic compatibility testing in China and to exclude from the registration certificate the documentation on product technical requirements, which might be confidential. Finally, the EU again asked China to grant a transitional period of three years. Further guidelines detailing the relevant processes would be also welcomed.

- 3.183. The representative of <u>Canada</u> acknowledged the response provided by China at the March 2016 meeting regarding Order No. 650 of the State Council but requested further clarification of specific elements of the regulations. With regards to duplicative clinical trials, Canada was aware that in 2014 and 2015 China had issued clinical trial exemption catalogues for Class II and Class III medical devices and the Medical Device Clinical Trial Evaluation Guidelines. Canada understood from various news reports that China would further expand the scope of the exemption catalogues and would publish a second batch of medical device clinical trial exemption catalogues in 2016. Canada acknowledged China's response that medical devices not listed in the catalogue could be the subject of applications for exemption if relevant materials could be provided when registered to prove the safety and effectiveness of the medical devices. However, Canada remained concerned that the requirement for companies to apply for exemptions posed an unnecessary administrative burden on Canadian medical device exporters.
- 3.184. In addition, Canada continued to have concerns with regards to Article 35 of Order No. 5, which stated that, for in vitro diagnostic products, a focused clinical evaluation should be conducted in China. As mentioned in the November 2015 Committee meeting, Canada was concerned that this constituted an unnecessary and duplicative clinical trial requirement for Canadian exporters of in vitro diagnostic products that had received prior regulatory approval in other foreign jurisdictions, including Canada. Canada would appreciate an update from China on whether it intended to make changes to this regulation to allow in vitro diagnostic products that had received prior regulatory approval without requesting a duplicative clinical evaluation. With respect to Article 13 of Order No. 4 and Article 15 of Order No. 5, which required imported medical devices to "obtain market approval from the country (region) where the applicant's business registration was or the product was produced", Canada continued to be of the view that restricting access to products that might not be registered in the country of origin might create unnecessary barriers to trade while further limiting Chinese consumers' access to life-saving and life-improving medical devices. Canada was aware that, at the November 2015 meeting of the US-China Joint Commission on Commerce and Trade, China had agreed that, in the area of market access, it would give imported medical devices the same treatment as those manufactured or developed domestically. China was asked to provide clarification regarding this agreement, e.g. whether it applied to all imported medical devices, regardless of their country of origin, and whether it meant that imported medical devices were no longer required to be approved in their country of origin.
- 3.185. As mentioned in the March 2016 Committee meeting, Canada remained concerned with the Electromagnetic Compatibility (EMC) testing that was required by Chinese regulators in order for a medical device to be registered. The EMC standard that China used was identical to the one issued by the International Electrotechnical Commission (IEC), to which China was a member. However, China had not accepted test reports issued by internationally accredited laboratories that abided by the IEC standard. Canada was aware that, in March 2016, the global safety science company UL had announced the launch of its new China Food and Drug Administration (CFDA) testing programme for medical device manufacturers. According to UL, this programme allowed medical device manufacturers outside of China the option to participate in and complete the required series of tests for CFDA approval at a local UL laboratory outside of China, with the support of onsite engineers from CFDA testing lab. China was requested to confirm that it would now accept the results of safety and EMC testing of medical devices conducted at UL laboratories outside of China. Canada was looking forward to working with China in a constructive manner with a view to addressing these and other aspects of the regulation.
- 3.186. The representative of <u>China</u> stated that Regulations for the Supervision and Administration of Medical Devices divided medical devices into three categories according to the level of risk: Class I, II and III, from low risk to high risk, each one regulated differently. Class I medical devices only needed to be filed, while Classes II and III needed to go through registration. Regarding manufacture, Class I medical devices only needed to be filed, while Classes II and III had to be examined and approved by CFDA. Regarding business operation, no special limits were set by CFDA on Class I medical devices, Class II medical devices needed to be filed, while Class III medical devices had to be licensed. The medical devices not listed in the catalogue could also

apply for exception if relevant materials could be provided when registered to prove the security and effectiveness of the medical devices.

- 3.187. In order to further improve the management of medical device registration and unify the clinical evaluation requirements of medical devices, in May 2015 CFDA had issued a Technical Guideline on Clinical Evaluation of Medical Devices. The guideline clarified the requirements for clinical trial. For data collection of clinical trial or clinical use of the same category of medical devices, the data obtained from clinical trial or clinical use could be generated either from China or abroad. For imported medical devices, if their clinical trial was in accordance with relevant Chinese laws and the technical requirements in the guideline, applicants might submit the clinical trial data used when they were listed in other countries. The application files should at least contain ethics committee opinion, clinical trials protocol and clinical trial reports. The applicants were also required to submit relevant supporting data on whether the clinical performance and/or safety of the product differed from ethics. CFDA was working on a second catalogue of medical devices that could be exempted from clinical trials. This catalogue would also contain some of the *in vitro* diagnostic reagents products, which had not been included in the first catalogue. The catalogue was currently undergoing public comment.
- 3.188. To address Members' concerns on market approval from the country of origin, China stressed the importance of this requirement in order to ensure the security and effectiveness of medical devices and to protect the health of Chinese consumers. If the country/region where the applicant filing for registration or the production address was located did not administrate the product as a medical device, the applicant could submit market approval in the country/region where the registration or production address was located. For the formality of the above-mentioned certificates, CFDA had no additional requirements on the form. CFDA would continue to communicate with relevant enterprises and associations both foreign and domestic on these measures and would fully considered comments received from Members.

3.2.3.21 Ecuador – Proposed Motor Vehicle Safety Regulatory Requirements (RTE INEN 034), G/TBT/N/ECU/32, G/TBT/N/ECU/32/Add.1-6 (IMS ID 409)

- 3.189. The representative of <u>Mexico</u> thanked Ecuador for taking into account Mexico's comments on the recognition of foreign standards being considered equivalent to those of the United Nations Economic Commission for Europe (UNECE). However, she specified a number of persisting issues with regard to the current measure. Mexico understood that RTE INEN No. 034 on domestically-produced or imported motor vehicle safety parts, notified to the WTO on 31 March 2016, took into account UNECE standards, including acceptance of conformity assessments based on the standards of the United States (FMVSS), China (GB), Australia (ADR), Korea (KMVSS) and Japan (JIS).
- 3.190. Mexico reiterated its concern over the transition period for the entry into force of the regulation, as despite the initial establishment of a 180-day deadline (six months), and extension to enable domestic industry to adapt to the new specifications of the measure, by granting a transition period of one year and six months, Mexico still considered that the period should have been extended to April 2017. This would allow for two years in which to offset the trade losses for enterprises that exported vehicles to Ecuador.
- 3.191. Self-certification continued to cause difficulties for those subject to the regulation. The measure appeared to be more burdensome than necessary, thus potentially violating the principle of proportionality enshrined in the TBT Agreement. As this was a sector that was highly regulated at an international level, there was no reason not to accept this type of certification for vehicles circulating in Ecuador. Therefore Mexico requested that Ecuador accept self-certification as a demonstration of compliance with the technical regulation by producers and to extend the transition period by two years for compliance.
- 3.192. The representative of the <u>United States</u> supported the objectives of Technical Regulation RTE INEN 034 and thanked Ecuador for its openness to explore solutions, find the least traderestrictive approach to its objective, and ultimately accept US Federal Motor Vehicle Safety Standards (FMVSS) compliant products.
- 3.193. US automotive regulations were amongst the most stringent and effective at protecting safety and reducing emissions. While lauding Ecuador for the change, she highlighted that the

requirement for third-party certification presented a problem for products built to FMVSS. Automotive products manufactured to US requirements would incur additional costs to acquire third-party certification since it was not a normal part of the US compliance process.

- 3.194. The requirement for third-party certification thereby put them at a competitive disadvantage to products built under different compliance verification systems, as they would need to obtain it at an additional expense for the Ecuadorian market whereas products built under schemes relying on third-party certification had already spread those costs across their entire fleets. Manufacturers carried out their own product testing and verification prior to selling automotive products in the US market. Moreover, the National Highway Traffic Safety Administration (NHTSA) provided strong compliance oversight through random, anonymous purchasing and testing of products that are sold in the US market. NHTSA anonymously bought and tested automotive products subject to its regulations. It then provided diligent enforcement for those products found non-compliant. Recent high level cases had proven the effectiveness of the US system for rooting out problems with conformity of production. NHTSA's Blue Ribbon Letter programme gave trading partners the confidence that the automotive products exported under the programme were subject to this same high standard safety compliance process in the United States. The US further expressed confidence that the programme could provide compliance surety as an alternative to third party certification. The US also offered any assistance necessary to help to assure Ecuador of the effectiveness of its regulatory processes and the Blue Ribbon Letter programme for compliance verification.
- 3.195. The representative of <u>Canada</u> supported the interventions from Mexico and the US on this issue. Most motor vehicles manufactured in Canada were actually built to similar standards as the US Federal Motor Vehicle Safety Standards (FMVSS) and they were called the Canadian Motor Vehicle Safety Standards. As the US delegate had indicated in respect to the US standards, Canada also provided one of the most stringent and comprehensive performance outcomes with respect to vehicle safety. Canada strongly encouraged Ecuador to, in addition to the recognition that they had given for FMVSS standards, do the same for the Canadian version of those standards. He further noted that the conformity assessment procedures were as important as technical regulations to facilitate trade. Obligations under the WTO required that compliance testing in conformity assessment procedures be no more trade restrictive than necessary. Canada requested that Ecuador consider self-certification of vehicles built to both the US and Canadian safety standards. Canada also encouraged Ecuador to maintain a flexible vehicle certification process open to both type-approval and self-certification.
- 3.196. The representative of <u>Ecuador</u> said many comments and concerns had been received which had been analyzed among the competent bodies and sectors involved. Based on this, Ecuador had made various modifications to the measure. Technical Regulation No. 034 had again been modified (third amendment), in relation to the safety element "Electronic stability control", and would be compulsory for the year 2020 models, which were previously compulsory for the 2018 year models. In addition, the measures in this regulation could be fulfilled under the UNECE standards for the economic condition as well as the Australian, American, South Korean, and Japanese measures. These were already established in Annex b to the modification 3 of the Regulation 034.

3.2.3.22 Kingdom of Saudi Arabia – Decree of the Saudi Arabian Ministerial Council on the sale and marketing of energy drinks of 4 March 2014, G/TBT/N/SAU/669, G/TBT/N/ARE/262, G/TBT/N/QAT/389, G/TBT/N/SAU/910, G/TBT/N/SAU/912 (IMS ID 442)

- 3.197. The representative of the <u>United States</u> supported the Gulf Cooperation Council's (GCC) efforts to promote public health through increased consumer information and thanked the GCC for considering her delegation's comments. As had been stated in US comments submitted in April, the US remained concerned that the size and content of the warning labels and restrictions on container size were unnecessarily trade restrictive and requested the GCC to provide scientific evidence for these requirements. She also asked the GCC to provide the timeframe to finalize this measure and to update on the next steps before implementation.
- 3.198. The representative of the <u>European Union</u> supported the points made by the US. In particular, the EU shared concerns regarding the large discretionary restrictions which, on the basis of the notified draft, could be imposed on the marketing of these products by regional or local authorities. Such an approach made it possible for lower level authorities to create barriers to

trade and as such was a source of 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 thanked the Kingdom of Saudi Arabia for constructive bilateral discussions and reiterated his delegation's proposal to engage in bilateral dialogue.

3.199. The representative of the <u>Kingdom of Saudi Arabia</u> thanked the EU and the US for their comments. The GCC technical committee received Members' comments on the draft technical regulation for energy drinks which would be discussed at their next meeting in October. As explained at the previous TBT Committee meeting, the objective of the Decree of the Saudi Arabian Ministerial Council was to protect public health. Finally, he indicated that this Decree would be reviewed and Members' comments would be taken in consideration.

3.2.3.23 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)

3.200. The representative of Mexico reiterated concerns regarding Brazil's Draft Resolution No. 69, of 9 September 2014, on the compulsory listing of product ingredients in Portuguese on the labels of personal hygiene products, cosmetics and perfumes. She focused on three points raised during the last meeting of the TBT Committee. 10 Firstly, by failing to consider the existence of a widely accepted international nomenclature for the ingredients of cosmetic products (INCI nomenclature), the proposed measure might not be in line with Article 2.4 of the TBT Agreement. Furthermore, Mexico was concerned with the distinction that the draft made between products from the European Union and imports from Brazil's other trading partners (specifically those of the Latin American region), was in violation of the non-discrimination principle in Article 2.1 of the TBT Agreement. On 19 January 2015 Mexico had submitted formal comments to Brazil about the non-reliance on the INCI nomenclature system. Mexico had also requested an explanation of - or justification for - the benefits of translating the names of product ingredients into Portuguese, since these use a large number of raw materials with highly complex technical names. In response, Brazil had said that the matter was subject to domestic judicial proceedings. Mexico therefore requested Brazil to update Members on how these judicial proceedings were progressing and, if deemed appropriate, whether the comments made in regard to compliance with Article 2.1 and 2.4 of the TBT Agreement could be taken into consideration.

3.201. The representative of <u>Brazil</u> explained that the measure at issue was not yet in force and the comments received at the last public consultation process were still under technical analysis by the Brazilian Health Regulatory Agency (ANVISA). He recalled that the draft resolution was developed in order to comply with a judicial decision based on Brazil's consumer law, which established the obligation for producers of cosmetics to display on the label the chemical composition in Portuguese. However, this decision had been appealed and its effects suspended until further decision of a higher court. The draft measure did not prevent the use of the INCI (the International Nomenclature of Cosmetic Ingredients). All producers, regardless of origin, must comply with the requirement to use the INCI and translate the chemical composition into Portuguese. The Brazilian Government believed this regulation was in full compliance with WTO law.

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

3.202. The representative of <u>China</u> reiterated its concern about 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. China had repeatedly asked the EU for additional information and to facilitate addressing concerns from the Chinese industry, and was disappointed that no meaningful information had been shared, while stating that the CC certification does not fall within the scope of the TBT Agreement.

3.203. According to China, Article 5 or Article 8 of the TBT Agreement applied to EU Certification Bodies, depending on the nature of the body; if a central governmental body, both articles applied.

¹⁰ G/TBT/M/68, para. 2.205.

China referred to the following obligations for Members in this regard: national treatment, avoidance of unnecessary obstacles to international trade, prompt acceptance of applications, expeditious undertaking and completion of conformity assessment procedures, publication of the standard processing period of each conformity assessment procedures or communication of the anticipated processing period. China also pointed out that while the EU stated that EU companies were treated discriminatorily under China's regulatory framework, dozens of foreign companies received production permits according to Chinese statistics, e.g. Giesecke & Dervrient from Germany received production and sales permission for cryptogram products. The EU was urged to comply with its obligations under the TBT Agreement and to address the raised concerns in a timely manner.

