



Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 4-6 NOVEMBER 2015

CHAIRPERSON: MS ALANA LANZA

Note by the Secretariat¹

1 ADOPTION OF THE AGENDA	1
2 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT	1
2.1 Statements from Members under Article 15.2	1
2.2 Specific Trade Concerns (STCs)	2
2.2.1 Withdrawn concerns	2
2.2.2 New Concerns	2
2.2.3 Previously raised Specific Trade Concerns.....	18
2.3 Exchange of experiences	59
2.3.1 Discussion on Seventh Triennial Review adoption ad referendum	59
2.3.2 Other matters	63
3 TECHNICAL COOPERATION ACTIVITIES	63
4 UPDATE BY OBSERVERS	64
5 REPORT (2015) OF THE COMMITTEE ON TECHNICAL BARRIERS TO TRADE	64
6 DATE OF NEXT MEETING	64

1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in WTO/AIR/TBT/3.

2 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

2.1 Statements from Members under Article 15.2

2.1. The Chairperson reminded the Committee of Members' notification obligation under Article 15.2 of the TBT Agreement and further informed the Committee that the latest list of statements on implementation submitted under this provision were contained in document G/TBT/GEN/1/Rev.14, issued 23 February 2015. She informed the Committee that since the last meeting in June 2015, Seychelles and Senegal had submitted their statements. She further informed the Committee that since 1995, 131 Members had submitted at least one statement of implementation. Information on the list of statements is available at <http://tbtime.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.

2.2 Specific Trade Concerns (STCs)

2.2.1 Withdrawn concerns

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 The Chairperson reported that the following STCs had been withdrawn from the agenda at the request of the concerned Member:

- a. Peru – Labelling of pre-packaged food (New) withdrawn by Mexico.
- b. Tunisia - Tyre Import Restriction (New) withdrawn by the Japan.
- c. India - Drugs and Cosmetics 2007 (Previously raised) withdrawn by the European Union.

2.2.2 New Concerns

2.2.2.1 Russian Federation - Measure affecting the import of Ukrainian wallpaper

2.3. The representative of Ukraine expressed concern about a ban on imports to the Russian Federation of Ukrainian wallpaper, which had been imposed on 13 April 2015 by the Federal Service on Customers' Rights Protection and Human Well-being Surveillance (*Rospotrebnadzor*) based on alleged incompliance with sanitary and hygienic norms for emission of formaldehyde and styrene. The full statement is contained in G/TBT/W/425.

2.4. The representative of the Russian Federation explained that within Russian territory as well as of the EAEU, the Common Sanitary and Epidemiological and Hygienic requirements for products subject to sanitary and epidemiological supervision (control), established by the Decision of Customs Union's Commission on 28 of May 2010 No. 299, were currently being applied. These mandatory requirements applied equally to both Russian and foreign goods. The requirements on migration of chemicals into air were based on the relevant available scientific and technical information. The suspension of imports of Ukrainian wallpaper produced by certain enterprises had been introduced by Russia in April 2015 given the violation of the Russian hygienic requirements on migration of formaldehyde and sterol into air. *Rospotrebnadzor*, which was responsible for market supervision and surveillance, detected large-scale violations of the above-mentioned requirements with respect to wallpaper sold in the Russian internal market. The suspension was thus introduced to maintain: (i) the appropriate level of safety protection; (ii) the protection of human life and health; and (iii) the protection of the environment. She expressed her delegation's regret that the quality and safety of certain Ukrainian products did not appropriately correspond to Russian rules. The Competent Authority in Russia informed the Sanitary and Epidemiological Service of Ukraine of the necessity of providing additional materials in Russian in order to resume the supply of wallpaper of certain Ukrainian enterprises to the Russian market. *Rospotrebnadzor* informed the restricted enterprises on that list of additional materials as well. However, until now all the requests made by the Ukrainian competent authority failed to prove any evidence for quality of the products. Moreover, since the establishment of the measure, Ukrainian competent authorities had still not provided the requested documents confirming the quality and safety of this kind of Ukrainian products. This was the reason Russia's measures were still in force. It was noted that the suspension was only temporary and only targeted three Ukraine enterprises and was not therefore a ban on all Ukrainian wallpaper products as such. This measure therefore did not violate Russia's TBT obligations, in particular those under Articles 2.1 and 2.2. Upon receipt of the requested information, Russia was ready to continue cooperating with the competent Ukrainian authorities in order to take steps for the resumption of the supply of wallpaper to the Russian Federation.

2.2.2.2 China - Interim Measures for Quality Management of Commercial Coal (G/TBT/N/CHN/1057)

2.5. The representative of Canada noted that: (i) there had been delays associated with coal testing at Chinese ports; (ii) China did not recognize the results of independent third-party inspectorate services at the ports of loading in foreign coal producing countries; (iii) Canada had received reports that imported coal from Mongolia had not been tested; and (iv) there was concern that Chinese domestic coal might not be subjected to the same inspection procedures as coal imported from abroad. Canada was also concerned that China's quality requirements for coal did

not conform to international standards, and that the testing methods employed by Chinese officials did not conform with international norms. He said that, while Canada appreciated China's objective of decreasing air pollution, it was also important to ensure consistency and transparency of coal testing procedures. In other words, all coal, both domestic and imported, should be treated equally in order to reach the ultimate environmental goal of decreasing pollution. Canadian coal companies already used internationally recognized coal inspectorate services. If pre-inspection in Canadian ports of loading were accepted by China, this would not only avoid duplication of testing in the country of loading and in China, but it would also alleviate the burden on Chinese inspectorate services and significantly reduce delays of clearing shipments in Chinese ports, which therefore was a net benefit for all parties.

2.6. The representative of Australia thanked China for the bilateral meetings and discussions held to date on the introduction of this measure. He noted that as China was Australia's second largest coal export market, there was great interest from industry and exporters regarding the implementation and application of this measure. Australia supported China's environmental objectives of improving air quality and promoting the efficient and clean use of coal. Australia remained committed to being a reliable supplier of high-quality thermal and metallurgical coal to China and supported China's efforts to improve the quality of coal used in China's energy and industry sectors. Australia was nonetheless concerned with, and posed various questions about, the regulation in the following three areas: (i) *Timeframe*: why was the measure notified to the TBT Committee as "urgent" under Article 2.10 of the TBT Agreement? What did China mean by calling its measures "interim measures" in its TBT notification? Were the measures still considered interim or were they now permanent? Would there be a revised notification to reflect the duration of the measure?; (ii) *Standards*: Was the coal quality standard used by China based on an international standard, including from the ISO?; and (iii) *Conformity assessment procedures*: Whether and how all Chinese domestic coal was being tested? How was China ensuring consistency between testing conducted on imported coal and domestic Chinese coal? What have been the results of the tests conducted for domestic coal which have been undertaken so far? What would happen to domestic coal not meeting the quality standard? How was China ensuring consistency of testing across all of the entry ports?

2.7. Australia also urged China to consider enabling test results undertaken in other countries at accredited testing facilities to be accepted under the "interim measures", and in this respect posed the following questions to China: Why did it take so long for China to test imported coal after arrival in China, with some testing taking up to four weeks? What interaction was there between national accredited testing authorities to discuss test results obtained in China, where those test results differed from results obtained elsewhere? What review or appeal process was there to question cases of Chinese test results differing from Australian or other countries' test results? Had China given any 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? Further, with respect to the Quality Evaluation and Control Guide for Commercial Coal, Australia asked: (i) whether the Guide would become mandatory, and if so, when; (ii) whether the Guide was intended to replace the current coal standards, given that there were some differences; and (iii) whether China intended to notify the TBT Committee about implementation of the Guide.

2.8. The representative of China explained that since the winter of 2012, China had continuously suffered severe air pollution. Haze days had reached more than 100 days annually in Beijing, Tianjin, and regions like the Yangtze River Delta and the Pearl River Delta. Data from the Ministry of Environmental Protection of China showed that the annual concentration of fine particulate matter (PM 2.5) in China was 2-4 times more than the air quality standards recommended by the WHO. The main reason for such haze weather was the excess of PM 2.5, which had a direct connection to the increase of coal consumption in China in recent years. In order to protect consumer health and contribute to global environmental protection, China published the Interim Measures for Quality Management of Commercial Coal in 2014, which entered into force in 2015.

2.9. With respect to the specific concerns raised, she explained that China needed an effective and strict measure urgently. Rather than setting up unrealistic stringent standards, the Measure had standards that were adapted to the current level of economic and social development. The standards and requirements would be reviewed and changed in the future in tandem with the Chinese economy's growth rate. She said that the globalCOAL's Standard Coal Trading Agreement

("SCoTA")² set standards on sulphur content, calorific value and ash content of coal. The relevant standards in the Chinese interim measure, which equally applied to both domestic and foreign products, were consistent with SCoTA. Regarding testing agencies, she explained that, according to China's Law on Import and Export Commodity Inspection and its implementing rules, the statutory inspection of imported goods should be carried out by China's import and export inspection and quarantine agencies. Additionally, according to the law, bulk commodity inspections should be carried out at the port of entry and pre-shipment inspection results were not legally binding. Regarding the lengthy inspection period, she said that, while the testing items for imported coal increased, the capacity had not improved, which caused the delay of testing. China was thus increasing the inspection personnel and relevant testing equipment for most Chinese ports so as to improve the work efficiency and shorten the inspection period. Regarding consistency of testing results, she explained that given that the product standards and testing methods were consistent with international standards, and a widely permissible deviation was acceptable under the "interim measure", if there were differences in results between tests conducted outside China and at Chinese ports, the result of Chinese statutory inspection shall prevail. Finally, regarding Quality Evaluation and Control Guide for Commercial Coal, she stated that this was a voluntary document. As some indicators of the standards under the Guide were higher than those in the interim measures, its aim was to encourage enterprises to use high-quality coal and promote the efficient and clean use of coal. Currently, China had no plan to replace the "Interim Measures" with the "Guide".

2.2.2.3 Brazil - Toy Certification; Ordinance No. 89, No. 310 and draft administrative rule No. 321

2.10. The representative of Canada expressed his delegation's view that Ordinance No. 489 had been largely influenced by similar ordinances that applied to broad product categories under INMETRO's jurisdiction. This created problems for the toy industry, particularly for manufacturers with large-scale production lines which turned over on a seasonal basis. Canada considered that these Ordinances imposed unjustified costs and delays to the toy industry without resulting in any measureable increase in consumer safety when compared to internationally recognized and robust certification system already in place for toys. He urged Brazil to consider a review of the ordinance where currently-valid registration numbers would not be terminated and instead permit a Suppliers Declaration of Conformity (SDoC) or sampling by any International Laboratory Accreditation Cooperation (ILAC) accredited laboratories. Canada also failed to understand the purpose of the recently-amended Administrative Rule No. 321, whereby laboratories were required to film the actual testing of toys as a mandatory requirement of the registration process. Furthermore, Canada failed to understand how the information storage and retention requirements (for example, keeping records for a minimum of five years), would enhance consumer safety. Canada thus considered these requirements to be unnecessary and overly burdensome as they would increase costs to exporters and consumers with no tangible benefits.

2.11. The representative of the United States associated herself with Canada's concerns and said that US industry had submitted several rounds of comments on this Brazilian measure in January, February and August 2015, and most recently attended a public hearing on 4 August 2015. Since there had been many changes since the draft was released in November 2014, the US asked Brazil to provide an updated version of the measure so Members would be able to have a better understanding of when the measure would be expected to be finalized and when it would enter into force. She also said that the US remained concerned about several aspects of the draft measure, including the requirement to audit each family of products versus one audit per factory, which seemed to be an arduous way to verify either the manufacturing process or the safety of the product. The US was also concerned with the requirement to add the production date on the label, and wondered how this would contribute to the understanding of how safe the product was or what additional safety information it provided to Brazilian consumers. Further, as the requirement to have a registration number for each toy package appeared to be overly burdensome, she asked Brazil to explain the purpose of having each package registered. The US was in this respect particularly concerned that the Ordinance would require manufacturers to release confidential business information to INMETRO. Under Certification Model 5, which US toy manufacturers followed, testing was based on samples taken from the market, production line or distribution centre. Sections 6.1 (b) of Ordinance No. 489 would limit the samples to those taken from the market. Could Brazil explain how foreign manufacturers would be able to test and certify new toys

² <https://www.globalcoal.com/Brochureware/standardTradingContract/>

not already on the market? The US asked that Brazil accept test results of ISO/IEC 17025 laboratories.

2.12. The representative of the European Union expressed his delegation's appreciation that in August 2015 INMETRO had held a public hearing open to stakeholders and that as a result, certain adjustments had been made to the draft Ordinance. Like the US, the EU also asked Brazil to provide a consolidated draft of the measure so that changes could be properly assessed. A key issue was the criteria for a given toy model to be considered part of the same family and therefore be subject to a single conformity assessment that would cover all models belonging to the same family. It was important to provide clarity in that regard because toy models not considered part of the same family would need to undergo separate conformity assessment. The EU's other main concerns related to: (i) the number and frequency of factory audits; (ii) the mention of the age grading in Portuguese language; (iii) the registration of each product family for traceability purposes; and (iv) the administrative rule introducing peculiar requirements concerning the filming of the testing of toys. The EU asked Brazil to provide further clarification as to the rationale for such requirements, in particular on what aspects of toy testing would the requirement be applicable. In general, it appeared that the step taken by INMETRO to consolidate all requirements into a single text was needed given the plurality of ordinances and administrative rules dealing with toy safety and conformity assessment on toys. The EU thus encouraged INMETRO to proceed in that direction.

2.13. The representative of Brazil said that Brazil attached great importance to the safety of toys. Given that toys were used by children, the highest standards should be applied to these products. He explained that the purpose of the Ordinance, which was in line with international good practice, was to improve the monitoring system of accidents involving products used by children. A draft version of the Ordinance was published and opened for public consultations since 2014. Contributions received through public consultations were under technical review of the technical body: INMETRO. The publication of the final version would take place by December 2015. Regarding sensitivity of data, he said that INMETRO was a governmental body with strict internal policies to ensure confidentiality of data provided to it. This policy extended to the bodies of certification of products accredited by INMETRO. With regard to regular audits, he explained that improving surveillance involved, for instance, placing a registration number in the conformity identification field that could be affixed to the box or the toy. He said that this measure would facilitate the identification of products. Regarding the possibility of carrying out the certification for family or product groups, he stated that INMETRO believed that this measure would prevent multiple tests, thereby reducing costs related to certification.

2.2.2.4 Colombia - Testing Requirements to be met by Toys and their Components and Accessories

2.14. The representative of Canada expressed his delegation's concerns with the provisions contained in Article 12 of Resolution 3.388 of Colombia's Ministry of Health and Social Protection. Canada was of the view that local testing and certification requirements for toy imports were discriminatory and at odds with Colombia's MFN and National Treatment obligations. This was particularly so given that Colombia was not accepting test results from overseas laboratories accredited by ILAC. Canada also believed that the proposed 50 ppm total lead limit was unrealistic and at variance with currently accepted international standards and was also not technically achievable. By way of comparison, Canada's understanding was that other leading jurisdictions' requirements varied from 90 to 600 ppm. Canada thus believed that achieving 50 ppm was almost impossible given that lead was a naturally-occurring element and was also present due to erosion, and otherwise ubiquitous in the environment due to human activity. Scientific evidence showed that even the purest soil in wilderness areas contained approximately 40 ppm of lead and several hundred ppm was not uncommon in urban areas. Canada also believed that the measure's labelling provision would lead to unnecessary consumer concern and would add costly processing steps for companies selling products which did not pose a risk from lead. Canada recommended that the Colombian Government adopt a lead limit that would be aligned with generally accepted international standards.

2.15. The representative of the United States associated herself with Canada's concerns. She noted that this new toy safety measure, which had been published on 25 August 2015 under the new name "Ministry of Health and Social Protection Resolution 3117 of 2015", had not been notified to the WTO. Further, the changes in Resolution No. 3117 appeared to be the result of the

implementation of Decree No. 1595, which also had not been notified. The August 2015 resolution imposed local testing and certification requirements for toy imports in Colombia, except in circumstances in which the local laboratories lacked the capacity to carry out the requisite testing. The Resolution only allowed testing to be performed outside Colombia under the following limited circumstances: (i) if there were no laboratories in Colombia that had been designated by the Ministry to perform the requisite tests; or (ii) even if one or more such laboratories existed within Colombia, they were unable to perform the testing in a timely manner. If there were no qualifying laboratories within the country, testing could be performed in a laboratory accredited to ISO 17025 or belonging to ILAC upon approval of the certification body accredited by ONAC (Colombia's certification entity). If qualifying laboratories existed within Colombia but they were unable to perform timely testing, the applicant could then demonstrate compliance using the Declaration of Compliance Provider, to be signed in accordance with the provisions of ISO 17050. The US noted that there were not usually so many pre-qualifiers to a manufacturer to use either supplier's declaration of conformity or the test results from an ISO/IEC 17025 accredited laboratory participating in the ILAC mutual recognition arrangement. The US thus hoped Colombia would consider simplifying the terms of its conformity assessment procedures. Finally, she reiterated the request made in May 2015 that Colombia notify Resolution No. 3388 and provide a timeline for anticipated finalization of the measure.

2.16. The representative of Colombia said that his delegation took due note of the concerns expressed by the US and Canada. Colombia respected its obligations, particularly those related to transparency, under the TBT Agreement. He said the Colombian authorities were taking the necessary measures and the outcome of such actions would be transmitted to concerned Members as soon as possible.

2.2.2.5 European Union - Restriction on Polycyclic Aromatic Hydrocarbons (PAHs) in Tyres as specified in Annex XVII of REACH

2.17. The representative of China expressed his delegation's concern with the scientific basis of the test method under ISO 21461 (Rubber — Determination of aromaticity of oil in vulcanised rubber compounds), which was referred to in Entry 50 of Annex XVII of REACH (Regulation (EC) No 1907/2006). China considered this test to be an unusual and indirect quantitative method for the determination of PAHs. By comparison, GC-MS and HPLC — specified in several technical regulations and international standards — were more accurate and mature test methods to determine PAHs. Given the foregoing, China believed that the use of the test method ISO 21461 was inappropriate and could cause misleading test results. In this respect, China noted that there had been several cases of Chinese tyres found non-compliant with REACH, after being tested according to this standard, while in fact they would have been compliant if tested according to other more accurate, mature and commonly used test methods, such as GC-MS and HPLC. China was also concerned with the high costs of the test method to tyre manufacturers, which required testing laboratories to be equipped with very expensive and unusual instrument, such as 200 MHz NMR spectrometer. China thus requested the EU to provide the scientific rationale of the existing test method ISO 21461, to conduct a timely review, and make relevant revisions accordingly. Finally, China, clarified that its concern related mainly to the relevance, appropriateness and costs of this ISO standard in the specific context of the measure at issue under the TBT Agreement. These remarks were not therefore intended as a criticism of the important value of the relevant ISO standards and other international standards, when used appropriately by WTO Members.

2.18. The representative of the European Union explained that the method for determination of aromaticity of oil in vulcanised rubber compounds — based on the international standard ISO 21461 — had been applied by the EU since January 2010. Furthermore, the equipment needed to perform such a test (nuclear magnetic resonance spectroscopy) was an instrument typically available in specialised laboratories.

2.2.2.6 United Arab Emirates - Labelling - Energy efficiency label for electrical appliances

2.19. The representative of the Republic of Korea expressed his delegation's concern that this energy labelling regulation required companies to place unique serial numbers approved by ESMA on each individual product and its package. This made it very difficult for companies to purchase unique serial numbers by predicting the number of sales. Compliance with this labelling requirement was also difficult because the unique serial number should be placed in the country of

production, after the unique serial number was given to the company. This labelling measure, unique in the world, constituted an immoderate requirement and should therefore be withdrawn. Additionally, if the regulation, which was due to be enforced as of 1 November 2015, would apply to all products in the marketplace, Korean companies would have difficulties recalling air conditioning products using the old labels that would have already been sold before that date. Korea therefore requested UAE to, in accordance with Article 2.12 of the TBT Agreement, to allow a reasonable interval between the publication date and the entry into force of the regulation, or to apply the regulation only to products which passed customs entry as of 1 November 2015.

2.20. The representative of Qatar noted that the delegation of the United Arab Emirates was not present at the meeting, and, as the general coordinator of the GCC, he encouraged interested Members to raise their concerns bilaterally with the UAE. His delegation would also convey the concerns raised to the delegation of the UAE.

2.2.2.7 India - Secondary cells and batteries containing alkaline or other non-acid Electrolytes (G/TBT/N/IND/47/Add.1)

2.21. The representative of the Republic of Korea said that his delegation was still concerned with this measure despite certain improvements made by India. He noted that, although the date of enforcement had been postponed from 31 August 2015 to 1 December 2015, according to the official gazette of 7 August 2015 the issuance of the certificate had also been delayed. The delay was mainly due to the suspension of the Indian testing laboratories and the lack of capacity to handle samples. Among the five testing labs for secondary batteries, UL India had been suspended since 18 August 2015 and Bharat Test House had recently been released from a three-week suspension. Given the foregoing, Korea was concerned with the possibility that its companies would not be able to get the certificates before the date of enforcement. He asked that India provide a reasonable grace period in accordance with Article 2.9 of the TBT Agreement. Moreover, although India was a member country of IECEE CB, it did not accept the internationally recognized IECEE CB certification, and also required additional tests. Local labs had been unable to handle the resulting workload and thus the issuing of the certificate had been delayed. By way of comparison, in Korea, when companies had IECEE CB certification, the evaluation items were reduced. India could do the same and accept IECEE CB certification, or simplify the evaluating criteria so as to facilitate the process for goods which already had IECEE CB certificates.

2.22. The representative of the United States associated herself with Korea's concerns.

2.23. The representative of India explained that "Sealed Secondary Cells or Batteries containing Alkaline or other non-acid Electrolytes for use in portable applications" were incorporated in the Compulsory Registration Scheme as per a notification, dated 7 November 2014, of the Department of Electronics and Information Technology. Initially, a transition period of nine months was allowed, which was subsequently extended considering various requests received from stakeholders and WTO Members. Currently the Order would enter into force and be enforced as from 1 December 2015 (G/TBT/N/IND/47/Add.1). The Order required goods – including "portable sealed secondary cells and batteries containing alkaline or other non-acidic electrolyte" - to conform to the Indian Standard IS 16046:2012, the requirements of which were in accordance with IEC 62133. The 2012 version of IS 16046 was subsequently revised and published as IS 16046:2015, which was equivalent to IEC 62133 (second version). With respect to the products at issue, he explained that these cells or batteries needed to be separately registered, even when used in other products. However, if the battery was an integral part of a host product and was non-detachable, then it could be tested as part of the host product and a separate registration for the battery was not required.

2.24. With respect to the concern on the availability of testing labs, the Bureau of Indian Standards (BIS) had recognized 18 laboratories for testing of electronic goods under the Compulsory Registration Scheme. The services of these laboratories could be utilized depending upon their scope of recognition. With respect to the request for allowing an additional grace period for implementation, he noted that the implementation of Order, issued in November 2014, had already been extended until 1 December 2015, thus allowing for more than a one year transition period. However, this request for an additional grace period was being forwarded to the concerned authorities for their consideration. Finally, regarding the concern with the acceptance of CB test reports, he recalled that this point had been clarified several times in previous meetings while

responding to the STC "India - Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order, 2012" (paras.2.123-2.126 below).

2.2.2.8 EU – Withdrawal of equivalence for processed organic products

2.25. The representative of India said that India's National Program for Organic Production (NPOP) had been recognized by the EU in 2006 to be equivalent with that of the European standards. The scope of this recognition covered only crops and its products (raw and processed). In recent years, the demand, from both importers and consumers, for blended organic products with a variety of ingredients, such as flavours, colours, additives, herbs or herbals products of other country origin was increasing. However, Indian producers were unable to blend such ingredients with the principal product produced in India for supplying the EU market. This difficulty stemmed from the fact that the EU equivalence recognition clearly indicated that exports from India should have been grown in India. India raised this issue several times at different occasions during the Joint Working Group meetings it held with the EU for considering export of organic products with blended imported EU certified organic ingredients. There was however no response from the EU side on the use of imported ingredients for processed products for re-exportation. Since trade was being adversely affected due to the delay in certification of blended organic products, India made guidelines for the import of ingredients and the re-exportation of blended organic value added products. These guidelines were supposed to be implemented with effect as from 1 September 2012. However, in view of the reservation shown by EU, India withdrew the guidelines on 1 March 2013. After the issuance of these guidelines, no product with imported ingredients was exported to EU from 1 September 2012 until 1 March 2013. However, the EU unilaterally withdrew the processed products equivalency for organic products with effect as from 1 April 2013. As a result, Indian exporters now have to comply with the additional Certification for processed products by six EU recognized certification bodies for export of processed products to EU. This was adding to the cost of certification to the exporters. He further noted that the renewal of such equivalence arrangements with third countries was done every three years. India's renewal was thus due in June 2015. In this connection, an EU-FVO (Food and Veterinary Office) Mission, comprising of three Members and one observer from USDA-NOP, visited APEDA in India from 13–23 April 2015 to evaluate the compliance of the NPOP procedures under the Equivalency arrangements between India and the EU for export of organic products. The final report was still pending, despite a lapse of more than six months.

2.26. He drew Members' attention to the fact that India had also raised this issue at the SPS Committee meetings several times. However, in that Committee, the EU had taken a position that this was not an SPS issue and the TBT Committee was the right forum for such a discussion to take place. While his delegation disagreed with such a view, given that EU regulation itself mentioned food safety aspect several times in its text, at the same time India would like to get this issue resolved so the equivalency arrangements could be restored as soon as possible.

2.27. The representative of the European Union expressed her delegation's preference for discussing this bilaterally with India as had been the case until this meeting. For instance, Indian concerns had been discussed bilaterally on 7 October 2015 during the 8th meeting of the EU-India Joint Working Group on Agriculture and Marine Products. With respect to the specific concern raised by India, she explained that in April 2013 the EU had been obliged to withdraw the recognition of the equivalence agreement with India on processed organic products because India had not been able to satisfy the provisions contained in the bilateral agreement. In this specific case, certain organic ingredients of non-Indian origin had been included in processed organic products produced in India and destined to the EU market. The recognition agreement was clear in that it did not foresee this possibility. Furthermore, when recognition was then restricted to unprocessed plant products and seeds, India could not provide guarantees that only these types of products were exported to the EU. An audit from the Food and Veterinary Office (FVO) of the Commission's Directorate General for Health and Food Safety took place in April 2015 to further assess the situation. However, the results of this audit were not yet available. She also said that before India's request for reinstatement of processed products could be addressed, the EU must ensure that India would be able to provide enough guarantees so as to respect the basic requirements of the equivalency arrangement. In addition, the EU needed to be satisfied with India's control system overall, as well as with India's response on irregularities.

2.2.2.9 Singapore - Plain Packaging for Tobacco Products

2.28. The representative of Indonesia thanked the Singaporean Ministry of Trade and Industry for the written responses and clarifications sent to the BSN (TBT Enquiry Point) on 17 September 2015. He also thanked Singapore for the further clarification, given bilaterally, that the draft regulation was not yet published during the public consultation. Based on the information that was publicly available on Singapore's Ministry of Health of website, Indonesia noted that the concepts of plain packaging policy, as discussed in the public consultation, were similar to those implemented, or about to be implemented, by some other Members. Indonesia was of the opinion that a plain packaging policy did not have a scientific evidence basis regarding its effectiveness to achieve the legitimate objectives. This policy was not assessed in accordance with the provisions of the TBT and TRIPS Agreements, and there was no empirical evidence that the policy could reduce the number of smokers. Indonesia had thus systemic concerns with this issue and requested Singapore to consider delaying the policy until there was a decision by the DSB on this matter.

