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G/TBT/M/65

28 May 2015

(15-2757)

Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 18-19 MARCH 2015

CHAIRPERSON: MR. FILIPE RAMALHEIRA

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1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in WTO/AIR/TBT/1.

2 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

2.1 Statements from Members under Article 15.2

2.1. The Chairman 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 submitted under Article 15.2 of the TBT Agreement were contained in document G/TBT/GEN/1/Rev.14, issued 23 February 2015. He informed the Committee that in total, since 1995, 129 Members had submitted at least one statement of implementation under the above-mentioned Article. Information on the list of statements was available, and regularly updated on the TBT Information Management System ("http://tbtims.wto.org/").

2.2 Specific Trade Concerns

2.2.1 Withdrawn concerns

2.2. The Chairman reported that the following Specific Trade Concerns had been withdrawn from the Agenda at the request of the concerned Member:

a. Ecuador – Ministry of Public Health Executive Decree (Agreement) No. 00004522 amending the Sanitary Regulations for the Labelling of Processed Foods for Human Consumption - withdrawn by Brazil

b. Ecuador – Systematic failure to publish notices at an early appropriate stage – withdrawn by Brazil

2.2.2 New Concerns

2.2.2.1 China - Administrative Measures on Cosmetic Labelling (AMCL) G/TBT/N/CHN/1064

2.3. The representative of Canada commended China for notifying its proposed changes to the requirements for the labelling of cosmetic products and welcomed the opportunity for foreign governments and industries to comment on the measure. China's proposed regulation would prohibit the widely accepted practice of over-labelling of cosmetic products and significantly disrupt production lines and schedules, increase costs for foreign manufacturers and create confusion among consumers who were accustomed to global branding of cosmetic products. Canada was deeply concerned that the proposed regulation would inflict a disproportionate burden for non-Chinese manufactured cosmetics, permanently increasing the costs of doing business in China and placing foreign products at a competitive disadvantage when compared to domestic manufacturers. Furthermore, the new requirements compelling companies to use third-party facilities in China in order to verify claims would undermine China Food and Drug Administration's (CFDA's) efforts to have manufacturers take additional responsibility on themselves and self-regulate their products.

2.4. Canada also expressed concerns with the entry into force date proposed in CFDA's draft. Canadian manufacturers had expressed their inability to comply with these new requirements within six months as significant adjustments to package design and production lines would be required. Given that compliance would be extremely labour intensive, Canada urged China to provide a more appropriate timeline. In addition, Canada requested that products already approved for sale remain on the market until their expiration date in order to minimize any further disruption or lost sales. While Canada acknowledged the need to provide information to consumers, the new requirements did not appear to provide any additional information to consumers. In this respect, Canada welcomed any additional details China would be able to provide on how the proposed changes would enhance consumer safety. Canada trusted that China would make proper adjustments to its current draft to ensure that there was a level-playing field

for Canadian and Chinese cosmetic manufacturers, consistent with China's most-favoured nation obligations and in compliance with its obligations under the TBT Agreement, taking into account widely accepted international practices in this sector.

2.5. The representative of the United States supported the public health objective of China's Administrative Measure on Cosmetic Labelling, indicating that the US also utilized labelling to educate consumers. When providing information on overlay labels before importing, the US Food and Drug Administration (FDA) required that stickers be permanently affixed to the package such that they could not be easily removed, as cosmetics came in different shapes, sizes and materials (of particular concern were slick plastic tube containers), while not causing additional violations such as covering or obscuring required information on the original package. The US Federal Food Drug and Cosmetic Act (FDCA) required that labels contain the following information: (1) the name and place of business of the manufacturer, packer, or distributor; (2) a statement of the net quantity of contents; (3) a statement of identity; (4) a list of ingredients; and (5) in certain cases, a warning statement required by an FDA regulation issued under the authority of section 602 or a colour additive regulation. The FDA's regulations also provided that, if the label for a cosmetic product contained any representation in a foreign language, then all of the information required to appear on the label under the FDCA must also appear in that foreign language.

2.6. She explained further that when providing information on overlay labels after import, the FDA required a written agreement be in place with the import broker that the importer would meet the conditions prescribed above. For the import of cosmetics, for which the importer was the operator of an establishment where the cosmetic was going to be repackaged and labelled, the FDA required evidence to establish the relationship between the importer and the cosmetic products at the time of import. If an agreement was not in place, the product was subject to FDA refusal because the product appeared to be misbranded. The written agreement for import brokers needed to include (1) the compliant labelling information; (2) signature by the consignee; (3) the post office address of the person or operator; and (4) a statement that the cosmetic product would not be adulterated or misbranded upon the completion of processing, labelling, or repackaging. The agreement needed to be retained for two years after the final shipment and both parties needed to have a copy.