3.204. The representative of the <u>European Union</u> thanked China for its continued interest and noted that arguments had been raised before by China. China, according to the EU, failed to identify concrete measures, technical regulations or conformity assessment procedures, falling within the scope of the TBT Agreement and its claims were not substantiated. The EU referred to previous statements putting forward its view regarding coverage 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.

3.205. As in this sector all interested parties faced similar challenges, namely cyberattacks, a threat to information security, a combined effort for strengthened cooperation for the use of international security standards was called for, while approaches should not prevent authorities and IT system operators to produce and use the best technology available, regardless of ownership of technology or location of equipment manufactured. The EU noted the shared interest in aiming for interoperable solutions using the best technology to increase information security. The EU invited China to continue to discuss these issues with the EU during existing bilateral dialogues on this matter.

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

3.206. The representative of Japan welcomed the clarification made by China in previous meetings that this measure would allow "over-labelling" on imported cosmetic products but highlighted her delegation's three remaining concerns. First, regarding manufacturer labelling, Articles 14 and 15 of the draft measures required, inter alia, labelling of the names and addresses of manufacturing subcontractors, which Japan considered 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. Second, 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. Third, she 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, her delegation requested that China provide a plan, such as a two-year transition period, for the smooth implementation of the new labelling regulation. As the old implementation date of 1 July 2015 had already passed, she asked China to indicate when the new implementation date would be, and whether or not China would establish a public comment period.

3.207. The representative of the <u>European Union</u> reiterated its concerns raised during recent meetings of the Committee, also sent to the Chinese authorities on 12 January 2015. In its written reply of 18 March 2015, China had indicated that it would consider the comments received. The EU welcomed the possibility of labelling cosmetic products by means of stickers, but nevertheless reiterated a number of issues included in the notified draft. First, 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. Second, the need to confirm that the efficacy assessment and the cosmetic claim verification could be conducted by any verifying organization that is scientifically and technically competent to do so, according to CFDA criteria and guidance; it was the EU's belief that any requirement for third-party verification by a Chinese organization would be

more trade restrictive than necessary. Third, the need to align the requirements regarding cosmetic claim substantiation with international best practices; it was the EU's understanding 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 ongoing, and asked China to confirm that the Administrative Measures for Cosmetic Labelling would be developed in parallel with this general framework and would not enter into force before the regulation did. Finally, the EU repeated its request to China 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.

3.208. The representative of <u>Australia</u> said that Australian businesses particularly valued transparency of regulations that impact their ability to operate in the Chinese market and expressed support for the comments from Japan, Canada and the EU on labelling requirements. He said that his delegation would welcome clearer guidance and longer implementation timeframes in order to allow time for industry to adjust to these significant changes. He further sought clarification on two aspects of the regulation that were raised at the last meeting: (i) whether animal testing for the safety of cosmetic products was not required when widely accepted alternatives were available; and (ii) if all domestic and foreign cosmetic manufacturers were treated equally with respect to product registration and approval. Clarification would be welcome once the issues were finalized.

3.209. The representative of <u>China</u> reported that the AMCL was currently still being drafted and that CFDA would follow international rules and give full consideration to valuable inputs from interested parties before finalizing the measure.

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

- 3.210. The representative of <u>Japan</u> reiterated its concern about and requested an information update on the revision of "the <u>Guideline for promoting the Application of Secure and controllable Information Technology in Banking Sector</u>", issued in December 2014. Concerns expressed related to requirements of source codes submission for risk assessment without clarifying the range of data scope being more trade restrictive than necessary in relation to the guidelines purpose. Japan asked China to revise the guideline in a transparent manner and in line with international standards.
- 3.211. The representative of the <u>European Union</u> mentioned that the EU appreciated the suspension of the implementation of the banking guidelines and listed several issues of concern such as disclosure of source code and use of indigenous technology. The EU supported Japan's statement on international standards to be taken into account and also underscored the importance of transparency and inclusiveness in the revision process, during which concerns raised should be addressed. The EU hoped that the revised regulation would be notified to the Committee, providing opportunity for comments, and referred to the revised regulation on Chinese insurance advisor authority as a good example in this regard. The EU requested an update on the process and timeline of the revision process.
- 3.212. The representative of the <u>United States</u> supported the statements of Japan and the EU, and requested an update on the revision and adoption process of the guideline. She also mentioned China's transparency obligations under the TBT agreement.
- 3.213. The representative of <u>Canada</u> supported interventions from Japan, the EU and the US, and stated that the measures were more trade restrictive than necessary, while possibly decreasing cyber security for China's network and banking IT infrastructure. He asked China to indicate whether the suspension of implementation was permanent.
- 3.214. The representative of Australia requested information on the status of the regulation.
- 3.215. The representative of <u>China</u> thanked the respective delegations for their interventions and stated that there was still no timeline for the guideline currently under revision and that China would take comments into consideration.

- 3.2.3.27 Indonesia Regulation of the Minister of Agriculture No. 139/Permentan/PD.4, 10 December 2014, concerning Importation of Carcass, Meat and/or Processed Meat Products into the Territory of the Republic of Indonesia, and Regulation of the Minister of Agriculture No. 02/Permentan/PD.4, 10 January 2015, concerning the Amendment of the Regulation of the Minister for Agriculture No. 139/Permentan/PD.4, 10 December 2014, G/TBT/N/IND/98, G/TBT/N/IND/98/Add.1 (IMS ID 461)
- 3.216. The representative of Australia thanked Indonesia for the bilateral meeting held in the margins of the previous meeting to discuss this and other issues, as well as Indonesia's statement replying to some of the concerns raised. His delegation, nevertheless, continued to have concerns about the proposed measures on the importation of meat and meat products and urged Indonesia to provide clarity on them. He noted that Indonesia had replaced Minister of Agriculture Regulations No. 139/2014 and No. 2/2015 with Minister of Agriculture Regulation No. 58/2015, which entered into force on 7 December 2015. He said that the new regulation did not address the concerns previously raised by Australia and other WTO Members, and retained trade-restrictive measures inconsistent with Indonesia's WTO obligations. The new regulation continued to prohibit the importation of a range of meat products and cuts, including certain types of offal. He underlined that Australian offal was produced for human consumption and was regulated under the same food health standards and legislation as meat for human consumption. Furthermore, Australian beef and offal had a reputation for quality, safety and reliability around the world and Australia prided itself in providing safe products. He stated that the new regulation actually imposed additional restrictions on imports of meat and meat products, including: new restrictions on how long meat products could be stored before arrival in Indonesia; and additional packing, labelling and purpose-of-use requirements on imported meat products that did not apply to domestic products. He further underlined Australia's concern that the new regulation continued to allow only State Owned Enterprises (SOEs) and Regional State Enterprises to import secondary beef cuts and carcasses, and then only in limited defined circumstances at the direction of Government Ministers, in volumes determined by Ministers in a "coordination meeting". Australia asked Indonesia to provide detailed information from Indonesia on how its new regulation was consistent with its WTO obligations, recalling Indonesia's statement that the measures are "to ensure that importers do not distort the market and cause the price to increase unfairly". Australia remained concerned that the measures would have the opposite effect of the intended result, as the limited numbers of importers would result in decreased supply, leading to price increases for Indonesian consumers. His delegation looked forward to ongoing constructive bilateral discussions on the issue.
- 3.217. The representative of <u>Brazil</u> echoed the concerns raised by Australia, recalling that Regulation No. 139/2014 fell under the scope of Brazil's request for DSB consultations in the case "Indonesia Bovine Meat" (DS506). Brazil considered that several requirements and procedures set forth in the regulation were not in conformity with WTO Agreements, especially those related to the obligation of local purchases (Article 5 of Regulation No. 139/2014); obligation of direct shipment (Article 20(1) of Regulation No. 139/2014); the discretion of the Ministry of Trade concerning the allocation of quantities allowed to each importer (Article 28 of Regulation No. 139/2014); and restriction of intended uses for the imported products (Article 32 of Regulation No. 139/2014).
- 3.218. The representative of the <u>European Union</u> shared Australia's concerns. He pointed out that the requirements included in Regulation No. 58/2015 for production premises seemed to deviate from the provisions contained in Codex Alimentarius Guidelines for the use of the term "Halal", by not allowing the processing of non-Halal and Halal products within the same premises. Indeed, the above-mentioned guidelines allow for the processing of both (Halal and non-Halal products), within the same premises or processing establishments, provided that appropriate measures are taken to prevent any contact between Halal and non-Halal products. In addition, the same guidelines provided that Halal food could be transported using facilities which had been previously used for non-Halal products if proper cleaning procedures, according to Islamic requirements, were observed.
- 3.219. The representative of <u>Indonesia</u> thanked Members for their continued interest on the matter and for raising it before the Committee. Since the concerns raised were subject to the ongoing DSU process, he committed to informing the Committee once the process had been resolved.

3.2.3.28 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)

- 3.220. The representative of <u>Canada</u> shared the concerns of the United States, mentioned at the last TBT Committee meeting¹¹, regarding Indonesia's intention to introduce local content requirements for smartphones using 4G/LTE technology. These were additional requirements to other Indonesian local content requirements, whereby telecom service providers and telecommunication operators were forced to allocate 50% of capital expenditures to local companies. Canada sought clarification on whether these new local content requirements had been notified to the WTO and whether Indonesia planned to take Members' concerns into account when finalizing these draft regulations, as per their obligation under Article 2.9.2 of the TBT Agreement. By providing treatment that was less favourable to foreign firms than that accorded to like products of national origin, Indonesia's approach was at odds with the provisions of Article 2.1 of the TBT Agreement. Canada requested that Indonesia justify the approach and indicate the legitimate objective pursued. Canada also enquired whether Indonesia had considered less traderestrictive means given the objective of the regulation and what would be the consequences for a foreign company if it were to sell 4G-enabled equipment that did not meet the local content threshold in Indonesia. He asked when KOMINFO was planning to finalize the regulation. He noted that there were many competent telecoms test labs worldwide and joined other delegations in recommending that Indonesia accept test results from duly accredited laboratories regardless of their location. 12 He sought clarification as to whether local testing of software might count towards the local content requirements and whether the Ministry of Industry intended to release the formula for local content calculation by the end of June.
- 3.221. The representative of <u>Australia</u> acknowledged that Indonesia had notified the WTO of changes to regulations on LTE technologies on 17 March 2016 and confirmed Australia's ongoing interest in this issue. He sought explanations on the consistency of the local content requirements with the TBT national treatment obligations.
- 3.222. The representative of <u>Chinese Taipei</u> raised concern regarding Indonesia's local content requirements for 4G smartphones. As Indonesia was one of its main trading partners in South East Asia, Chinese Taipei hoped that Indonesia could provide a detailed clarification on the measure and bring it into consistency with WTO rules.
- 3.223. The representative of <u>Indonesia</u> explained that the regulation concerned a set of technical standards which dealt with, among others, administration procedures for 4G services, ensuring compatibility of such device with the existing system in Indonesia. The objective of the measure was to ensure consumer protection and to bolster business environment fields in the sector, and applied to both local and foreign device manufacturers. He said that the nature of the system allowed businesses to make adjustments including resubmitting application for certification.

3.2.3.29 Chinese Taipei – GMO Labelling, G/TBT/N/TPKM/168, G/TBT/N/TPKM/168/Add.1, G/TBT/N/TPKM/168/Rev.1 (IMS ID 467)

- 3.224. The representative of <u>Canada</u> said that while recognizing and supporting Chinese Taipei's right to implement regulations that provided consumers with adequate information to make informed choices, Canada believed that mandatory labels should only be used to convey important information about the health and safety of a product. Products of biotechnology that had been assessed as safe and authorized for sale did not pose any risk to human health or safety and should therefore not require labelling. Canada believed that this objective could be best achieved through voluntary, industry-led market-driven initiatives, as these were less trade restrictive. Voluntary standards could also help ensure that labelling claims were truthful and not misleading. He reiterated Canada's concern that, in the absence of identified safety risks, mandatory GMO labelling could be misleading to consumers, as it implied that there might be "issues" with the product, where in fact there were none.
- 3.225. The representative of <u>Australia</u> said that while Australia recognized Chinese Taipei's right to implement measures that provided consumers with the information necessary to make informed

¹¹ G/TBT/M/68, para. 2.243.

¹² G/TBT/M/67, paras. 2.230 and 2.232.

food choices, he asked that Chinese Taipei reconsider the proposed requirement to label food products with no altered characteristics and no discernible GM material. Australia had outlined their concerns in previous meetings of the Committee.

- 3.226. The representative of New Zealand welcomed Chinese Taipei's engagement both bilaterally and in the Committee on the regulations on pre-packaged food, food additives and unpackaged food containing ingredients of GMOs. New Zealand considered that the labelling requirements promulgated through the regulations could be confusing to consumers, resulting in unjustified concerns. When applied to food that was highly refined, where processing removed all transgenic DNA and transgenic proteins, the labelling requirements could raise unnecessary consumer concern and potentially desensitize them to labelling regarding GMOs. Consumers might not readily appreciate the difference between food derived from GMOs that no longer contained transgenic DNA or transgenic protein and food that did not contain transgenic DNA or transgenic protein. Food or food ingredients containing GMOs that were highly refined or where the processing removed all transgenic DNA or transgenic proteins had the same composition and characteristics as non-GMO food. There was no food safety concern for the consumer. Therefore, New Zealand encouraged consideration of an exemption in the regulation for foods and/or ingredients produced using GMO, where the final product did not contain transgenic DNA and and/or transgenic proteins and for highly refined ingredients.
- 3.227. The representative of <u>Chinese Taipei</u> thanked Members for their continued interest in the measure regarding GMO labelling and the traceability system. Concerns had been noted on the potentially misleading message conveyed by mandatory labelling, the 3% threshold for labelling, the exemption of highly refined products, the traceability system, and the implementation time-frame.
- 3.228. He said the issue of GMO labelling had been the subject of heated discussion since 1998 and while the debate continued on the differences between products of biotechnology and conventional food products, Chinese Taipei noted that there had been an increase in notifications on GMO-related measures in recent years with products subject to labelling requirements and threshold levels for labelling varying amongst Members. He explained that these requirements for GMO labelling were introduced in response to requests from consumer groups to be informed when food contained GMO ingredients. During the regulatory process, Chinese Taipei had fully observed the principle of transparency by notifying the measure at all stages of the process. Following technical expert meetings where comments from interested parties were reviewed, the threshold of 3% was considered appropriate and the measure was implemented on 31 December 2015.
- 3.229. GMO labelling was required in highly refined food if GMO food raw materials were directly used in the manufacturing process, and the final product did not contain transgenic DNA fragments or transgenic proteins. Products that used highly refined food in the manufacturing process did not require GMO labelling. The traceability system did not impose any additional burden on GMO food producers as it applied to all food businesses so as to track the flow of food through the supply chain.
- 3.230. Chinese Taipei believed consumers had the right to be informed of food containing GMO ingredients but that the presence of GMO labelling was not a critical factor in consumers' purchasing behaviour and he asked that other Members share the results of their studies conducted on how consumer habits were affected by GMO labelling. If further information was required about the details of this labelling regulation, Chinese Taipei would be happy to provide assistance.