2.29. The representative of Australia expressed his delegation's strong support for the decision by other WTO Members to legislate for the mandatory plain packaging of tobacco products and, in this respect, welcomed Singapore's recent announcement that it would launch a public consultation on the introduction of tobacco plain packaging. The important steps taken by Members in the area of tobacco control demonstrated that efforts to delay the adoption of tobacco plain packaging measures in these countries had not been successful. Australia was of the view that Members had the right to implement measures necessary to protect public health while complying with the relevant international treaty obligations including the TBT Agreement. Tobacco plain packaging was a legitimate measure designed to achieve a fundamental objective, namely, the protection of human health. Tobacco plain packaging measures were endorsed by leading experts as well as the WHO and were supported by extensive peer review research, reports and studies. Australia was currently defending its measures in the WTO. It was thus inappropriate for complainants in WTO disputes currently underway against Australia to invoke proceedings in an attempt to delay or discourage others Members from developing or implementing their own legitimate tobacco control measures.

2.30. The representative of New Zealand expressed her delegation's support for Singapore's decision to conduct consultations on its proposal to introduce standardised packaging for tobacco and tobacco products. There was an extensive and growing body of international research which established that plain packaging, as part of a comprehensive tobacco control programme, would contribute to the objective of improving public health. Additionally, the experience of Members which have implemented plain packaging showed that, post-implementation, plain packaging was working as intended. The TBT Agreement recognised the fundamental right of Members to implement non-discriminatory measures necessary to protect public health and provided appropriate flexibilities for Members to do so. New Zealand believed that it was possible for Members to implement a tobacco plain packaging regime in a manner consistent with all of their WTO obligations, including those under the TBT Agreement.

2.31. The representative of the Dominican Republic said that her delegation shared the same concerns expressed by Indonesia. The Dominican Republic believed that these measures were not compatible with the WTO Agreements and together with other developing countries it had challenged a similar measure under the DSU.

2.32. The representative of Guatemala requested Singapore to wait until a decision was reached by the DSB on this matter, which could provide useful guidance for other Members.

2.33. The representative of Norway associates herself with Singapore, Australia and New Zealand. In March 2015, the Norwegian government launched public consultation of standardised tobacco packaging. Norway was currently preparing a paper for the Norwegian parliament on this issue.

2.34. The representative of Canada said that his delegation followed with interest the ongoing international developments regarding plain packaging and how such measures interacted with international trade and public health. Canada was a pioneer in packaging labelling requirements for tobacco products and considered such requirements as core components of the right to regulate in the interest of the Canadian public. 37,000 people died annually from tobacco use in Canada. Tobacco use was thus a significant problem and was Canada's leading cause of

preventable death and disease. Tobacco products were also the only goods that were the subject of international, legally binding health obligations, namely, those under the WHO Framework Convention on Tobacco Control (FCTC).

2.35. The representative of Singapore clarified that Singapore currently did not have a proposed regulation on standardised packaging. As tobacco control was a long standing public health priority in Singapore, the government had been studying and closely monitoring international developments on tobacco control measures, including standardised packaging. In March 2015 Singapore's Ministry of Health announced its intention to conduct a public consultation on standardised packaging at the end of this year. The purpose of this public consultation was to gather public feedback on standardised packaging, if it would be introduced. The decision on whether to proceed with standardised packaging would be based on the public health merits of this measure. Any such measure would be designed in the manner consistent with Singapore's international obligations.

2.36. The representative of the World Health Organization requested that her organization's previous statement on tobacco plain packaging be entered into the record of this meeting.³

2.2.2.10 Kingdom of Bahrain, State of Kuwait, Kingdom of Saudi Arabia, Qatar - Motor Vehicles: General Requirements "No. GSO 42:2003"

2.37. The representative of the European Union said that in November 2014 and February 2015, after the measure (referred to as GSO 42:2003) had been notified, his delegation had sent written comments to the Kingdom of Bahrain, the State of Kuwait, Kingdom of Saudi Arabia and Qatar. Members were later informed of the final text, referred to as GSO 42:2015. The EU noted that this measure, which should be aligned with the relevant international standards, required that windshield glass of motor vehicles be laminated and all their windows be made of safety glass or laminated. The EU underlined in this respect that both UNECE Regulation 43 and Global Technical Regulation 6 allowed the use of a mixture of glass and plastic glazing for all windows, including for the windscreen. The use of pure plastic glazing was allowed for all windows with the exception of the windshield. He also noted that the notified measure also stated that the "minimum light transmissibility" for the glasses and plastic of windows of motor vehicles shall not be less than 70%. In this respect, the EU recalled that UNECE Regulation 43 also contained the requirement of minimum light transmissibility for the windshield and the front side windows, but without imposing a minimum light transmissibility for the rear side windows and the rear window in cases where two exterior rear view mirrors were fitted. The EU invited the authorities of the four notifying Members to reconsider imposing the requirements for the rear side windows and the rear window, as a high light transmissibility for these items did not seem to be necessary for the driver to have good visibility. Furthermore, the EU noted that this notified provision referred to plastic for windows whereas the requirements mentioned above regarding the windshield and all windows only referred to safety glass or laminated.

2.38. Additionally, he noted that the notified measure also required a label on fuel consumption efficiency to be displayed on the inner side of the vehicle on the rear left hand side by the manufacturer of the vehicle. This provision would require that all vehicles produced by foreign manufacturers intended for the markets of the four notifying Members to be identified already at the stage of their production. The EU therefore asked the authorities of the four notifying Members to consider modifying this provision in the following way. First, to require this label when displaying the vehicles for sale, rather than as currently proposed, when the certification of the vehicle was undertaken. Second, to allow the label to be alternatively placed on the front windshield for vehicles that have only two doors. In relation to the requirement that the maximum amount of fuel leakage should not be more than 28 g/min, the EU asked the alignment to the maximum rate of continuous leakage to be set at 30 g/min, as per UNECE Regulation 34. With respect to the measure's stipulation that all instructions indicated on the driver's monitor/display be available in Arabic and English, the EU asked for clarification that in the measure itself the Arabic language requirement did not apply to general single words or letters on the monitor/display (such as "display" or "on/off") and that the Arabic language could be replaced by the use of the symbols, as per UNECE Regulation 121 on "Identification of controls, tell-tales and indicators" and ISO 2575 on "Symbols for use on controls, indicators and tell-tales applying to passenger cars, light and heavy commercial vehicles and buses". Finally, in relation to the

³ G/TBT/M/66, para. 3.61.

requirement for additional safety cut off devices for vehicles with batteries at the rear, the EU noted that this requirement did not correspond to any international standard. Its application would entail that vehicles in conformity with international standards could not be sold within the territories of the notifying Members. The EU therefore asked the authorities of the four notifying Members to reconsider this requirement.

2.39. The representative of Qatar, on behalf of the four Members, said that the GSO had received concerns from other Members which the GSO TBT Committee was currently reviewing. Replies would be provided in due course.

2.2.2.11 India - The Stainless Steel Products (Quality Control) Order, 2015

2.40. The representative of the European Union noted that the notified draft followed similar certification measures adopted by India for steel products, such as that notified in G/TBT/N/IND/32 - Steel and Steel Products (Quality Control) Order, 2006.⁴ It further extended the scope of the existing Bureau of Indian Standards (BIS) mandatory certification system to 3 other steel products: stainless steel plates, sheets and strips. A BIS mandatory certification was introduced for 15 steel products in 2014 and then was subsequently extended to 21 additional steel products. At that time the EU highlighted the additional burden and cost for the steel companies imposed by the necessity of going through the process of obtaining certification in India, which implied additional tests for steel products which have already been tested. The EU considered that third-party conformity assessment should be reserved for those products that might contain serious health and safety hazards. This was not the case of steel products which were intermediate products not reaching the final consumer. Therefore the BIS certification requirements were too burdensome to attain the legitimate objective pursued. Furthermore, testing for conformity with the BIS Quality Orders could only be performed in laboratories authorized by the BIS. This implied the need to re-test steel products which had already been tested against the relevant international standards. In this context, the EU asked India to accept tests carried out in foreign accredited laboratories attesting compliance with ISO standards or Indian standards, thus not requiring local testing in India for all types of steel products. In relation to the Indian standards referred to in the notified draft, the EU asked India to confirm that these standards were equivalent to the relevant international standards and if so, the EU believed that those international standards should also be referred to in the text. Finally, the EU asked India whether factory inspections would be required by the BIS certification scheme. If this would be the case, the EU would draw India's attention to the fact that steel mills in the EU had in place quality management systems, as defined in ISO 9001, and that, therefore, factory visits for these steel mills had no added value.

2.41. The representative of India explained that the Ministry of Steel had proposed a Quality Control Order on three stainless steel products/standards with a direct bearing on consumer health and safety. The critical and strategic nature of industrial application demanded that the quality of the stainless steel was of utmost importance as it concerned public health and safety. The draft order was published on the Ministry of Steel website and also notified to the TBT Committee on 25 August 2015, giving a 60-day public comment period until 24 October 2015. Several representations from domestic and foreign producers, users as well as their associations, and other stakeholders, had been received both in support and against the draft Order. These comments were currently under examination in the Ministry. A final decision on the matter would be taken after consideration of all the views and comments received.

2.2.2.12 India - Amendments in the import policy conditions applicable to apples

2.42. The representative of the European Union asked India for clarifications concerning this measure, which limited the ports of entry for imports of apples into India to just one port, namely the Nhava Sheva Port. The measure had been published in the Gazette of India under Notification No. 21/2015 2020. She said that this limitation to one port of entry had a restrictive effect on imports of EU apples into India, including by resulting in higher transportation costs and delays. This issue had been previously raised in other WTO Committees (the Committee on Agriculture on 24 September 2015; the SPS Committee on 14-16 October 2015; and the Committee on Import Licensing on 20 October 2015). However, no explanation had been provided by India thus far as to the reason and nature of this restriction. Consequently, due to the unclear nature of the measure,

⁴ India – Mandatory Certification for Steel Products (STC IMS ID 224).

the EU was also using the TBT Committee meeting to seek clarification as to the justification of this restriction and its envisaged duration.

2.43. The representative of New Zealand echoed the EU's concerns and noted that prior to implementation of this decision New Zealand apples exports had entered India through six ports (Nhava Shiva, Chennai, Kolkata, Vizak, Kochin and Tuticorin). She asked India to explain for how long these port restrictions would be in place, when a WTO notification would be provided and the rationale and justification for the measure. New Zealand noted that, together with other Members, it had also raised this issue in the Import Licensing and SPS Committees and asked India what WTO committee this issue should be best considered.

2.44. The representative of the United States supported the concerns of the EU and New Zealand regarding India's announcement on 14 September that limited apple imports to the Nhava Sheva port in Maharashtra. The US understood that the Nhava Sheva port was not able to meet the storage and other infrastructure requirements needed to handle this year's expected US apple exports to India. This port restriction would thus significantly impact US apple exports to India. It was also unclear why India did not notify this measure to the WTO. The US and other Members had also raised this issue recently in other WTO fora, namely, the Committees on Agriculture, Import Licensing and on Sanitary and Phytosanitary Measures. However, no satisfactory response was provided in those fora. On 30 September 2015 the US received a brief written communication from India in response to an earlier request for information. This response only contained a mere consideration to internal challenges with managing port procedures. In this regard, she noted that in this response, India indicated the following issues in connection with this measure, namely: (i) material handling; (ii) inspection; (iii) quality assurance; and (iv) considerations associated with import and consumption of apples. The US asked India to elaborate on this list of rational basis for the measure.

2.45. Based on the foregoing, this measure was overly restrictive and significantly affected US exports. She drew India's attention to its obligations under Article 5.1.2 of the TBT Agreement. This provision, related to conformity assessment procedures, meant, inter alia, that such procedures shall not be more strict or be applied more strictly than would be necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create. The US therefore requested India to immediately withdraw this measure and work bilaterally with trading partners towards finding a solution to this issue, including exploring cooperation venues in the areas of material handling, inspection, quality assurance and conformity assessment mechanisms.

2.46. The representative of Chile asked when this measure would be notified to the WTO. This measure had already been raised before the SPS and Agriculture Committees but no satisfactory answer had been given by India as to its basis under the WTO agreements.

2.47. The representative of Australia noted the fact that this measure, without being previously notified or Members consulted, had entered into force immediately upon publication and it had the effect of directing imports through a port that was already heavily congested. India was asked to provide the rationale for its decision.

2.48. The representative of India said that the policy in question did not fall under the category of measures covered by the TBT Agreement (technical regulations, standards and conformity assessment procedures) and was hence outside the purview of the TBT Committee.

2.2.2.13 Kingdom of Saudi Arabia - Draft for update of the Technical Regulation No. SASO 2857:2014 "Vehicle Tires Rolling Resistance and Wet Grip Requirements"

2.49. The representative of the European Union noted that the labelling requirements for C1 and C2 tyres would be enforced from 1 November 2015, although originally the envisaged date was 1 November 2016 for C2 tyres. He said that compliance with these requirements required a sequence of actions, including laboratory approval, tyre family declaration, submission of tyre performance values, printing of labels by an external party, affixing the labels on each tyre and shipping. The complexity of this process was further enhanced by requiring that the stickers be affixed at the moment of entry into the country and not at the moment of displaying the tyres for sale. A sufficient transition time should therefore be provided from the day of publication of the

final measure. He also noted that the notified draft limited the validity of the licence to print and use the labels to one year. Taking into consideration that the notified draft also stipulated that any modification of the tyres rendered the license invalid, the limitation of the validity to one year was redundant and would create unnecessary administrative burdens and costs for the manufacturer. Furthermore, given that the purpose of the labels was to inform customers, the obligation to affix the stickers should therefore be when displaying the tyres and not when entering into the territory. Finally, the EU asked the Saudi Arabian authorities to notify all the implementing measures, including the recent "*Regulation for procedure of data registration and issuance of the energy efficiency labels in vehicles and tires*".

2.50. The representative of the Kingdom of Saudi Arabia invited the EU to discuss the concern bilaterally.

2.2.2.14 China - Insurance Regulatory Commission (CIRC) Information and Communication Technology Regulation

2.51. The representative of the United States noted that on 9 October 2015, China's Insurance Regulatory Commission (CIRC) published draft regulations imposing information security-related requirements on ICT systems in the insurance sector with less than a 30-day comment period. The US asked China to notify this regulation to the WTO and give a 60-day comment period. She also said that the US Government and a coalition of US industry as well as the EU and Canada provided comments on 30 October 2015 where they conveyed their understanding that the draft Informatization regulation would replace the current guidelines for the Management of Informatization work in insurance companies (for trial implementation) and elevate such documents from voluntary guidelines to the status of administrative regulations. The US had several concerns centred on the following three requirements: secure and controllable technology and indigenous encryption. Specifically, the US believed that the provision in Article 53 to require secure and controllable ICT was overly broad, and it was unclear what ICT systems covered by the regulation were expected to meet. The US was concerned that the clause in Article 53 may be used as justification to impose trade restrictive measures and limit participation of ICT manufacturers in China's insurance sector. With regard to Article 56 of the draft regulations, she said that, by mandating compliance with the Multilevel Protection Scheme, the draft regulation appeared to require compliance with certain information security technical regulations and encryption regulations, which would require indigenous intellectual property for the selection of information security requirements. The US also believed the Level 3 security requirement was an over classification of this industry's security needs, and imposed a requirement, which would exclude foreign ICT products from the Chinese market. Encryption requirements in the draft regulation (Articles 25, 54, and 58) appeared to require, for a wide range of commercial ICT products, encryption pre-approval by government regulators. According to the current Chinese law, this pre-approval would require divulging source code and other sensitive design information in a certification process, a matter of enormous concern to the global industry. Since 1999 China agreed to impose such requirements only on ICT products whose core function was encryption and not apply encryption registration requirements to the broader world of commercial ICT products. This insurance rule appeared to abandon this agreement. This was not the first time the US have raised these types of concerns, as it had raised similar concerns with China's government policies related to ICT requirements for banking regulations, which were eventually suspended.

2.52. The representative of the European Union associated his delegation with the US statement. Regarding the process, while the EU welcomed the consultation on the draft, it nonetheless also considered the comment period provided to be very short. In substance, he said that this draft measure raised the same concerns as expressed previously with regard to the banking guidelines which were the subject of another STC in the TBT Committee. As already said by the US, this draft regulation appeared to classify IT systems in the insurance sector as critical infrastructure under the Multilevel Protection Scheme, thereby triggering a number of consequences, such as the impossibility for the insurance sector to procure encryption products incorporating foreign technology. The EU also expressed concerns with other aspects of this measure, such as the potential source code disclosure. In this respect, the EU believed that this approach to information security deprived China from procuring the most developed and innovative encryption solutions that were available in the world market. The unintended consequences of such a policy was therefore weakening information and network security in the sectors which were covered by such policies, rather than contributing to reinforcing information security. The EU looked forward to

further bilateral discussions and urged China to suspend the measures and carry out a substantive review of the draft in light of the comments received.

2.53. The representative of Canada supported the comments by the US and EU. While understanding China's desire to minimize threats to its ICT infrastructure, Canada was of the view that China's approach to "secure and controllable" ICT would decrease, not increase cyber security for its network and insurance ICT infrastructure. With respect to China's draft insurance security regulations, Canada asked China to provide further information on the definition and scope of what constituted "core systems" and how "national security" would be defined in this context. Canada also requested China to clarify how this article would function in relation to the Multi-level Protection Scheme (MLPS). With respect to development and testing identified in Article 22, Canada requested China to give additional information on how the provisions related to testing by third-party institutions would be operationalized.

2.54. He also noted that Article 25(2) described the security management mechanism requirements, including the use of technologies and products that complied with national standards and encryption requirements. Canada asked China to clarify whether this article was referencing other existing legislation or if the terms would be uniquely defined for these Rules. He then noted that Article 31 outlined that, where data came from within the Chinese territory, the data centres handling the information should be located within China. This provision 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 was in this respect concerned that these requirements could be overly restrictive for the intended purposes of ensuring secure data infrastructure. Canada also sought clarification as to why these measures were thought to be necessary for the insurance sector in China. With respect to Article 53, which provided for 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. If not, Canada asked China to clarify as to why China considered it necessary to impose such limitations. With respect to Article 54, which contained an objective to work towards an "all-round application of domestic cryptography in the electronic insurance policy and insurance sector," Canada asked China to explain how this would work in practice and any additional information about such an objective. With respect to Article 55, asked China to clarify the meaning of "indigenous IP protection", as well as to provide information on CIRC's associated expectations regarding the implementation and interpretation of this Article. With respect to Article 56, which appeared to reference MLPS security requirements, although in a non-specific manner, could China provide additional information with respect to what level of security might be required? How would this article function in relation to Article 20, which also appeared to set out security requirements? Could China provide additional information on the "security certification" process? Will China adhere to international standards and accept third-party test reports in this regard?

2.55. The representative of Japan expressed her delegation's view that the articles regarding terms definitions, concrete requirements for examination and evaluation and scope of regulation were unclear and asked China to clarify them. In addition, with respect to the requirement of, inter alia, usage of Chinese national standards and domestic code in China, Japan asked that China to be consistent with the TBT Agreement, in particular with the principles of non-discrimination and of not being more trade-restrictive than necessary. Moreover, Japan requested China to notify this Regulation.

2.56. The representative of China said that the rapid development of the global information technology and financial innovation had brought new challenges to the insurance industry that required all Members to strengthen security of information network and operational management in the insurance system. In 2014, consistent with international practice, China had issued guidelines for applying secure and controllable information technology to enhance cyber security and construct an IT risk control mechanism in the insurance sector. The relevant regulations adopted by CIRC would equally apply to domestic and foreign suppliers. The public consultation on the CRIC Information and Communication Technology Regulation ended on 31 October 2015 and the regulation was currently being finalized. China would take all comments into full consideration.

2.2.2.15 China - Guidance for Notification and Registration for New Chemicals

2.57. The representative of the United States noted that China's Solid Waste and Chemical Management Technology Centre (SCC-MEP) had issued a consultation draft of the Guidance for the Notification of Registration of New Chemicals in June 2015. The US industry provided comments in the public consultation. The US requested China to notify this Guidance to the TBT Committee so as to provide WTO Members an opportunity to comment on the draft. She recalled that the original regulation, Order 7, came into effect in October 2010 and set requirements for the registration of chemicals. The requirements from the original 2010 regulation were difficult to understand, and imposed very significant administrative and compliance burdens on manufacturers. While the US welcomed the attempt the Guidance offered to clarify those requirements, the Guidance itself raised a series of troubling concerns. In particular, the new language in Chapter I (1) 2.4 on articles exempted from the New Chemical Notification (NCN) Guidance implied that any new chemical substance in an article, potentially having exposure to humans or the environment, would be subject to the full NCN obligations as per Order 7. Specifically, this requirement would be applicable to all articles and their subcomponents, even if there was extremely low risk of hazard or exposure to humans or the environment. The US considered that this requirement would not only impose significant administrative and compliance burdens on industry. It would also impose a new administrative burden on the SCC-MEP itself, significantly increasing the number of applications it would have to review.

2.58. She further noted that US industry recommended that SCC-MEP maintained the previous version of the Article Exemption, under which articles and substances used in, or released by, articles would be exempt since they posed negligible risk to human health or the environment. Otherwise, the provision could potentially place an undue burden on manufacturers in China's marketplace. Global suppliers to Chinese importers would be required to proactively inform their Chinese customers of substances new to China that may be contained in, or released from, their manufactured articles. This would place a significant burden on exporters to China since they would have to ensure that substances would be notified. This would result in amplified implications throughout the global supply chain, including on Chinese companies. Further, such requirements could impact global suppliers' future decisions to export substances and articles to China due to the increased administrative burden as well as the possibility of disclosing sensitive Confidential Business Information to customers. The US thus requested China to take US industry's concerns into account, and asked for an update on the timeline for the finalization of the Guidance.

2.59. The representative of China said that the revision of the Guidance for Notification and Registration for New Chemicals started in January 2014 and that the public consultation had taken place from 25 June until 31 July 2015. The Guidance was currently still under revision and China would take Members' comments into consideration.

2.2.2.16 Korea - Standards and Specifications for Wood Products (G/TBT/N/KOR/599)

2.60. The representative of the United States expressed her delegation's concern about Korea's lack of transparency in drafting the standards at issue, especially since compliance with them seemed to be mandatory. In the case of plywood and glued-laminated timber, she said that US industry got involved too late in the standardization process to have its concerns reflected in the final text because the draft standards were not notified to the WTO until Korea was prompted by them to do so. The US was also concerned that the implementation date was immediately after the standards were adopted, not allowing any time period to become acquainted with them. Although Korea sent a response to the US comments submitted on these standards shortly after adoption, it had never been made clear how these concerns were taken into consideration. US industry was therefore concerned that the final standards may not reflect any of the suggestions made that would help Korea avoid unnecessary trade barriers. In this respect, she noted that to date the US had not received any indication of how Korea's standards would pursue the least trade restrictive approach available or how they aimed to turn these documents into performance-based standards. US industry stakeholders were also becoming increasingly concerned about the costs of compliance, such as those incurred when shipments were detained while waiting for inspection by Korean officials - shipments already certified to international standards by accredited bodies.

2.61. The US requested that Korea suspend the adoption, promulgation and enforcement of the quality standards for plywood and glued laminated timber. Given the degree of uncertainty

regarding how infrastructure to inspect the high volume of wood products coming through its ports of entry would operate, the US also asked that the Korean Forestry Service recognize test data generated from, as well as the registered trademarks applied through, ISO 17025 accredited laboratories. The US recommended that Korea continue its active participation in ISO Technical Committees in order to develop performance-based standards instead of national prescriptive standards. As currently written, the Korean Forestry Service's draft regulations prevented Korean manufacturers from purchasing engineered wood that was lighter, thinner, and stronger than what its regulation would allow. Performance-based regulations would allow adapting to technologies that would enhance the quality of wood products without the need for the Korean Forestry Service to issue amendments every time a wood product changed due to improvements in technology. She also said that, as drafted, the standards at issue would not be able to protect Korean consumers because the Korea-unique certification requirements lacked the details available in requirements accepted by international certifying bodies. Finally, regarding the draft standard on oriented strand board, she asked that Korea take US comments into account; choose the least trade restrictive approach, and base requirements on performance instead of prescriptive characteristics of the product.

2.62. The representative of Canada praised Korea's ongoing efforts to work with Canadian trade and forestry officials to resolve issues related to a number of forest-product standards, and expressed appreciation for the level of engagement and collaboration demonstrated by Korean counterparts. He also noted that the new standard for Oriented Strand Board (OSB) was of particular concern and recalled the Canadian industry submitted comments on Korea's recent notification of this standard (G/TBT/N/KOR/599) on 26 October 2015. Of particular concern to Canada was the fact that Korea was basing its draft OSB standard on an ISO standard that was explicitly indicated not to be used for structural design, and which was based upon property testing rather than performance testing. Canada thus asked Korea to take into the account the fact that OSB in Korea was primarily used for structural applications. It also asked Korea to: (i) reconsider its draft standard to address the performance requirements of OSB used for structural purposes; and (ii) to recognize that North American OSB, which was the vast majority of the product in this market, should continue to be allowed in Korea based upon its well-known quality, safety and reliability.

2.63. The representative of the Republic of Korea remarked that Korea had been facing a significant expansion in the use of wood products as one of the eco-friendly materials. At the same time, issues and concerns over increasing low quality due to price competition and poor quality management had arisen. Against this backdrop, Korea prepared and circulated, in accordance with WTO transparency obligations, a notification of a draft quality indication system of wood products for comments and questions. US comments were already taken into account. He further explained that the process to amend the Korean standard at issue had been conducted since May 2013. There had been three meetings for technical discussion between Korea and Canada since October 2014. In those meetings, an APA representative and a US delegation participated as observers to discuss their concerns and future plans as well as the contents of a draft amendment on plywood, glulam and OSB. The regulation on specifications and quality criteria of wood products, including plywood as attachments, was promulgated and entered into force on 19 June 2015, after receiving opinions from WTO Members from 26 February to 15 May 2015. However, the newly attached regulation on glulam would be implemented as from 30 December 2015, after a 6-month grace period. With respect to the regulation on OSB, a public hearing for the draft was held on 23 July 2015, with representatives from the US Embassy and the Engineered Wood Association (APA). Furthermore, the draft was distributed to both US and Canadian Embassy in Korea during the domestic opinion gathering period. The notification on the draft regulation was circulated to Members through the WTO Secretariat, with an opportunity for comments between 2 September and 31 October 2015. The measure was scheduled to be promulgated in late December 2015 and would come into effect as from June 2016, after a six month grace period. However, if the suggestions and comments from WTO Members would be reasonable enough to be reflected in the notification, Korea said there might be an option to delay the promulgation for further consideration. As mentioned before, sufficient time and opportunities were provided to collect comments from stakeholders with a view to ensuring transparency when regulations were made or amended.

2.64. With regard to the use of international standards, the Korean Government had actively participated in technical committees of ISO, including: ISO/TC 89 (wood-based panels), ISO/TC 165 (timber structures), ISO/TC 218 (timbers), ISO/TC 238 (solid bio-fuels). In addition,

when enacting or amending the regulation, the Korean Government would consider ISO as a top priority reference. If the ISO standard and the Korean regulation on wood products would have the same test methods and criteria, the recognition of test data or reports of ISO 17025 or ISO 17020 accredited laboratory might be considered. However, in case of items that were not specified in ISO, the Korean Government would develop standards that would best fit the Korean situation. Korea would review the possibility of recognition of ISO-accredited certification bodies, institutes and trademarks only if they would apply the same standards as those of Korea. With respect to other specific questions, including performance-based regulation and structural design related issues, given their technical nature, they would be conveyed to the relevant agency in capital.