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

- 3.231. The representative of the <u>Republic of Korea</u> noted that, following the registration fee policy published on 27 May 2015, the application fees for first registration were differently priced between Chinese manufacturers and importers.
- 3.232. He recalled the explanation given by China, according to which the difference came from the on-site inspection fees of importers. To ensure transparency as well as non-discriminatory treatment between Chinese manufacturers and importers, Korea requested Chinese authorities to

separate the costs for on-site inspection from the registration fees, which was a general practice performed globally, including in Korea.

- 3.233. The representative of <u>Canada</u> acknowledged China's response provided at the March 2016 TBT Committee meeting¹³ regarding registration fees for drugs and medical device products. Canada remained concerned about important aspects of the regulation and about the general lack of clarity and transparency regarding this measure.
- 3.234. In particular, Canada continued to have concerns regarding China's Medical Device Registration Fee Schedule published on 27 May 2015, which had entered into force without any notification to the WTO, failing to give Members a "reasonable interval between the publication of requirements concerning conformity assessment procedures and their entry into force", as per Members' obligation under the TBT Agreement
- 3.235. As already mentioned at the previous Committee meeting¹⁴, Canada was concerned with China's approach of combining registration fees with on-site inspection fees for foreign manufacturers and with respect to the lack of transparency regarding the registration fees for domestic products, which were to be levied by China's provinces. Canada asked that China publish the on-site inspection fees separately from the registration fees for foreign manufacturers as well as the registration fees to be levied by China's provinces on domestic manufacturers so that it was clear what manufacturers were being charged and for which services.
- 3.236. Finally, as raised at the March 2016 WTO TBT Committee meeting¹⁵, Canada had recently taken note of China's WTO notification G/TBT/N/CHN/1169, issued on 26 February 2016, regarding new registration categories of chemical drugs, and sought additional information concerning the changes, in particular regarding the rationale for the changes to the drug registration categories. Regarding registration categories 1 to 5 for chemical drugs, Canada asked whether China was going to charge different registration fees for these categories and whether this would result in drug registration fees that differed from those announced on 27 May 2016.
- 3.237. Furthermore, Canada had been made aware by industry of regulatory exclusivity periods associated with the new drug classes (5 years for Class 1, 3-4 years for Class 2, and zero years for Class 3, 4 and 5). Canada would appreciate if China could provide clarification as to what these regulatory exclusivity periods involved and the rationale for the differing periods.
- 3.238. The representative of <u>Australia</u> continued to express the interest of his delegation in this issue. Australian businesses had raised concerns with the Australian Government regarding the introduction of the new fee schedule and resulting processes. Australia continued to share concerns raised by other delegations regarding the fee structures and process requirements for domestic and imported drug and medical device products. He asked China to outline 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.
- 3.239. The representative of Australia recalled that some of the domestic prices were based on what was termed a "provincial price". He asked China to confirm what the provincial price was, how it was determined and whether the same testing processes and requirements applied for the provincial price. Australia understood that the regulations allowed for small and micro business with an innovative medical device to have their registration fees waived for first time registration and asked for additional information on how innovative products were defined, what the criteria were, and whether domestic as well as imported products could be considered as innovative.
- 3.240. Australia acknowledged that on-site inspections were necessary to promote public health and ensure that products were safe and effective and also that inspections at foreign facilities might be more expensive. However, fees associated with foreign inspections needed to be transparent and non-discriminatory and include industry consultation prior to implementation.

¹³ G/TBT/M/68, para. 2.256.

¹⁴ G/TBT/M/68, para. 2.252.

 $^{^{15}}$ G/TBT/M/68, para. 2.253.

- 3.241. The representative of <u>Malaysia</u> joined the concerns of other delegations, and reiterated that any fees imposed for assessing the conformity of products originating in the territories of other Members should be equitable and consistent with the TBT Agreement.
- 3.242. The representative of $\underline{\text{China}}$ said that medical devices criteria were available on the website of CFDA. In the absence of other updates on the measure, she invited interested Members to refer to the minutes of the last meeting. 16

3.2.3.31 Turkey - Toy Communiqué 01/2015 (IMS ID 473)

- 3.243. The representative of the <u>United States</u> recalled her intervention made at the previous TBT Committee meeting. The US did not understand the continued disconnect between Turkey's Ministry of the Economy and Ministry of Customs. The US had thought their concerns had been addressed through the issuance of the 2016 Toy Communiqué. However, US toy shipments were still being subject to duplicative testing so she asked again when Turkey Customs would begin to adhere to the 2016 Communiqué and cease duplicative testing on toy shipments destined for the Turkish market.
- 3.244. The representative of <u>Canada</u> thanked Turkey for its willingness to address Canada's concerns. A letter dated 21 January 2016 stated that in-country toy verifications would cease in 2016. This had also been reiterated by Turkey at the March 2016 TBT Committee meeting. Despite these assertions, Canada's toy industry continued to face delays as virtually every shipment was being subjected to additional local testing prior to entry into Turkey. Canada understood that toys carrying the "CE" mark continued to be tested, regardless that this marking signified that products had been assessed to meet high safety, health, and environmental protection requirements. Therefore, products bearing this mark should not have to undergo further testing.
- 3.245. The representative of <u>Mexico</u> supported the concerns raised by the US and Canada and requested an update from Turkey.
- 3.246. The representative of <u>Turkey</u> reiterated that following a comprehensive domestic consultation process, all verifications in question of the Ministry of Customs and Trade for toys had ceased. According to Communiqué 2016/10 of the Ministry of Economy, toy imports were subject to risk analysis under the Risk Based Trade Control System (TAREKS), whereby import controls of toys were carried out electronically and on a risk basis. Inspections were conducted as physical checks and controls, including document/marking checks. Products were sent to accredited laboratories only when there were doubts concerning product safety within the framework of the communiqué. Laboratory testing was done on exceptional basis and was not systematic. Turkey was ready to discuss further with trading partners on this issue and he asked that Members submit the specific information on their claims so that they could be carefully and thoroughly examined.

3.2.3.32 Brazil - Draft Ordinance Act No. 374, 27 November 2014 (Portaria SDA/MAPA 374/2014), G/TBT/N/BRA/613 (IMS ID 478)

- 3.247. The representative of the <u>European Union</u> appreciated that the Brazilian authorities had recently opened a public consultation regarding Ordinance No. 43, 18 May 2016, notified as G/TBT/N/BRA/675, which revised draft Ordinance Act No. 374 establishing quality requirements for wine and derivatives of grape and wine, notified as G/TBT/N/BRA/613. The EU thanked the Brazilian authorities for the bilateral contacts that had taken place during the revision of the ordinance. The EU was currently analysing the text of the revised ordinance and would provide Brazil with comments accordingly.
- 3.248. The representative of the <u>United States</u> expressed concern with Brazil's wine regulations, and noted several specific issues including: proposed minimum and maximum content requirements for alcohol in table and fine wines versus sparkling wine; volatile acidity; chloride sodium; and, ash content. The US asked Brazil to explain the health and/or safety rationale behind these requirements, which were more restrictive than those set by other Members. Also of particular concern to the US was Brazil's proposed definition of "cooler", which was limited to products containing sugar, but not other sweeteners, and required a minimum of 10% fruit juice

¹⁶ G/TBT/M/68, para. 2.256.

by volume. The US found this definition to be unnecessarily restrictive and emphasized that these requirements would prevent wine with added flavours and certain wine coolers exported from the US from entering the Brazilian market. In this respect, she asked that Brazil explain the legitimate objective achieved through the enforcement of these requirements. The US was also aware of Brazil's recently notified revised wine standards, and she said her delegation was currently reviewing these standards and intended to submit comments by the 19 July 2016 deadline. Finally, she requested Brazil to provide a timeline for expected implementation of these revised wine standards.

3.249. The representative of <u>Brazil</u> stated that the measure at issue had been revoked by the Brazilian Ministry of Agriculture, and a new draft measure (Portaria SDA/MAPA No. 43/2016) was currently under public consultation, and open for comments from 18 May to 18 July 2016. This new measure had been notified as G/TBT/N/BRA/675, and he invited the EU, the US and any other interested Member to present their comments. Notwithstanding this recent development, Brazil noted that the old measure did not change labelling and quality criteria currently in force, which were in accordance with MERCOSUR rules. He repeated that the intention was not to disturb wine trade flows between Brazil and its trading partners. Members' comments from this meeting would be transmitted to capital, and he said Brazil would provide answers at the next TBT Committee meeting.

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

3.250. The representative of the <u>European Union</u> noted that on 19 April 2016, China notified to the TBT Committee the draft provisions on insurance system informatization developed by the China Insurance Regulatory Commission. He said that the quality of the regulatory process clearly benefited from the opportunity given to interested WTO Members and their stakeholders to provide comments, and shared the expectation that this approach would be applied to any other measure developed by China in this area. These draft revisions were a specific implementation in the insurance sector of the general approach to information security laid down in the series of framework regulations; the other important measures related to the multilevel protection scheme and the national security law, which were already mentioned in another STC¹⁷, but were still relevant in this particular case. The EU's comments on the TBT notification were sent on 10 June 2016, and are publicly available on the EU TBT notification database website.

3.251. As a general remark, the EU acknowledged the need to reinforce network and information security in the insurance sector. Cyber threats were complex and continuously evolving, and industry and regulators needed to respond to the emerging security risks in the financial sector, requiring sophisticated advanced technology measures. The management of cybersecurity risk was a global challenge which the EU took a close interest in. Its fundamental position in the development of its cyber-related policy was to be geographically and technologically neutral, so that policies in this area did not cause market fragmentation or distortion and did not favour or require the use of domestic products for technology; for example, it was not required that EU businesses segment certain activities in the EU, nor were EU products or solutions favoured. The EU would expect similar treatment from their global trade partners. In particular, this applied to the policies implemented in the financial and insurance sectors, but also to any sector operating essential and critical IT systems. The EU emphasised that policies in this area should not unduly hamper economic growth and innovations, but needed to be in line with international best practices, reflect ongoing discussions at international level (e.g. in the Financial Stability Board), and fully live up to WTO obligations.

3.252. As specific comments, the EU firstly noted that Article 20 and Article 56 of the notified draft referred to the need to classify information systems in accordance with the MLPS. The EU was concerned that a possible mandating of MLPS level three would prevent foreign ICT products manufactured outside China, and incorporating foreign technology, to be used in such core systems in insurance institutions. The EU requested clarification from China regarding this aspect.

¹⁷ 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) on page 16.

- 3.253. Secondly, the EU observed that the draft referred to the need for insurance institutions to induce in their system "secure and controllable hardware equipment and software products". This appeared to cross reference the language in the national security law of 2015 concerning the use of core technologies in information technology critical infrastructure and the development of the internal structure which are secure and controllable. As it has been mentioned in the related STC¹⁸, the notion of "secure and controllable" was nowhere defined in detail. The EU was concerned that those notions might be interpreted in light of the MLPS criteria for critical infrastructure, meaning that only products manufactured domestically and incorporating indigenous technology were deemed secure and controllable.
- 3.254. As the third point, the EU noticed that the notified draft contained revisions, which required insurance institutions to obtain the ownership of the source code of the equipment they induced in their system via contracts with equipment vendors, in order to control the authorized use of their source codes. The fact that the source code was an essential asset for information security equipment manufacturers had been repeatedly mentioned in the discussions concerning information security. The importance of the source code related to the core proprietary information and business secrets around which information security equipment development was based; accordingly, it would be impossible to comply with this requirement without putting at risk the whole viability of the business in this area. Moreover, the notified draft required insurance institutions to protect information security products with special protection for indigenous intellectual property owned by insurance institutions. The EU requested an explanation of the meaning of this requirement: its current understanding was that, reading these provisions in conjunction, insurance institutions should become the owner of the intellectual property rights over the encryption technology used in their system.
- 3.255. As a fourth point, the EU noted that the notified draft referred to the use of products and technologies complying with "national standards" and encryption requirements, and also referred to the application of national cryptographic application requirements for the financial sector and insurance institutions, to gradually achieve the general application of cryptographic technologies. This appeared to require the use of domestic algorithms in the encryption technology, which is used in equipment to be procured for institutions. The combined fact of using national standards and domestic encryption technology was clearly cause for concern, since it reinforced the effect of the other provisions concerning the disclosure of the source code and possibly further qualified the meaning of secure and controllable equipment. The EU encouraged China to develop a framework which built on and took fully into account international standards and practices and worked towards interoperable solutions in line with the approach of other global regulatory authorities.
- 3.256. The representative of the <u>United States</u> associated her delegation with the comments of others and thanked China for notifying the CIRC draft rule on "Supervision Rules on Insurance Institutions Adopting Digitalized Operations". Although the review of the updated draft revealed the improvement of some problematic provisions, including the requirements on "indigenous IP" and "domestic algorithms", the US still found many draft provisions problematic. The US asked for their comments to be seriously considered by the relevant agencies and to be addressed before the rule was adopted in final form and implemented. The US noted that China's current plan to finalize the rule the day following conclusion of the comment period suggested that the comment process was simply perfunctory, and expressed the hope that the draft regulation would be developed in an open, transparent, and least trade-restrictive manner.
- 3.257. With respect to Article 53 regarding the "Secure and Controllable Highest Priority", the US was still concerned over wide-spread efforts by China to impose "secure and controllable" requirements on companies using ICT products, which unnecessarily disadvantaged foreign ICT firms. While the requirement of "indigenous R&D" was removed in Article 55, Article 53 still demanded institutions to give preference in procurement to products that were "secure and controllable". Pursuant to the regulations, these institutions needed to promote gradual implementation of secure and controllable technologies. Given the lack of definition of "secure and controllable", the regulations were of major concern for US ICT companies; to the US' knowledge and understanding, the meaning of "secure and controllable" in the past included references to domestic technology requirements, and companies sourcing ICT products were already interpreting this language conservatively, meaning that domestic goods must be procured. Similar trends occurred in banking, telecommunications and other industries that China had deemed critical

¹⁸ See previous footnote.

infrastructure. The US asked China to provide a clear definition of "secure and controllable" and to confirm that no nationality-based conditions or restrictions on the purchase, sale or use of ICT products exist or were implicitly recommended.

- 3.258. The US also raised concerns about Article 54 regard Domestic Cryptography and Article 25(e) regarding Security Mechanism. While China explicitly removed the mandate for domestic encryption, there is still a reference to the "national implementation requirements on cryptography in the financial sector" without specifying in the meaning of these requirements in Articles 54 and 25(2). The US was concerned that a Chinese domestic 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 not having cryptography as their core function could still be sold in China, the regulation from 2014 covered products that overlapped with non-core function items. The US asked China to confirm that Article 54 did not require domestic encryption.
- 3.259. Furthermore, MLPS of Article 56 and "Classification and security levels" of Article 20 appeared to discriminate against foreign providers by mandating that all insurance institutions within China follow the MLPS and requiring that everything from security level 3 and above use domestic intellectual property (IP). The US stated that MLPS was inflexibly prescriptive and could restrict the ability for consumers to purchase technologies established as safe everywhere else in the world. Next to that, it was likely to be discriminatory against foreign companies. While other Members had rules to ensure security of critical infrastructure, China was including non-critical infrastructure without providing an explanation for it. The US suggested that China adopt a non-discriminatory approach and focus on legitimate security concerns within a clearly-defined category of critical information infrastructure.
- 3.260. Moreover, Article 57 regarding Information Security System Certification required that an information security system certification be accredited by China's National Certification and Accreditation Administration (CNCA), which may unnecessarily raise costs or cause potential threats for 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 it met licensing requirements. The US stated that China should recognize relevant international certification results to remove unnecessary or duplicative requirements.
- 3.261. The US also reiterated its general concerns that China seemed to be expanding its "secure and controllable" doctrine in a way that disadvantaged foreign companies, despite positive assurances bilaterally that this would not occur. In the circumstances where regulation may be necessary, the US asked China to ensure transparent process consistent with its commitments in the TBT Agreement. The US reemphasized the importance of avoiding onerous testing and certification requirements for encryption technology that would either be unnecessarily burdensome, discriminatory, or include a review of source code, or other sensitive business confidential information.
- 3.262. The representative of <u>Canada</u> understood China's desire to minimize threats to its ICT infrastructure. He agreed with the concerns raised by the EU and the US and reiterated the concerns raised by Canada at the November and March TBT Committee meetings to which additional clarifications were still being awaited. It was Canada's view that China's approach to "secure and controllable" ICT would decrease, rather than increase, the cybersecurity of China's network and insurance ICT infrastructure.
- 3.263. With respect to the Draft Supervision Rules on Insurance Institutions Adopting Digitalized Operations, he requested further information on: (i) the definition and criteria for determining security levels, and clarification on how this article would function in relation to the MLPS; (ii) how the provisions related to testing by third party institutions in Article 22 would be operationalized; and (iii) if China could clarify whether Article 25(2) which described the security management mechanism requirements, including the use of technologies and products that complied with national standards and encryption requirements, was referencing other existing legislation or if the terms would be uniquely defined for those rules.

- 3.264. Canada also noted that, following Article 31, where data was from within the territory of China, the data centres handling the information should be located within China. This article also required that the design of the computing facility comply with national standards as well as the requirements of the China Insurance Regulatory Commission (CIRC). Canada had concerns that these requirements could be overly restrictive for the intended purposes of ensuring secure data infrastructure, and sought clarifications as to why these measures were necessary for the insurance sector in China.
- 3.265. On Article 53, which provided guidelines as to the type of equipment and software that insurance institutions should consider purchasing (i.e. secure and controllable hardware equipment and software products), Canada asked China to clarify whether foreign-made software and equipment would qualify under these draft regulations, and if not, could China explain why it was necessary to impose such a limitation.
- 3.266. Article 54 highlighted the objective to work towards an "all-round application of domestic cryptography in the electronic insurance policy and insurance sector". Canada asked how this would work in practice and for any additional information about the objective.
- 3.267. As regards Article 55, Canada also requested clarification on the meaning of "indigenous IP protection" as well as information on CIRC's associated expectations regarding the implementation and interpretation of this Article.
- 3.268. On Article 56, Canada asked China to provide additional information on what level of security might be required, as it appeared to reference MLPS security requirements but was non-specific. In addition, Canada asked China to indicate how this article would function in relation to Article 20, which also appeared to set out security requirements.
- 3.269. Furthermore, Canada noted that Article 81 would allow the CIRC to authorize an "accredited information security monitoring agency" to conduct a "risk penetration test". Canada requested clarifications as to: (i) whether the accredited information security agencies would be state or private entities; (ii) what agency or agencies would be accrediting the information security monitoring agencies in question; (iii) whether such tests would be covered by non-disclosure agreements signed on mutually agreed terms between the insurance institution, CIRC and the relevant information security monitoring agency or agencies; (iv) whether insurance institutions would be advised before or, at least, following the conduct of any such test; and (v) whether the article would require separate "risk penetration tests", one authorized by CIRC and one authorized by the insurance institution. Canada also understood that Article 81 could entail the surreptitious accessing of sensitive and potentially undisclosed business information and/or trade secrets by third parties, which could be of concern to insurance institutions. Canada inquired whether CIRC had considered alternative means to reach the goal of Article 81 (e.g. through tests to be conducted internally by the insurance institution itself) and what the rationale was for excluding such alternatives.
- 3.270. Finally, Canada requested China to provide additional information on the "security certification" process and asked whether China would be adhering to international standards of accepting third-party test reports in this regard.
- 3.271. The representative of <u>Japan</u> supported the positions of previous speakers on this issue. She recalled that last October, China had issued the draft proposal for public comment to which Japan submitted its opinion, and that China had notified the issue to the WTO in April. Although the article on the requirement for the application of Chinese domestic cryptography had been reconsidered, it was Japan's view that the articles regarding terms definitions, concrete requirements for examination and evaluation and scope of the regulation were still unclear. Japan was concerned that market access of foreign companies to China might be hampered by this regulation, depending on its implementation. Japan requested China to clarify the terms definitions, the concrete contents of requirements and scope of regulation, and to ensure transparency.
- 3.272. Article 25 stated that "An insurance institution shall tighten management of cryptographic devices and operators, and use technologies and products complying with national standards and encryption requirements," and Article 54 also stated that "An insurance institution should,

according to the national implementation requirements of cryptography in financial sector, work towards all-round application of cryptography in electronic insurance and insurance sector." Those requirements might be implemented in a way which was more trade restrictive than necessary upon import of relevant products, and conformity assessment procedures of those requirements could be regarded as questionable, for example if they contained requirements for source code disclosure. Japan sought clarifications as to which requirements or conformity assessment procedures were to be applied in concrete, and claimed that foreign companies were at a disadvantage compared with domestic companies.

- 3.273. In addition, Article 53 provided that "Insurance institutions shall [...] steadily introduce the application of secure and controllable equipment". Depending on the content of measures and requirements for secure and controllable equipment, there could be similar concerns in Article 25. Japan requested China to bring Article 53 in consistency with the TBT agreement in view of principles of non-discrimination and of not being more trade-restrictive than necessary.
- 3.274. Moreover, it was Japan's view that the MLPS, referred to in Article 56, might cause discrimination of foreign companies at some levels, by requiring Chinese intellectual property in core technologies or by requiring domestic certification in China. Japan sought clarifications as to the implementation procedure of MLPS. Finally, Japan requested that the revised draft regulation be transparently implemented based on the opinions of Japan and other Members.
- 3.275. The representative of <u>Australia</u> said that Australian industry and enterprises had a great interest in any potential regulations that might impact their ability to operate in the Chinese market. ICT and cybersecurity were global issues and to be most effective, required globally consistent solutions. Australia encouraged the use of internationally accepted approaches to encryption and ICT security, thereby minimizing conflicts across systems and ensuring best practices globally. He requested further information on the status of the regulations and, specifically, on whether they would be notified to the TBT Committee. He also sought clarification on the definition of "secure and controllable ICT" in Article 53 as it was unclear what was expected of ICT systems so as to fulfil this criterion.
- 3.276. The representative of China recalled that the provisions on insurance system informatization were aimed at ensuring information security in the insurance sector. He drew Members' attention to the fact that the rule was drafted in a very transparent manner, and assured that China valued comments and input from domestic and foreign stakeholders. He informed that the draft rule was first open for public comment in October 2015, and that the CIRC, China's insurance regulator, substantially changed the relevant provisions of the rule based on the comments and suggestions of the relevant stakeholders. The CIRC officials respectively exchanged information on this rule with representatives from the USITO and the EU Chamber of Commerce in December 2015. Moreover, China had notified the revised draft rule to the WTO TBT Committee in April 2016 as G/TBT/N/CHN/1172 with a 60-day comment period and a 6-month implementation period starting from the date of circulation by the Secretariat. For these reasons, China did not understand some Members' concerns regarding transparency. China assured Members that the rule was applied in a non-discriminatory manner, also with regard to commercial encryption. China informed that dozens of foreign companies had already obtained production licences in China. China's requirements regarding "secure and controllable" did not discriminate against foreign products, services and technology either.
- 3.277. In response to the concerns of Members about the term "secure and controllable", China provided more clarity on the criteria for the determination of what constituted "safe and controllable", for the sake of transparency. First, the user's information system should not be remotely controlled without their knowledge. Second, the user's data and information should not be obtained without their prior consent. Third, the products or services providing a user's information system should not stop services without a justifiable reason. China pointed out that the term "secure and controllable" had not been created by China and was globally used.
- 3.278. Moreover, China stated that its notification of this rule to the WTO did not necessarily mean China's agreement that the rule would constitute a trade barrier or fall within the scope of the TBT Agreement. The WTO TBT Committee encouraged Members to notify trade facilitating measures and encouraged notification when a Member was unsure about his obligation to notify. China recalled that this rule was basically a requirement for an insurance service provider to establish and maintain a secure information system. For a measure to be considered a technical

- regulation within the meaning of Annex 1 of the TBT Agreement, it had to pass a three-tier test: (i) the document must apply to an identifiable product or group of products; (ii) the document must lay down one of more characteristics of the product; (iii) compliance with the product characteristics must be mandatory. China stated that Members' concerns about data residency, cross-border data transfer and other related issues had clearly gone beyond the scope of the TBT Agreement, and hence the TBT Committee was not an appropriate forum for such issues.
- 3.279. The <u>United States</u> noted that it was very important for Members to understand this measure, to be able to comment on it and to have a reasonable interval for implementation. The US was unsure whether China would implement the measure on 18 June, which would not give enough time for compliance, and sought confirmation in this regard.
- 3.280. The representative of <u>China</u> asked where the information about the 18 June date for the implementation of this rule came from, and restated that the measure had been notified to the TBT Committee in April 2016 and that a 60-day comment period and a six-month transition period had been provided.
- 3.281. The representative of the <u>United States</u> said that the implementation date of 18 June was mentioned during the recent bilateral discussions.
- 3.282. <u>China</u> drew Member's attention to the notification form China submitted to the Committee for clarity on the matter.
- 3.283. The representative of <u>Canada</u> added that, although some light was shed on the measure, there were many outstanding and unanswered technical questions. Canada would be grateful if China could answer those specific questions in writing due to their quantity and highly technical nature.

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

- 3.284. The representative of the European Union thanked Brazil for their engagement on this issue and the information provided in the bilateral meeting. His delegation understood that Ordinance 489 aimed to consolidate all existing rules on conformity assessment for toys, while Ordinance 310 dealt with safety requirements and standards. With respect to conformity assessment procedures, he asked Brazil to confirm the timeline for completing this work. The EU understood that this was in the final deliberation phase and expected an outcome by autumn of this year. Regarding specifically draft Ordinance 489, the EU was concerned with the new requirement for registration of each product for traceability purposes. The EU understood that this requirement aimed at (i) establishing a direct link between the Brazilian National Institute of Metrology, Quality and Technology (INMETRO) and each toy manufacturer or importer; (ii) facilitating the enforcement of product recall; and (iii) enabling consumers to access information about toys through a database that matched a registration number on the toy with the number for the product in the database. While the EU supported the policy objective of the proposal, it asked Brazil to consider less burdensome alternatives. The EU toy industry proposal was 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 representative highlighted the importance of further dialogue and engagement between INMETRO and stakeholders in order to develop solutions that took into account the specificity of toy business and the already existing burden on toy manufacturers around the world to comply with traceability requirements of the US and EU toy safety regulations.
- 3.285. Concerning draft Ordinance 310, the EU requested Brazil to ensure consistency between its requirements and MERCOSUR series of standards MM 300 on toy safety. His delegation appreciated that the proposed amendment to Administrative Rule 321 pursuant a requirement to film toy testing would be removed from the draft as it was an unprecedented requirement for testing laboratories.
- 3.286. The representative of the <u>United States</u> thanked Brazil for its detailed response to their intervention in March and for clarifying that the filming requirement would be removed. She asked

Brazil to confirm: (i) whether sticker labels with the registration number would be allowed to be affixed to the product or package; (ii) whether the final draft measure would be notified to the TBT Committee; (iii) whether there would be transition periods for various products and, if so, their duration and the products they would be conferred to. The US continued to monitor Brazil's progress with respect to the requests made by Members. She was concerned about the impact of these requirements on the trade with Brazil in this sector, particularly the high costs that Ordinance 489 would impose on the toy industry because of the sheer number of products. The US did not understand how the proposed changes would result in any improvement in safety. For example, the requirements for toy companies to register toys in a "family of products", was overly burdensome. Moreover, concern was expressed that the Registration System would increase costs without comparable improvements in safety. The US delegation understood the objective of improving consumer information, but noted that it was unclear how the registration system and labelling requirement increased consumer safety beyond the current system.

- 3.287. The US delegation was further concerned that a reduction in consumer choice in the market could result in many small and medium-sized enterprises abandoning the Brazilian toy market. She asked Brazil to clarify which methods INMETRO was considering for reducing the impact on these small and medium-sized businesses. Regarding confidential information, she further asked Brazil to clarify: (i) the methods to protect the information it would require to be submitted by industry; (ii) the methods to address potential CBI leaks; and (iii) whether legal liability would be one of such methods. She expressed the US's willingness to work with Brazil on this matter bilaterally.
- 3.288. The representative of <u>Canada</u> expressed appreciation for Brazil's engagement on its toy safety measures. He was concerned that these ordinances imposed unjustified costs to the toy industry without resulting in any benefit in consumer safety in comparison to the internationally recognized certification systems already in place for toys. On Ordinance 489, Canada was concerned that the requirement for factory audits for each product family would add unnecessary complexity and costs. He urged Brazil to consider a review of the ordinance and permit a Suppliers Declaration of Conformity or sampling by any laboratory accredited by the International Laboratory Accreditation Cooperation. Canada understood that Brazil contemplated changes to Administrative Rule 321 regarding the requirement for laboratories to film the testing of toys in order to register. He asked Brazil to provide an update on the status of Administrative Rule 321.
- 3.289. The representative of <u>Mexico</u> supported the concerns of other delegations and expressed willingness to dialogue with Brazil on updates of this measure and ways to avoid it becoming a barrier to trade.
- 3.290. The representative of <u>Brazil</u> clarified that the comments made both in this Committee and in the public consultation in regards of the filming and recording requirements had been taken into consideration, but that it was not possible to ensure that the requirements would be eliminated. 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. 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 recalled that the final rule was not yet in force. He said that INMETRO held a public consultation in 2014 and was considering the inputs it received. He recalled that this registration system was implemented in other sectors in Brazil without difficulties. Concerning timelines, he expected to have a final rule by August 2016. Regarding confidentiality of information, he said that INMETRO had a strict policy which was consistent with ISO/IEC 17065. His delegation would take all comments made back to capital and provide answers at the next meeting of the TBT Committee.