2.2.2.17 European Union - Proposal for a Directive of the European Parliament and of the Council on the Cloning of Animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes (197) and Proposal for a Council Directive on the placing on the market of food from animal clones (198) (G/TBT/N/EU/197 and G/TBT/N/EU/198)

2.65. The representative of the United States expressed her delegation's concern regarding the cloning measures currently under consideration by the EU, and, in particular, the amendments recently adopted by the European Parliament. The US considered that these proposed measures may be more trade restrictive than necessary and perhaps did not fulfil any legitimate objective the EU may have. At the outset, the US highlighted that the amendments adopted by the European Parliament expanded the scope of the Commission's original proposals, as notified in G/TBT/N/EU/197 and G/TBT/N/EU/198, to include all farmed animals, poultry and fish and to make the restrictions permanent rather than temporary. There were substantial trade implications for imposing bans or labelling requirements on animal clones, their genetics, their sexually-reproduced offspring and descendants, and the edible food products from such animals. Further, there did not appear to be any scientific or other legitimate rationale for the EU to impose restrictions on food from cloned animals, let alone on food or products from the descendants of cloned animals. Both the US Food and Drug Administration (FDA) and the European Food Safety Authority (EFSA) concluded that meat and milk from cow, pig, and goat clones and the offspring of any livestock clones present no food safety risk. Indeed, EFSA had also explicitly noted that there was also no scientific evidence that suggested a risk to genetic diversity, biodiversity, or the environment from farmed clones in comparison with conventionally farmed animals. Moreover, the International Embryo Transfer Society (IETS) had published guidelines for the health assessment and care for animals involved in the cloning process, which detailed the recommended care for cattle, swine, goat, and sheep clones and surrogates to protect the welfare of the animals. These guidelines for the protection of animal welfare were met or exceeded by the US cloning industry. This was a worldwide, not US-focused, issue. Descendants of clones were likely in every country that imports genetics. The US trusted that the EU would recognize that their own herds were not free of descendants of clones - and it was critical that EU measures did not unfairly disadvantage imports. Moreover, the US was concerned with the potential burden that would be imposed if the European Parliament's amendments became law. It was not possible to test if an animal was descended from a clone. Cloning left no genetic signature that would allow these animals to be distinguished from descendants of the original, thus creating the need for extensive traceability requirements that did not exist in many countries. In short, the US hoped the EU would be able to address these concerns by avoiding measures that failed to recognize the relevant science, that discriminated against imports, and that were unlikely to fulfil any legitimate objective.

2.66. The representative of Brazil said that his delegation shared the concerns raised by the US.

2.67. The representative of the European Union noted that the draft proposals were adopted by the Commission in late 2013 and notified to the TBT Committee in March 2014. The first Directive would prohibit the use of the cloning technique in the EU for 5 species likely to be cloned for farming purposes and the import of live clones produced in third countries. The second Directive would prohibit the placing on the market of any food from clones. The EU thanked Argentina, Australia, Canada, Paraguay and the US for their written comments, which had been replied to. The European Parliament recently completed its first reading on the first Directive. In its resolution, it proposed to merge both proposals and to extend the aggregate ban to reproductive material from clones, descendants of clones and products thereof. Moreover, a traceability system that would extend to third country trade partners was requested. The Commission maintained its proposals. The next procedural step would be the completion of the first reading by the Council of

the European Union and, if deemed necessary, the EU would inform the TBT Committee on any further developments on this subject.

2.2.3 Previously raised Specific Trade Concerns

2.2.3.1 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)

2.68. The representative of Japan recalled his delegation's longstanding concerns with this measure, which had first been raised in 2011. He highlighted four points of concern: the ISI marking fee requirement on every tyre on which ISI mark was attached, regardless of the destination country; the expensive marking fee; the lengthy certification process; and, the bank guarantee fee which was required only for tyre factories outside India.

2.69. Regarding the ISI marking fee on every tyre, Japan explained that from the viewpoint of cost efficiency, many tyre manufacturers which exported tyres to foreign countries, including India, attached the ISI mark on all the tyres in the same manufacturing line even if the tyres were not exported to India. If manufacturers were only to attach the ISI mark on tyres exported to India, they would need to have separate manufacturing lines for India, which meant that foreign tyre manufacturers would have to increase the number of manufacturing lines and incur additional cost. Even if manufacturers used the same production lines and changed the indications with plaquettes or inserts in order to manufacture both tyres for India and for other markets with the same tooling, this would lead to production losses when manufacturers changed indications of tooling or to additional management cost in order to separate its stock as different products. As a result, Japan stated that this requirement would lead to an increase in manufacturing cost, which tyre manufacturers would pass on to consumers in terms of higher price. In addition, Japan still considered the ISI marking fee to be expensive in comparison with other countries and asked that India show evidence of how the ISI marking fee was equivalent or cheaper than those of other countries. If India did not have such evidence, Japan requested India to reduce the fee to the same level as other countries.

2.70. The representative of the European Union reiterated concerns raised in previous meetings about the certification procedure for mandatory marking for tyres. He referred Members to his delegation's statements in previous meetings concerning the ISI marking fee and the US \$10,000 bank guarantee⁵, and highlighted in particular the EU request that India 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. Furthermore, the EU informed Members that they were aware that a new Indian scheme for testing and inspection for certification of automotive vehicles, and pneumatic tyres for passenger car vehicles, had been issued by the Bureau of Indian Standards in March 2015. This measure seemed to require that Conformity of Production (COP) tests be performed on all sizes of tyres exported to India every three months as opposed to every two years as required previously. The EU was of the view that this frequency did not seem to be justified as the international practice required such tests to be carried out every two or three years. Such a requirement also imposed an eightfold increase of testing requirements for tyre manufacturers. Therefore, the EU sought clarification from India as to the reasons for requiring COP tests with such a frequency and to consider requiring them every two years as was the case before. Finally as this requirement seemed to stem from a new measure which had not been notified under the TBT Agreement, the EU requested that it be so notified.

2.71. The representative of India noted that most of concerns raised were not new and had already been sufficiently explained at previous Committee meetings. Therefore, the interested delegations were requested to refer to India's intervention at the March 2015 Committee meeting.⁶ With respect to Japan's concern that BIS marking would necessitate setting up additional production lines and thus increase costs, his delegation understood that most manufacturers used plaquettes or inserts for various types of marking on tyres. These plaquettes or inserts could be removed and replaced by blanks when such marking was not required. It should, therefore, be possible not to place ISI marks on tyres not meant for Indian market using the same production line. On the related concern raised by Japan that use of plaquettes or insert would result in production loss and would add to management cost, India invited the delegation of Japan to

⁵ G/TBT/M/65, para. 2.40.

⁶ G/TBT/M/65, paras. 2.41, 2.42 and 2.43.

conduct a cost-benefit analysis in respect of using insert or plaquettes. His delegation believed that there would be a net benefit when compared with the existing situation in which all tyres were marked with BIS marking. He noted other additional questions, and would forward them to his capital for a response.

2.2.3.2 China – Provisions for the Administration of Cosmetics Application Acceptance, Cosmetics Label Instructions Regulations and Guidance for the Cosmetics Label Instructions, G/TBT/N/CHN/821 G/TBT/N/CHN/937 (IMS ID 296)

2.72. The representative of Japan reiterated the following three specific concerns with the "Guidance for Application and Evaluation of New Cosmetic Ingredients". First, regarding the speed of examination, he said that since the measure's implementation only four new ingredients had been registered to date and there continued to be significant difficulty in exporting cosmetic products with new ingredients. Japan again requested China to accelerate the examination process. At the June 2015 Committee meeting, China had said that it was considering an effective way of solving problems regarding registration including the speed of examination, and he asked China for an update in this respect. Second, regarding the safety evaluation requirement for plant extract and fermented solvents, Japan again asked China to revise the requirement to submit the data for each single isolated molecule, in particular given that no explanation had been given on the scientific grounds for such a requirement. Third, regarding disclosure of information, Japan again pointed out that companies were obliged to provide detailed information on manufacturing process, the reaction process and conditions of reaction. In some cases, this information appeared on the CFDA's website. While some improvements had been made, some points remained unclear and Japan requested that further action be taken so as to ensure that a company's confidential information not be disclosed.

2.73. The representative of the European Union reiterated concerns it had raised during previous meetings, and in particular with respect to the pace of progress in the procedure for authorization of new ingredients. The EU was still of the opinion that the new registration procedure did not deliver in an efficient and predictable manner. Recently, the EU had learned that the new Chinese draft on Cosmetics Supervision and Administration Regulation would set up a differentiated approach between priority ingredients, which were of higher risk, requiring premarket registration, and ordinary ingredients, which would only need to be notified to the competent Chinese authorities. The EU sought confirmation from China that this approach had been taken on board, and also asked about the relationship between the new Chinese draft on Cosmetics Supervision and Administration Regulation and the notified measure.

2.74. The representative of China explained that, according to the Regulations Concerning the Hygiene Supervision over Cosmetics, "new ingredients" refers to natural or synthetic materials that are used to make cosmetics for the first time in China. Before a new ingredient was used to make cosmetics, a registration must be made to the relevant authority for approval. Previously, the determination of a new ingredient had been done solely by experts on the basis of their personal experience, since an objective criterion was absent. China attached great importance to this issue, and was in communication with both domestic and foreign businesses and industry organizations to carry out research on this issue in order to find effective ways to solve this problem. After three rounds of public consultations, a catalogue of 8,783 cosmetic ingredients already used in China was published on 30 June 2014. She explained that another deficiency hindering the registration process was the absence of a classification system for new ingredients. According to the draft revision of Regulations Concerning the Hygiene Supervision over Cosmetics, a new classification system will be set up for cosmetics. In the new system, she said, only higher risk substances such as aseptic, sun-screening agents, colouring agents, hair colorants, and skin lighteners require registration with the relevant authority, while lower-risk substances just need to be filed. Moreover, different documentation requirements would apply to different substances to accelerate the authorization process in an efficient and predictable manner. China would keep the bilateral channel open and welcomed interested parties to continue to cooperate with China and put forward valuable inputs.

2.2.3.3 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)

2.75. The representative of the European Union welcomed India's statement at the June 2015 Committee meeting that the testing clearance for telecommunication equipment would be postponed until such a time as the required infrastructure was in place, and he asked for confirmation of the current situation. The EU also understood that until entry into force (currently postponed until 1 April 2016), the status quo would continue to apply and therefore foreign test results would continue to be accepted as the basis for the declarations of conformity to be issued by equipment suppliers. He asked for confirmation that the testing done by laboratories approved under the Common Criteria Recognition Arrangement (CCRA) would be accepted and leveraged for the purpose of compliance with India requirements to the extent these tests cover the applicable requirements. For specific aspects not covered by the CCRA, he sought confirmation that standards developed under the Third Generation Partnership Project (3GPP) would be used as a basis for Indian standards and that there would be the possibility for foreign laboratories which demonstrate competence through adequate accreditation to perform the relevant tests.

2.76. The representative of Canada reiterated concerns regarding India's test requirements for telecommunications products. In addition to the concerns raised by the EU, his delegation believed that India's in-country security testing regulations for telecommunications products would hinder or possibly shut exporters out of the Indian market. Canada disagreed with India's blanket approach to testing in the telecommunications sector and did not understand why CCRA testing was not appropriate for India's telecommunications framework, given that it was already internationally accepted. Canada believed that allowing accredited foreign conformity assessment bodies to test and certify to India's regulatory requirements would reduce testing costs and permit exporters to bring their products to the Indian market more quickly. Canada appreciated India's explanation given at previous TBT Committee meetings, but remained unconvinced that deviating from CCRA testing would enhance the security of these products. He requested that India provide an explanation of how this alternative approach might improve security.

2.77. The representative of the United States again requested that India notify these regulations to the TBT Committee. The US noted that the entry into force of the in-country testing requirement had been delayed to 15 April 2016. She requested an update from India on the entry into force of its telecommunication security testing requirements, and requested that any implementation be delayed until the proposed regulations had been notified. More substantively, the US again urged India to remove the in-India testing requirement from the proposed regulation. As the US and other Members had articulated repeatedly, such a requirement placed significant additional costs on market operators who already certify to international standards and high private standards. This approach was troubling as India had not demonstrated through any formal risk analysis, or shared any data on such risk analysis, that in-country testing added any significant assurance of product security. She therefore again urged India to use a less trade restrictive approach.

2.78. Given India's certification under the CCRA, India had agreed to accept the results of CC tests conducted outside its territory. The CC tests were sufficient for the US and many other markets and she therefore asked that India explain the unique circumstances in the Indian market that rendered such tests inadequate. She recalled her delegation's previous interventions regarding concerns that India had not presented an explanation for how the in-country testing requirement furthers India's stated national security objective and she requested that India explain why CCRA testing was not sufficient. Because of companies' experience and capacity, the US encouraged India to allow telecommunications service providers to determine from whom to source based on each company's ability to address these concerns. This approach typically promoted market competition and, as a result, more secure products. As India was one of the world's largest economies, the US believed that avoiding unnecessary trade obstacles would help not only improve outcomes for India's consumers, but also encourage foreign direct investment in India. She again encouraged India to accept international testing standards, as well as the 3GPP standard, and also sought the involvement of India in related standards development activity.

2.79. The representative of Japan supported the Canadian, EU and US positions and confirmed Japan's interest in the new Unified Access Service Licence Agreement. She recalled India's statement at the June 2015 Committee meeting that "IT product testing carried out against the CC process would be leveraged without necessarily repeat testing. However, some additional test could be conducted if required in the interest of nation".⁷ Japan asked that India clarify the concrete meaning of "interest of nation". Japan requested that India ensure its telecom regulations do not impede market access for foreign industries.

2.80. The representative of India reported no change in the status of this issue since the last Committee meeting and therefore invited interested delegations to refer to India's intervention at that meeting.⁸ However, he informed the Committee that the date of in-country security testing of telecom equipment through authorized and certified labs within India had now been extended to 1 April 2016. A copy of the notification was available on the website of Department of Telecommunication. His delegation took note of the additional questions raised at this meeting, and said these would be forwarded to capital for response.

2.2.3.4 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)

2.81. The representative of the European Union asked for an update on the status of the revision of the regulations on commercial encryption products by the OSCCA, which had been on-going for several years. The EU requested that China expedite the process and provide a clear timeline for its finalisation. Under the current framework, there was no possibility for foreign companies to apply for the necessary certificates from OSCCA, creating trade disruption in commercial encryption products. He added that the notion of critical infrastructure as laid out in the Multi-Level Protection Scheme (MLPS) required further clarification with regard to its relationship with OSCCA. The current situation was creating a lot of uncertainty as also illustrated by the STCs concerning the other two measures applied in the banking and insurance sectors. Finally, he reiterated the importance of ensuring transparency and predictability for market access and the need for enhanced international cooperation in this area in order to ensure compatible regimes, which harnessed security without hindering trade in encryption commercial products.

2.82. The representative of Canada said that his delegation shared the EU's concerns with respect to China's overall regulatory approach in this sector. Canada was particularly concerned that China's regime for regulating the information technology sector was overly burdensome and restrictive to international trade. Canada recognized that China was seeking to address security concerns; however, avoiding duplication of conformity testing by recognizing foreign accreditation would significantly reduce the burden on industry and would be a net benefit for all parties. China's approach to regulating IT security lacked coordination domestically and appeared to run counter to well-established international best practices in the sector.

2.83. The representative of Japan, supporting the statements made by the EU and Canada, said that Japan still paid particular attention to following the various schemes and regulations within China from the perspective of how they could negatively affect the trade of information security products. Japan asked China to provide an update regarding their statement made during the March 2015 meeting indicating that the revision of OSCCA was listed in the legislation plan and that an opportunity for public comment was going to be arranged.

2.84. The representative of the United States said that the US associated with the concerns raised by the EU, Canada and Japan.

2.85. The representative of China referred to explanations and clarifications made at previous meetings of the TBT Committee. Since there were no further updates and for the sake of efficiency, China invited interested Members to refer to the minutes of the previous Committee meeting.⁹

⁷ G/TBT/M/66, para. 3.79.

⁸ G/TBT/M/66, para. 3.79.

⁹ G/TBT/M/66, para.3.83; G/TBT/M/65/Rev.1, para. 2.68.

2.2.3.5 Russian Federation – Draft on Technical Regulation of Alcohol Drinks Safety (published on 24 October 2011) G/TBT/N/RUS/2 (IMS ID 332)

2.86. The representative of the European Union invited Russia to update the Committee on the status and timeline for adoption and implementation of the draft technical regulation on alcohol products safety of the Customs Union, now Eurasian Economic Union, which had been notified in 2012. She recalled Russia's statements from previous TBT Committee meetings that most of the EU comments, submitted in writing in 2013 regarding wine, spirit drinks and beer, would be taken on board in the revised draft technical regulation. However, no revised text had been notified under the TBT Agreement or published. The EU asked whether Russia intended to re-notify the revised text to the TBT Committee as it would likely include substantial changes as compared to the text notified in 2012. A re-notification would give WTO Members the opportunity to analyse how their comments had been taken into consideration. The EU also requested that a sufficient delay be provided for implementation so that manufacturers could adapt their products to the requirements of the technical regulation.

2.87. The representatives of the United States and Ukraine supported concerns expressed by the EU.

2.88. The representative of the Russian Federation said that the draft technical regulation was being developed with the purpose of establishing unified requirements for commercialization of alcoholic products – both imported and produced domestically. Despite the fact that the public hearing on the draft technical regulation had been completed before Russia's accession to the WTO in December 2011, all engaged shareholders had been invited to provide comments during a 60-day period, in full conformity with the provisions of the TBT Agreement. The draft technical regulation on Alcohol Drinks Safety was not finalized. In May 2015, the Eurasian Economic Commission had sent an amended text of the technical regulation to Eurasian Economic Union (EAEU) member states, taking into account comments and suggestions of stakeholders and WTO Members. It also reflected some differences of opinion among the EAEU member states. Taking into account the accession of the Republic of Armenia and the Kyrgyz Republic to the EAEU, the Eurasian Economic Commission had also sent the draft technical regulation to these new member states. Consultations on the draft were on-going with the participation of all EAEU member states, including Russia. It was difficult to predict a definitive deadline for the finalization of this process. Nevertheless, he reassured Members that Russia was taking into account concerns of WTO Members while finalizing the draft.

2.2.3.6 Korea – Regulation on Registration and Evaluation of Chemical Material G/TBT/N/KOR/305 (IMS ID 305)

2.89. The representative of the United States said that there still seemed to be a general lack of guidance for the constantly changing regulation. The US industry continued to request detailed guidance documents to assist manufacturers, importers, suppliers and stakeholders in ensuring accurate and consistent compliance with K-REACH. For example, much more specific guidance was needed on all products that would be classified under the biocides group. The guidance document available had not been clearly communicated to all stakeholders and it was confusing that it continued to change. Additionally, the guidance document had been published in Korean only, making it difficult for stakeholders to comprehend fully. Registrants, especially for manufacturers, needed time to determine the substances covered by the regulation, identify the representatives that establish agreements for joint-registration conduct studies and submit the necessary information to be in compliance with K-REACH. She reiterated US support for the definition of Confidential Business Information (CBI), which recognised the possibility of protecting the specific chemical identity composition and uses while respecting the legitimate government interest in allowing the reporting of generic chemical names and providing adequate hazard information to downstream users. The US requested that the Ministry of Environment (MOE) allow registrants to declare specific uses for confidential business information for hazardous and non-hazardous substances, similar to type of substance or chemical group. With respect to data acceptance, the US asked the MOE to confirm that it would accept a qualitative or quantitative structure activity relationship model, read across techniques, in order to reduce duplicative testing. When such data was submitted, the US suggested that the MOE accept the scientific expert statement without requiring additional evidence for the waiver or omission.

2.90. The representative of Japan reiterated her delegations' previously raised concerns regarding the "Act on Registration and Evaluation of Chemical substances" (hereinafter, "the Act"). With respect to the report of manufacturing of chemical substances (Article 8 of the Act), Japan asked Korea to adopt an exemption scheme for new chemical substances of small volume, as already pointed out at the Committee meeting in October 2013. During that meeting, Korea had commented on the possibility of simplifying procedures for the registration of chemical substances (Article 10 of the Act), which would ease the burden on industry. However, concerning the "report" (Article 8 of the Act), Korea had not mentioned anything concrete. In case of existing chemical substances, reporting was required on only chemical substances that were manufactured, imported or sold one ton or more per year. Meanwhile, in the case of new chemical substances, there was no minimum threshold for quantity; therefore, even if its quantity was one gram, the new chemical substances needed to be reported. Although there would be less risk for chemical substances of small volume, reporting was required every year, imposing a heavy burden on businesses. Japan requested Korea to establish a minimum threshold to report on new chemical substances such as more than 0.1 ton per year, as done in other countries.

2.91. The representative of Australia said that his delegation supported the objective to report products which contained hazardous substances so as to protect consumers and the environment. However, there was also a need to control regulatory quality in terms of predictability, transparency and adequate stakeholder consultation. Australia was of the understanding that there was a grace period of three years for implementation but requested further clarification.

2.92. The representative of the Republic of Korea said that Korea continued to make an effort for smooth implementation of the regulation through communication with relevant foreign and domestic stakeholders. An amendment had been developed to relieve the burden on companies. This amendment, which was promulgated and entered into force on 30 October 2015, simplified the documents required, clarified the target of the report and strengthened the protection of "confidential business information" without imposing further obligations. For the future, Korea would continue to collect extensive opinions, including through consultations with the American Chamber of Commerce, the Japanese Club, the EU Chamber of Commerce, the European Chemical Industry Council (CEFIC), etc. whenever additional amendments were needed. Any amendments, which had legal force or influence on the right of stakeholders of foreign companies, would be notified to the WTO, inviting comments from Members. Korea had published and distributed the English version of the Act as well as four kinds of guidelines such as handbook, brochure, etc. Moreover, Korea was planning to issue English versions of the subordinate statutes, such as presidential and ministerial decrees during 2015. Korea would also continue to improve vague or uncertain parts in the guidelines.

2.93. As stated during the previous meeting, the definition of Confidential Business Information (CBI) was stipulated in the "Unfair Competition Prevention and Trade Secret Protection Act" (Article 2.2 of the Act) and whether information was regarded as CIB or not would be determined based on that Act. Thus, if information on identity, component and use of specific chemicals was worthy of protection, it would be classified as CIB. In addition, CIB of K-REACH was protected at the international level of the European Union and the United States. However, information for hazardous chemicals, in principle, was not included under CIB; thus evaluation results of harmfulness based on registration information would be open to the public. Korea wished to continue to work with the US, Japan and Australia on this issue. Specific points raised during the meeting would be conveyed to the relevant Ministry for consideration and prompt feedback.

2.2.3.7 Indonesia - Technical Guidelines for the Implementation of the Adoption and Supervision of Indonesian National Standards for Obligatory Toy Safety, G/TBT/N/IDN/64 G/TBT/N/IDN/64/Add.2 (IMS ID 328)

2.94. The representative of the European Union requested Indonesia to confirm that the anticipated Toy Safety Decree No. 24 review would be carried out in a transparent manner and there would be opportunity for foreign stakeholders to work with the Ministry of Industry and the outcome would be notified to the TBT Committee. He invited Indonesia to consider extending the current two-year grace period during which tests results by foreign laboratories would be accepted for the purpose of compliance with the decree beyond the current expiry date which was April 2016. He highlighted that the priorities for the review would be the elimination of the current discriminatory conformity assessment procedures (tests on every imported batch as compared with tests of samples taken every six months from the production line for domestic toys) and the

general acceptance of tests results by foreign laboratories based on adequate demonstration of their technical competence which could normally be achieved through accreditation issued by ILAC MRA signatories. He invited Indonesia to review the current limits for formaldehyde in toys as the current limits appeared to be more stringent than those enforced in other major markets and, moreover, appeared to be based on limits that applied to infants' clothing, which are much stricter due to the prolonged skin contact with clothing. Hence, whereas the exposure scenarios, as compared with toys, were quite different.

2.95. The representative of Canada said that he considered certain aspects of Indonesia's toy regulatory regime to be considerably more restrictive than necessary and at odds with internationally recognized practices in the sector. He said he was concerned with the provisions relating to laboratory accreditation, testing frequency, sampling, documentation, and substance restrictions. He noted that despite repeated interventions in the Committee, the concerns had not been adequately addressed. Canada urged Indonesia to adhere to international best practices by allowing ILAC signatories and properly accredited ISO 17025 labs to test without requiring additional approval. He also noted that the differences in sampling criteria for domestic and imported products adopted by Indonesia were discriminatory towards imported products. He requested additional information with respect to the implementation date for the new formaldehyde test method. He said that Canada was concerned that the 20ppm requirement was very close to existing feasible detection limits which made it very difficult to conduct accurate tests. He suggested that Indonesia should use existing international standards and limits.

2.96. The representative of the United States said that the US concerns related to lab accreditation, testing frequency, sampling, documentation, and substance restrictions, as well as the requirement to have a bilateral MRA in place by April 2016.

2.97. The representative of Japan noted that delays had been caused by a sequence of events such as sampling, test, SNI certification and pre-shipment inspection. She requested Indonesia to revise requirements which appeared to be more trade-restrictive than necessary. Japan requested Indonesia to continue to accredit overseas laboratories located in countries with which Indonesia did not have MRA.

2.98. The representative of Indonesia responded that there had been no further developments regarding the mandatory application of SNI Toys. She referred the concerned Members to responses provided at the June meeting.¹⁰ She further said that Indonesia planned to conduct a review on the implementation of regulations on mandatory application of SNI Toys to ensure effective and efficient application.

2.2.3.8 India – Food Safety and Standards Regulation - Food labelling requirements (IMS ID 298)

2.99. The representative of the European Union invited India to align its rules with the CODEX Standard for the labelling of pre-packaged foods (CODEX STAN 1-1985). India was requested to allow all type of labelling information and not only the Indian specific one to be provided by means of stickers. She said it was a sound alternative to labelling in the country of origin that would allow India to fulfil its legitimate objectives in a non-trade restrictive manner. India was also asked to update the Committee on the process of amending specific parts of the Indian food standards to align them further with the CODEX standards. She said that the process was important to allow the imports of products such as olives, whole-wheat pasta, vinegar and mineral water among others. She welcomed the launch of a public consultation on a specific technical regulation on alcoholic drinks and sought confirmation that the text would be notified to the WTO TBT Committee.

2.100. The representative of the United States sought an update on the status of India's efforts to align their domestic requirements with international standards. She asked India to provide the expected timeline for the publication of the amended FSSAI Rules. The US appreciated the opportunity to comment on an early draft of FSSAI's alcoholic beverage standard and the specific alcoholic beverage labelling requirements for wine and distilled spirits; however, the US was concerned about how India planned to define whisky. India was asked to provide information on the time at which the proposed measure would be notified to the WTO SPS and TBT Committees.

¹⁰ G/TBT/M/66.

2.101. The representative of Australia said that they would continue to work with India to ensure progress and completion of the CODEX harmonisation process. He asked India to advise delegations on when the process of harmonisation of India's food standards and CODEX standards would be finalised and, also, whether India was planning another review of its standards considering the issues raised by WTO Members, and, if so, if the process would be through finalisation or extension of the CODEX harmonisation process or as a separate review.

2.102. The representative of Chile requested that the technical regulation be notified.

2.103. The representative of India informed the Committee that there had been no change in India's stand with respect to permitting additional stickers as a means of information from any other source, or even the manufacturer. He said that CODEX did not prescribe that the labelling requirement could be met through additional stickers. The core information regarding product ingredients, composition, nutritional values, and best before date could only be provided by the manufacturer and that the label had to be an inseparable part of the container or package. Hence, permitting additional stickers as a means of information from any other source or even by the manufacturer was likely to compromise with the authenticity of the information which was the basic requirement for a consumer when making informed choices. Information regarding (i) FSSAI logo and license number, (ii) name and address of importer, and (iii) vegetarian and non-vegetarian logo were allowed to be affixed in the customs bonded warehouse in the form of an additional sticker and it was not allowed for other requirements of labelling as per the Food Safety and Standards (Packaging and Labelling) Regulations, 2011. He informed the Committee that harmonization of food standards was a continuous process and that FSSAI had notified the draft standards of food additives on 04.08.2015 in the Gazette of India as well as the WTO-SPS Committee on 05.08.2015. He said that the draft standard for alcoholic beverages, including on whiskies, was presently under consultation and India was considering a WTO notification.

2.2.3.9 European Union - Draft Implementing Regulations amending Regulation (EC) No. 607/2009 laying down detailed rules for the application of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products (IMS ID 345)

2.104. The representative of Argentina said that he was concerned about the EU's unjustified delay and the various instances outside the regular procedure that the EU had used to avoid replying to the specific trade concern (STC) which had been raised since 2009. He said that Regulations (EC) No 479/2008 and (EC) No 607/2009 seriously affected the image and prestige of Argentine wines destined for the European market since the EU arbitrarily grants its member States the exclusive right to use certain traditional expressions in each of their own languages, thereby restricting the rights of third States to use these expressions on their labels, and in fact prohibiting such use. Since the EU had agreed with Argentina's interpretation that traditional expressions constituted indications of quality that fall within the scope of the TBT Agreement, not the TRIPS Agreement, and therefore not liable to registration or the granting of exclusive rights for their use, he did not understand why the EU had not yet dismantled the regulatory regime which was inconsistent with its multilateral obligations. Argentina in 2009 had submitted its dossier for approval of the terms "Reserva" and "Gran Reserva", but the regime had been applied in a discriminatory manner against Argentina and against any other producer country wishing to export wines to the European market using traditional expressions on their labels.

2.105. Regarding the delays, the substantive process of analysing the dossier lasted two years and seven months; the delay in completing the formal administrative steps already extended this to three years and eight months. He said it was Argentina's view that the objective of the EU policy, in respect of traditional terms relating to wine, was neither to protect consumers from being misled nor to preserve specific characteristics of wine associated with these terms, since there were multiple definitions for each term that had been accepted by the EU through different mechanisms. Argentina had made persistent efforts to obtain a reasonable explanation from the EU for the undue delay in resolving the matter and had pursued efforts bilaterally, multilaterally and plurilaterally, through the many notes submitted by the World Wine Trade Group, but had received no positive response or valid explanation to justify the EU's undue delay. He further said that the situation had affected the entry of high quality and differentially priced Argentine wines, thereby placing their wine exports at a disadvantage compared with those of competitor countries that had access to certain European consumers who prefer wines identified and labelled as high

quality. He said that he had recently noted that the EU had consulted member States on the approach to be followed in modifying the Regulation. He inquired if the EU would bring the issue to public attention, whether it planned to consult interested third countries and whether it would conduct a public assessment of the impact of the proposal.

2.106. If the proposed new system sought to maintain the current registration and exclusive rights of use, it would continue to be inconsistent with the multilateral agreements since the traditional expressions were not subject to commitments derived from the TRIPS Agreement. He said that he understood that the registration files that were initiated and processed in accordance with the legislation in force must be concluded under the same regulations. Consequently, he believed that the new European registration system should grant recognition to the traditional expressions "Reserva" and "Gran Reserva". He requested the EU to include the item in the agenda of the next meeting of the College of Commissioners and that it publish the relevant regulatory act in its Official Journal so that Argentine wines may enter the European market.

2.107. The representative of the United States noted that the measure would severely restrict the ability of non-EU wine to use common or descriptive and commercially valuable terms, on the grounds that those terms were traditional to European wines. This was a concern particularly when some of these terms did not have a common definition across all EU member states. Some US suppliers which currently used these terms remained unable to ship their products to the EU. The US did not understand why some countries had already been granted permission to use some traditional terms, while other countries, including the US, continued to wait on their applications for years. She reported that in a conversation with the Commission on 8 June 2015, the Commission had stated that it was not acting on the applications pending the completion of a review of the regulations and simplification of the entire process. She suggested that the existing applications be reviewed while the simplification process was ongoing. While her delegation appreciated that the European Commission shared information and solicited feedback, this process still lacked transparency, as not all necessary information on the comment procedures had been provided. The EU was requested to inform the Committee about when it would publish information about its review of the traditional terms regulations and notify the simplification process to the WTO.

2.108. In addition, the EU had not responded to the WWTG's October 2014 letter and that the Commission had declined an invitation to speak on the issue of applications at the 30 April 2015 WWTG Intersessional meeting in Brussels. The US had requested information on the proposed revisions to the traditional terms scheme, and five months later no response had been received. Due to the lack of transparency, the US had not been able to comment on the proposed revisions. The Wine Institute, a US based trade organization, had submitted proposed changes to the traditional terms legislation in August – again, no response to the comments had been received. The consistent delay and lack of information about the process was unacceptable and the US would continue to raise the matter until the Commission resolved the issue.

2.109. The representative of South Africa said that he was of the view that the EU regulations created uncertainty for wine producers, as the Traditional Expressions issued remained an unresolved issue. South Africa had always been against the elevated protection of Traditional Expressions by the EU, as South Africa perceived Traditional Expressions as generic and therefore could be used freely by every-one. South Africa had been using a number of the traditional expressions in question since the time when European settlers first started wine production in the Western Cape province of South Africa in the year 1685. Thus these traditional terms also formed part of South Africa's valued national heritage. He said that the Commission was taking too long to react to applications of 3rd countries to continue the use of the traditional expressions on the labels of wines exported to the EU and thus unfairly discriminated against the countries. He requested the EU not to use general terms and words commonly used in many languages for the description of wine as a trade barrier, and to expeditiously engage with Members concerned to ensure that a mutually acceptable solution could be found.

2.110. The representative of the European Union explained that an internal assessment on traditional terms had been carried out within the EU with stakeholders and experts from the member States. She said that the consultation as regards the conditions and specificities under which the terms could be used on the labels of wine was still ongoing. The EU would continue to make the 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

handling of the pending files, whether from EU member States or third countries, would be part of the process. She said that developments were expected on this issue in the near future and hoped that, at the next TBT Committee, she would be in a position to give more information on the progress. She also said that review of pending applications would be pursued alongside and in close coherence with the simplification exercise.

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

2.111. The representative of Canada noted that this issue had been raised on several occasions at previous TBT Committee meetings and he took this opportunity to reiterate his delegation's concerns. Canada recalled that it had submitted comments on Chile's draft regulations by letter in October 2014, but had yet to receive a response from Chile. He said that his delegation was concerned that the regulations published on 26 June 2015 deviated from international standards, were not based on science, and were more trade restrictive than necessary. Canada supported Chile's policy objective of promoting healthy dietary choices and reducing obesity and related non-communicable diseases, but encouraged Chile to consider a less trade restrictive alternative. Such an approach would be consistent with international standards and would be based on science. For example, nutrient content limits based on actual serving sizes normally consumed at one sitting would provide an effective way of meeting the policy objective. He also requested an update on the timelines for implementation of the regulations and the transition period provided.

2.112. The representative of Mexico raised concerns over this measure. Mexico's full statement is contained in document G/TBT/W/428.

2.113. The representative of the United States expressed support to Chile's public health objectives of reducing obesity and related non-communicable diseases, and appreciated the extensive bilateral engagement on Chile's nutrition labelling regulation. She thanked Chile for the responses to their comments on the draft and final measure. She also appreciated the inclusion of an implementation review mechanism in the final measure. Nonetheless, the US requested Chile to consider comments received from foreign stakeholders in the context of this review mechanism set forth under Article 4 of Decree 13. The US also encouraged Chile to consider the trade impact of the "warning" element of the icons and the use of a standard 100 gram or ml portion size in its evaluation of this measure as these remained areas of concern for U.S. trade agencies and industry. Additionally, she thanked Chile for providing clarification regarding the final regulation, but noted that there were still several important issues, such as whether concentrated fruit juice would be considered "sugar". Another issue was how Chile would verify the addition of sodium, saturated fats, sugar, honey, etc. Chile 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. The US urged Chile to develop guidance or otherwise provide transparency with respect to these issues and consult with all stakeholders in doing so. The US also requested confirmation that voluntary claims were allowed so long as the claim was not with respect to a nutrient that exceeded the relevant threshold.

2.114. The representative of Guatemala reiterated concerns expressed over this measure and noted Chile's failure to respond to the comments which had been submitted in writing. Guatemala's concerns related to how the establishment of these labelling requirements could potentially reduce obesity when the levels of nutritional content for each individual depended on their personal circumstances. Guatemala also expressed concern with the deviation from international standards, in particular with respect to CODEX Alimentarius standards. While his delegation appreciated that Chile took into account some concerns that had been raised by other Members, he noted that this did not answer Guatemala's question on how the measure would reduce obesity and what controls would Chile intend to adopt to ensure that the measure would not constitute an unnecessary obstacle to trade.

2.115. The representative of Costa Rica reiterated concerns expressed over this measure, in particular with respect to the consistency of the measures with provisions of the TBT Agreement, given the lack of scientific evidence and the need to subscribe to international standards such as of the Codex Alimentarius. She urged Chile to adopt other less restrictive measures in order to safeguard the legitimate objective of protecting its population's health. She also asked for an

update on the current state of this regulation since her delegation was aware that the measures were currently being reviewed by the competent authority in Chile.

2.116. The representative of Chile explained that the measure was aimed to fulfil the mandate established in Law No. 20.606 on the nutritional composition of food and food advertising. He noted the Draft Regulation had been notified in accordance with the TBT Agreement on 22 August 2014 in document G/TBT/N/CHL/282. The text concerned had been available for public consultation for more than 60 days, from 19 August to 23 October 2014. Around 350 comments had been received from citizens, national and international institutions, academic establishments, trade associations, consumer organizations and the food industry. On the basis of this Committee's recommendation, Chile prepared its formal replies. Given the number of comments received, the majority of which covered the same issues, the replies were grouped together conceptually according to topic and sub-topic. Chile's replies to the comments made by WTO Members were transmitted to the Members concerned via their respective TBT enquiry points on 28 August 2015. The document containing the replies was, however, available to all Members on the Chilean Ministry of Health website. Chile noted that some of the replies in the document fell outside the scope of the TBT Agreement, but were included for reasons of judicial economy and to ensure a response to the concerns raised. The final version of the measure, published in the Official Journal on 26 June 2015, had been notified in document G/TBT/N/CHL/282/Add.1 and would enter into force 12 months after its publication, on 26 June 2016. Chile reiterated that it had fulfilled its obligations under the Marrakesh Agreement establishing the WTO, and pointed out that this measure was adopted due to the alarming rates of obesity, particularly in children, and obesity related non transmissible chronic diseases that were currently being recorded. Consequently, Chile introduced this measure in conjunction with other measures related to education and sports. Finally, Chile said that it was open to any requests from Members for further information on the implementation of the measure.

2.117. The representative of the World Health Organization (WHO) provided comments with respect to this STC. The full statement is contained in document G/TBT/GEN/185.

2.2.3.11 India – Electronics and Information technology Goods (Requirements for Compulsory Registration) Order, 2012, G/TBT/N/IND/44, G/TBT/N/IND/44/Add.1, G/TBT/N/IND/44/Add.2, G/TBT/N/IND/44/Add.3, G/TBT/N/IND/47 (IMS ID 367)

2.118. The representative of the European Union appreciated clarifications provided both bilaterally and also in the context of a new STC concerning secondary cells and batteries. In particular, with respect to the timeline for entry into force of the compulsory registration system for the additional 15 product categories notified under G/TBT/N/IND/47, he appreciated the further extension for the 8 categories of products which were not covered by the initial extension of the entry into force date. For the sake of greater clarity, he asked India to confirm the exact dates of entry into force for the different product categories covered by that notification.

2.119. The EU continued to view the requirements for compulsory registration and mandatory third party testing as excessively burdensome in view of the low safety risk associated with the products at issue. Therefore, the EU would appreciate efforts aimed at streamlining registration procedures. In this regard, the EU asked for confirmation whether a single registration for multiple factories was under consideration by the policy advisory committee set up by the Department of Electronics and Information Technology of the Indian Ministry of Communication and Information Technology. The EU also asked for an update on the state of this measure and in general, any steps taken to reduce the lead time for processing registration and simplifying the registration modalities. He noted that India currently accepted test reports for safety critical components issued under the IECEE-CB scheme or by laboratories accredited to international standards ISO 17025 by an ILAC MRA signatory. He urged India to improve reliance on the IECEE-CB scheme to increase acceptability of test reports issued under the scheme beyond safety critical components in order to cover the full products and the same should apply to foreign laboratories. Also related to the test reports, the validity of the test reports limited to 90 days for the purpose of filling an application for registration appeared to be overly restrictive and in principle there seemed to be no valid reason to impose such validity date if the product covered by the registration was also covered by a test report which was issued 90 days before. The validity of registration was currently two years and the EU welcomed the extension of the validity from one to two years. The EU asked for confirmation whether the renewal of the registration would be done according to a simplified procedure and would not imply a genuine new registration.

2.120. The representative of Canada supported the intervention made by the EU with respect to the ongoing issues related to this measure. He said his delegation was still concerned that the order continued to hinder or possibly shut Canadian exporters out of the Indian market due to delays in registration and testing. He noted that recognition by India 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 that wished to export to India while at the same time provided assurance to India that the recognized conformity assessment bodies were competent. He also said that 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. He recalled that at the last meeting, India noted that the Bureau of Indian Standards required a mutual recognition agreement in order to accept test results from non-BIS labs, even if they were ILAC, IAF accredited and produced test reports following the IECEE-CB scheme. He asked India to provide a rationale for requiring an MRA and what was the scope of those agreements. Finally, Canada said that substantive amendments to the order, such as those with respect to marking and labelling requirements, should be notified to the Committee on Technical Barriers to trade.

2.121. The representative of the United States appreciated India's continued engagement with industry on the Compulsory Registration Order's (CRO) implementation. She also appreciated the removal of Chartered Accountant requirement and product valuation requirement from the renewal form. The US encouraged India to consider more simplification in its review of the renewal form to ensure that only that information necessary for renewal was required.

2.122. Despite the positive engagement, the US continued to express concerns with the CRO's requirement that foreign products were re-tested to an Indian standard that was identical to an international standard, particularly when the products had already been tested to that international standard. The US was of the view that this appeared to be an instance where the CRO presented an unnecessary obstacle. The US took note of India's explanation during the March TBT Committee meeting that under the BIS Rules, the items covered by the Compulsory Registration Scheme were required to be tested at a lab in India recognized by the BIS or at a lab covered under a Mutual Recognition Agreement with BIS. In addition, the US reiterated its request that an appointed laboratory should only require a product sampling in it to conduct verification testing if the laboratory could not resolve a suspected non-compliance issue from information exchanged between the certification body issuing the CB test report and the manufacture. This would provide immediate relief to manufacturers and would allow Indian labs to improve testing. The US also took note of India's previous response that the expiration of reports within 90 days was adequate. The US assured India that such an expiration period was not adequate by the industry and this practice was not aligned with international norms as no other international certification agency had expiration on test reports. The US requested the elimination of such expiration period.

2.123. The representative of India thanked delegations for their continued interest in the measure and said that he took note of the issues highlighted by the concerned delegations. He pointed out that many of the issues were a repetition of what had been raised at previous meetings. Some Members asked for recognition of foreign conformity assessment bodies accredited by signatories to ILAC and IAF to test and certify India's regulatory requirements. Some Members questioned the BIS requirement of mutual recognition agreement in order to accept test results. In this regard, he said that there was no change in the regulatory position since the previous meeting. While India recognized the role of international and regional systems in the area of conformity assessment, it was also noted that TBT Article 9 asked Central Government bodies to rely on such systems only to the extent they comply with the provisions of Articles 5 and 6. Further, Article 6 was largely to encourage recognition of conformity assessment procedures that were also only based on mutually satisfactory understanding, to the extent as far as practicable, and without ruling out methods of mutual negotiations for such arrangements. Article 6.3 clearly recognized mutual recognition agreements or MRAs in the area of conformity assessment. Further, the CB Scheme was a scheme of reciprocal acceptance between the National Certification Bodies and not the regulators and hence, it did not find favours with all regulators. The acceptance of IECEE CB scheme was restricted in varying measures by different regulators, even when the scheme was accepted. Nevertheless, the India's Conformity Assessment process under CRO still accepted the CB test reports on critical components.

2.124. India noted that at the previous meeting, a suggestion had been made to postpone the implementation of registration requirement for the newly notified products. In this regard, India

informed the Committee that the implementation was postponed for 8 out of 15 new products, based on representations received from stakeholders and WTO Members. The postponement was notified to the Committee in G/TBT/N/IND/47/Add.1. On the issue of validity of test reports, there was no change in the status. The BIS Rules required a valid test report (not older than 90 days) from any BIS recognized test laboratory to be submitted while applying for Registration. India said that once the registration was granted, no further report of the same product was required to be submitted unless there was any change in the product. In this regard, it was not clear to India why a period of 90 days was not sufficient for the stated purpose, and why more time would be needed.

2.125. In respect of the validity period of registration certificate, India recalled that it had already been explained at a previous meeting that the validity was increased from one year to two years. India also decided that all registrations granted previously for one year would be valid for two years. After the validity period of two years, the registered manufacturer had to renew the registration. India explained that the renewal process was not a re-registration process, but it was limited to extending the validity of registration through an administrative decision. During this process of renewal, the performance of the registered manufacturer was reviewed based on the outcome of the market surveillance and consumer complaints on the product, if any. This mechanism of renewing the registration provided for an opportunity to review the safety of the product available to the consumers in the country.

2.126. India also informed the Committee that it had finalized guidelines for series approval of products for the implementation of Compulsory Registration Order Phase-II. Under these guidelines, identical models with minor changes would be accommodated for registration without any testing. It would now be possible to get future models included in existing series (as part of 10 models in a series) after grant of registration to the representative model already registered. One delegation raised the issue of Highly Specialized Equipment. In this regard, India provided criteria for Highly Specialized Equipment which would stand exempted from application of Compulsory Registration Order, provided they were manufactured/imported in less than 100 units per model per year. These criteria were available in the FAQ section of the website of Compulsory Registration Order.¹¹ A question had also been raised about providing single registration for multiple factories. In this regard, India noted that the draft scheme was still under consultation and was yet to be finalized. On the issue of renewal of application form, India said that the BIS had already reviewed the renewal form and it had been simplified to the extent possible.

2.2.3.12 Peru – Act to Promote Healthy Eating Among Children and Adolescents, G/TBT/N/PER/59 (IMS ID 383)

2.127. The representative of Canada reiterated concerns about the lack of information regarding the measure at issue. He supported Peru's objective of reducing obesity and other non-communicable diseases. However, his delegation was still concerned that this measure would deviated from international standards and would be more trade restrictive than necessary to achieve its objective. Noting that Peru's final technical parameters for sugar, salt and fat levels in food had been published on 18 April 2015, Canada asked whether Peru had considered a less trade restrictive alternative to achieve its policy goals. For example, nutrient content limits based on actual serving sizes normally consumed at one sitting would provide an effective way of meeting the policy objective. Such an approach would be implemented in a manner consistent with international standards. Canada requested an update on when these regulations would come into force. Canada also encouraged Peru to provide an adequate transition period to allow industry time to adjust to any new labelling requirements.

2.128. The representative of the United States expressed support to Peru's public health objectives of reducing obesity and related non-communicable diseases, and appreciated the extensive bilateral engagement on the proposed regulation. She said that her delegation was monitoring the development of Peru's regulations to implement the Healthy Eating Act. While her delegation supported the objective of encouraging healthy eating, it remained concerned that certain aspects of the measure lacked clarity and could unfortunately and unnecessarily disrupt trade. The US urged Peru to notify Supreme Decree 007-201-SA as a revised notification, G/TBT/N/PERU/59, given that it significantly differed from the originally notified text. The US noted that it had submitted an enquiry point request for notification of this measure on 24 April 2015.

¹¹ <http://electronicstds.gov.in/CREITG/>.

2.129. The US also recalled that Peru had indicated at the June 2015 TBT Committee meeting that the technical parameters for labelling were only one of the various other components of Law 30,021, and that in particular, two main elements needed to be finalized before the law could become fully operational: promotion of nutrition education and the implementation of a monitoring study of nutrition and obesity. The US asked Peru to elaborate on the process for the establishment of these components and the timeline it considered for completion as well as the development of the guidance. Extending the period for compliance was important. The US also reiterated substantive concerns expressed about Supreme Decree 007-201-SA. In particular, the fact that nutrition labelling was only mandatory when either a voluntary claim was made or the consumption warning was required. Nutrition panels could be regarded by consumers in a negative way if only the least healthy foods were required to display nutrition information. In this regard, the US asked whether Peru considered other less trade restrictive alternatives. The consumption warning, as specified in the Act, would apply to significantly more foods and non-alcoholic beverages than those specified in WTO notification G/TBT/N/PERU/59. The US requested Peru to explain why it decided to expand the scope of the foods subject to advisory nutrient labelling.

2.130. Peru's proposed threshold for the amount of sodium and saturated fats that would require a consumption warning and nutrient facts panel was significantly lower than what would correspond with the Codex guidance NRV-NCD of 2000 mg/day. The US requested Peru to clarify how it determined the proposed limit and why Peru chose it, rather than the Codex NRV. The US also requested Peru to clarify as to the basis by which it established the per portion nutrient content limit for sugar and why it determined an across the board nutrient threshold based on 100 gram or 100 millilitre amounts of large categories of foods that was appropriate for its population.

2.131. The representative of Mexico raised concerns over this measure. Mexico's full statement is contained in document G/TBT/W/429.

2.132. The representative of Guatemala reiterated substantive concerns expressed in previous interventions and said that his delegation was waiting for a response to the comments provided. He then asked Peru to share more information with respect to the internal process regarding the development of the measure. He said that his delegation had submitted comments within the appropriate time-frame and had raised this concern multiple times in the Committee. Guatemala expressed its concern with respect to the lack of notification of the measure. Additionally, Guatemala was of the view that there was no scientific or technical basis so as to determine whether the threshold could be considered to be high. Guatemala asked Peru to provide clarification with regard to this particular issue and asked for a formal response to the comments provided to their Inquiry Point.

2.133. The representative of Peru stressed the importance Peru placed on the protection of human health. Peru was committed to developing and introducing legislation aimed at reducing levels of obesity and non-communicable diseases amongst children and adolescents. As had been indicated at previous TBT Committee meetings, the regulatory provisions implementing the Act, as a package of activities designed for protecting the health of children and adolescents, had not yet been issued. A multi-sectoral commission had been established so as to work on the provisions but no date had been set for the entry into force of the measure. She nevertheless assured the Committee that businesses would have a lengthy and reasonable time period to adjust to the requirements. The technical parameters contained in the notified regulation were based on the recommendations from expert consultations with the Pan American Health Organization and the WHO on the promotion and advertising of food and non-alcoholic beverages for children. The values established in the reference document took into consideration the parameters laid down in the Codex Alimentarius Guidelines on Nutrition and Health Claims with regard to sugar, sodium and saturated fat. Thus, the proposals received during the comment period from interested parties had been taken into account. She said Peru would once again take note of the concerns and reiterated her delegation's firm conviction that this did not constitute an unnecessary trade barrier. Peru remained open to bilateral discussion on further developments.

2.2.3.13 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 (IMS ID 389)

2.134. The representative of the European Union reiterated her delegation's concerns with regard to the Indonesian Ministry of Health (MOH) regulation, issued on 16 May 2013, introducing a

mandatory health warning message on sugar, salt and fat content on the label of all processed food products. The EU requested confirmation that the application of the measure had been postponed to 2019 due to a review announced by Indonesia. The EU also remained interested in the results of the total diet study undertaken by the MOH with the aim of determining types of food to be included in high risk and low risk classifications. As manifested on previous occasions, the EU looked forward to the issuance of implementing provisions for the regulation, addressing product coverage in detail as well as providing further technical guidance. The EU requested that both measures be notified to the TBT Committee while still in draft form so that Members were provided with sufficient time for comments. In particular, the EU wished to receive clarification and detailed information on three issues: (i) on how nutrition information and related health warnings would be placed on the label, on testing methods for nutrition levels and on the conduct of risk assessment related to non-communicable diseases (NCDs); (ii) on 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 a Mutual Recognition Arrangement (MRA) with KAN; and (iii) on the possibility to place stickers after importation, and before the placement of the products on the market in Indonesia, for instance, in customs warehouses, as an alternative to labelling in the country of origin.

2.135. The representative of Canada said that while supporting Indonesia's objective of reducing the risk of NCDs and being appreciative of their transparency on the issue, his delegation was concerned about Indonesia's regulatory proposal requiring labels for all processed and fast foods containing sugar, salt and fat. Canada continued to have concerns about how this nutritional information and warning would be placed on the product and whether this information could be affixed after importation of the good but before it was placed on the market. Canada still questioned whether Indonesia's requirement to include a message identifying certain risks in relation to the quantity of sugar or fat ingested per day was necessary to achieve its policy objective and asked whether Indonesia could provide any scientific evidence supporting the use of such measures and also identify on which international standards they would be based. Canada also requested Indonesia to provide an update on the acceptance of test results from accredited laboratories that used internationally recognized and appropriate methodologies. In addition, he asked Indonesia to provide an update on the status of the technical guidance for the regulation and encouraged Indonesia to notify further amendments to the regulation.

2.136. The representative of the United States noted that the Decree of the Ministry of Health lacked clear guidance on how to implement and comply with the new labelling regulations. While Indonesia allowed three years for compliance from the original publication date, companies were not in a position to work towards compliance until the additional guidance was made available. Therefore, the US requested a more definite timeline as to when the ministry would issue further technical guidance for implementation, as promised during previous discussions in the TBT Committee, especially since the measure had already become effective and enforcement could begin by April 2016. In addition, the US disagreed with Indonesia's lack of acceptance of test results from laboratories other than those accredited by, or having an MRA with, KAN, and continued to request recognition of test results from laboratories using appropriate or recognized methodologies, especially given the level of risk associated with nutritional information and other labelling elements. In the case of the US, for example, they recognized the appropriate method from the Association of Analytical Communities (AOAC) International. Furthermore, the US encouraged Indonesia to take into account potentially less trade restrictive approaches, such as following a process of random sampling and testing of products in commerce, which could ensure the accuracy of label information for the vast majority of food and beverages. The US indicated its continued interest in the findings of the total diet study, which Indonesia had conducted and referred to during the previous TBT Committee meeting. Finally, the US asked Indonesia to provide updates on the status of Indonesia's recently announced plans to revise several regulations including the Ministry of Health Regulation 30/2013 and corresponding notifications under the TBT Agreement.