3.2.3.35 Colombia – Testing Requirements to be met by Toys and their Components and Accessories, G/TBT/N/COL/109, G/TBT/N/COL/109/Add.1 (IMS ID 479)

3.291. The representative of <u>Canada</u> thanked Colombia for the video-conference meeting where they discussed the recognition of third-party conformity assessment results and certificates between the two Members. His delegation understood that a draft amendment of Resolution 3388 was notified by Colombia on May 13 2016 and that comments would be received by 12 August 2016. Canada was planning to provide comments on the new draft, but understood that local testing requirements in Colombia would still be required for imported toys. Canada was of the view

that these requirements would be discriminatory and at odds with Colombia's Most Favoured Nation and National Treatment obligations. He urged Colombia to use their mutual membership in Multilateral Recognition Arrangements (MLAs), such as the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation, to mutually recognize conformity assessment results in toys. He also thanked Colombia for its engagement on this issue.

3.292. The representative of <u>Colombia</u> said that both the draft and resolution 3167 had been notified recently, providing Members with the opportunity to comment in accordance with their obligation of transparency. He confirmed that the deadline for comments was 12 August 2016 and invited Members to make comments. His delegation was aware that Canada had held discussions with the Ministry of Health of Colombia and looked forward to receiving their comments in writing.

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

- 3.293. The representative of the <u>United States</u> thanked Korea for considering allowing the use of visual grading for plywood and for accepting data submitted by its industry stakeholders. An update was sought on priority requests made at the March 2016 TBT Committee meeting. Her delegation was particularly interested to know whether Korea would suspend enforcement of the standards for plywood, glued laminated timber, and oriented strand board until Korea had a suitable method for allowing conformity assessment to be conducted in the country of origin. In addition, the US requested an update from Korea on the following requests: (i) that the Korea Forest Service (KFS) recognize the US Department of Commerce (DOC) PS 1 standard for plywood and did not require on-going testing on a per lot basis at the port of entry in Korea when the products have been marked in accordance with PS 1 by a qualified US certification body (based on the testing data recently submitted by APA, the KFS accepts PS 1 plywood of less than 12 mm that meets its strength requirements, irrespective of the Korea Forest Research Institute (KFRI) plywood standard's "five ply minimum requirement"); that the KFS recognize American National Standards on glulam along with the structural glulam standard and did not require on-going testing on a per lot basis at the port of entry when the products have been marked in accordance with those standard by an appropriate US certification body; that the KFS accept certified glulam that uses visually graded lumber in its core pursuant to provisions in the KFRI glulam standard and test data provided which demonstrates that necessary strength properties have been met; that the KFS recognize US DOC PS 2 standard for oriented strand board, recognize grades and span ratings for construction applications, and did not require on-going testing on a per lot basis at the port of entry when the products have been marked in accordance with PS 2 by a qualified US certification body; that the KFS recognize the voluminous data already gathered related to negligible formaldehyde emissions for the above products and did not require on-going testing on a per lot basis at the port of entry in Korea when the products have been marked in accordance with PS 1, PS 2, or the American National Standards for glulam by an appropriate US certification body; and that the Korean government pass the Foreign Quality Inspection Institute Law allowing US entities possessing appropriate credentials (such as accreditation to ISO 17065) to conduct conformity assessment within the US that is recognized by the Government of Korea.
- 3.294. The representative of <u>Malaysia</u> echoed concerns raised by the US, in particular with regard to the transparency of the conformity assessment procedures, the procedures for the designation of Foreign Quality Inspection Institute (FQII), and the acceptance of test reports issued by foreign testing bodies. His delegation was ready to engage with Korea on the matter.
- 3.295. The representative of <u>Canada</u> expressed appreciation for the level of engagement and collaboration demonstrated by his Korean counterparts. His delegation shared concerns raised by the US on the issue of standards, in particular the new standard for Oriented Strand Board (OSB) and requested that the KFS recognize CSA standard O325 for construction sheathing, including the grade and span ratings for structural construction applications. Further, Canada requested Korea not to require testing at or beyond the point of entry when the products had been marked in accordance with CSA O325 by a qualified North American certification body, noting that standard CSA O325 was harmonized with the US DOC's PS 2 standard. Canada also looked forward to Korea's adoption of a law or regulations regarding FQIIs that would allow Canadian entities with the appropriate mandate and experience to conduct conformity assessment within Canada that is recognized by the Government of Korea. As his delegation understood that such a law may not be in place until late 2016, Canada requested that until such a time, forest products continue to be imported without hindrance due to uncertainty over conformity assessment procedures.

- 3.296. The representative of <u>Chile</u> expressed support for the concerns raised by other delegations.
- 3.297. The representative of the Republic of Korea stressed that his delegation had abided by due process in submitting a notification to Members and providing a 60-day comment period, promulgated on 30 December 2015 with a 6-month grace period. Implementation would begin on 1 July 2016. Secondly, KFS had held some meetings on environmental law, in particular on the sustainable use of wood, which was needed for the designation of FQII through government process. The Korean national assembly had concluded its role at the end of May 2016 so KFS would resubmit it for FQII approval, at which point KFS would reinitiate the process of legislation on the notification on designation. Lastly, he stressed that Korea's notification on the OSB standard was not only for the purpose of structure but also for more general purpose, for example the manufacture of furniture interior. Furthermore, like EU practice, Korea had submitted its notification on the OSB standard on the quality standards treaty which was the same as the ISO standard. The performance standard adopted by the US and Canada was different from Korea's notified OSB standard. However, Korea was in the process of amending the notification regarding the plywood standard to accept 3 ply restructural plywood, as mentioned by the US and Canada, so as to specify Korea's bending strength requirement. Korea remained open to hold transparent discussions with concerned parties on its notification of wood products.

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

- 3.298. The representative of <u>Australia</u> thanked China for continued bilateral discussions over many months on the new coal standard and conformity assessment measures which had been notified as "urgent" in September 2014, and which had become effective in January 2015. However, Australia remained significantly concerned with the regulation and asked for a formal response to queries raised through the China TBT enquiry point over previous years and which remained unanswered. China being Australia's second largest coal export market, its industry and exporters continued to have great interest in the implementation and application of the measure.
- 3.299. Australia had noted that production from Chinese coal mines was estimated to have dropped by only 4.5% in 2015, compared with a total drop in imports from all countries of around 32%. Australia supported China's environmental objectives of improving air quality and promoting the efficient and cleaner use of coal, as well as efforts to improve the quality of coal used in its energy and industry sectors. Australia remained committed to being a reliable supplier to China of high quality thermal and metallurgical coal with low levels of impurities. However, Australia considered it important to implement these measures in a way that enhanced trade in coal and maintained competition between imports and domestic production. With this in mind, Australia requested China to respond to the following queries. Firstly, it appeared that China had based the standard on the interim measure on globalCOAL's Standard Coal Trading Agreement, which was not recognized as a standard for testing coal quality. As provided for in the TBT Agreement, Australia asked for the reason for using the globalCOAL Standard Coal Trading Agreement measure rather than the relevant and internationally recognized ISO standard ISO 13909, and also how the globalCOAL standard Coal Trading Agreement applied to domestic and imported coal.
- 3.300. Secondly, on conformity assessment procedures, China was urged to accept the test results undertaken in other countries at internationally accredited testing facilities. This would reduce duplication and costs, and would enable tests to be undertaken in a more expeditious manner, preventing potential delays at points of import when test results had to be received prior to unload. China was requested to provide an update on any improvements to timeframes and capacity for testing imported coal after arrival in China and to explain what interaction there was between national accredited testing authorities to discuss test results obtained in China where these test results differed from results obtained elsewhere. What review or appeal process existed to question cases of Chinese test results differing from Australian or other countries' test results? Moreover, Australia questioned whether China had given consideration to an independent review or appeal process in the case of differences in results between tests conducted outside China and at Chinese ports, or different results between tests at different Chinese ports, on the same shipment of coal.
- 3.301. Australia continued to have concerns as to how over 3.6 billion tonnes of Chinese domestic coal were being tested. Further, Australia asked how China was ensuring consistency between

testing conducted on imported coal and domestic Chinese coal. China was asked to provide details of the authorities that undertook testing of domestic coal in China. In this regard, what had been the results of the tests conducted for domestic coal which had been undertaken thus far, and what happened to the domestic coal that did not meet the quality standard? How was China ensuring consistency of testing across all of the import entries into China by sea, rail and road? As requested, Australia had provided multiple comments on the measure to China's TBT enquiry point and asked when a formal response would be received from China. Australia looked forward to continued discussions with China on the implementation of the measure.

3.302. The representative of <u>China</u> stressed that interim measures for quality management of coal had come into force in January 2015 and referred the Committee back to her delegation's answer to specific concerns of Australia from the November 2015 meeting. ¹⁹ China further shared a set of statistics with Members. Due to domestic and international economic downturn and other factors, China's coal consumption and import volume had significantly decreased in 2015. In 2014, coal consumption in China was valued at 4.12 billion tonnes, down to 3.96 billion tonnes in 2015, a drop of 3.88%. The import volume of coal in 2014 was 2.91 billion tonnes, down by 29.9% to 2.04 billion tonnes in 2015. Against this background, coal imports from Australia represented 0.709 million tonnes, down by 24.97% - 5 points lower than the total volume of coal imports to China. It was therefore China's belief that the interim measures had not placed any trade restrictions on Australia.

3.2.3.38 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)

3.303. The representative of <u>China</u> reiterated its concern about test method ISO 21461, referenced in Entry 50 of Annex XVII of REACH (1907/2006/EC). While appreciating the EU's restrictions on PAHs, China stated that ISO 21461 was not suitable for related conformity assessments as it was an indirect quantitative, unscientific and inappropriate method to determine PAHs, causing misleading test results. The tests also induced a high cost. GC-MS and HPLC, test methods specified in technical regulations and international standards, were more accurate and mature according to China. China asked the EU to provide the scientific rationale for using this test, to conduct a timely review and revise accordingly.

3.304. The representative of the <u>European Union</u> repeated that the REACH regulation had been notified under the TBT agreement in 2004 and had been extensively discussed with WTO Members and other stakeholders. The ISO 21461 test method was an international standard, applied by the EU since 2010. The necessary equipment (nuclear magnetic resonance spectroscopy) was a standard instrument in specialized laboratories. The EU invited China to share more details about the alternative tests referred to by China.

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

3.305. The representative of the <u>European Union</u> reminded the Committee that his delegation had provided written comments on the draft Stainless Steel Products (Quality Control) Order, 2015 on 23 October 2015 and reiterated concerns it had raised during previous meetings. He recalled that the notified draft followed similar certification measures adopted by India for steel products, such as the measure notified under G/TBT/N/IND/32 - Steel and Steel Products (Quality Control) Order, 2006, and further extended the scope of the existing Bureau of Indian Standards (BIS) mandatory certification system to three other steel products, namely stainless steel plates, sheets and strips.

3.306. The EU was generally concerned that these measures constituted an unnecessary technical barrier to trade. In particular, the EU reiterated its concerns about the necessity and costs related to the BIS mandatory certification requirements and the re-testing by BIS-authorized laboratories of steel products that had already been tested against the relevant international standards. The EU therefore asked India to confirm that the standards referred in the notified measure were equivalent to relevant international standards and, if so, urged India to refer to them in the text as well. Finally, the EU asked whether factory inspections would be required by the BIS certification scheme. According to the EU, factory visits to EU steel mills that operated quality management systems as defined in ISO 9001 would be of no added value.

¹⁹ G/TBT/M/65, para. 2.9.

3.307. The representative of <u>India</u> welcomed the opportunity to update the Committee on the latest developments. The Ministry of Steel had issued the Stainless Steel Products (Quality Control) Order 2016 on 10 June 2016, based on the draft notified to the WTO and covering three products under IS:5522, IS:6911 and IS:15997. The order was available on the Ministry's website and would come into force three months after the date of publication in the official Gazette. The Quality Control Order aimed to ensure the quality and durability of stainless steel products intended for critical end-use applications. Many of the steel products were also used as final products. He pointed out that the order applied equally to both domestic and foreign manufacturers. Regarding the concern raised on the additional cost burden for steel companies, his delegation reported that the BIS cost of certification involved marking fee, testing charges and other nominal charges and was comparable to the fees charged by other Members in similar schemes. On the requirement of testing by BIS-recognized labs, such testing was carried out as per the test methods and requirements defined in Indian Standards.

3.308. Concerning a suggestion made by the EU delegation that steel mills operating with the ISO 9001 quality management system should be exempt from the requirement of factory inspections, India was of the view that product certification differed from QMS certification. Visits to factory premises as well as on-site verification testing were part of the BIS Conformity Assessment Scheme. On the other hand, ISO 9001 certification did not cover factory testing as per Indian Standards. All remaining concerns and suggestions would be forwarded to the relevant Indian authorities for consideration.

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

3.309. The representative of the European Union, recalling its concerns raised at the March 2016 TBT meeting as well as written comments on the notified draft provided in January 2016, asked India to update the Committee on the current state of play and to explain how and to what extent India had taken Members' comments into account. He reiterated that, due to a number of inconsistencies between the notified draft and current international practices, notably the oenological practices and definitions as set by the International Organisation of Vine and Wine (OIV) and Codex, there was an expectation that, in order to be fully in line with Article 2.2 of the TBT Agreement, India would align its draft alcoholic beverages regulation with those international practices and standards. In particular, regarding wines, the notified draft established that alcohol content in wine should not be more than 15.5% by volume. Some wines actually exceeded that limit and, as OIV did not provide for maximum alcohol strength in wines, India was recommended to remove such a limit. Moreover, the content of sugar, as set in the notified draft related to "dry", "medium" and "sweet" wine, was also not in line with the OIV standard. Regarding beers, the notified draft set a maximum level of 8% alcohol by volume whereas the maximum alcohol by volume level which may be obtained with traditional brewing (i.e. without fortification) was in the range of 15 to 18%. Furthermore, the notified draft limited the type of flavours that could be used in the production of beers to natural flavours. The EU recommended that those requirements be amended. Regarding spirits, a maximum alcohol content of 50% by volume was fixed in the notified draft for some distillates and the definitions/requirements for products such as brandy and cognac were not in line with OIV standards. For other spirits such as vodka and whisky the Indian requirements were not in line with widely accepted practices. In this context, and in order to avoid unnecessary restrictions in international trade, the EU recommended that India align its requirements to OIV standards when available and, in their absence, to align its requirements to widely accepted practices.