2.137. The representative of Australia said that his delegation recognized and supported Indonesia's right to implement measures to provide consumers with information to make appropriate dietary choices and reduce the risk of diet-related NCDs, consistent with WTO obligations. Indonesia would be one of the first countries in the world to implement a mandatory labelling scheme for foods containing sugar, salt and fat and there could be less restrictive measures available to promote consumer health that had been considered by other countries. He asked for clarification as to why Indonesia considered that a mandatory health message on

processed foods was necessary. In this respect, he recalled that the Codex Alimentarius Guidelines on Nutrition Labelling (CAC/GL 2-1985) set out the principles for nutrition labelling at the international level. One of these principles was that "the information should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product". Australia considered that the application of a mandatory health message referring to levels of specific critical nutrients would not be consistent with this principle. Expressing its concern regarding the extra costs and delays incurred by foreign companies importing food products if they were required to produce a separate label for Indonesia, Australia asked whether Indonesia would allow stickers containing the health message to be applied to the labels of processed food *after* importation and before being placed in the market. Furthermore, Australia noted that the proposed nutrition declarations needed to be based on tests carried out by accredited labs and sought clarification on the methods that would be used for the tests verifying the nutrition declarations and whether tests performed by foreign laboratories, or in-house laboratories of companies, would be accepted. Finally, Australia also asked whether the proposed requirement would be enforced for both domestic and imported products and how compliance would be tested.

2.138. The representative of Indonesia informed the Committee that the MOH Regulation 30/2013 had been amended by MOH Regulation No. 63/2015, which delayed the implementation date originally set for April 2016 to four years after the regulation was issued, coming into effect in 2019. During the transition period, Indonesia would provide cross-sector (policy makers in ministries and agencies, professionals and industry sectors) and cross-program (internally in the MOH) dissemination and advocacy, and would prepare the ministerial decree derivatives in cooperation with relevant ministries and agencies, in particular regarding the type of processed food that was covered by MOH Regulation 30/2013. She also said that Indonesia would continue to conduct studies on total diet to measure changes in the pattern of consumption of salt, sugar and fat in the community, and evaluate the results of a study to determine the type of processed food which would be covered by the regulation, taking into account the risk of occurrence of NCDs. Indonesia would also undertake programs to increase public awareness on the prevention and control of NCDs and their risk factors, in particular with respect to restrictions on the consumption of sugar, salt and fat. Finally, Indonesia would monitor and evaluate the implementation of such activities. Regarding transparency, Indonesia would notify an addendum to inform WTO Members on the changes in the implementation of these regulations.

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

2.139. The representative of Argentina reiterated his delegation's concern with regard to the review process being undertaken by the EU to define criteria at the European level for the identification of substances that may have endocrine disrupting properties. Argentina recalled the importance of adopting policies to protect the environment and public health which are consistent with multilateral obligations, particularly the WTO Agreements on SPS and TBT. In order to avoid unnecessary barriers to trade, the future regulation to be adopted by the EU should rely on an effective risk-analysis and not merely a hazard-based assessment decoupled from the risk probability of its occurrence. Such approach had already been recognized by the European Food Safety Agency (EFSA) itself. Argentina also affirmed that any measure adopted should be based on solid scientific evidence, should not create unnecessary barriers to trade and should be applied in a transparent and non-discriminatory manner without constituting a disguised restriction on international trade. Argentina considered that the review under analysis would have ample commercial and socio-economic impacts, affecting producers of raw materials, in particular in developing countries, and thus should avoid creating unjustified or disproportionate negative impacts on international trade. Argentina also considered that due to the relevance, complexity and magnitude of the subject, a multifocal approach should be adopted, involving all multilateral system stakeholders such as the Codex Alimentarius, the World Health Organization (WHO), the United Nations Environment Programme (UNEP) and others. Furthermore, Argentina welcomed the opportunities to provide comments in the context of public consultations and emphasized the importance of continuing to conduct the process in a transparent manner, taking due account of contributions from stakeholders. Finally, Argentina requested the EU to provide information on the first phase of substance classification as well as any changes to the calendar included in the regulatory proposal presentation.

2.140. The representative of Canada shared the concerns raised by Argentina and referred to the potential trade impacts of Endocrine Disrupting Chemicals (EDCs) regulations in the EU that had been outlined at a previous conference in Brussels by the EU Commission Directorate General for Health and Food Safety (DG Sante).¹² While Canada would await the outcome of these discussions and the related report by the Commission, Canada reiterated its request for further clarifications on the interplay between Regulation 1107/2009 and Regulation 396/2005. Canada considered that a more restrictive hazard-based cut-off criterion raised concerns over how maximum residue limits under Regulation 396/2005 would be established and renewed. While sharing EU's objective of ensuring safe food and environment, Canada's position was that a risk-based approach would equally achieve such objective while avoiding any unnecessary impediments to global agricultural trade and referred to the similar conclusion reached by the EFSA Scientific Committee in their 2013 Scientific Opinion on the hazard assessment of endocrine disruptors.¹³ Canada considered that the EU's hazard-based approach could disrupt trade in food and feed and unnecessarily create a level of uncertainty among exporting countries while increasing costs for agricultural and agri-food stakeholders in both the EU and exporting countries such as Canada.

2.141. The representative of the United States noted that the US Government strongly supported strengthening public health and environmental protection by properly identifying, understanding, and regulating the use of plant protection products that may have endocrine disrupting properties. She emphasized however that, for several years, the US had been raising concerns with the EU process for identifying endocrine disruptors (EDs) and that in January 2015 it had submitted extensive comments on the EU Public Consultation on Defining Criteria for Identifying EDs regarding the possible impact on billions of dollars of trade worldwide. The US remained concerned that a large number of substances, and the products that contained them, could be affected by the new categories and be withdrawn from the EU market as a result. Noting the great deal of uncertainty that the issue was causing for global trade, the US urged the EU to adopt an evidence-based approach that considered risk from exposure, provided timely updates on the status of this issue and followed a process which allowed for broad public participation.

2.142. The representative of the Brazil supported the concerns expressed by Argentina, Canada and the US and reiterated his delegation's concerns regarding the negative impacts on trade of the measure which Brazil considered discriminatory, arbitrary and unjustifiable. Brazil noted that according to the European Crop Protection statistics, 65 billion Euros of imports could be affected by the new requirements, impacting particularly imports from South and Central American countries, with Brazil as the main affected country. Brazil thus urged the EU not to adopt the measure as it was drafted.

2.143. The representative of Egypt shared the concerns expressed by the delegations of Argentina, Canada, the US and Brazil. The representative of Chile also echoed the concerns expressed by the delegation of the US.

2.144. The representative of the European Union said that, as had been mentioned in previous meetings, the EU had initiated a comprehensive impact assessment that would analyse different options for defining criteria for the identification of endocrine disruptors and their corresponding health, socio-economic and environmental effects, once incorporated in different pieces of EU legislation. In this context, the European Commission had published, in mid-June 2014, a roadmap setting out the scope of the impact assessment, and presenting the policy options that were being assessed. At least two sequential studies supporting the impact assessment were needed. The first one had started and would assess which chemicals might be identified as endocrine disruptors under each of the various options for the criteria. The second one would assess the socio-economic, health and environmental impacts of the implementation of the various options for the criteria into the relevant legislation. A public consultation on the definition of criteria for identifying endocrine disruptors in the context of the implementation of the EU's regulations on plant protection products and biocidal products had been carried out between September 2014 and January 2015 to collect information relevant to the impact assessment. The responses received

¹² EU Conference on Endocrine Disrupting Chemicals, 1st June, 2015. Available at <http://env-health.org/news/latest-news/article/eu-conference-on-endocrine>.

¹³ EFSA Scientific Committee, "Scientific Opinion on the hazard assessment of endocrine disruptors: Scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment", *EFSA Journal* 2013;11(3):3132, European Food Safety Authority (EFSA), Parma, Italy.

under such consultation were published on 2 February 2015 and an analytical report of the responses was provided by on 24 July 2015. The factual and quantitative report would feed into the work for the impact assessment, the outcome of which would not prejudge or constitute the announcement of any position on the part of the European Commission. Instead, it would allow the Commission to take an informed decision as regards further EU legislative work, as appropriate.

2.145. The EU representative also informed the Committee that the Commission had organized a series of roundtable meetings between April and May 2015 as well as a public conference on 1 June 2015, informing EU member States, MEPs, third countries and stakeholders about the ongoing impact assessment. A technical meeting on the Joint Research Centre methodology, developed as part of phase one supporting the impact assessment, would take place on 6 November 2015 to estimate which chemicals might fall under the different options for criteria to identify endocrine disruptors as outlined in the roadmap. Detailed information about the impact assessment had been published on the website of DG SANTE.¹⁴ The European Commission would present proposals for new criteria to identify endocrine disruptors in the EU's plant protection products and biocidal products regulations only after the conclusion of the impact assessment. She added that the criteria might also have an impact on other pieces of EU legislation. Pending the new criteria, interim criteria were applicable in both the biocidal products and plant protection products regulations. The EU would notify the new proposal to the WTO in order to allow third parties' eventual comments to be duly taken into account.

2.2.3.15 Ecuador – Resolution No. 116 of the Foreign Trade Committee of Ecuador of 19 November 2013 and Technical Regulation of the Ecuadorian Standardization Institute RTE INEN 022 on the labelling of processed and packaged food products, G/TBT/N/ECU/19/Add.3, G/TBT/N/ECU/19/Add.5, G/TBT/N/ECU/19/Add.6 G/TBT/N/ECU/19/Add.8 G/TBT/N/ECU/19/Add.9 G/TBT/N/ECU/19/Add.10 (IMS ID 411)

2.146. The delegation of Canada expressed concern that this regulation was already having an impact on trade and could be more trade restrictive than necessary. Canadian authorities had received complaints from industry 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 welcomed Ecuador's views concerning the restrictive elements of the new law and asked if improvements in the product certification process were being considered.

2.147. The representative of Mexico reiterated concerns already highlighted in previous meetings with resolution 116 which established the requirement of "Certificate of recognition". The full statement is contained in the document G/TBT/W/430.

2.148. The representative of the European Union joined others in reiterating concerns with the Ecuadorian Technical Regulation 022 on the labelling of processed and packaged food products. While the EU fully shared Ecuador's public health objective, there were doubts as to whether the approach taken was the best way to achieve that objective. She also questioned whether the measure was proportionate to the pursued aim of allowing consumers to make informed choices. She referred the Committee to the minutes of previous meetings where interventions regarding the lack of proportionality of the measure, its departure from CODEX guidelines and the use of "high in" warnings were well recorded.

2.149. The representative of the United States expressed her delegation's appreciation for the productive bilateral engagement on standards and certification, in particular related to food exports that had taken place in recent months. The US looked forward to continued cooperation with Ecuador so as to facilitate trade in other sectors affected by this measure.

2.150. The representative of Guatemala reiterated concerns expressed in previous Committee meetings regarding the lack of notification of the measure and the consultation process. As the requirements hindered trade, it was essential to establish the necessary timeframes and criteria so as to ensure the measure would not create trade obstacles. While Ecuador argued that the objective of the measure was to address obesity, the labelling requirements made an assumption that processed meat was the sole cause of obesity. The measure failed to address the issue from a

¹⁴ http://ec.europa.eu/health/endocrine_disruptors/events/ev_20150416_en.htm.

multifactorial perspective and was not aligned with the relevant Codex standards. Ecuador had failed to provide any kind of scientific evidence indicating that the measure was likely to achieve positive outcomes. He urged Ecuador to reconsider the design and scope of the measure and to share the scientific evidence used as the basis for the measure.

2.151. The representative of Costa Rica echoed concerns raised by other Members. She said her delegation was particularly concerned with the lack of scientific evidence to support the measure and the departure from relevant international standards. She invited Ecuador to consider less trade restrictive measures which were aligned with the principles contained in the TBT Agreement.

2.152. The representative of Ecuador explained that the Ministry of Health's national study on health and nutrition, conducted in 2012, had revealed that Ecuador's epidemiological profile reflected an upward trend in the number of non-communicable diseases across the population, regardless of age or socio-economic status. Therefore, policies had been established to prevent such diseases and to raise consumer awareness regarding the content and characteristics of foods. In addition, Ecuador was complying with paragraph 3.3.1 of the "Action Plan for the Prevention Obesity in Children and Adolescents" of the Pan American Health Organization (PAHO), which had established that a "number of countries that have norms in place for front-of-package labelling that allow for quick and easy identification of energy-dense nutrient-poor products and sugar sweetened beverages, which take into consideration Codex norms."¹⁵ The procedures for assessing compliance with Regulation No. 022 and for obtaining sanitary registration had been reassessed by both INEN (the Ecuadorian Standardization Service) and ARCSA (Sanitary Regulation and Control Agency) and the processing time had been substantially reduced. RTE No. 022 was being properly implemented and both industry and importers were complying with the Regulation.

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

2.153. The representative of the European Union requested further information concerning the timeframe for the adoption of amendments notified in G/TBT/N/RUS/29. The EU asked Russia to confirm whether the amendments had indeed been adopted, as had been indicated in the previous TBT Committee meeting. If this was the case, he requested that the information on the date of adoption and date of the entry into force of the measure be shared with the Committee and the final adopted text be made available.

2.154. The representative of the Russian Federation reiterated what had been said in previous meetings, whereby the actual implementation of the original technical regulation had revealed the need to change certain requirements. Draft amendments to the technical regulation had been developed and duly notified in G/TBT/N/RUS/29. The EAEU technical regulations and amendments to them were developed and adopted in accordance with the Regulations on the Development, Adoption, Amendment and Cancellation of Technical Regulations of the Customs Union, approved by the Board of the Commission (Regulation No. 28) on 20 June 2012 which described all the necessary stages for the adoption of technical regulations, including at least 60 days for public discussion and no more than one month for responses to comments. The regulation on Safety of Products for Children and Adolescents was however, still under internal EAEU discussion where there was no such time limits imposed. Therefore it was not possible to predict an exact date of adoption of the amendments. He said his delegation would continue to share information with Members on this on-going process.

2.2.3.17 India – Labelling Regulations for Canola Oil (IMS ID 413)

2.155. The representative of Canada reiterated concerns relating to the Food Safety and Standards Authority of India reaffirming India's position that this product must be labelled and marketed as: "Imported Rapeseed - Low Erucic Acid Oil (Canola Oil)." He said that the labelling requirements directly affected exports, marketing and sales of canola oil in India. Canada expressed concern that these changes to India's labelling regulations were not notified to the WTO and could be more trade restrictive than necessary to achieve India's legitimate objective of food safety. Canada strongly encouraged India to accept "canola oil" as a synonym for "rapeseed low erucic acid oil". This would be consistent with India's past practice and the existing Codex standard

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for naming of vegetable oils as it did for other vegetable oils such as maize and arachis. She asked that India update the Committee on the Supreme Court of India ruling against the FSSAI's interpretation of the regulation that had been sent to the Bombay High Court for final ruling. He encouraged India to consider an alternative measure to the currently enforced labelling requirements for canola oil that would not unnecessarily create a barrier to trade.

2.156. The representative of Australia sought an update on the status of the measure and said that Australia remained concerned over the regulation's requirement that the use of the term "canola oil" was only permitted as a secondary term. His delegation believed that this regulation contradicted the Codex Alimentarius Standard for named vegetable oils, which permitted the use of synonym descriptors for "rapeseed oil", including "canola oil" (Codex Standard 210 - 1999, section 2.1.16). These Codex provisions, he said, were designed to provide manufacturers with the flexibility to use a range of synonyms in labels. They were not designed as a basis to restrict labelling to a subset of those synonyms. This was an unnecessary labelling burden for Australian exporters of refined canola oil to India. It was Australia's understanding that the term "Canola oil" was often used to describe domestic products on sale in India. India's quarantine order of 2003 outlined India's import quarantine requirements for plants and plant products and allowed the use of alternative terms "rape" and "canola". Australia continued to support FSSAI's initiative of harmonizing India's food standards with Codex (2003).

2.157. The representative of India thanked the delegations of Canada and Australia for their continued interest in the measure. As there had been no change in the regulatory status since the previous TBT Committee meeting, he invited delegations to refer to the intervention made by India at the previous meeting (G/TBT/M/66, para. 3.167).

2.2.3.18 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 and G/TBT/N/THA/437/Add.1

2.158. The representative of the European Union reiterated her delegation's concerns regarding the Regulation on Criteria, Procedures and Conditions for Labels of Alcoholic Beverages (B.E. 2558/2015), which had entered into force on 22 April 2015 and was applicable since 19 October. Thailand's reply of 28 October 2015, to the EU's written comments of 30 July 2015, was under assessment. While welcoming the technical guidelines on the implementation of the Regulation issued on 30 September 2015, the EU noted that the period between the availability of the technical guidance and the date of effective application of the measure was short. The EU had addressed a letter to the competent Thai authorities on 13 October 2015 asking for a delay in the application of the measure for a period of at least 6 to 12 months from the date of availability of the technical guidance document. She said that this was for industry to get acquainted with the guidance document and with the labelling changes proposed in the regulation.

2.159. The EU remained concerned about the strict labelling requirements introduced by the regulation. In particular, EU industry had expressed concerns that specific terms in common use and linked to the ageing or maturation process, related to the conditions, quality or characteristics of the product could be considered contrary to the regulation. Even with the technical guidance document for implementation of the regulation, there were still several aspects that remained unclear. For instance, the interpretation of key clauses in the regulation, including: factual statements concerning production processes and origin; the use of cartoon images in labels; statements relating to the quality and nature of products; the system of ex-post label control through market surveillance; the mechanism for enforcement of the regulation and the role of the different national bodies involved; the compliance of definitions with international standards; and the current wording of definitions which could be open to different interpretations. The EU also noted that the use of graphic health warnings was not part of the recently adopted regulations. Nevertheless, the EU asked about its possible introduction in the future as Thailand's reply of 28 October 2015 had indicated that the Alcoholic Beverages Control Committee was in the process of considering graphic health warnings to be included in a different draft regulation. The EU requested further clarifications on the outcome of the matters referred to.

2.160. The representative of Mexico expressed her delegation's concerns regarding the measure. Mexico's full statement is contained in document G/TBT/W/431.

2.161. The representative of Canada reiterated concerns his delegation had expressed at previous TBT Committee meetings as well as through a letter sent to Thailand's enquiry point in May 2014. Canada understood that the regulation entered into force in March 2015 and had been fully implemented as of 19 October 2015. Canada remained concerned about the measures prohibiting the use of wine labels that contained images of athletes, artists, singers or cartoons; and messages affiliated with certain activities, such as sport, music and contests. Some Canadian wine labels portrayed these images and other artistic depictions which could be considered "cartoons". Consequently, he was concerned that these Canadian wine labels, if imported into Thailand, would be considered to be in breach of the regulations. He added that Canadian wine labels were not intended to appeal to children or promote irresponsible alcohol consumption. Moreover, Canada had not witnessed any correlation between the sale of products with sport figures or cartoon-like images and increased youth or irresponsible drinking.

2.162. Canada said that some of the terms and definitions in the regulations lacked clarity and could therefore result in uncertainty for wine exporters. Given the broad restriction on the use of "unfair messages", it remained unclear whether certain terms that related to the quality or the characteristics of the product would be permitted, including commonly used terms such as "finest", "premium", "original", "rare" and "limited". He noted that the Office of Alcohol Beverage Control had issued guidelines only at the end of September 2015 and asked if Thailand would be extending the grace period for compliance with these regulations. While Canada recognized Thailand's right to implement regulations to protect consumers' health and safety and provide them with adequate information to make informed choices, his delegation was nonetheless still concerned that these regulations could be more trade restrictive than necessary to meet their objective, and could have an undue impact on the trade of Canadian alcoholic beverages to Thailand. In this respect, he asked Thailand to point to studies suggesting that such labelling constraints would help achieve the desired policy objectives and whether Thailand had considered any less trade restrictive alternatives to achieve these policy objectives. Finally, he noted that Thailand was still considering the use of graphic warning labels and sought further information in this regard.

2.163. The representative of the United States said that her delegation supported Thailand's desire to address its valid public safety and health concerns related to excessive alcohol consumption, and requested further consultation to define a solution that addressed this concern without restricting trade unnecessarily. The US expressed concerns with Thailand's recently implemented measure on alcoholic beverage labelling, and had submitted comments on the original text notified by Thailand as G/TBT/N/THA/437 in March 2014, and noted that many of these comments were not reflected in the final measure notified as G/TBT/N/THA/437/Add.1. While the US noted that there were many scientifically viable approaches to reducing alcohol abuse or excessive drinking, her delegation would have appreciated a response from the Enquiry Point regarding the study that Thailand mentioned at the previous TBT Committee meeting. The US again reiterated that the Act's vague language was open to misinterpretation and there was no guidance on how it would be enforced, which could result in unnecessary obstacles to trade. She expressed concern that the final regulation contained elements that could affect more than USD10 million in US exports annually. The US was, therefore, extremely concerned that Thailand was moving ahead with implementation without providing industry with the necessary clarity on these new requirements.

2.164. The US stated that the current regulation was unclear and lacked: enforcement procedures; 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 a definition for terms such as "immoral" and "exaggerated statements". The US had hoped that the long-promised technical guidelines would have answered these questions, but the recently published guidelines had failed to provide further clarity to the requirements. Without this clarity, she said that it was impossible for companies to comply with the regulation. The US and its alcoholic beverage industry were concerned that a significant amount of trade would be disrupted. She added that US industry required a clear enforcement policy and sufficient time to come into compliance with Thailand's new alcohol labelling requirements. The US requested Thailand to delay implementation of this measure until new and revised guidelines were provided that addressed her delegation's specific concerns. In addition, the US also asked that Thailand grant a 12-month implementation period after revised guidelines were released in order to provide sufficient time for further consultation and guidance to industry. Her delegation planned to monitor the impact of Thailand's requirements on US alcoholic beverage exports and asked whether Thailand was considering an evaluation of the regulation after 18 months. If so, she asked whether Thailand

could explain the evaluation process and whether the evaluation results would be shared with trading partners.

2.165. The representative of New Zealand acknowledged and supported Thailand's right to introduce new regulations to address specific public health concerns but, has been raised previously, New Zealand remained concerned that the new labelling requirements were unnecessarily trade restrictive, and that the regulation was unclear. While New Zealand thanked Thailand's Alcohol Beverage Control Committee for the set of technical guidelines published on 30 September, her delegation stated that the regulation was still subjective and open to interpretation, which could lead to uncertainty for manufacturers and importers and have a disproportionate impact on trade. New Zealand sought further clarification from Thailand around terms such as "cartoon" and as to what constituted an overstating of the "properties, benefits, or quality of the product". New Zealand encouraged the Thai Ministry of Public Health to hold a briefing with industry to settle outstanding questions on the regulation. Noting that the 180 day "grace period" for compliance expired on 19 October, and that the guidelines on implementation of this regulation were only published at the end of September, New Zealand asked that the transition/grace period be extended, to provide industry with sufficient time to ensure that their products met this regulation.

2.166. New Zealand sought guidance from Thailand as to the procedures for determining whether specific labels met the requirements of the regulation. Information was also requested on whether there was an appeals process if a company chose to challenge a decision made by the Office of Alcohol Beverage Committee in relation to the regulation. Finally, New Zealand sought an update on Thailand's proposal to implement a graphic health warning label system for alcoholic beverages. She asked whether Thailand intended to introduce mandatory graphic health warnings on alcohol labels and if so, when Thailand expected to notify WTO Members of the new draft regulation.

2.167. The representative of South Africa thanked Thailand for its notification of 27 April 2015 (G/TBT/N/THA/437/Add/1) informing Members of the adoption of the Notification of the Alcoholic Beverages Control, Regarding Rules, Procedure and Condition for Labels of Alcoholic Beverages. Although South Africa and its alcoholic beverage industry were fully committed to the responsible consumption of alcohol and respected the role of regulation, his delegation did have concerns with the regulation approved by the Thai authorities. Several WTO Members, including South Africa, had raised specific trade concerns during the November 2014, March and June 2015 TBT Committee meetings and had submitted comments to Thailand regarding the problematic nature of the regulation. South Africa was of the view that Thailand's regulatory authority, the Office of the Alcohol Control Committee, Department of Disease Control of the Ministry of Public Health, had not taken the majority of Members' comments into account in finalising the regulation. He also considered that Thailand had not provided satisfactory responses to the comments and to the specific trade concerns raised during the previous TBT Committee meetings. South Africa had, therefore, sent further comments and questions for clarification to the concerned authorities on 7 July 2015 via Thailand's TBT enquiry point. Thus far, no acknowledgement of South Africa's comments had been received despite a follow-up via the South African Embassy in Thailand. He recalled that the TBT Committee in its Triennial Reviews had recommended that: "a Member receiving comments through the designated body should without further request: acknowledge the receipt of such comments; and, explain within a reasonable time to any Member from which it received comments, how it will proceed in order to take these comments into account and, where appropriate, provide additional relevant information on the proposed technical regulations or procedures for assessment of conformity concerned".¹⁶

2.168. South Africa said that several provisions in clauses 1 and 2 of the regulation were vague and confusing to industry. These ambiguous provisions included lack of clarity in many of the terms used, and the broad scope afforded to the regulator in application and enforcement of the regulation that could distort fair competition, confuse industry and consumers, and lead to unintended consequences. South Africa's alcoholic beverage exporters were concerned that the regulation could lead to the banning of some internationally-recognised brands, restricting consumer choice, and the ability of new brands to enter the Thai market. Furthermore, he said that this could lead to the possible counterfeiting of brands. Even though the Thai market was relatively small for South Africa's alcoholic beverage exports, the Asian market was important and his delegation was concerned that such labelling requirements could be adopted by other countries

¹⁶ G/TBT/1/Rev.12, page 24.

in the future, which would inhibit trade in general and South African wine exports in particular. While South Africa supported Thailand's endeavours to reduce the misuse of alcohol, it would encourage regulation in line with Article 2.2 of the WTO TBT Agreement that would lead to the responsible consumption of alcohol without creating unnecessary obstacles to international trade. South Africa had sought further clarification of clauses 1 and 2 of the adopted regulation in its letter of 7 July 2015 and looked forward to receiving clarification from Thailand in due course.

2.169. The representative of Chile shared the concerns raised by other delegations and said that Thailand's proposed regulation should be clearer in terms of its objective and its interpretation. As the implementation guidelines had only recently be notified (in September), Chile considered that time should be given for its entry into force. His delegation was also concerned about the possible introduction of graphical representation on labels of alcoholic drinks and Chile sought further information and a notification from Thailand of any such measure in the TBT Committee.

2.170. The representative of Japan shared the concerns raised by other delegations on Thailand's notification G/TBT/N/THA/437, issued on 28 March 2014, and the guideline dated 13 September 2015. Japan said that the guideline provided some examples of messages that would be prohibited in order to avoid false, exaggerated or overstated claims. According to the guideline, "100% malt", "finest", "premium", "light and low calories" were examples of such messages. However, Japan considered that accurate information should not be excluded on labels and if an alcoholic beverage was made with 100% malt, it should be allowed to print such information on the label. In addition, with regard to "finest", "premium", "light and low calories", his delegation recognized that these messages were widely used as expressions of indicated qualities of alcoholic beverages. Japan believed that such messages did not overstate the properties, benefits or qualities of the produce in such a way that increased consumption. Japan requested Thailand to reconsider the examples listed in the guideline.

2.171. The representative of Australia recognized the right of governments to take measures necessary to protect public health and Thailand's effort to address a legitimate public health concern with the proposed labelling regulation for alcoholic beverages. He noted that the new regulation had entered into force on 15 April 2015 and that importers/manufacturers had until 18 October 2015 to comply with its provisions. Australia welcomed the release of technical guidance on 30 September but noted that this document was available only in Thai. He urged the Thai government to submit an official translation of the technical guidance to the TBT Committee in one of the WTO languages. The late release of the guidelines had meant that importers and manufacturers did not have sufficient time to fully comply with the 18 October deadline. Australian industry was still seeking specific guidance to ensure that they could comply with some of the requirements, particularly those that were broad in scope. Australia requested Thailand to undertake consultations with industry to assist them develop labels that would fully comply with the requirements and sought an extension of time or a stay of enforcement until this had occurred.