3.310. The EU representative invited India to fully align its labelling provisions with the Codex standard for the labelling of pre-packaged foods (CODEX STAN 1-1985) and to modify and clarify the proposed "allergen and health warnings". Regarding the list of additives allowed in the production of alcoholic beverages, the European Union welcomed India's statement at the March 2016 meeting that the list of additives would be amended, and requested an update on the matter. Finally, the EU asked the Indian authorities 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.

3.311. The representative of the <u>United States</u>, while voicing support for India's efforts to develop safe and effective standards for regulating alcoholic beverages, expressed concern that there were a number of areas where India had proposed standards that fell outside of widely accepted

international norms and standards, and may restrict trade more than necessary. Following up on comments submitted in February, she noted that the Indian standard set a number of compositional limits for which standards did not exist in Codex Alimentarius, for example, chemical contaminants in alcoholic beverages. India also set limits with regard to pH, carbon dioxide, and sugar levels that seemed to pertain to the quality of alcoholic beverages more than the safety thereof. Her delegation would welcome an update on whether India intended to include a number of additives commonly used in winemaking in the list of permitted additives, and in particular sought a response to specific additives requests the US had included in its comments on G/SPS/N/IND/108, G/TBT/N/IND/51 and G/SPS/N/IND/119, submitted the previous year. Further, India was asked to provide scientific justification for these limits, as well as reference to specific scientific studies if any had been used in setting them.

- 3.312. Her delegation was also concerned with the labelling requirements associated with the measure and asked India to clarify whether stickers would be allowed to be placed on alcoholic beverages at port before the items went through customs. She reiterated her delegation's request for a response to comments submitted on 1 February on other important issues and concerns, including irregular serving size measurements, 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 of concern. In summing up, she flagged her delegation's readiness to discuss the process India had followed in order to create this standard. Had India considered existing regulations of other countries and international standards on alcoholic beverages? Her delegation would welcome the opportunity to explain its own regulations and the rationale behind their formation. Finally, the US requested a timeline for implementation of the measure, the provision of an adequate transition period to allow industry to comply with the measure, and an indication of when India planned to release an updated list of allowable additives, as it had committed.
- 3.313. The representative of <u>Canada</u> announced that his delegation continued to follow the development of India's proposed regulation, and encouraged India to ensure that it was not more trade restrictive than necessary to meet its legitimate objectives and did not discriminate among like products. He asked India to confirm whether its intention was for the proposed regulations to supersede existing standards for alcoholic beverages manufactured or sold in India. He further noted that India was proposing to limit the range for alcohol content for whiskies from 36% to 50%; however, as certain types of whisky exceeded 50%, he requested the removal of this limitation.
- 3.314. The representative of <u>New Zealand</u> expressed her delegation's 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 both seasonal and regional variants in wine production, thereby constituting an unnecessary burden on particular wine producers. Her delegation looked forward to hearing how India planned to respond to the concerns of wine producers and importers and requested an update on how comments made by Members in March had been taken into account.
- 3.315. The representative of <u>Australia</u> reported that the Food Safety Standards Authority of India had recently met with Australia's Agriculture Counsellor in Delhi and that progress had been made on the issue. His delegation also looked forward to India's favourable response to comments submitted on 28 January 2016.
- 3.316. The representative of <u>Chile</u> thanked India for the meetings held in Delhi between Indian regulatory authorities and the Chilean agricultural delegate. His delegation had also submitted comments with regard to the standards and regulations of India and suggested the possibility of separating brandy and pisco within the classifications of alcoholic beverages. He thanked India for its replies and encouraged them to continue moving towards international standards in the OIV and the Codex, as well to incorporate their concerns and comments into the development of the regulation.
- 3.317. The representative of <u>Japan</u> echoed concerns raised by other Members and recalled India's announcement at the previous meeting that the draft measure was still under consideration by the Indian authorities pending finalization and that comments were being considered appropriately in finalizing the measure. In this light, Japan requested an update on the status of the revision of the regulations as well as a timeline for adoption and urged India to take into consideration Japan's

comments on notification G/TBT/N/IND/51 whilst ensuring the consistency of the proposed regulation with international standards and practice.

- 3.318. The representative of <u>South Africa</u>, whilst supporting India's endeavours to provide its citizens with safe and high quality alcoholic beverages, remained concerned that the draft regulation contained provisions that were not in line with the oenological practices and definitions set by the OIV, the ISO and Codex. As India was an important market for South African alcoholic beverage exports, his delegation requested India to amend the draft regulations in line with the international standards as developed by the OIV, ISO and Codex, in accordance with the obligation under Article 2.4 of the TBT Agreement.
- 3.319. The representative of <u>Guatemala</u> expressed her delegation's systemic interest in the topic, and committed to following discussions closely on the measure.
- 3.320. The representative of <u>India</u> recalled that the FSSAI had published the "Draft Food Safety and Standards (Alcoholic Beverages Standards) Regulation, 2015" on its website on 29 October 2015, seeking comments from all stakeholders, followed by its notification document G/TBT/N/IND/51 with a 60-day comment period. The draft measure was still under consideration by the Indian authorities pending finalization. He assured that all comments and suggestions submitted by Members and stakeholders would be duly considered at the time of finalization of the Draft Regulation, after referral to the Scientific Panel. Further, his delegation informed that in addition to the food additives already permitted by Indian regulations for inclusion in alcoholic beverages, a further list of additives in alignment with OIV standards had been approved by the Indian Food Authority, and would be notified to the WTO in due course. Finally, in response to questions on a likely date for adoption, he informed that the measure would probably be finalized within the year, after due consideration of comments by all Members and stakeholders.

3.2.3.41 Indonesia - Halal Product Assurance Law No. 33 of 2014 (IMS ID 502)

- 3.321. The representative of the <u>United States</u> expressed gratitude to the Indonesian Government, including the Ministry of Religious Affairs, for bilateral meetings held in Geneva and in Jakarta. Her delegation recognized the importance for Indonesian consumers of knowing whether products are halal and expressed its commitment to working with Indonesia to ensure that, once the law was implemented, this objective would be achieved without creating any unnecessary barriers to trade. She reiterated her delegation's hope that previously raised concerns would be addressed in the implementing regulations. It was her delegation's understanding that the Ministry of Religious Affairs, in conjunction with a number of other government ministries, was currently drafting the new implementing regulations; an update on their content and status was welcomed. Finally, the US urged Indonesia to ensure that drafts be submitted to the WTO TBT Committee prior to being finalized in order to allow for sufficient notice and comment from all stakeholders and to allow time for those comments to be taken into account.
- 3.322. The representative of <u>New Zealand</u> noted that some issues in the draft regulation still remained unclear, and welcomed the opportunity to learn more and to provide feedback on the draft. She also noted Indonesia's obligation to notify regulatory changes to the WTO, and recalled that the current initial implementation date mentioned in the draft was 1 November 2016 for food and beverages. Her delegation asked Indonesia to ensure that WTO Members would be given adequate time to comment on the issue.
- 3.323. The representative of the <u>European Union</u> shared concerns raised by the US and New Zealand, and considered that the draft law had a very broad scope, affecting, *inter alia*, food and beverages, pharmaceuticals and cosmetics. His delegation understood that the law would require mandatory halal certification, which would imply significant additional costs for economic operators, and that it would be implemented gradually and enforced as from 2019. However, 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 this fragmented approach created uncertainty as to which requirements were applicable at any point in time. According to recent information, a draft implementing regulation would be signed and published in July 2016; his delegation would appreciate information on any developments in this respect and on the time frame for the adoption of the said regulation. He further noted the EU's request that Indonesia notify the law, in accordance with Article 2.9 of the TBT Agreement, as

well as any subsequent implementing rules, and allow reasonable time for Members' comments to be taken into consideration. Finally, the EU requested clarification on whether the provisions on mandatory labelling would also apply to non-halal products and on any other potential trade restrictions that the law may bring to such products.

- 3.324. The representative of <u>Australia</u> urged Indonesia to comply with its international trade obligations and notify the Halal Product Assurance Bill and related regulations to the WTO, providing an opportunity for trading partners to submit comments. Australia was aware that Indonesia's Ministry of Religious Affairs had issued a decree establishing a new halal certification body (BPJPH), which would come into effect from 1 November 2016. His delegation requested confirmation that interim arrangements would be put in place to ensure that imports from 1 November 2016 would not be adversely affected. Would the halal standards applied by BPJPH be the same as the standards currently applied by Indonesia's existing halal certification body?
- 3.325. The representative of <u>Indonesia</u> explained that Law No. 33 of 2014 on Halal Product Assurance addressed certain aspects regarding halal standards, including obtaining a halal certificate. The halal standard ensured the certainty of halal products for public consumption and had been created in accordance with well-known international principles of protection, justice, assurance, accountability, transparency, effectiveness and efficiency. She pointed out that the law covered food, beverages, drugs, cosmetics, chemical products, biological products and genetically engineered products in which the elements and process followed the Sharia to ensure that products were halal for consumption and utilization. Implementation of the law would be divided into three stages: firstly food and beverages, secondly cosmetics, chemical products, and genetically engineered products, and finally drugs and biological products.
- 3.326. She reported that Indonesia was in the process of establishing an agency responsible for providing halal certification (Implementing Agency of Halal Products Assurance) which would collaborate with non-government institutions to make necessary arrangements for matters related to halal issues. The treatment of halal had to be free of najis (defiled) and non-halal material at all times, in accordance with Codex General Guidelines for Use of the Term "Halal" CAC/GL-24-1997. She further reported that Indonesia was in the process of establishing the halal standard, namely RSNI for Halal Management System, i.e. RSNI 099001. The standard was being developed by a technical committee on halal, involving relevant stakeholders. Further procedures related to the Halal Accreditation and Certification Scheme, including the conformity assessment, would be dealt with by KAN (National Accreditation Body of Indonesia) and public consultation with various stakeholders, including representatives from countries based in Jakarta, had recently been concluded. As a follow-up process, the government would develop regulation concerning Implementation of Halal Product Assurance.
- 3.327. Indonesia summed up by recalling that Quran and Sunnah were the primary indispensable normative references for the standards. Moreover, each country had its own fatwa (school of thought) and fiqh for halal standards, developed according the beliefs of each society; her delegation therefore encouraged Members to respect the prevailing fatwa and fiqh in each country. She reminded Members of Indonesia's willingness to work together, in order to support and strengthen the multilateral trading system.

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

3.328. The representative of the <u>Republic of Korea</u> raised a number of issues in respect of the Chinese measure at issue and recalled that her delegation had raised the matter at the March meeting of the Committee, but had not received an official response. Instead, the CFDA (China Food and Drug Administration) had published the Regulation on its website on 6 June 2016 and it would go into effect on 1 October 2016. While the Korean government fully understood the need for strict control of infant formula, there were several reasons for concern. First, according to the regulation, infant formula products manufactured/distributed in or imported to China had to be registered at the CFDA. Article 8 stipulated that an applicant needed to submit, *inter alia*, a formula composition research report and safety data, and Articles 13 and 14 rendered on-site inspection and product quality test by a qualified agency compulsory. According to Article 9, one company could not register more than 3 series of products, and 9 product formulas. As such, the new regulation restricted Chinese customers' rights and freedom to select and purchase safe and

sanitary products. The additional cost and time needed for duplicate registration would be a burden to exporting companies and could pose an unnecessary barrier to trade.

- 3.329. She explained that products being exported to the Chinese market had been assessed by the Certification and Accreditation Administration of China (CNCA) during the site-inspection in 2014 and facilities and formula composition had been registered. In other words, all Korean dairy product exporting companies had been audited by the CNCA in 2014 and information, including formula compositions, had been submitted to get registration of facilities of exporters, product types and individual products. Therefore, the requirement of registration at the CFDA for infant formulas in accordance with the new Regulation, including repeated submission of data and on-site inspection, was duplicative.
- 3.330. Accordingly, the Korean Government made the following requests: China was (i) asked to recognize the Korean formula products (and their compositions) previously assessed and registered by the CNCA in 2014 after the CFDA's new regulation came into effect; (ii) asked to simplify the registration process for new infant and follow-up formula product compositions in order to ensure that on-site inspection and expert assessments were not duplicated; and (iii) was requested to allow registration of new formula products through scientific demonstration of ingredients and compositions without limitation on the number of brands or formula compositions, if obvious differences in ingredients were scientifically demonstrated.
- 3.331. The representative of the <u>European Union</u> continued to have serious concerns about some aspects of the draft measure. First, the limitation: the draft measure appeared to apply to each company setting a maximum of 9 recipes within 3 product lines. This was a major concern for the EU as it would have a serious and unnecessarily negative trade impact on current exports from the EU to China. The impact of such a limitation would be aggravated by the fact that the limitation fell on production companies these would be deprived of the possibility of serving major brands of infant formula that, as outlined above, currently relied on them as production partners for their products. It was estimated that, without modification of this article, the number of brands on the Chinese market would be reduced by 80%. The EU could not find a justification for this limitation, neither on the basis of food safety nor on the basis of other legitimate objectives. China was therefore requested to remove it.
- 3.332. Second, the inspection regime would imply on-site inspections by the Chinese agency CFDA, which would be added on top of other inspections by other Chinese agencies (AQSIQ/CNCA) in accordance with China Food Safety Law. Therefore the EU wished to renew its request to China to consolidate these inspections. Third, the EU considered that the new registration and approval procedure required an appropriate transition time (from the current system) in order to avoid disruption of trade. A period of 18 months seemed reasonable. In this regard, the recent publication by CFDA of a revised measure to become applicable on 1 October 2016 was of great concern to the EU. It was unclear how companies could continue to place products on the market without an appropriate transition period.
- 3.333. The representative of <u>Japan</u> shared the concerns raised by the EU and Korea. In Japan's view, how the regulation would contribute to achieve a legitimate objective based on scientific or other related information needed to be assessed. Replies received to date from China were not satisfactory. China was requested to reconsider the quantitative limitation of the product registration and take into account that the regulation would seriously restrict the business opportunities for manufacturers in Member countries.
- 3.334. The representative of <u>New Zealand</u> said that China was a major export market for New Zealand, including for infant formula. New Zealand noted that the regulation had recently been published and looked forward to working with CFDA to ensure a smooth transition to the new regulatory environment for imported products.
- 3.335. The representative of the <u>United States</u> said that her delegation had provided comments on 4 March, and US industry had also provided comments and were still waiting to hear a reply. The US wanted to ensure that trade would not be disrupted and to gain a full understanding of China's draft measure as the process moved forward. The US remained concerned about the issue of limitations on the production of different brands, the potentially duplicative inspection

requirements and the need for clarification on the coverage of what age groups for formula this measure would apply to.