2.172. The representative of Thailand thanked delegations for their comments with regard to the Notification on Alcoholic Beverages Control, Rules, Procedure and Condition for Labels of Alcoholic Beverages and for the bilateral meetings with some delegations. Thailand had notified this regulation to the TBT Committee on 28 March 2014 (G/TBT/N/THA/437) and on 27 April 2015 (G/TBT/N/THA/437/Add.1). Thailand reiterated that the objective of this regulation was to address alcohol-related problems for consumer protection and it was not intended to create unnecessary obstacles to trade. With respect to timelines, she said that Thailand had promulgated the regulation in the Official Gazette dated 22 January 2015, and had provided 90 days before its entry into force. Moreover, the regulation also included and extended a transitional period of 180 days for implementation. Thailand, therefore, considered that importers and manufactures had a sufficient period of 270 days, from the date of publication in the Official Gazette. With a view to facilitate trade, Thailand said that there was no additional label approval process according to this regulation. In addition, the Office of Alcohol Control Committee under the Department of Disease Control had also developed technical documents providing a practical guideline for implementation of the regulation. Information could be accessed on the website: <http://www.thaiantialcohol.com/>. As mentioned in the technical document, in case of doubt, exporters could send the example of the labels to the Department of Disease Control for advice or consultations. Thailand would reply to any queries upon request and her delegation would convey all the comments received from Members at this TBT Committee meeting to the concerned authority for an appropriate response.

2.2.3.19 Ecuador – Draft Technical Regulation of the Ecuadorian Standardization Institute (PRTE INEN) No. 189: "Labelling of alcoholic beverages", G/TBT/N/ECU243 (IMS ID 433)

2.173. The representative of Canada said that he was concerned that Ecuador's customs regulation (SENAE-DGN-2013-0300-RE), along with the related technical regulation notified were more trade restrictive than necessary with respect to labelling requirements. He said that Ecuador's requirement that the labelling of products be done in the country of origin was of concern to Canada. He explained 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. The representative of Canada asked Ecuador to explain why they were not allowing alcoholic beverages to be labelled in their customs bonded warehouses prior to import release and how the requirement was necessary to achieve its objective of protecting human health and preventing deceptive labelling. Canada was of the view that Article 4.3 of the Regulation No. SENAE-DGN-2013-0300-RE was more trade restrictive than necessary by requiring the name of the Ecuadorian importer to be included on the label that was to be affixed at the country of origin. He requested an update on whether the received comments had been taken into account whilst revising the measure. He further asked if Ecuador would be notifying any amendments to the regulation.

2.174. The representative of the European Union recalled the concerns previously expressed in the Committee, as follows: (i) the obligation to state the name of the importer in the front label; (ii) the requirement that the labelling of alcoholic products shall be done in the country of origin, not allowing labelling or relabelling in a primary customs area, and (iii) the need to undergo certification by a conformity assessment bodies in order to verify compliance with labelling requirements. She requested an update on Ecuador's process of considering Members' comments.

2.175. The representative of Mexico expressed concerns reflected in full document G/TBT/W/432.

2.176. The representative of the United States said that her delegation was concerned 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 such as stickers. She inquired about the status of the review. Many countries allowed country-specific label changes in customs bonded warehouses and requested that Ecuador explain the reason for not allowing the said common international practice. She encouraged Ecuador to accept common international practice and to incorporate specific language allowing for it in existing and future norms and standards.

2.177. The representative of Chile supported the concerns raised by Canada, Mexico, the European Union and the United States and said he was awaiting responses from Ecuador to questions and comments submitted on time.

2.178. The representative of Ecuador said that the Ecuadorian National Customs Service Resolution SENAE DGN 2013 0300 RE, "Resolutions relating to post entry control of imported alcoholic beverages", had been developed from a customs measure implemented by SENAE to prevent the illegal entry of liquor into the country. She said that Liquor was one of the most highly smuggled goods and that large quantities of adulterated liquor had been found on sale with serious consequences for consumers. On the basis of the objectives established in the TBT Agreement, INEN had issued draft RTE No. 189. The regulation established labelling requirements for liquor marketed in Ecuador without making any distinction between beverages. The draft Technical Regulation No. 189 set forth labelling requirements for alcoholic beverages with a view to protecting human life and health and preventing practices likely to mislead consumers. She noted that the enquiry point had received comments from Members and they were brought to the attention of the competent authorities for analysis and evaluation. As soon as a decision was reached it would be communicated to WTO Members; the draft text was currently on hold.

2.2.3.20 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)

2.179. The representative of the Republic of Korea reiterated his concern about the regulations for the supervision and administration of medical devices, specifically about test reports. He said that China did not accept test reports issued by internationally accredited laboratories and that this led to unnecessary duplication of testing for imported medical devices – and subsequent additional expenses and export delays. He requested China to accept internationally accredited laboratories' test reports and internationally recognized test reports if the reports were based on the same criteria that China adopted under its regulations.

2.180. The representative of the European Union expressed concerns related to the issue of clinical trials required for the registration in China for Class II or Class III medical devices, the speed of the registration procedure, and the requirement to register the medical devices in the country of origin. The European Union was also concerned about duplicative clinical trials to be conducted in China. He noted the possibility presented in the CFDA (China Food and Drug Administration) Technical Guideline for Clinical Evaluation of 19th May 2015 for manufacturers to present during the marketing approval of medical devices data obtained in clinical trials carried out abroad, and asked China to confirm that the possibility would be consolidated in future legislative revisions. China was requested: to accept test reports from foreign laboratories accredited by accreditation bodies that are members of ILAC as an alternative to in-country electromagnetic compatibility testing in China; to exclude from the registration certificate the documentation on product technical requirements, which might be confidential; and, to provide a transitional period of three years as well as further guidelines detailing the relevant processes.

2.181. The representative of Canada said that despite clarifications by China, certain aspects of the regulation still adversely affected Canadian manufacturers of medical devices. He requested information on the status of Article 13 of Order No. 4 and Article 15 of Order No. 5. Canada understood that in order to register an imported medical device or list its applications, there was a requirement for the product to "obtain market approval from the country (region) where the applicant's business registration is or the product is produced." He requested further clarification on the accuracy of the interpretation and the types of documents required to ensure that Canadian companies fully comprehend the new requirements. Such a requirement would be an issue for Canadian exporters who might not necessarily seek regulatory approval domestically. He asked if applications could be made for Canadian-originating medical devices or in vitro diagnostic products which had received approvals in other leading jurisdictions but which were not approved in Canada.

2.182. Canada was also concerned about duplicative clinical trials and that due consideration to clinical results from other Members of the International Medical Device Regulators Forum (IMDRF) would be preferable. China could consider requiring a bridge study to ensure that the original data was relevant to China. He asked China to confirm whether clinical trial results from jurisdictions that are members of the IMDRF would be acceptable. On 20 July 2015, the CFDA issued a Draft Measure on the Accreditation of Medical Device Clinical Trial Institutions. He further said that the draft measure had not been notified to the WTO, therefore not providing for a comment period and a "reasonable interval" between the publication and its entry into force. One criteria of the accreditation was to have a Practice License of Medical Institution but only medical institutions (including foreign-invested) established in mainland China could obtain the license. Canada was of the view that if there was only a defined number of Clinical Trial Institutions available, it could create a bottle neck effect for manufacturers to get their product trial done.

2.183. Canada also sought clarifications on Article 17 of Order No. 650 regarding the catalogue of products exempted from requiring China-based clinical trials. He said that the current draft list of products that were exempt was limited and lacked an effective regulatory mechanism to update. He asked whether the CFDA was developing a system that would allow for prompt updates to the catalogue and if China could indicate when a final combined catalogue of Medical Devices would be released. Moreover, Article 35 of Order No. 5 stated that, for in vitro diagnostic products, a focused clinical evaluation should be conducted in China. This requirement constituted an unnecessary and duplicative clinical trial requirement for Canadian exporters that have received prior regulatory approval in other leading foreign jurisdictions. He also said that he was concerned

with the Electromagnetic Compatibility (EMC) testing that was required by Chinese regulators in order for a medical device to be registered. It was noted that the EMC standard that China used was identical to the one issued by the International Electro-technical Commission (IEC) for which China was a member. However, China had not accepted test reports issued by internationally accredited laboratories that abide by the IEC standard. He requested China to accept test reports that were consistent with China's technical requirements, even though they originated from internationally accredited laboratories.

2.184. The representative of China said that according to the new regulation, medical devices were divided into three categories based on the level of risk, and were regulated differently. She said that medical devices in the first category only have to be filed, while medical devices in the second and the third category needed to be registered. Regulations notified under G/TBT/N/CHN/1022 to 1026 and 1029 were the implementing rules of the regulations for the Supervision and Administration of Medical Devices. Before it had been implemented, CFDA had adequately communicated the measures to relevant foreign and domestic enterprises and industry associations and had fully considered comments received from Members. In addition, China had organized specialized training to help relevant enterprises and organizations to understand the measures. She also said that according to Article 22 of the regulation, 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. She reiterated that market approval from the country of origin was necessary to ensure the security and effectiveness of medical devices and to protect the health of Chinese consumers.

2.2.3.21 Kingdom of Saudi Arabia – Certificate of Conformity (not notified) and GSO marking requirements for toys (IMS ID 435)

2.185. The representative of Canada said that Canada's understanding was that the original proposal was to require toy manufacturers to register each model of product, assign a registration number unique to that model, and to print that registration number on all product packaging. He also said that Canada understood that the registration scheme was intended to improve product traceability and reduce misuse of the G Mark, however, that industry consultations had yet to be conducted. He urged the Gulf Cooperation Council to ensure that: (i) consultation with the industry was conducted in an open and transparent manner; (ii) consideration was given to register manufacturers instead of each model; and (iii) pursuant to these consultations, issue a regional guidance document that Gulf countries would apply in a uniform manner.

2.186. The representative of the Kingdom of Saudi Arabia said that the issue was discussed in the last TBT Meeting. He invited Canada to have a bilateral meeting to discuss the concern.

2.2.3.22 Ecuador – Proposed Motor Vehicle Safety Regulatory Requirements (RTE INEN 034) G/TBT/N/ECU/32, G/TBT/N/ECU/32/Add.1-9 (IMS ID 409)

2.187. The representative of Mexico raised concerns over this measure. Mexico's full statement is contained in document G/TBT/W/433.

2.188. The representative of Ecuador informed the Committee that on 14 May 2013, the National Agency for Transit, Land Transport and Road Safety presented a draft amendment to Ecuadorian Technical Regulation RTE INEN No. 034, "Minimum safety requirements for motor vehicle parts". She noted that this amendment was drawn up in coordination with the Ministry of Transport and Public Works and the private sector, with a view to the implementation of the "Safer Vehicles" project. Its purpose was to ensure the safety of users and reduce the levels of mortality and disability caused by road accidents due to mechanical faults in road vehicles. She said that the regulation complied with the notification procedures established in the TBT Agreement and that it was subject to various comments submitted by Member countries. Ecuador pointed out that it had maintained an open dialogue ever since it began working on Regulation RTE INEN No.034, therefore, promoting understanding and cooperation with manufacturers, importers and assembly plants which, in turn, were responsive and adapted their models to the new requirements. The period of implementation was constantly being assessed by the Ecuadorian authorities so that the time periods were feasible. Consequently, Ecuador informed the Committee that there was a new transition period until October 2016 and therefore Ecuador would be accepting self-certification until October 2016.

2.2.3.23 Ecuador – Cosmetic products, G/TBT/N/ECU/116, G/TBT/N/ECU/116/Add.1, G/TBT/N/ECU/116/Add.2, G/TBT/N/ECU/116/Add.3, G/TBT/N/ECU/111, G/TBT/N/ECU/111/Add.1, G/TBT/N/ECU/111/Add.2, G/TBT/N/ECU/111/Add.3 (IMS ID 417)

2.189. The representative of Mexico raised concerns over this measure. Mexico's full statement is contained in document G/TBT/W/434.

2.190. The representative of Ecuador stressed that Ecuadorian Technical Regulation RTE INEN No. 093 on cosmetic products was based on Andean Community Decision No. 516 on the harmonization of legislation on cosmetic products, and Annex 2 of the Good Manufacturing Practices for the Cosmetic Industry in the Andean Community. She noted that Decision No. 516, which objective was to harmonize cosmetic product marketing, was currently being revised by the Andean authorities. She also said that any comments made would be examined so as to be reflected in the Regulation that was currently under internal review.

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

2.191. The representative of Mexico raised concerns over this measure. Mexico's full statement is contained in document G/TBT/W/435.

2.192. The representative of the European Union informed the Committee that its delegation had sent written comments to Brazil on 19 January 2015 and raised concerns during the March and June TBT Committee meetings about the requirement which made it mandatory to indicate, in Portuguese, all ingredients of the product formulation on the labels of personal hygiene products, cosmetics and perfumes marketed in Brazil. He noted that during the March 2015 meeting Brazil had said this could be done in other ways, for example in the form of allowing the Portuguese language label on stickers on the secondary packaging or on leaflets. He also recalled that the Committee had been informed during both the Committee's March and June meetings that these possibilities were still under consideration by the Brazilian authorities at that time and dependent also on on-going court proceedings in Brazil on this issue. The EU reported that it had received information that the issue that was referred to the Supreme Federal Tribunal of Brazil and consequently the lower level judicial decision which was the basis of the mandatory indication of the ingredients in Portuguese was suspended. Consequently, it seemed that the obligation to indicate the ingredients in the Portuguese language was not being implemented. The EU asked Brazil to provide an update on the current state of play, especially whether the requirement to indicate in Portuguese all ingredients of the product formulation on the labels of personal hygiene products, cosmetics and perfumes marketed in Brazil was indeed not in force and not applicable and therefore products not bearing such labels could be freely marketed in Brazil. The EU also asked whether Brazil could provide any further information on the possible time-frame of the on-going court procedures.

2.193. The representative of Brazil explained that the draft resolution stemmed from a court ruling stating that ANVISA needed to ensure that information regarding the chemical composition of personal hygiene products, cosmetic products and perfumes was available to consumers in Portuguese. He also said that this ruling was due to the fact that the official language of Brazil was Portuguese and they had a consumer law allowing people to have access to information in Portuguese. Notwithstanding this fact, Brazil informed the Committee that the federal government appealed the decision to the Superior Court of Justice. Consequently, the Superior Court of Justice issued a ruling suspending the initial decision of the judge which obliged the technical body of Brazil to add the obligation of Portuguese in labelling. Brazil also said that according to the available information, the decision of the first ruling was suspended. Consequently, goods could be sold in Brazil until a final decision under merit was to be taken. Finally, Brazil noted that since the judiciary branch was independent there was no possibility of foreseeing when the final decision would be taken.

2.2.3.25 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 (IMS ID 442)

2.194. The representative of the European Union thanked Saudi Arabia for its notifications, G/TBT/N/SAU/669 and G/SPS/N/SAU/73, introducing requirements on energy drinks and, G/TBT/SAU/789, regulating the labelling and marketing of energy drinks. She informed the Committee that her delegation had submitted comments to these notifications. The response of Saudi Arabia of June 2015 referred to the revision of the technical regulation in order to take into account the latest development in sciences. Therefore, the EU thanked Saudi Arabia and invited Saudi Arabia to update the Committee on the status and timeline for adoption and implementation of the draft technical regulation.

2.195. The representative of the United States supported Saudi Arabia in its efforts to promote public health in accordance with scientific and other technical evidence. According to the comments submitted by the US in August, the US requested further information regarding the rationale for, as well as any research or data supporting the regulation, including size and total acidity limits, and the need for multiple health warnings. The US expressed concerns over the Gulf Cooperation Council's approach, particularly with regard to the ban of advertising and sponsoring events, which went beyond the approach that many other countries had adopted, unnecessarily restricting trade without improving public health outcomes. The US then requested the Gulf Cooperation Council to provide a timeframe by which it planned to respond to these concerns and asked how they expected the rulemaking process would progress. Finally, the US said that it looked forward to working with the Gulf Cooperation Council to find a resolution to this issue that met the public health objective of the measure without unnecessarily restricting trade.

2.196. The representative of the Kingdom of Saudi Arabia said that according to its statements in previous meetings, the GSO TBT Committee was still working on the GSO draft regulation for energy drinks and the GCC members would notify this committee for updates in due course.

2.2.3.26 Ecuador - (PRTE INEN) No. 111: Energy efficiency. Clothes dryers. Labelling: RTE INEN 111; RTE INEN 077; RTE INEN 072; RTE INEN 094; RTE INEN 124; RTE INEN 109; RTE INEN 110; RTE INEN 112; RTE INEN 117; RTE INEN 122; RTE INEN 123, y RTE INEN 133 (IMS ID 455)

2.197. The representative of Mexico raised concerns over this measure. Mexico's full statement is contained in document G/TBT/W/436.

2.198. The representative of Ecuador explained that its policy in this area involved changing the energy matrix by seeking to use energy efficient and environmentally friendly appliances. In an effort to improve the quality of products marketed in Ecuador, the national government, led by the Ministry of Electricity and Renewable Energy, issued RTE No. 111 in order to ensure the energy efficiency of such products. Regarding energy consuming appliances and equipment, efforts to ensure energy efficiency involved a combination of energy efficiency standards for appliances, a proper labelling system, and awareness rising among consumers. Ecuador was of the view that with energy efficiency standards, there would be efforts to ensure that appliances and products consumed less energy and used energy more efficiently. Ecuador informed the Committee that Under RTE INEN No. 111, clothes dryers marketed in the country had to comply with energy efficiency and labelling requirements so as to abide by the State's policy on energy saving. Additionally, household electrical products were required to comply with the highest energy efficiency level established by the competent national authority, and had to bear a label indicating their efficiency class. Lastly, in response to other countries' concerns, Ecuador said that it had amended its technical regulations, thus making it possible to comply with them by submitting a first party declaration.

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

2.199. The representative of China reiterated his delegation's concerns about the refusal of Common Criteria (CC) evaluation and the validation bodies of EU member States to accept and process applications of Chinese producers for CC certification and the lack of opportunities for

Chinese companies to join CC-related standard organisations, such as JIL Hardware Attack Subgroup. She recalled that her delegation had repeatedly asked the EU delegation to provide additional CC-related information, and to take a constructive approach to address the concerns of the Chinese industry. China expressed their disappointment since no meaningful information had been provided by the EU. Rather, China was of the view that the EU delegation responded by simply claiming that CC certification did not fall within the scope of the TBT Agreement.

2.200. With regard to the coverage of the TBT Agreement, China still believed that depending on the nature of CC validation bodies of the EU member States, either Article 5 "Assessment of Conformity by Central Governmental Bodies" or Article 8 "Assessment of Conformity by Non-governmental Bodies" of the TBT Agreement were applicable. In the case of central governmental bodies, China was of the view that both articles applied. China stressed that the obligations imposed on Members under the TBT Agreement in this regard included, among others, 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.

2.201. China recalled that the EU had mentioned that EU companies received discriminatory treatment under China's regulatory framework. However, according to Chinese statistics, dozens of foreign companies had received production permits in China. For example, Giesecke & Dervrient from Germany received not only a production permit, but also sales permission for a cryptogram product. The Chinese delegation urged the EU delegation to honour its obligations under the TBT Agreement and take concrete steps to address the concerns of China in a timely manner.

2.202. The representative of the European Union recalled his delegation's previous statement that the EU considered this matter as not within the scope of the TBT Agreement. The EU noted that there were no mandatory requirements for commercial encryption products in the EU and the ownership of a conformity assessment body by the state did not make ipso facto the activities of such bodies as falling within the scope of the TBT Agreement unless they were related to the application of technical regulations that provided for mandatory third party conformity assessment. The EU then expressed their willingness to have bilateral discussions with China at an expert level given the highly specialised nature of the topic.

2.2.3.28 China - Administrative Measures on Cosmetic Labelling (AMCL) (IMS ID 456)

2.203. The representative of Japan welcomed China's clarification at the last meeting that it would allow over-labelling on imported cosmetic products.¹⁷ Japan, however, again invited China to consider the remaining concerns with the AMCL. First, regarding manufacturer labelling, she noted that Articles 14 and 15 of the draft measures also required labelling of the names and addresses of manufacturing sub-contractors. Japan considered that this could conversely cause consumer misunderstanding and market confusion. Japan held that manufacturer labelling should, therefore, only present the name and address of the company with final legal responsibility for the quality and safety of the concerned products. Second, regarding promotional advertising of cosmetics efficacy claims, Japan noted that according to Article 19 and 20 of the draft measures, results tested by an "efficacy assessment testing organization" had to be disclosed. However, since testing results could include companies' know-how, Japan was of the view that test results should not be disclosed. In addition, Japan considered that the "efficacy assessment testing organization" should not be limited to institutions inside China. Finally, she said that clear guidance with detailed regulations were indispensable to promote the appropriate operation of the draft measures. Japan invited China to provide a sufficient implementation plan, such as a two year transition period, for the new labelling regulation since significant changes to existing labelling were required and this would have a negative influence on the distribution of products into the Chinese market. She noted that the implementation date of 1 July 2015 had passed and asked China to clarify on the new implementation date and whether a public comment period would be established.

2.204. The representative of the Republic of Korea appreciated China's decision to remove the over-labelling ban for cosmetics in light of Members' concerns. He stressed that over-labelling was a key practice in the export and import procedure of cosmetic products. Korea remained nonetheless concerned with the regulations on the efficacy verification of cosmetics. Korea was of

¹⁷ G/TBT/M/66, para 3.239.

the view that Article 19 and 20 of the AMCL, notified to the TBT Committee in December 2014, would create unnecessary expenses and a burden to exporting companies, because every listed efficacy claim had to be verified by testing organizations in China and reported on the website. Korea agreed that information on labels must be valid, but believed that basic efficacies, such as moisturizing and astringent functions, did not need to be proved. Therefore, Korea requested China to reduce the scope of the efficacy verification and allow manufacturers to self-verify, instead of requiring third-party verification. Korea also suggested that reports of efficacy verification should be kept with the manufacturers and should be made accessible only when governmental bodies needed the data. Finally, Korea requested China to provide a transitional period of 24 months from the date of finalization of this regulation, so that companies could adapt. His delegation would continue to work together with China to find a reasonable solution as soon as possible.

2.205. The representative of the European Union reiterated concerns expressed at the last TBT Committee meeting, and also sent to the Chinese authorities on 12 January 2015. The EU noted that China, in its written reply of 18 March 2015, had indicated that it would consider the comments received. The EU welcomed the possibility of allowing labelling of cosmetic products by means of stickers, but still had concerns with regard to the requirement for products to display the name and address of the manufacturer and of the sub-contractors when part of the production was done by sub-contractors. Furthermore, the EU believed that any requirement for third-party verification by a Chinese organisation would be more trade-restrictive than necessary and requested confirmation that efficacy assessment and cosmetic claim verification could be conducted by any verifying organisation that was scientifically and technically competent to do so according to the criteria and guidance established by the China Food and Drug Administration. She stressed the need to align the requirements regarding cosmetic claim substantiation with international best practices. The EU noted that with the future Cosmetics Supervision and Administration Regulation, the process of revising the general legal framework for placing cosmetics in the Chinese market was on-going, and requested China to confirm that the AMCL would be developed in parallel with this general framework and would not enter into force before the future Regulation.

2.206. The representative of Canada reiterated concerns and sought further clarity from China on the timeline for implementation of the Cosmetics Supervision and Administration Regulation (CSAR) and the China Food and Drug Administration (CFDA) labelling regulations. On timelines, Canada requested an update on the expected implementation of the CFDA labelling regulation and whether it would be included in the CSAR, or pulled out prior to the implementation of CSAR. He asked if companies were required to change the non-Chinese product names and sub-lines for compliance with CFDA labelling regulations and, if so, would they need to re-register those products. For products that had already been registered but not launched, he asked if exporters would be allowed to export into the Chinese market. Furthermore, how much time would companies have to sell products already existing on the Chinese market? Regarding trademarks, Canada stated that product names registered as trademarks in English or other foreign languages should fall outside the scope of the proposed CFDA labelling regulation. He said that if companies were required to create a different name or remove an English name from products sold in China, it would create confusion among Chinese consumers and could lead to the production of counterfeit goods. Canada was also concerned with over-labelling practices. While industry appreciated the Chinese government's willingness to allow over-labelling as a method to apply Chinese language on product packaging, exporters needed to understand if they could continue to use global packaging variants that included regulatory warnings and claims that were compliant with other countries and were in other languages, applying the over-label to cover only the unacceptable portions under the proposed CFDA labelling regulation. Companies would otherwise have difficulty bearing expenses of supporting a China-only packaging variant and exporters could lose the ability to sell in the Chinese market. Canada noted that under the current regulation, Chinese language was a requirement on the primary and secondary packaging as well as on the leaflet. Given that the consumer could only view the outermost packaging at the point of sale, Canada was of the view that it should be acceptable to include the required information such as warning and usage on the secondary label or on the leaflet in Chinese and not put it on the primary packaging. Regarding the certificate of free sale, he noted that the proposed CFDA labelling regulation required the formula be sold in the country of origin before it could be sold in China. If implemented, China would be the only major market with such a requirement as other jurisdictions only required a statement from manufacturers that the product was compliant for sale

in the country of origin. Canada believed this requirement would fundamentally disturb the distribution of innovative products in the Chinese market and would be disruptive to industry.

2.207. The representative of China thanked delegations for their continued interest in this measure and said that labelling was essential for consumers to understand basic information regarding cosmetic products and was among the most important aspects of cosmetic supervision for most Members. In November 2014, AMCL was made available online so as to solicit public comments, and China had subsequently received feedback from domestic as well as foreign cosmetic enterprises and industry associations. She said that China would consider Members' constructive views and follow international best practices. China restated that once AMCL was finalized, the measure would allow "over-labelling" on imported cosmetic products.

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

2.208. The representative of Japan said that his Government still had concerns about the Chinese Banking IT Equipment Security Regulation. Japan was aware of the notice dated 13 April 2015 issued to banks in China of the intention to review the "Guideline for Promoting the Application of Secure and Controllable Information Technology in Banking Sector (2014-2015)". He requested China to provide for sufficient exchange of views with stakeholders; revise the guidance in accordance with international common standards; and ensure transparency during the review process. Furthermore, Japan sought clarification on the review schedule; on the process for stakeholder hearings; and on how public comments would be implemented.

2.209. The representative of the European Union requested an update on the review of the banking guidelines. He also requested that this process be conducted in a transparent and inclusive manner. The EU said that any further revisions to the guidelines should be notified in order to provide WTO Members with an adequate opportunity to comment.

2.210. The representative of Australia said that his delegation continued to monitor progress on this issue as Australian industry and businesses were interested in any potential regulations that could impact their ability to operate in the Chinese market. As noted at the last meeting, Australia was aware that the regulations had been suspended and requested further information on the status, including any notification of the regulations.

2.211. The representative of the United States supported the interventions made by the previous delegations on this issue.

2.212. The representative of Canada echoed the comments made by delegations on this issue.

2.213. The representative of China thanked delegations for their continued interest in this measure. He again clarified that the relevant regulation was still under revision. China did not require a full disclosure of the source code, but only that a file be kept of it. China would improve the rules and ensure that the legitimate interests of domestic and foreign enterprises would be protected. He reiterated that China attached great importance to the protection of intellectual property rights and only required enterprises to prove a legitimate source of software intellectual property.

2.2.3.30 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/IDN/98 (IMS ID 461)

2.214. The representative of Australia said that his delegation was still concerned with the regulations that allowed only state owned enterprises to import secondary beef cuts and that these imports could only be undertaken at the direction of government ministers, in volumes determined by officials, and in limited defined circumstances. Noting the general prohibition on quantitative restrictions under GATT 1994 including those made effective through State trading and that Article XVII of GATT 1994 required State trading enterprises to make purchases solely on commercial considerations, he asked how Indonesia considered these restrictions to be consistent with WTO

obligations. Furthermore, Australia remained concerned that additional packaging, labelling and purpose requirements had been imposed on imported and not on domestic meat products. He also noted that Indonesia had raised concerns about the safety of offal imports. He said that Australian offal was produced for human consumption and was regulated under the same food health standards and legislation as meat for human consumption. Australian beef and offal had a reputation for quality, safety and reliability. He added that food safety was an SPS issue.

2.215. The representative of Canada said that her delegation remained concerned with the measures notified by Indonesia in G/TBT/N/IDN/98, in particular with the broad product coverage of the regulations and the lack of clarity surrounding its intended objectives. Canada added that the proposed measures could be unduly trade restrictive and inconsistent with national treatment obligations of the TBT Agreement and the GATT 1994. She urged Indonesia to provide clarity on how the proposed measures fell within the scope of the TBT Agreement and how they would be consistent with Indonesia's national treatment obligations. Canada again requested Indonesia to take into consideration the comments received and make the necessary modifications.

2.216. The representative of Brazil shared the concerns raised by the previous delegations.

2.217. The representative of the European Union said that the EU had expressed concerns and provided written comments to Indonesia on 15 April 2015 and would appreciate a written reply.

2.218. The representative of Indonesia requested interested delegations to refer to Indonesia's responses at the previous TBT Committee meetings.¹⁸ Indonesia said that the halal requirement was, in principle, an obligation to be fulfilled pursuant to the Indonesian Ministry of Agriculture Regulation 139/2014. Halal and non-halal products needed to be separated as set out in the provisions of Law No. 33 of "Halal Product Guarantee". She added that this provision was aimed to provide a guarantee on halal products to the predominantly Muslim population in Indonesia.

2.2.3.31 European Union - Proposed modification of Regulation (EC)1829/2003 referring to genetically modified organisms, G/TBT/N/EU/284 (IMS ID 464)

2.219. The representative of the United States expressed her delegation's appreciation for the bilateral meeting held with the EU regarding notification G/TBT/N/EU/284 on a Commission proposal to amend current EU law, Regulation (EC) No 1829/2003, to allow member States to restrict or prohibit the use of genetically engineered (GE) food and feed in their territory even where the product had previously been subject to risk assessment and approved as safe by the EU. She reiterated her delegation's concern that the proposed regulation amended an SPS measure and should have been notified to the SPS Committee. The European Union was dependent on imports of feed to maintain its own livestock industry. Therefore, the US requested that the Commission take into account the needs of the seed providers, growers and grain traders for regulatory predictability in order to serve producers in the EU market with high quality, competitively priced feed. The US agreed with others, including the European Parliament, that the Commission should withdraw this proposal.

2.220. The representative of Canada shared the concerns raised by the US on the Commission proposal, on which they had submitted comments in August 2015 in response to EU's notification to the TBT Committee. Canada continued to believe that any EU member State measure taken under this proposal could have the potential to disrupt trade and would unnecessarily introduce further uncertainty with respect to food and feed imports into the EU. Canada was continuing to monitor the progress of this proposal as it made its way through the EU's legislative process.

2.221. The representative of South Africa thanked the European Union for the opportunity to submit comments on notification G/TBT/N/EU/284, circulated on 20 May 2015, within a period of 90 days after notification. The South African Government had received comments and concerns from organized agriculture consisting of farmers, the food processing industry and food and feed exporters concerning the EU's proposed modification of Regulation (EC) No 1829/2003. It was noted that the EU's proposed modification of Regulation (EC) No 1829/2003 would allow member States to adopt measures restricting or prohibiting the use of genetically modified food and feed on their territory. It was South Africa's assessment that the proposed modification created

¹⁸ G/TBT/M/66, para. 3.247 and G/TBT/M/65, para. 2.33.

uncertainty and would create an unjustifiable barrier to international trade, especially when it was not clear how EU member States would conduct the respective scientific risk assessment process to determine compliance with any measures introduced in terms of the proposed amended regulation. If the proposed modification was adopted in the European Union and a member State implemented it by restricting or prohibiting the use of GM food or feed in its territory, it might not be fully compliant with its obligations under Articles 2.1 and 2.2 of the TBT Agreement.

2.222. Article 2.1 of the TBT Agreement contained most-favoured nation and national treatment provisions, much like Articles I:1 and III:4 of GATT 1994, stipulating that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like product of national origin and to like product originating in any other country. Thus, any restriction or prohibition on GM food or feed adopted by an EU member State was likely to result in less favourable treatment of GM food and feed imported from certain destinations, in comparison to non-GM food and feed imported from such destinations, or produced domestically or imported from other nations. The existence of the measure restricting or prohibiting the use of GM food and feed in a member State undoubtedly would convey an advantage to nations that can supply non-GM substitutes or alternatives, and to domestic European producers. Article 2.2 required that a technical measure "shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create." Considering the proposal was silent on what "compelling grounds" could be used as the basis for implementing a GM food and feed restriction or prohibition, it was unclear what the European Union would claim as a legitimate objective for pursuing such a measure.

2.223. In its response to the specific trade concern raised by Argentina, Paraguay, the United States and some other delegations during the TBT Committee meeting of 17-18 June 2015, the EU's representative had said that this proposal was not a renationalisation of the decision to authorise GMOs and that GM food and feed would remain to be assessed by the European Food Safety Authority, based on harmonised science-based criteria and would continue to be authorised at Union level, following an EU decision of authorisation. As such, the proposal would not introduce any restriction or ban but would only provide the possibility for the EU member States, which so wished, to opt out from the EU decision of authorisation based on overriding reasons of public interest, distinct from the assessment of risks to health and to the environment. Although South Africa recognised the rights of the individual EU member States in terms of the TBT Agreement, the proposal to create a legal basis for the EU member States to restrict or ban, if they deemed it necessary in a given case, the use of EU authorised genetically modified food and feed on the basis of compelling grounds, provided to EU member States an opportunity to introduce undefined reasons of public interest. In South Africa's view, this was contrary to the objectives of an economic union such as the EU, where an objective of harmonized regulation was followed.

2.224. As Article 2.2 of the TBT Agreement stipulated that WTO Members were allowed to regulate for legitimate objectives that include inter alia, national security requirements, the prevention of deceptive practices, protection of human health or safety, animal or plant life or health, or the environment, South Africa was concerned that the EU was introducing a new objective "overriding reasons of public interest distinct from the assessment of risks to health and to the environment", which was not in accordance with the TBT Agreement's legitimate objectives. He further noted that the proposed amendment explicitly enabled a member State to opt-out of a European-wide scientific decision to allow the import of GM food or feed, without basing the "opt-out" on science or a risk assessment. He asked that South Africa's written comments be taken into consideration.

2.225. The representative of Argentina stated that his delegation shared the concerns expressed by the United States and Canada with regard to the European Commission's proposal, the purpose of which was to modify the existing authorization procedure for GMOs provided in Regulation (EC) No 1829/2003, with a view to enabling its member States to restrict or prohibit the use of genetically modified food and feed in all or part of their territory, even though such use was authorized at European level, following completion of a rigorous risk assessment process which demonstrated its safety for health and the environment. Argentina drew attention to the categorical rejection of the proposal by the plenary of the European Parliament on 28 October 2015 given the obvious inconsistencies of the proposal in terms of both European Union regulations and the EU's international obligations in the WTO. Therefore, Argentina requested that the EU withdraw the notified proposal and implement, in a timely and proper manner, the current

EU legislation on the approval and authorization of GMOs throughout EU territory. Otherwise, the EU was urged to notify the proposal to the SPS Committee.

2.226. The representative of Brazil supported the interventions of the US, Canada, South Africa and Argentina on this matter and recalled that his delegation had raised this concern in previous SPS Committee meetings.

2.227. The representative of Chile shared the concerns raised by other delegations regarding this EU proposal.

2.228. The representative of the European Union said that on 13 October 2015, the Committee on Environment, Public Health and Food Safety of the European Parliament had rejected the Commission's proposal through the adoption of a draft European Parliament legislative resolution and had called on the Commission to withdraw it and to propose a new one. On 28 October 2015, the Commission proposal had been rejected in the European Parliament plenary. Discussions at the Council of Ministers, which was co-legislator together with the European Parliament, were still ongoing and the legislative process would continue. The EU would keep the TBT Committee informed of developments regarding this proposal.

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

2.229. The representative of the European Union said that her delegation continued to follow the developments regarding this concern and wished to have updated information on the status of the draft regulation. The EU reiterated its request for Indonesia to notify the two draft regulations adopted by the Ministry of Communications and Information Technology in January 2015 and September 2014 under the TBT Agreement, and to postpone their implementation until a notification had been submitted, providing an opportunity for other WTO Members and their stakeholders to analyse the proposed measures and comment on them. The EU noted that it had addressed the Indonesian TBT Notification and Enquiry Point in February 2015, soliciting such notification, but no response had been received to date.

2.230. The EU had a number of concerns regarding the technical content of the proposed requirements. First, the draft regulations required the test for compliance with the referenced mandatory standard to be carried out in Indonesia by a laboratory accredited and approved by the Indonesian administration. Taking into account the global nature of markets for mobile communication equipment and the availability of global agreements for accreditation of laboratories and in order to avoid unnecessary repetition of tests, the EU invited Indonesia to accept the results of testing carried out outside Indonesia in properly accredited laboratories. Second, the draft regulations prescribed compliance with a specific standard. Taking into account the rapid pace of evolution in the area of mobile communication technologies, the EU asked Indonesia about its plans to cope with a possible future need to update the mandatory standard. The EU requested Indonesia to consider making a dynamic reference to the latest available version of the standard in question, which would be regularly updated in light of technological developments, instead of a static reference to a dated reference of that standard. Regarding the substance of the two proposed regulations, the EU echoed the concerns expressed by other Members about the requirements for local content. The EU looked forward to following up on this matter bilaterally with the Indonesian authorities.

2.231. The representative of Australia stated that his delegation was monitoring the status of implementation of the regulation and was particularly interested in maintaining transparency. He asked that Indonesia notify these regulations to the TBT Committee to ensure that Members' concerns are considered during the implementation phase.

2.232. The representative of the United States agreed with and supported the concerns raised by Australia and the EU.

2.233. The representative of Canada said that his delegation followed with interest this regulation and agreed with the comments made by the EU. Canada would be providing comments in due course.

2.234. The representative of Indonesia suggested that the concerned Members refer to the response provided in the previous TBT meeting.¹⁹ She informed the Committee that the Ministerial Decree No.69/2014 related to the Domestic Component Level (DCL) requirement had been revised through the Ministry of Industry Ministerial Regulation No.68 / M-IND/PER/ 8/2015 regarding Provisions and Procedures for DCL Calculation of Electronics and Telematics Products. The Ministry of Communications and Informatics had set the Ministerial Regulation No.27 of 2015 regarding Technical Requirements Tool or Technology Telecommunication Standards-Based Long Term Evolution. The Regulation of the Ministry of Industry No. 68 and its amendments only regulated DCL for general electronics and telematics products while the Regulation of the Ministry of Communications and Informatics set the technical requirements of LTE standards-based telecommunications equipment as well as its domestic components. The setting of technical specifications regarding 4G LTE products was based on the applicable international standards and Indonesia had also adopted ETSI standards.

2.235. With regard to testing of these products, including mutual recognition requests by conformity assessment bodies, the applicable rules were contained in the Ministry of Communications and Informatics No. 18/2014 on Certification of Telecommunication Tools and Equipment. In principle, Indonesia accepted the test results issued by foreign test institutions, which were accredited internationally. In addition, MRA requirements were stipulated in Article 18 of Regulation No. 18/2014. The previous regulations - the Ministry of Communications and Informatics regulation No.5 / 2013 and Regulation of the Ministry of Communications and Information Technology No.18 / 2015 - had been notified to the WTO in line with the TBT Agreement.

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

2.236. The representative of Republic of Korea thanked China for the clarification provided on this matter at the last Committee meeting. However, Korea considered that important aspects of the registration fees still needed to be addressed. According to the registration fee policy published on 27 May 2015, the application fees for first registration were different for Chinese manufacturers and importers. For Class III medical devices, new registration fees were approximately twice as high for importers as compared to domestic producers.

2.237. At the last Committee meeting, China had explained that the higher fees for imported medical devices were only related to the different cost needed for on-site inspection. Her delegation understood that an on-site inspection for medical devices required additional costs, for example, for flights, accommodation and differences in prices between countries. However, in her delegation's view, fees twice as high for foreign as compared to like domestic devices was excessive. Moreover, according to Article 13 of the Regulation of Supervision and Administration of Medical Devices, on-site quality inspections were not compulsory and inspections could be postponed and were performed only when Chinese authorities considered them necessary. Therefore, Korea requested that Chinese authorities separate the costs for on-site inspection from the registration fees, which was a general practice performed by most countries, including Korea. Lastly, Korea would like to know when the registration fees for domestic Class II medical devices would be available, and the criteria for these fees. Currently, fees for Class II medical devices were only imposed on imported medical devices. Korea pledged to continue to work together with China on this issue, and hoped to find reasonable solutions as soon as possible.

2.238. The representative of Canada thanked the delegation of China for the clarification they provided at the last meeting and bilaterally to Canadian officials in Beijing. However, Canada continued to express disappointment at China's Medical Device Registration Fee Schedule that was published 27 May 2015. This new fee schedule entered into force without any notification to WTO, failing to give Members a "reasonable interval between the publication of requirements concerning conformity assessment procedures and their entry into force", as required by Article 5.9 of TBT Agreement. The fact that China had adopted a non-transparent approach by combining registration fees with on-site inspection fees for foreign manufacturers was also of concern to Canada. Further, with respect to transparency, he noted that some registration fees for domestic products were unspecified as they were to be levied by China's provinces. In order to enhance transparency, could China publish the on-site inspection fees separately from the registration fees for foreign manufacturers? Also, could China publish the registration fees to be levied by China's

¹⁹ G/TBT/M/66, para. 3.45.

provinces on domestic manufacturers? Canada also asked that these fees be clearly separated, so that it was clear what manufacturers were being charged, with a view to ensuring that: i) the registration fees conformed with China's WTO national treatment obligations; and, ii) that the on-site inspection fees corresponded to international averages.

2.239. In addition, Canada continued to be concerned about a lack of clarity regarding eligibility for the accelerated service being offered by the CFDA to fast-track applications for drugs and medical devices. Could China confirm that domestic and foreign firms would be charged the same fast-track fee in-line with national treatment provisions? In addition, the representative of Canada highlighted that certain innovative imported products would not need to pay registration fees to the CFDA. His delegation understood that the "innovative" definition was based on China's "Green Channel" framework, which had only accepted one imported product as innovative in over a year. Would China be providing clear guidelines as to how they plan to determine whether a product was innovative or not? Would the same definition of "innovative" be applied to domestic and foreign products alike? Canada requested further clarifications in this respect, and looked forward to working collaboratively with the CFDA and Chinese government to make progress in this matter.

2.240. The representative of Australia expressed interest in this issue and was monitoring the status of implementation of the regulation, noting that Australian business and industry organizations had raised concerns to the Australian government regarding the introduction of the new fee schedule and resulting processes. Australia considered that the fee structure and process might not be based on international best practice and was a technical regulation within the meaning of Annex 1 of the TBT Agreement. As such, Australia asked China to notify this measure to the TBT Committee in accordance with Articles 2.9 and 5.9 of the Agreement. In particular, Australia was concerned that the implemented fee structure and process requirements provided for different fees for domestic and imported drug and medical device products. He requested that China outline how the fee structure and process requirements for imported products were proportionate, including for the costs of transportation, accommodation and allowances. He asked if domestically produced drugs and medical devices were subject to the same testing process and registration requirements, though at different fees? It was noted that some of the domestic prices were based on what was termed a provincial price. Could China confirm what the provincial price was and how it was determined, as well as whether the same testing process requirements were required 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 the first time registration. Could China provide additional information about how innovative products were defined, and what were their criteria? Were domestic and imported products able to be considered as innovative?

2.241. Finally, Australia acknowledged that on-site inspections were necessary to promote public health and to ensure products were safe and effective, and accepted that inspections at foreign facilities may be more expensive. However, fees associated with foreign inspections should be transparent, non-discriminatory and include industry consultation prior to implementation. Australia had submitted enquiries to China's TBT enquiry point on this measure and was seeking a response to the query.

2.242. The representative of China said that before the measure at issue was published, for a long time China did not charge any fees for the registration of medical devices. She said that charging registration fees on drugs and medical devices was a global norm and, in any case, these new Chinese fees were far lower than the international level. With regard to different registration fee structures for domestic and foreign drug and medical devices, he clarified that the gap only related to the different costs needed for on-site inspection. Between domestic and foreign products, the costs arising from communication, transportation, accommodation and others relating to on-site inspectors could differ greatly. In this respect, he noted that Article 5.2.5 of the TBT Agreement required that any conformity assessment fees on foreign products should be "equitable in relation to any fees chargeable for assessing the conformity of like products of national origin or originating in any other country, taking into account communications, transportation and other costs arising from differences between location of facilities of the applicant and the conformity assessment body." Additionally, it was international common practice to charge differently on domestic and foreign products for on-site inspection. For example, according to the US Prescription Drug Use Fee Act (PDUFA), the US FDA required foreign companies to pay USD 15,000 more than domestic ones.

2.243. Regarding transparency, he said that, according to Article 5.6 of the TBT Agreement, Members should notify WTO "whenever a relevant guide or recommendation issued by an international standardizing body does not exist or the technical content of a proposed conformity assessment procedure is not in accordance with relevant guides and recommendations issued by international standardizing bodies." However, in this case, the fee system did not belong to the "technical content" of a conformity assessment procedure, so China had no obligation to notify it. In fact, China did not find any notifications to the WTO by other Members of similar fee structures.

2.2.3.34 Chinese Taipei - GMO Labelling, G/TBT/N/TPKM/168/Rev.1 (ID 467)

2.244. The representative of the United States continued to question the science and risk-based justification for Chinese Taipei to increase the stringency of its genetically engineered (GE) labelling requirements. Such labels implied an inherent difference in products when no such difference existed, and were often taken by the consumer to imply a safety or health hazard when no such hazard existed. Although mandatory labelling may be proposed to ensure "consumer choice," she highlighted that economies with overly restrictive mandatory GE labelling requirements actually experienced reduced consumer choice as companies usually sourced non-biotech ingredients rather than use a label. She noted US comments on this measure dated 16 April 2015 and 27 July 2015, as well as concerns expressed to Chinese Taipei in letters to the Ministry of Health and Welfare from the Office of the United States Trade Representative in March 2015, and the US Department of Agriculture in May 2105.

2.245. In particular, since the presence of authorized GE ingredients in food products did not pose a greater human health risk in comparison with conventional foods on a categorical basis, there was no scientific basis for these amendments and they could raise unjustified food safety concerns among the public. Overall, the US believed that more restrictive mandatory labelling requirements would have a negative impact on Chinese Taipei's domestic food processing industries, increase the administrative burden and potential for corruption, and limit consumer choice, without improving food safety. The US was concerned these requirements could significantly disrupt US agricultural exports to Chinese Taipei, especially as enforcement and traceability requirements were currently unclear. The US believed the requirements had the potential to impose additional burdens on food producers, exporters, and importers; for increased costs to consumers; and for affected companies to exit Chinese Taipei's market.

2.246. The US asked Chinese Taipei to explain how the labelling requirements would be applied and enforced, including with respect to refined products that do not contain genetically engineered protein or DNA. Additionally, she noted that Chinese Taipei notified a traceability system on 17 August 2015 (G/TBT/N/TPKM/207/Add.1). What was the intent of the proposed traceability system for GE and other agricultural products? The US requested clarification on how this proposed traceability system would work, and that Chinese Taipei notify details to the WTO so Members would have an opportunity to review and comment. Given enforcement and traceability requirements were currently unclear the US was of the view that the new regulations could not be implemented on a fair and transparent basis. She therefore requested that Chinese Taipei revise its decision to implement regulatory changes on biotech labelling and continue with previous GE labelling requirements of a 5.0% threshold for labelling of food where introduced protein and DNA may be present, since they have sufficiently addressed consumer choice for many years.

2.247. The representative of Canada recognized and supported Chinese Taipei's right to implement regulations that provide consumers with adequate information to make informed choices. However, Canada believed this objective could be achieved through less trade restrictive voluntary measures. Canada was concerned that, in the absence of food safety concerns, mandatory labelling would be misleading to consumers by not providing them with straightforward, meaningful information. Mandatory labelling should be reserved for legitimate health concerns and was not an appropriate tool to address concerns about food quality and fraud. The scientific consensus was that GM products that have been safety assessed and approved for sale were safe for human consumption and therefore should not require additional labelling. Implementing unnecessarily restrictive measures may be counterproductive to Chinese Taipei's efforts to modernize its food regulations, and could inadvertently generate concerns related to food safety among consumers where there were none. Canada continued to be concerned with what seemed to be a trend developing for TFDA to pre-empt potential political or public reaction through trade restricting regulations. Canada followed this issue with interest and looked forward to working with Chinese Taipei to bring this issue to closure.

2.248. The representative of Australia thanked Chinese Taipei for its response to Australia's comments on the proposed draft food labelling requirements for food containing Genetically Modified Organisms, notified on 17 March 2015 (G/TBT/N/TPKM/168/Rev.1). Australia recognised Chinese Taipei's right to amend and expand technical regulations to provide consumers with information to make informed food choices, and considered that it was very important to secure food safety and public health. However, Australia had reservations about the proposed amendments to the labelling of food which was processed using genetically modified (GM) material. In relation to Article 2, Paragraph 3: Labelling Requirements for Pre-packaged Food, Food Additives and Unpackaged Food Containing Ingredients of Genetically Modified Organisms, Australia again requested that Chinese Taipei reconsider the proposed requirement to label food products with no altered characteristics and do not contain GM material. With no scientific methodology to test highly refined food products derived from GM ingredients, he said there were no incentives for food manufacturers to implement and maintain costly traceability records. Furthermore, an inability to enforce the proposed labelling requirements may undermine consumer confidence in Chinese Taipei's food labelling regulations. Ensuring compliance to the proposed changes would potentially require the imposition of additional traceability measures on producers, and he noted such measures would present significant costs and practical challenges, which would also ultimately be passed on to consumers. Australia also pointed out that the proposed messages "this product is made of Genetically Modified Organisms (GMOs), but this product do not contain any transgenic DNA fragment or transgenic proteins" and "this product's raw materials contain GMOs, but this product does not contain any transgenic DNA fragment or transgenic proteins" were excessively long and the required label size to accommodate them would be impractical.

2.249. The representative of Australia said that the proposed requirements were not consistent with regulations in Australia or other trading partners, and implementation could be costly for food manufacturers, including because of their potential impact on label design, package redesign, marketing and regulatory expertise. In this respect, he observed that Australia's GM food labelling laws were designed to be practical and enforceable, and food products which do not contain any novel DNA or protein or altered characteristics do not require labelling in Australia. The decision not to label these foods was made because the composition and characteristics of these foods was the same as the non-GM food. He explained that these foods were typically highly refined foods, such as sugars and oils, where processing had removed DNA and protein from the food, including novel DNA and novel protein. In this case, there was no way of being able to detect a difference between the GM and non-GM product and therefore, there was no quantifiable mechanism for enforcing labelling. Turning to the implementation time-frame, Australia understood that the proposed date of entry into force for the regulations had been advanced from 1 January 2016 to 1 July 2015. Australia requested advice from Chinese Taipei on the implementation timeframe and recalled Australia's previous request that Chinese Taipei reconsider the proposed time-frame. Australia suggested a period of two years at minimum for the implementation of new requirements for food products which contain no GM material.

2.250. The representative of New Zealand welcomed Chinese Taipei's engagement in the Committee, both bilaterally and in the Committee. New Zealand considered that the labelling requirements promulgated through the regulations could be confusing to consumers which could result in unjustified concerns. Where applied to food that was highly refined and where processing removed all transgenic DNA and/or transgenic proteins, the labelling requirements could raise unnecessary consumer concern and potentially desensitise them to labels regarding GMO. She pointed out that consumers may not readily appreciate the difference between food derived from GMO that no longer contained transgenic DNA or transgenic protein and food that did contain transgenic DNA or transgenic protein. New Zealand encouraged Chinese Taipei to consider exempting from the regulation foods and/or ingredients produced using GMO where the final product did not contain any transgenic DNA and/or transgenic proteins and for highly refined ingredients. There would be no transgenic DNA or transgenic protein introduced by gene technology present in these foods, and therefore the characteristics of the food would remain unaltered.

2.251. The representative of South Africa shared the concerns raised by other Members.

2.252. The representative of Chinese Taipei provided an update on its labelling requirements. Chinese Taipei's full statement is contained in document G/TBT/W/427.

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

2.253. The representative of Canada raised concerns with the commitment made by Turkey to exempt toys cleared within the European Union from the new testing requirement on all products intended for use by children. This text required three to four samples per stock keeping unit to be sent for additional testing at the Turkish Government laboratory (Kimyane). This was at odds with Turkey's MFN obligations as the vast majority of Canadian toys imported into Turkey also complied with the EU's and other internationally accepted standards. Therefore Turkey should consider extending the exemption to all manufacturers complying with the EU requirements. Concerning compliant products that entered Turkey directly, adequate documentation of conformity to EU requirements such as test reports from an ISO 17025 accredited laboratories should be appropriate.

2.254. The representative of the United States supported the comments made by Canada. She recalled the intervention made at the previous Committee meeting where concerns were expressed about duplicative and unnecessary border inspections and the requirements for additional testing. Turkish authorities had not yet replied to the concerns raised despite continuous complaints by the US. Increased inspections had caused long delays and had significantly raised costs for US toy industry. As the peak toy season was approaching, the US hoped this issue would be resolved immediately.

2.255. The representative of Turkey reminded the Committee that Communiqué 2016/10 did not contain any legislative change or additional provisions regarding technical requirements and conformity assessment procedures for toy imports in comparison to the previous year. Due to serious issues being faced in the domestic market, the Ministry of Customs and Trade commenced stricter verifications of colourants and phthalates in toys so as to protect the health and safety of children. Equal treatment was being applied to both domestic and foreign companies whereby in order to place products on the Turkish market, all had to comply with the safety requirements and were subject to the same rules and procedures. Toys on the domestic market were verified through market surveillance, while foreign toys entering the Turkish market had to have CE marking. The CE marking did not exempt toys from government controls, but showed the products were manufactured in compliance with the related technical regulation. This did not remove the risk of considerably unsafe non-compliant toys with fake test reports or improper marking or labelling trying to enter the market. Under the customs union agreement with the EU established in 1995, the EU was the only exception regarding Turkey's import control, so products, including toys, originating in the EU or 3rd party countries accompanied with ATR documents in principle were not subject to safety and conformity checks. Those coming from EU member States were subject to market surveillance rather than import control. This, she said, did not prevent Turkey from taking supplementary action at the customs if products considered unsafe or non-compliant were identified. Finally she said that the Ministry of Customs and Trade consultation process was still on-going and any new developments would be conveyed to the US and Canada on a bilateral basis.