- 3.336. The representative of <u>China</u> explained that China attached great importance to the safety of infant formula milk and powder quality. Infant formula milk powder had always been the most stringently regulated food in China. China's infant formula milk powder market was very different from foreign ones. On the one hand, China had great market demand and rapid industrial development in this area; on the other hand, many problematic situations appeared, such as consumers' confusion caused by too many brands and formulas. China had issued the Formula Registration Regulation for Infant and Follow-Up Formula to urge enterprises to improve R&D capabilities, and prohibit the use of exaggerated advertisements to mislead consumers. This regulation would further regulate China's infant formula milk powder market to ensure high quality of milk powder. In fact, it was also beneficial to the development of related enterprises, both domestic and abroad.
- 3.337. The representative of China noted that before drafting the regulation, China had carried out research in infant formula milk powder. Theoretically, she noted, infant formula milk powder should only be the nutritional supplements to breastfeeding. Therefore, the composition of infant formula milk powder should be similar to breast milk and there should not be too many formulas. Also, research data reflected that, in general, large foreign infant formula milk powder manufacturers had no more than three brands in production and sales.
- 3.338. To address Members' concerns about on-site inspection, China clarified that the on-site inspection mainly focused on the R&D data of milk powder formulas and manufacturers' capacity to turn formulas into production. It focused on different aspects compared to the systematic inspections held in the past. China had also noted Members' concerns on possible duplicative inspections. China would endeavour to avoid such duplication by more internal communication. The regulation had been notified in January 2016 and had offered a 60-day comment period and a transition period of more than six months the transparency obligations under the TBT Agreement had thus been fulfilled.

3.2.3.43 Russia - Rules of cement certification, G/TBT/N/RUS/48 and G/TBT/N/RUS/49 (IMS ID 497)

- 3.339. The representative of the <u>European Union</u> recalled that having raised the issue during the March 2016 meeting of the Committee, Russia had notified on 8 March 2016, as G/TBT/N/RUS/48, 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. 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 as 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 asked Russia to suspend the measures and renotify them under the TBT Agreement at a draft stage, allowing WTO Members' comments to still be taken into account. On the content of the measures, the EU raised several concerns.
- 3.340. Section 8.2, fourth sentence, 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.
- 3.341. 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 (whether it should take on average 28 days).

- 3.342. The EU also requested a clarification on the following issues. Firstly, it requested confirmation that the certificates issued by a certification body had to be registered with Rossacreditation. If the answer was positive, Russia should clarify the reasons for which such a registration should 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.
- 3.343. The representative of <u>Mexico</u> thanked Russia for the bilateral meeting they had held on 15 June 2016 and shared some of the concerns expressed by the EU. She noted that Mexico would follow up on this STC.
- 3.344. The representative of the <u>Russian Federation</u> recalled that the Government Resolution No. 930 of 3 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 under document G/TBT/N/RUS/48. 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 the Russian Federation and by the urgent problems of safety, health and environmental protection. The new standard GOST-R had been adopted by the Federal Agency for Technical Regulation and Metrology and notified to the WTO under document G/TBT/N/RUS/49. The lists of certification bodies and of issued certificates were available on the website of the Federal Accreditation Body. Russia noted that following the entry into force of Regulation No. 930, more than 250 certificates had been issued to date, including certificates for cement imported to the Russian Federation from WTO Members. Russia had taken note of concerns raised by the EU and Mexico and would continue to work with them as well as with other interested Members on this matter.

3.2.3.44 Thailand - Milk Code - Draft Act on Controlling to the Marketing Promotion on Food for Infant and Young Children and Other Related Products BE, G/TBT/N/THA/471 (IMS ID 503)

3.345. The representative of the <u>United States</u> said that, while her delegation strongly supported efforts to ensure that the marketing of infant and follow-up formulas would not negatively impact breast feeding, it nonetheless remained concerned with the following aspects of the Thai measure at issue. With respect to the use of international standards, she noted that there were several Codex Alimentarius standards that were relevant to this measure, including one for infant formula and formulas for special medical purposes intended for infants. There were, more specifically, standards for 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. In this respect, she asked Thailand to explain how it had considered these existing standards, and why it had deviated from them in certain areas. She also expressed her delegation's view that, conversely, the new WHO guidance on ending the inappropriate promotion of foods for infants and young children²⁰ was not an international standard in accordance with the criteria established by the TBT Committee. She additionally noted, in this respect, that in the US the adherence to the application of the 1981 WHO's International Code of Marketing of Breast-milk Substitutes was voluntary. In the US, this International Code was also complemented by some more codes developed by leading US medical professional societies on the marketing of these products.

3.346. The US also had questions about whether the regulatory approach outlined in the Thai draft measure could be more trade restrictive than necessary. She requested Thailand to provide the scientific explanation for its complete ban on the marketing and advertising of infant and

²⁰ Maternal, infant and young child nutrition: Guidance on ending the inappropriate promotion of foods for infants and young children, Report by the Secretariat (doc. A69/7 Add.1, 13 May 2016), available at http://apps.who.int/gb/ebwha/pdf files/WHA69/A69 7Add1-en.pdf?ua=1& ga=1.199082543.1886800211.1468765934. See also WHA Resolution WHA69.9 (29 May 2016), footnote 1, available at http://apps.who.int/gb/ebwha/pdf files/WHA69/A69 R9-en.pdf

follow-up formula for babies up to 36 months of age. More specifically, the US asked Thailand to provide the scientific explanation of how a ban on health claims and trademark information on labels would contribute to the accomplishment of the desired goal of increasing and sustaining breastfeeding in Thailand's specific context. She also asked for available information on any assessment Thailand made with respect to the potential regulatory impacts of the proposed measure. Additionally, she noted that the draft provided for the punishment of violations of its advertising and marketing requirements under the Thai criminal code, including the imposition of prison time for certain offences. She then asked Thailand to provide the reasoning behind imposing such criminal penalties as well as any additional detail with respect to the procedures for prosecution.

- 3.347. Finally, the US requested Thailand to allow for sufficient time, both after the publication of the final rule and before implementation and enforcement of the regulation, so that industry would be able to come into compliance with the new requirements. In this respect, she also asked Thailand to confirm if it was indeed planning to provide for a 180-day transition period following ratification.
- 3.348. The representative of Australia noted that the Thai draft measure proposed measures that had similarities to new WHO guidance on ending the inappropriate promotion of foods for infants and young children, welcomed by WHO members, including Australia, at the World Health Assembly last month.²¹ He explained that in Australia the marketing of infant formulas was conducted under the auspices of a voluntary, self-regulatory Code of Conduct between manufacturers and importers of infant formula. This Code of Conduct applied to the marketing and promotion of formulas for infants up to 12 months of age only. Australia recognised, however, that countries regulate marketing of infant formulas in different ways so as to suit their own national circumstances. As a reliable supplier of high quality dairy products to Thailand, Australia would encourage Thailand to develop and implement standards for the marketing of food for infants and young children in a manner that would be as trade facilitating as possible. In this respect, Australia was concerned about the allowance for unspecified Ministerial requirements on marketing products under the legislation. Australia also asked Thailand for clarification on whether the proposed regulations would exclude nutritional labelling on products. Australia also requested more time for exporters, importers and manufacturers to adapt to Thailand's new regulation. Finally, he underscored Australia's belief in promoting harmonization with relevant Codex standards in this area.
- 3.349. The representative of the <u>European Union</u> expressed his delegation's concerns with this draft regulation, in particular, as regards certain definitions, which would either deviate from the relevant Codex Alimentarius standards, or whish, in some cases, would seem redundant. The EU also asked Thailand to explain more clearly the rationale for setting out certain restrictions in the proposed measure. Finally, the EU asked Thailand to reply to the written comments submitted to it in February 2016.
- 3.350. The representative of <u>New Zealand</u> noted that Thailand was an important export market for New Zealand products, including in particular infant formula products. She said that she looked forward to an update as to how comments her delegation had already sent to Thailand bilaterally had been taken into account.
- 3.351. The representative of <u>Thailand</u> informed that the draft measure was still undergoing its legislative process. Thus, he said, the estimated time-frame until its adoption could only be confirmed at a later stage. Further, as the draft measure was notified at an early stage, Members' comments submitted previously had already been taken into account in the revision of the draft by the Ministry of Public Health. He said that this measure aimed to protect, in a non-discriminatory manner, the health of mothers and children. This measure was therefore in full compliance with the TBT Agreement, including the obligations under Articles 2.2 to 2.6. Compliance with Article 2.4, in particular, stemmed from the fact that the proposed measure was developed based on the WHO's *International Code of Marketing of Breast-milk Substitutes*, as well as the relevant WHA Resolutions. Thailand considered this WHO instrument, also known as the "Milk Code", as an international standard for the protection of children's health from the effect of BMS marketing practices. Thailand further believed that the new WHO guidance on ending the inappropriate promotion of foods for infants and young children, together with a recently adopted 2016 WHA

²¹ See previous footnote.

Resolution²², stipulated clearly that follow-up formula and growing-up milk that were marketed for feeding infant and young children up to the age of three, were all breast-milk substitutes that should not be promoted. Moreover, the advertisement of milk products that were marketed as suitable for children over the age of 12 months may be used to cross-promote the products for younger children. Thus, under the proposed measure, products intended for young children of ages one to three would be regulated together with infant formula. Thailand thus intended to follow the recommendation of the Milk Code, similarly to other countries that had already implemented the regulation to control the marketing promotion of food products for children up to 36 months, or even 60 months.

3.352. He also clarified that the notified draft measure did not regulate trademark information on labelling so as to respect intellectual property rights. Moreover, after reviewing the draft with other related agencies, and taking into account comments received by Members, Thailand had revised the draft so that the section on labelling requirements had been removed. Thailand also believed that the revised measure on health claims complied with Codex Guidelines for Use of Nutrition and Health Claims. Additionally, he clarified that the draft proposed a different level of monetary fines for those who violated the marketing requirements. However, there would not be prison time for any violation of these requirements. Similarly to the penalty clause in many other Thai laws (e.g., the Food Act and the Public Health Act), under the proposed measure, imprisonment would only occur for those who failed to comply with summons, or those who obstructed officials in performing their duty.

3.2.3.45 United Arab Emirates - Control scheme to restrict the use of hazardous materials in electronic and electrical devices, G/TBT/N/ARE/265 (IMS ID 496)

3.353. The representative of the European Union said that his delegation shared the UAE's objective of protecting human health and the environment. Nonetheless he wished to raise the following issue of concern to his delegation. Firstly, 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. Secondly, 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. The 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. Thirdly, 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"; explanation was sought as to the exact scope of application of the exemptions at hand. Fourthly, 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. Finally, the EU requested an update on the status of the measure.

3.354. The <u>Chairperson</u> took note of the EU's statement and asked that their concerns be brought to the attention of the UAE.

²² See previous footnote.

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

- 3.355. The representative of <u>Canada</u> expressed concern about several aspects of the REACH regulation affecting SMEs negatively, in particular the "Only Representative" (OR) and "Letter of Access" (LoA) provisions and upcoming 2018 registration deadline for substances manufactured or imported in quantities from 1 to 100 tonnes. Canada had raised concerns in this regards before.
- 3.356. The cost for substance LoA was exceedingly high for some Canadian exporters for their volume of business (the LoA cost to register eight substances, for example, exceeded EUR 200,000 for an enterprise doing CAN\$2.5 million in annual business), while 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 addition, it seemed that a number of lead registrants and OR consultants were using their position to freeze out late entrants and non-EU SMEs, trying to use the LoA and OR processes for economic advantage. Canada asked the EU to explain the process for appealing/applying excessive LoA fees, why Substance Information Exchange Forums (SIEFs) were permitted to use the LoA process to effectively freeze out non-EU SMEs or late entrants to the EU market and urged the EU to ensure that SEIFs were not permitted to do so. Canadian SMEs had approached REACH helpdesks and would appeal LoA fees in due course. Canada stated that the EU should do more to ensure that SMEs and late entrants to the EU market were not unduly affected by these administrative and anti-competitive processes, which were not adding to the goals of the regulation.
- 3.357. Canada also 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 psychochemical properties were extremely well-known and traded in high volumes. Canada asked the EU what the process would be to nominate such substances. He also referred to the planned "fitness-check" of REACH, which was to include a review of support measures for SMEs, registration requirements for low tonnage substances, and the effect of the regulation on competitiveness of SMEs and downstream users. Canada asked the EU for more information on the time-frame for the public consultation, which was part of the "fitness-check".
- 3.358. The representative of <u>Israel</u> recognized the EU's objective to protect human health and environment from risks posed by chemicals, but supported Canada's concern regarding the fact that some provisions of the REACH regulation were more trade restrictive than necessary to achieve the objective. Israel referred to high costs of compliance, the administrative burden and lack of clarity on the obligations affecting Israeli manufactures and exporters, both SMEs exporting low volumes of chemicals to the EU and larger companies that exported small amounts of a specific chemical. She asked that the EU provide more transparency and clarity on these matters and to consider how to avoid trade-restrictive impacts of REACH.
- 3.359. The representative of the <u>European Union</u> stated that third countries' manufacturers exporting to the EU and domestic manufacturers were not treated differently under REACH. Importers or third countries' manufacturers using an OR were subject to the same registration requirements as the EU producers of the same substance. He noted that all substances to be registered in the lowest tonnage band (1-10 tonnes/year) benefitted from reduced registration obligations. Reductions on registration fees of up to 95% were provided for micro enterprises in comparison with big companies. The European Commission acknowledged that obligations under REACH did burden SMEs and, in this respect, the Commission had already taken corrective measures. In January 2016, the Commission adopted an Implementing Regulation on joint submission of data and data-sharing under REACH, increasing transparency of data and cost-sharing in SIEFs and thereby preventing abusive practices related to the price of LoA, in particular towards SMEs.

3.2.4 Exchange of Experiences

3.2.4.1 Thematic sessions on Standards and Regulatory Cooperation between Members

- 3.360. The <u>Chairperson</u> asked the three moderators of the thematic sessions to provide their summary reports. 23
- 3.361. The representative of the <u>Secretariat</u> reported on the teleconference arrangement used in order to enhance participation of capital-based delegates at the thematic sessions. He stated that capital-based officials had been allowed to listen-in (audio) to the discussion. Participation was limited. Looking ahead, the Secretariat intended to improve this facility. He thanked the Committee for agreeing to provide the audio recordings on the website to facilitate the interest of a wider audience.²⁴
- 3.362. The representative of <u>Chile</u> thanked the Secretariat for the teleconference arrangement which was important to his regulators. He stated that his regulators were also interested in the possibility of web-based streaming in the future.
- 3.363. The representative of <u>Canada</u> expressed appreciation for the teleconference arrangement as it had facilitated enhanced capital-based participation, which had aided the Canadian delegation in Geneva in providing accurate answers to the questions posed by Members.
- 3.364. The representative of <u>Pakistan</u> appreciated the effort made by the Secretariat; she hoped that it would be further pursued as it was a real and concrete way of enhancing capital-based participation.

3.2.4.2 Topic of the next Thematic Session

- 3.365. The <u>Chairperson</u> suggested the following topics for the thematic sessions in November: (i) transparency; (ii) technical assistance; and (iii) regulatory cooperation between Members. The first topic on transparency would include the Eighth Special Meeting on Procedures for Information Exchange which the Committee had agreed on at its 7th Triennial Review. The mandate for the Eighth Special Meeting was pursuant to the Committee's 1995 decision which stated "regular meetings of persons responsible; or information exchange, including persons responsible for, Enquiry Points and Notifications are to be convened". The transparency thematic session, including the Eighth Special Meeting, would be held on 8 November 2016. There would also be thematic sessions on technical assistance and regulatory cooperation between Members. The Chairperson proposed that on transparency the Secretariat would produce a first draft programme for discussion.²⁵ On technical assistance, the Chair was open to Members' proposals for speakers and presentations.
- 3.366. On the topic of regulatory cooperation between Members, the Chairperson recalled that in the 7th Triennial Review Report, the Committee had agreed "to hold thematic sessions on regulatory cooperation between Members in June and November 2016". The intent of these thematic sessions was to exchange experiences and allow for factual information sharing. A number of specific proposals for topics had been made in the 7th Triennial Review Report, including on energy efficiency and food labelling. Given that the Committee had now covered the topic of energy efficiency, she proposed that it consider the topic of food labelling at its November 2016 thematic session on regulatory cooperation between Members.
- 3.367. The representative of the <u>European Union</u> said that the comfort zone for Members was narrower on this issue than on energy efficiency, and consideration needed to be given to the sensitivities of various delegations in the development of a programme. The EU's support and engagement would depend on the content and objective of the discussions. He indicated that, at this stage, the EU would have been content to explore the identification of such comfort zones in order to organize a thematic session. He stated that a main topic for the discussions would be to raise awareness about activities in relevant international organizations such as the Codex

²³ The summary reports are contained in G/TBT/GEN/198 and G/TBT/GEN/199.

²⁴ The audio files was subsequently made available on the WTO website at ttps://www.wto.org/english/news_e/news16_e/tht_14iun16_e.htm

https://www.wto.org/english/news e/news16 e/tbt 14jun16 e.htm

25 A draft programme was circulated in a fax from the Chairperson on 26 August 2016.

Alimentarius or the World Health Organization. The EU was aware of the number of STCs on the agenda concerning issues related to food labelling and cautioned that the Committee should not over reach, through the thematic sessions – as has been highlighted during the 7th Triennial Review. With this caveat, the EU would be happy to continue to the work with the Chair and interested Members.

- 3.368. The representative of <u>Switzerland</u> supported the proposal. Reflecting on the session the Committee had held on energy efficiency, he said that it had been an informative and relevant event where delegations had engaged in a manner that had focused Members' attention upon a specific relevant issue, which was positive for the Committee. The aim for a session on food labelling, a comparable issue with global objectives, would be to share factual information and experiences with respect to on-going, new or emerging issues in that particular area. Switzerland had taken note of all the parameters that had been mentioned by the EU delegation and supported this approach. His delegation would work diligently in consultation with all interested Members during the summer to help elaborate the proposal for an outline of the thematic session. Switzerland welcomed all colleagues' participation and proposals to ensure a good discussion, giving due respect to Members sensitivities.
- 3.369. The <u>Chairperson</u> noted the comments of the EU and Switzerland and reiterated that the intent of thematic sessions was to provide factual information sharing, and to exchange experiences. She acknowledged that there had not been any strong objections to her suggestion but she recognized the Committee still had some work to do to ensure that all Members were comfortable with the approach taken as well as the programme proposed for the thematic session. She would follow up on Members' offers to work on preparing a programme for this thematic session. She intended to consult with Members over the summer and hold an informal meeting in September.
- 3.370. The representative of <u>Chile</u> said that the topic was important to his country and hoped that the Committee would dedicate at least half a day to the discussion.

3.2.4.3 Other Matters

3.2.4.3.1 ePing

3.371. The representative of the <u>Secretariat</u> informed the Committee that on 13 June 2016 it held an information session and presented, in collaboration with UNDESA and ITC, the main features of the pilot SPS/TBT Notification Alert System developed thus far. Delegations had also heard from the Enquiry Point of Uganda regarding their experience as a pilot country where the alert system had already been rolled out. Since the adoption of the Committee's recommendation for an alert system at the end of last year, the Secretariat had been working closely with UNDESA to build on an existing SPS/TBT notification alert system (called ePing) which UNDESA had already started to develop in light of needs identified in LDCs. The WTO had reached out to the ITC to join the initiative since ITC had developed a variety of complementary trade information tools with large numbers of subscribers and worked closely with SMEs, expected to be amongst the main beneficiaries of the system. The three organizations were in the final phase of signing a tripartite MOU to anchor this collaboration. The objective of the initiative was to offer a publicly available, reliable and sustainable service which enabled timely access to SPS/TBT notifications of interest, which could facilitate dialogue between the public and private sector in addressing potential trade problems at an early stage. Delegations were encouraged to subscribe to the pilot version and to provide feedback via www.epingalert.org. The Secretariat intended to launch the alert system during the Committee's Special Meeting on Procedures for Information Exchange, scheduled for 8 November. Capacity-building efforts would continue after the expected launch in November and the Secretariat would offer online training via Skype to interested Enquiry Points.

3.2.4.3.2 Private Standards

3.372. The representative of <u>China</u>, referring to Article 4.1 of the TBT Agreement, recalled concerns by Members about "private standards" and the trade impacts thereof during the previous reviews of the implementation and administration of the TBT Agreement. He recalled that during the 5th, 6th and 7th Triennial Reviews, it had been agreed to exchange information and experiences on "reasonable measures" taken by Members to ensure that non-governmental

standardizing bodies involved in the development of standards within their territories, accepted and complied with the Code of Good Practice. Considering current discussions on the topic within the WTO and outside, China had commenced the process of drafting a paper on "Best Practice Guidelines regarding Private Standards". It was in the interest of the whole Membership to encourage private standard setters and Members hosting such bodies to follow internationally recognized best practices in the preparation, adoption, application, certification, usage and supervision of private standards. The application of a voluntary "Best Practice Guidelines regarding Private Standards" by private standard setters and Members that hosted them could help private standards to make positive contributions to Members' economic, environmental and social progress while avoiding the creation of unnecessary barriers to trade. The representative of China invited interested Members to participate in this drafting exercise and assured Members that the drafting of this paper, and participation in the exercise itself, would be without prejudice to the rights and obligations of Members under the WTO, or to the views expressed by any Member regarding the scopes of the relevant WTO Agreements.

- 3.373. The representative of $\underline{\text{India}}$ said that the proliferation of private standards was a reality in business today since these standards had been generally put in place to achieve some crucial objectives such as health, quality, safety and environment. They could become barriers to trade due to burdensome and non-transparent compliance requirements. It was against this backdrop that India welcomed China's statement. He supported the basic idea elaborated by the delegation of China and expressed interest in being involved in the proposed drafting exercise.
- 3.374. The representative of <u>Egypt</u> said that, given the increasing importance of private standards to trade, an exchange of views would be very helpful to avoid creating unnecessary barriers to trade. She was interested in obtaining more information from China on their proposal and to participate in a discussion on this issue.
- 3.375. The representative of <u>Brazil</u> expressed interest in China's efforts in this regard and welcomed new ideas and approaches to generate a fruitful discussion on this matter.
- 3.376. The representative of the <u>Russian Federation</u> expressed appreciation for this effort to find a mutually satisfactory solution on the issue of private standards and guidelines. He stated that a broad and transparent discussion would be beneficial for the whole membership in light of the increased number of private standards. He stated Russia's interest in working with China and other interested Members on this matter.
- 3.377. The representative of <u>South Africa</u> stated that private standards had been an issue that, from time to time, had arisen in the Committee's discussions but had not really been addressed fully. He expressed interest in contributing to this process. He noted that the SPS Committee had done work on this topic and asked if it would be possible to make available information or a briefing document from a SPS colleague, within the Secretariat, to inform the TBT Committee on the progress within the SPS Committee on this matter.
- 3.378. The representative of <u>Pakistan</u> supported China's initiative and expressed interest in the drafting exercise. She highlighted that market access was closely linked with this issue. Therefore, the development of parameters for private standards, based on established principles within the TBT Agreement, would bring transparency and stability to the system. She implored other Members to be open to the approach.
- 3.379. The representative of the <u>United States</u> cautioned that she thought it was premature for the Committee to discuss any reactions to this initiative considering a formal paper had not yet been presented to the Committee. She indicated that she had spoken bilaterally with China about the initiative and she thought the idea needed to be better shaped prior to any further conversation within the Committee.
- 3.380. The representative of the <u>European Union</u> stated that an examination and discussion of the paper could only be undertaken if and when it would be formally submitted to the Committee. However, the EU's position on this issue was well known and unchanged. Private standards, whatever their definition or meaning (there was no agreement in this regard, as discussions in the SPS Committee demonstrated), were documents which did not meet the definition of standards

under the TBT Agreement, and, as such, were outside the scope of the Agreement and, hence, of the Committee's work.

- 3.381. The representative of <u>China</u> reiterated that the drafting exercise was without prejudice to the rights and obligations of Members of the WTO, or the views of Members with respect to the scope of the relevant WTO Agreement. However, China understood the scope of Article 4.1 of the TBT Agreement as relevant to private standards. He said that some Members had varying views on this issue and highlighted that during the 5th and 6th Triennial Reviews, Members had raised concerns about private standards whereby the Committee agreed on the need to further strengthen the implementation of Article 4 of the TBT Agreement.
- 3.382. The representative of <u>Japan</u> expressed his view that, as stated by the EU, private standards did not fall under the scope of the TBT Agreement.
- 3.383. The <u>Chairperson</u> suggested that the Committee consider this issue upon the circulation of a formal written proposal from China.

4 TECHNICAL COOPERATION ACTIVITIES

- 4.1. The representative of the <u>IEC</u> updated the Committee on recent technical assistance activities. These included visits by IEC regional directors to Botswana, Morocco, Namibia, South Africa and Tunisia. A training session organized by the IEC Asia Pacific Regional Centre had taken place in Singapore focussing on good electrotechnical standardization practices and the role of technical secretariats. The Philippines had also hosted a training session for experts at national technical committees. On conformity assessment, a seminar on IECX had taken place in Singapore and a seminar focussing on the CB scheme, cables and household equipment had taken place in Azerbaijan. A webinar within the framework of affiliate conformity assessment status (ACAS) had also been held with Ecuador.²⁶
- 4.2. The representatives of <u>ARSO</u> and the <u>UNECE</u> updated the Committee on their activities.²⁷
- 4.3. The <u>Secretariat</u> informed the Committee that funding would be provided by the WTO ITTC for a limited number of government officials to attend a Workshop on Transparency taking place, back to back with the Committee's Eighth Special Meeting for Procedures for Information Exchange on 8 November 2016.²⁸ The objective was to provide additional training on transparency provisions and on the various online tools, including the TBT Information Management System, the Notification Submission System and the new notification alert system(ePing). Invitations for this activity would be sent to eligible Members and Observers through their permanent missions.

5 UPDATING BY OBSERVERS

5.1. The representative of the <u>ACP</u> said that the ACP Group had long recognized the enormous significance of non-tariff barriers, and TBT in particular. The ACP had benefitted from the technical assistance support of the ACP-EU TBT Programme for a year and a half and this had led to an increase in TBT-related activities both in Geneva and in the ACP community in areas such as quality infrastructure. He thanked the ACP EU TBT Programme for its most valuable assistance to projects in capitals, at the regional level and in Geneva. The ACP group in Geneva was working with its members to make their work more effective in the TBT Committee and acted as a platform for coordination, cooperation and communication on TBT-related matters. This increased engagement would also benefit other WTO Members. He thanked the ACP-EU TBT Programme for its invaluable assistance and hoped that the work on TBT would continue beyond the current terms of the programme. Much work still needed to be done and support from donors wishing to work wish ACP would be welcome. He welcomed the news that financing for some capital-based officials was to be provided to attend the November Workshop on Transparency and offered to work with the WTO Secretariat on that task.

²⁶ The full report is available on the IEC website:

http://www.iec.ch/about/globalreach/partners/international/pdf wto/iec wto 2016 06 en iec.pdf

²⁷ These statements were circulated in documents G/TBT/GEN/200 and G/TBT/GEN/201.

²⁸ Eighth Special Meeting on Procedures for Information Exchange.

- 5.2. The representatives of BIPM and OIML updated the Committee on their activities.²⁹
- 5.3. The representative of the <u>IEC</u> reported that Tanzania had established its national electrotechnical committee. Burkina Faso, Guinea and Namibia had adopted their first national IEC standards, which, in the cases of Guinea and Namibia, upgraded them to affiliate class. Under the IEC mentoring programme, a partnership had been established between Mexico and Ecuador so as to reinforce the Ecuadorian national electroctechnical committee.³⁰
- 5.4. The representative of $\underline{\text{Trinidad}}$ and $\underline{\text{Tobago}}$ made a statement in support of granting ad hoc observership status to the CARICOM Regional Organization for Standards and Quality (CROSQ). The representatives of $\underline{\text{South Africa}}$, $\underline{\text{Uganda}}$, $\underline{\text{Jamaica}}$, $\underline{\text{Japan}}$, $\underline{\text{Canada}}$, $\underline{\text{China}}$ and $\underline{\text{Barbados}}$ also took the floor in support of this request.
- 5.5. The Committee <u>agreed</u> to grant ad hoc observer status to CROSQ.³²

6 DATE OF NEXT MEETING

6.1. The next regular meeting of the Committee is scheduled for <u>10-11 November 2016</u>. The full schedule of meetings is contained in JOB/TBT/189/Rev.1, issued on 24 June 2016.

²⁹ These statements were circulated in documents G/TBT/GEN/202 and G/TBT/GEN/203.

³⁰ The full report is available on the IEC website:

http://www.iec.ch/about/globalreach/partners/international/pdf wto/iec wto 2016 06 en iec.pdf

³¹ G/TBT/W/447.

³² The changes are reflected in G/TBT/GEN/2/Rev.12, issued on 23 August 2016.