2.256. The representative of the European Union took the floor to clarify that the EU and Turkey customs union agreement foresaw the free movement of goods in areas where both the EU and Turkey applied the same rules, such as for toys. He felt it was important to stress that goods placed legally on the market of either party, regardless of their origin were in free circulation without being subject to other checks within the customs union. Therefore this was not inconsistent with the MFN clause as it was waived under the enabling clause for customs union agreements.

2.257. The representative of the United States reiterated her concern regarding the acceptance of CE marking as a conformity assessment procedure for toys. If this CE mark was accepted then it should not be necessary to have to provide additional testing at the border. This was duplicative testing and therefore created an unnecessary barrier to trade.

2.258. The representative of Turkey said that despite having CE marking, if the authorities deemed products to be of risk, they could request additional testing.

2.2.3.36 Brazil - Draft Ordinance Act N°. 374, 27 November 2014 (Portaria SDA/MAPA 374/2014) Establishes quality requirements for wine and derivatives of grape and wine (ID 470)

2.259. The representative of the European Union said that while appreciating that Brazil was preparing a revised draft of the ordinance, her delegation nevertheless felt it necessary to reiterate the most important concerns. These concerns had been sent to Brazil on 13 February 2015 and were raised at the previous meeting of the TBT Committee. She noted that some provisions of this draft measure differed from the recommendations of the International Organisation of Vine and Wine (OIV), of which Brazil was a member. Some of these differences would oblige EU wine producers to modify their labels and therefore entail higher production costs. In particular, the draft measure departed from the relevant OIV recommendations as well as Codex standards with regard to a minimum content for indicating on the label the grape variety of lower share, and also with regard to a requirement to classify wine according to colour. In this respect, the EU recalled that Article 2.4 of the TBT Agreement called for the use of international standards. She asked Brazil to explain the reasons for these diverging requirements.

2.260. The EU was also concerned with the draft measure's provisions on sugar content of these products, for which OIV Recommendations also existed. She noted that the draft measure, together with an earlier decision of February 2014 (Decreto No. 8.198), was not in line with these OIV Recommendations, and was now creating problems at point of import, in particular for sparkling wines. The EU asked Brazil to clarify to what extent the draft measure would apply to wines imported from the EU, considering their "tipicity" (Article 52 of the Decreto No. 8.198). The EU said that it would welcome an interpretation of the draft measure in conjunction with the text of Decreto No. 8.198 so as to clarify applicable rules. The EU also sought clarification on the analytical parameters which diverged from the OIV recommendations including ashes and alcohol content. She noted that the use of caramel was not allowed in the production of spirit drinks while EU legislation allowed for its use in many spirit drinks produced by distillation of agricultural products, such as whisky, Cognac, brandy, fruit spirits etc. Brazil was requested to clarify the rationale for this prohibition which was the cause of much concern for EU producers and to also consider deferring from it in the revised draft. Concerns were also reiterated about the prohibition of terms "dry" or "reserve" on the label of grape and wine derivatives, the high levels of alcohol and wine content in sangria, the misleading use of term "moscato", as well as the evocations of names protected in the EU such as "conhaque", "grappa" and "champanha". Brazil was asked to take the EU comments into account during the revision process and to consider aligning the draft ordinance with international standards. Finally she asked what the notification timeline would be, given the substantial changes contained within the revised draft ordinance.

2.261. The representative of Brazil requested that Members refer to the statement made during the previous TBT Committee meeting as there were no further updates to provide.²⁰ The Ministry of Agriculture was still evaluating the results of the public consultation held earlier in the year. A large number of comments had been received from various governments and the private sector and these comments were being reviewed by the relevant authorities. He said that since this TBT notification referred to a proposed measure subject to public consultations, consequently the measure under discussion had not produced any affects whatsoever in the trade of wine and derivatives of grape and wine. He requested the EU to submit their remarks in writing so that they could be replied to in a comprehensive manner and said that Brazil was available for bilateral discussion with all Members on this matter.

2.2.3.37 Ecuador - Emergency Technical Regulation (RTE) No. 088: "Surface tension agents", of the Ecuadorian Standardization Institute (INEN) G/TBT/N/ECU/117 (IMS ID 453)

2.262. The representative of Mexico expressed concerns with this measure, and, in particular, the justification for the "emergency" measure and the requirements regarding accredited certification bodies that were to provide certificates of conformity prior to importation. Mexico's full statement is contained in document G/TBT/W/439.

2.263. The representative of Ecuador informed the Committee that Technical Regulation No. 088 had been developed to prevent risks to human health and safety, the environment and practices

²⁰ G/TBT/M/66, para. 3.38.

likely to mislead end-users. The regulation was based on Andean Community Decision No. 706 of 10 December 2008 on the harmonization of legislation on domestic hygiene products. She said the relevant authorities had studied the comments made by Members and a revision was being prepared. In view of the comments received on conformity assessment, the regulation had been amended to facilitate, among other mechanisms, the submission of a first party declaration, thereby resolving in a satisfactory manner the problem of proving the product's conformity. The technical regulation including the option of assessment through first party certification had been circulated broadly to industry and importers and was being revised by that sector.

2.2.3.38 Peru - Implementing Regulations of 14 November 2012 for Moratorium on Planting Genetically Engineered Crops (IMS ID 320)

2.264. The representative of Mexico raised concerns on the establishment of a 10 year moratorium on the import and production of living GMOs in Peru. Their full statement is contained in document G/TBT/W/426.

2.265. The representative of Peru reminded the Committee that, as had been stated in previous meetings, the moratorium for entry of GMOs into Peru was an environmental measure so to protect biodiversity. As it was not a technical regulation, a notification was not necessary. Given the complexity of the issue, and the possibility that the measure may be withdrawn, it was not possible to give any further information on the date of entry into force.

2.2.3.39 Colombia - Draft Ministry of Commerce, Industry and Tourism Decree "Restructuring the National Quality Subsystem and amending Decree No. 2269 of 1993", G/TBT/N/COL/201 (IMS ID 432)

2.266. The representative of Mexico raised concerns with this measure. Mexico's full statement is contained in document G/TBT/W/437.

2.267. The representative of the United States thanked Colombia for the constructive bilateral meeting that had taken place where some concerns on transparency had been clarified. As mentioned bilaterally, the US understood that Decree 1595, implemented as part of the law implementing the National Quality Subsystem required third party certification by an organization accredited by the National Accreditation Body. She asked that this decree be notified to the WTO either as a new notification or as an addendum to G/TBT/N/COL/201 (restructuring of the National Quality Subsystem). It was further requested that the associated technical regulations be re-notified as they were subject to the risk management assignments of Decree 1595. This would allow for a comment period, consideration of current conformity assessment practices, and a reasonable period of time for industry to adjust to the new conformity assessment requirements. The US had observed that the specific technical regulations impacted by Decree 1595 included: (i) Resolution of the Ministry of Transport Technical Regulation for Public Transport Vehicles and Adopting Other Provisions (G/TBT/N/COL/164); (ii) Technical Regulation on Quality Standards for Anhydride Fuel Ethanol and Denaturated Anhydride Fuel Ethanol, used as a Gasoline Oxygenator is Established and Other Dispositions are Made (G/TBT/N/COL/213); (iii) Ministry of Health and Social Protection Resolution 3117 of 2015 - Modification of Article 12 of Resolution 3388 of 2008, Toy Safety; and (iv) Ministry of Mines RETIE regulation (G/TBT/N/COL/20/Add.1-9).

2.268. The US also raised concerns with how products were designated as "medium" or "high" risk without any associated risk assessment. She asked if any such risk assessment existed and what was the purpose of creating a medium and high risk category when the conformity assessment applied was identical as indicted in paragraph 7 of Article 2.2.1.7.6.6 of Decree 1595. Could Colombia share the data and methodology used in determining in which category these products were placed? Complaints had been received from US motor vehicle manufactures, food and beverage producers, and toy and electrical manufacturers on the lack of transparency and the non-consideration of current industry practices for conformity assessment and associated levels of product risk.

2.269. In addition, the United States raised concerns with Article 2.2.1.7.9.2 regarding the option to accept a foreign certification, "as long as the issuing country accepts the Colombian certificates for national products" as acceptance of foreign certificates happened in a number of ways. This primarily happened through arrangements between the conformity assessment bodies to accept

certificates. Governments could also accept the certificates but they were not obliged to accept certificates of another country to the ILAC, IAAC, or IAF. She asked for additional information on the requirement of "additional procedure" contained in paragraph 2 of Article. 2.2.1.7.6.6 of Decree 1595 as this defeated the purpose of the mutual recognition arrangement among accreditation bodies. What type of evaluation would be required as indicated in Paragraph 3 of the same article which provided for a Colombian certification body to evaluate certificates issued by a foreign certification body? This could lead to a conflict of interest and raised issues of confidentiality as certification bodies were typically private sector bodies that competed with each other. She also questioned what was meant by "national evaluation organization".

2.270. The representative of the European Union said that his delegation shared the concerns raised by Mexico and the US. The EU had submitted comments on the draft decree initially notified in G/TBT/N/COL/201. However, the adopted draft (Decree 1471) had then been partially modified by Decree 1595 – but these amendments had not been notified as an addendum to the original notification. He therefore invited Colombia to notify the measure and allow enough time for Members to comment. Colombia was also asked to clarify Para 2 of Article 2.2.1.7.9.2 which established that conformity certificates issued by foreign conformity assessment bodies accredited by an accreditation body, which was a member of mutual recognition arrangements (MRA) of which the Colombian accreditation authority was also a Member could be accepted in Colombia so long as the country of origin of the certificate recognised certificates issued in Colombia. This meant that there needed to be a requirement for reciprocity, and the EU asked whether such reciprocity would be deemed to exist when the country of origin applied for that type of product a system of self-declaration of conformity. However, the same paragraph stated that, in those cases, the competent authority could require an additional procedure. He asked Colombia to elaborate on what type of additional procedure might be required. He also requested that Colombia explain what was meant in Paragraph 3 of the same article which established that conformity certificates issued by foreign conformity assessment bodies accredited by an accreditation body which was a member of an MRA of which the Colombian accreditation authority was not a member could be accepted subject to evaluation. What evaluation was envisaged? Finally, he asked that any amendments to the existing technical regulations or conformity assessment procedures aligning them with the national quality subsystem should be notified to the WTO.

2.271. The representative of Colombia explained that Decree 1595 was drafted so as to update rules pertaining to the Colombian Quality System so as to ensure the highest quality in the preparation of technical regulations. Colombia's full statement is contained in G/TBT/W/438.

2.3 Exchange of experiences

2.3.1 Discussion on Seventh Triennial Review adoption ad referendum

2.272. The Chairperson drew the Committee's attention to latest version of the Seventh Triennial Review draft report which had been made available as a Room Document at the back of the room (6 November 2015, version 15:00). She said that the draft report reflected much hard work of the Committee and had benefited from all Members' commitment and engagement. While she was aware that no Member was 100% comfortable with the draft, for the systemic value of the work of this Committee, she nevertheless hoped that the report would be acceptable to the Membership. Although she was aware that one or more delegations were not prepared to agree to formal adoption at the current time – for lack of formal clearance – she asked the Membership if it was prepared to adopt the document on an *ad referendum* basis by 1 December 2015. This meant that if no Member informed the Secretariat otherwise by that date, the report would be considered adopted and circulated.

2.273. The representative of Ecuador said that her delegation could not agree with the first proposal in relation to paragraph 2.3 of the text, and this was why a more general text had been proposed. She accepted the adoption on an *ad referendum* basis and would send the observations on paragraph 2.3 to capital.

2.274. The representative of the European Union said that his delegation could not agree with the proposal. There was a need to further discuss the wording of the outstanding paragraph and it was better to do so at once rather than inevitably shifting the discussion to the March 2016 meeting of the Committee. The EU said that his delegation had not had an opportunity to discuss the text in

paragraph 2.3(b) the previous day and regretted that it was being tabled on a take-it-or-leave it basis even if *ad referendum*. The EU still had comments to make and also wanted to address how the Committee had arrived at the current drafting.

2.275. The representative of Chile said that it was important to focus the discussion only on paragraph 2.3 as this was the only point of disagreement.

2.276. The Chairperson confirmed Chile's understanding: the focus was only on para 2.3.

2.277. The representative of China disagreed. He said that his delegation had exercised restraint in raising concerns about *other* pending issues in the draft report. He was of the view that the report needed to be considered as a whole. He did not, at the current time, have the mandate to change even one word in paragraph 2.3.

2.278. The representative of the United States supported the European Union and said that some discussion of paragraph 2.3 would be useful at the current stage. She agreed with the point made by Chile that the only point of disagreement was paragraph 2.3 and that the rest of the text was stable.

2.279. The representative of China said that his delegation could explain his position in response to delegations' questions if needed – but he did not have a mandate to change the text.

2.280. The representative of the European Union said that he was uncomfortable with the method used for the development of the text. It was questionable that a delegation started the discussion on a text by saying that there was no flexibility to accept any change at all. This meant that this delegation had seen this text. Had the text been agreed with this delegation and then the Committee as a whole was being asked here to take it or leave it? This was not acceptable. On substance, the European Union was of the view that, in terms of drafting style, it was not the practice to mention individual Members in the text of recommendations. The proponents were mentioned in the descriptive parts of triennial review reports, but recommendations did not make specific reference to Members. The best approach to the recommendation would be one that left the door open to consideration of existing proposals and any future proposals and that did not establish any priority between proposals and would allow the Committee to explore topics for the sessions at its future meetings. There was no need to add more specificity in this recommendation. Existing proposals had been very clearly identified in paragraph 2.1 of the draft report and these would be examined at the March 2016 meeting in view of the thematic sessions to be organized in June and November 2016, together with any other proposals that might be submitted later. This recommendation could not only reflect the view of the proponents for specific sectoral discussions; it had to be an output of a multilateral discussion. Clearly there could be no progress in a multilateral negotiation if one delegation entered the discussion by saying that it had no flexibility.

2.281. The representative of the United States supported the comments made by the EU and proposed that the Committee consider the suggested amendment originally proposed by Ecuador.

2.282. The representative of Nigeria recalled the previous extensive discussion on the subject and agreed with the EU that the proper names (of Members) *not* be specified in the recommendations.

2.283. The representative of China stressed that his delegation's proposal was about information exchange to improve transparency in sector-specific areas. Transparency was one of the most important principles of the WTO and also, indeed, one of the most important universal values promoted by a couple of the Members that had spoken. China's proposal was not targeting any given specific trade concern discussed in the Committee. China had no intention to challenge any Members' regulatory system; the proposal would do no harm to the industry of any Member. Thus it was very difficult to understand Members' concerns with regard to transparency. On the method, he stressed that all Members had been present at the meeting on the previous day, and, at that point, only Ecuador had raised a flag in relation to paragraph 2.3 of the text. No other Member had raised a concern. The current text (of paragraph 2.3) was exactly the same as the one that had been on the table the previous day. On substance, China was of the view that priority had been given to crosscutting issues rather than sector specific issues. Yet Article 15.4 of the TBT Agreement did not preclude any Member from proposing a topic for consideration in the context of the triennial review as long as the topic was conducive to the operation and implementation of the

TBT Agreement, regardless of whether it was cross-cutting or sector-specific in nature. Therefore, China's proposal had been treated in a discriminatory manner. This was not acceptable. If the naming was problematic, China proposed that the "China" and "Switzerland" be replaced with "energy efficiency standards" and "food labelling", respectively.

2.284. The representative of the United States stressed that no one was challenging the quality of the proposal from China. Delegations were referring to *one* sentence in the report and the interests of *all* Members in putting forward sectoral proposals. The fact that Switzerland and China had made proposals was already reflected in the text (in paragraph 2.1, last sentence). The Committee had, as a matter of fact, opened the door to sectoral discussions. This was the reason why the US was of the view that the EU suggestion was more accurate. On process, China had said that no one else had said anything after Ecuador had spoken on the previous day. But negotiations had immediately gone into bilateral mode and other Members had not been invited to comment further. It was therefore inaccurate to say that no one expressed concerns as the opportunity had not been there to do so. This needed to be put on the record.

2.285. The representative of China failed to understand the point made by the US. The Committee meeting prevailed over the bilateral one. At the Committee meeting, only concerns by Ecuador had been expressed – that was why Ecuador had been the focus of bilateral consultations. Nevertheless, China thanked the US for supporting its proposal that, as an outcome, there would be a thematic session on energy efficiency. China would work closely with the US on this topic as China was aware that the US had accumulated a lot of experience in this area.

2.286. The representative of Mexico supported the points made by the EU and the United States. The specific wording proposed by China was not acceptable to Mexico and this had been said on many occasions. A simple way needed to be found to accommodate *all* Members so that all proposals made to date – and which might be made in the future – would be taken into account.

2.287. The representative of Ecuador stressed the need for more time to consider the document. She said Ecuador was not blocking approval of the document, and again referred to her first proposal in relation to paragraph 2.3 of the text.

2.288. The representative of the European Union reiterated his proposal that the first sentence in paragraph 2.3(b.) could simply read: "to *hold* thematic sessions on regulatory cooperation between Members in June and November 2016". The insistence on including "on a sectoral basis" was unnecessary because it had already been mentioned higher up in the same paragraph. The text could then follow: "The Committee will identify topics for these sessions". For the sake of compromise, the EU could live with "...organize these sessions, based on proposals by Members". This was a neutral way to refer to proposals which existed to date (and already referenced in the report) and any proposal that might come at a later date. This was where there was consensus at the current time. There was not - at this point – consensus, in the framework of the triennial review, to have a specific discussion on the choice of topics, this would thus need to be postponed to a later date.

2.289. The Chairperson asked the delegation of Switzerland if the changes suggested by the EU were acceptable to Switzerland.

2.290. The representative of Switzerland said that the Committee had underlined that thematic sessions on specific topics were a future-oriented agenda that had the potential to include regulatory cooperation. The whole Membership, including developing country Members, had recognized that such an approach was worth exploring. Beyond the text, the Committee could agree to have a first session on the topic proposed by China that could serve as a "test run". The Committee had heard that some Members, other than China and Switzerland, might want to propose other topics too – this was welcome. Based on outlines for one or more topics that would be proposed by Members, and a willingness to engage on such topics, further sector-specific proposals could perhaps be the basis for sessions to be carried out in 2016 and 2017. On food labelling (the Swiss proposal) Switzerland understood that certain Members needed more time for clearance.

2.291. The representative of China said that the concerns expressed by Members appeared only to be about "comfort levels" rather than about substantive issues. This was not justifiable. It was not enough for China to change its position.

2.292. The representative of the Secretariat wished to provide some clarity on the method used to develop the draft report. The current draft report had been developed with input from Members on the basis of which the Secretariat had provided successive drafts, the usual practice for triennial reviews in the TBT Committee. The version currently before Members (date stamped 6 November 2015, 15:00) was the culmination of a process that had been agreed almost a year ago. In Secretariat drafts an attempt was always made to see where it was possible to fit language in the best possible way considering the mixed inputs received from Members – importantly, the drafts always went back to delegations, to the Committee – for review and comment. As had already been said, the version before the Committee was the one that had been circulated on the previous day with some additional few changes reflecting wording to address gaps that had been identified from the floor and which the Chairperson had introduced to the Membership. But the paragraph in question (2.3) had *not* been changed. The reason for this was that signals perceived from delegations had been that no further movement was possible, and one particular reason for no further movement had clearly been expressed by Ecuador, namely that Ecuador needed more time before accepting the particular language in the draft. Neither the Secretariat nor the Chair had heard from other delegations; but a break had been taken to allow Members to consult and to think about this particular paragraph. Hence, the outstanding paragraph was still with the Committee to reflect and agree on. The point needed to be made however, that the language that had been circulated the previous day, had not changed. What had changed was the *ad referendum* proposal by the Chair – and this was a practice (undertaken in some other committees) to give Members more time.

2.293. The representative of the United States noted that the Secretariat had mentioned "gaps". In fact, there was only *one* gap in *one* sentence (in a 26-page document). An outside viewer would most likely consider it a minor edit – but it was a minor edit that was holding up the entire report. It was difficult to understand that other Members were not reacting to this. So much time and energy was being spent on one sentence. There appeared to be a pattern here between the GRP disclaimer issue and this discussion that was deeply unconstructive. The proposal made by Ecuador, supported by the EU and her own delegation needed to be considered.

2.294. The representative of China said that his delegation had made several compromises from the first draft. The first draft had been a good basis for discussion but the second draft was not good enough because it did not do justice to Members' proposals. Indeed, China was exercising restraint. China was not comfortable with other parts of the report, including on quality infrastructure. This term was not clear enough. Also, with respect to RIAs, China's proposal had been based on a presentation from the World Bank – China wanted to have an exchange of experiences on how obligations in the TBT Agreement were taken into account in the RIA process. For example, according to the World Bank, some Members were beginning to take into account special and differential treatment obligations in conducting RIAs. Yet this language had not been reflected in the draft. So, in fact, China had exercised restraint. And this was the reason that China wanted to take the report as a whole.

2.295. The representative of the European Union said that China was diverting attention to other issues. The EU had made a proposal and his delegation now wanted to hear if other delegations objected to it. Indeed, how many Members were against the proposal?

2.296. The representative of Jamaica wished to speak on a matter of process. She was a bit uncomfortable with the way the discussion was evolving and recalled that agreement in the WTO was based on consensus. Nevertheless, Jamaica was flexible on paragraph 2.3b – and the inclusion of the latter part of the second paragraph did no harm, so Jamaica could live with it.

2.297. The representative of Brazil, supported by the Republic of Korea and Nigeria, stressed that his delegation was not part of the impasse, but definitely wanted to be part of the solution. The current mood of the discussion was not productive. He therefore suggested that Members break for 30 minutes so that concerned delegations could gather in another room and reflect on the way forward.

2.298. The meeting was suspended for one hour. A new text, contained in a room document dated 6 November 2015 and time-stamped at 18:00 was distributed.

2.299. The Chairperson reconvened the formal meeting and thanked delegations for the tremendous willingness to find a solution and cooperative spirit shown. Agreement had been reached. This involved changes to paragraphs 1.8(b)(iii) and 2.3(b). The revised texts had been incorporated in a new draft available at the back of the room with the title: "Room Document, 6 November 2015, 18:00". The Chairperson read out the two changes and then put the report before the Committee for adoption on an *ad referendum* basis for 1 December 2015.

2.300. The Committee agreed to adopt the report *ad referendum*.²¹

2.301. The representative of China thanked the Secretariat and Members for their support and flexibility. He was pleased that China's concern with regard to RIAs, although a small one, had been addressed. He would report to his capital and hoped to have final approval by 1 December.

2.3.2 Other matters

2.302. The representative of the United States brought the Committee's attention to recent notifications submitted under Article 10.7 of the TBT Agreement. These bilateral arrangements on organic products would facilitate trade with trading partners and while the scope of the products covered by these arrangements varied, they were comprehensive in approach. Partners recognised the equivalence of one another's national organic standards, accepted the results of conformity assessment conducted by conformity assessment bodies accredited by the other partner and recognised the equivalence of the organic fields used on the product labels. These bilateral arrangements developed with several Members were a useful model for how countries could work together to reduce technical barriers to trade in the interest of reducing costs to producers and consumers alike. With the growth of international trade in organic products, these notifications would further the transparency in this important sector. The US would continue to notify proposed changes in organic regulations to the Committee.

2.303. The representative of the European Union supported the statement made by the United States. These arrangements, he said, would facilitate trade in organic products and also ensured transparency in a sector where trade was rapidly growing. The EU intended to notify additional bilateral arrangements with its trading partners, and, like the US, the EU would continue to notify proposed changes to organic regulations through the notification procedure.

2.304. Switzerland and Canada supported the statement made by the United States.

3 TECHNICAL COOPERATION ACTIVITIES

3.1. The representative of OIML, on behalf of BIPM, informed the Committee that the General Conference on Weights and Measures (CGPM) had developed a capacity building and knowledge transfer programme which would enhance engagement from member states and associate members with emerging metrology systems and aimed at sharing the workload between the CIPM mutual recognition arrangement. The programme offered a range of activities which allowed donors to focus their support on those they considered the most beneficial. US NIST funding had already enabled BIPM to conduct two training courses which would take place in late 2016 and late 2017.

3.2. The representative of ISO informed the Committee that ISO was in the process of finalizing its five year action plan for developing countries. This would include the technical assistance, training and awareness raising and sponsorship of developing countries to participate in ISOs technical work from 2016-2020. At its General Assembly meeting in Korea, ISO had extended for four years its programme which allowed correspondent and subscriber members to participate in up to five standard development committees. This gave every ISO member the opportunity to be involved in shaping and developing international standards.

²¹ As no objection was received by 1 December 2015, the Committee's Seventh Triennial Review Report was formally adopted and circulated as G/TBT/37 on 3 December 2015.

3.3. The representative of IEC informed the Committee that the IEC continued to hold regional seminars on conformity assessment. The most recent one was held in Ghana which had been open to affiliates and members of the IEC. The next seminar would take place in Azerbaijan in 2016.

3.4. Information provided by the Secretariat is contained in document G/TBT/GEN/171/Rev.3.

4 UPDATE BY OBSERVERS

4.1. The representative of IEC informed the Committee that a report on TBT related activities was available on the IEC website. He highlighted three events: (i) Uzbekistan joined the IEC as an affiliate member bringing a total of 167 countries that were part of the IEC family, with 84 countries participating free of charge; (ii) the launch of the Africa Regional Centre in Nairobi which would increase participation in the region; and (iii) the first workshop on Conformity Assessment which would take place on 2 December 2016 under the auspices of the world standards cooperation.

4.2. The representative of ISO informed the Committee that the General Assembly had recently approved ISO's new strategy for 2016-2020. He also highlighted a co-sponsored workshop (ISO, IEC and UNECE) that had taken place on 2 November on the use of international standards to support public policies and technical regulations. This event had drawn attention to the good practices that leveraged the use of international voluntary standards in areas such as medical devices, food safety, energy efficiency, and disaster risk reduction. Challenges around access to standards that supported such policies, and the need to engage and educate policy makers in the use and the potential and the benefits of using international standards efficiently and strategically were amply discussed and provided a path for future such workshops on more targeted areas.

4.3. The representatives of OIML, UNECE, BIPM and SADC provided updates on their activities.²²

4.4. The representative of Uganda made statements²³ in support of granting ad hoc observership status to the African Organization for Standardisation (ARSO) and the Intergovernmental Authority on Development (IGAD). The representatives of Lesotho, Republic of Korea, Nigeria, South Africa, Kenya, United States, China, Mauritius, Ghana, Jamaica, Canada, Trinidad and Tobago, Barbados also took the floor in support of these requests.

4.5. The Committee agreed to grant ad hoc observer status to²⁴:

- a. the African Organization for Standardisation (ARSO), and
- b. the Intergovernmental Authority on Development (IGAD).

5 REPORT (2015) OF THE COMMITTEE ON TECHNICAL BARRIERS TO TRADE

5.1. The Committee adopted its 2015 Report to the Council for Trade in Goods (G/L/1138).

6 DATE OF NEXT MEETING

6.1. The next regular meeting of the Committee is scheduled for 9-10 March 2016. Two thematic sessions will be held on 8 March.

²² G/TBT/GEN/186, G/TBT/GEN/187, G/TBT/GEN/188 and G/TBT/GEN/189.

²³ G/TBT/W/423 and G/TBT/W/424.

²⁴ The changes are reflected in G/TBT/GEN/2/Rev.10, issued on 4 December 2015.