2.7. If the repacker/e-labeler was not the person introducing the shipment to the United States, then the party doing so needed to be properly listed as the consignee in the entry/ importation records. It was a best practice to notify the appropriate FDA District Office of upcoming entry of cosmetic products as it had the authority to inspect the consignee, after the release of the product, in order to verify that the relabelling or repackaging actually occurred in the agreed manner. This labelling exemption permitting over-labelling after import would be void, however, if the product was moved from the listed establishment without the required relabelling/repackaging. Cosmetic products that were allowed entry without conforming to FDA labelling specifications had to be repackaged or relabelled before distribution. If the original or revised labels declared a colour that was not certified or permitted by FDA, the product could be considered adulterated or misbranded and was subject to refusal by FDA.

2.8. The US was of the view that CFDA's proposal to ban over-labels on cosmetics imports appeared to be a departure from global norms and could lead to significant time-to-market delays and commercial losses for US cosmetics manufacturers. It could also negatively impact consumer safety in China by increasing counterfeiting and grey-market products. The US hoped that China would suspend implementation of the labelling regulation until further dialogue with Members and relevant stakeholders in order to develop a cosmetics labelling measure that addressed China's safety concerns without adversely affecting trade. It needed to include a reasonable transition period, allowing importers to comply fully with the regulation, and ensure that domestic and foreign companies received the same regulatory treatment without unnecessary burdens on foreign producers.

2.9. The representative of the Republic of Korea welcomed the continuing efforts made by CFDA to amend the regulations on cosmetics labelling, reflecting the concerns raised by WTO Members. However, Korea had new concerns associated with the proposed cosmetic labelling regulation. Firstly, it was Korea's understanding that Article 7 of the regulation prohibited over-labelling such as using stickers on cosmetic products, which was broadly allowed in many countries, including the US, EU and Korea. This meant that manufacturers would have to delay their exports to China because the required registration number could only be issued after obtaining the sanitary

approval according to the labelling regulation. Furthermore, manufacturers had to make separate packaging for the Chinese cosmetic market only. Therefore, Korea was of the view that China's over-labelling ban would not only incur significant burden but also generate extra costs for the cosmetic industry, in particular for SMEs. In this regard, Korea requested China to revoke the over-labelling ban in the notified measure.

2.10. Secondly, Article 19 and Article 20 of the regulation stated that each efficacy indicated on the labelling had to be verified by the testing organizations designated by the Chinese authorities. Korea agreed that this verification needed to be credible. Nonetheless, given that verification on basic efficacy of cosmetics such as moisturization was often conducted under the manufacturer's responsibility on a voluntary basis, requiring the verification by a third testing body appeared to be over-engineered regulation. The regulation would impose significant burdens and expenses to the cosmetic industry without any benefits to consumers and manufacturers. Korea sought further clarification on whether foreign testing bodies could also be designated by the Chinese authorities. In addition, Korea requested that China narrow the scope of cosmetic efficacy subject to verification by clarifying which efficacy claims needed to be proven and allow manufacturers to verify the efficacy of their own products. In conclusion, Korea requested China to provide a two-year transitional period so that manufacturers could be acquainted with the major changes introduced by the new provisions.

2.11. The representative of the European Union reiterated concerns sent to the Chinese authorities on 12 January 2015. He noted that the notified draft introduced significant changes to the current requirements on the labelling of cosmetics products, which would essentially oblige economic operators to produce specific packaging for the Chinese market. Firstly, the notified draft stated that "Cosmetic labels ... shall not be modified or supplemented by sticking, cutting, altering etc." Could Chinese authorities confirm whether they intended to prohibit the placing of stickers over the original label *per se* or whether only stickers that modified or altered the content of the original labelling were forbidden? In the EU, as well as in many other countries, cosmetic products could be labelled by means of stickers, provided those stickers were accurate and not easily detachable. Prohibiting the use of stickers would create a *de facto* systematic requirement for China-specific primary and secondary packaging, substantially increasing costs for packaging design, as well as continuous costs regarding specific production lines for packaging production, product filing and inventory management. He asked if complete and accurate labelling information in the Chinese language by means of stickers might be accepted as a sound alternative to China-specific labelling/packaging. The EU had recently received information that the Chinese authorities would allow the use of stickers on imported products, as long as all information indicated in the original language on the packaging was translated into Chinese.

2.12. Secondly, the notified draft required the products to display the name and address of the manufacturer and of the subcontractors when part of the production was done by subcontractors. The EU agreed that the name and address of the manufacturer or, in the case of imported products, of the Chinese enterprise responsible for the product, should be labelled on the product to establish clear and enforceable responsibility within China. However, additional labelling of the name and address of manufacturing subcontractor(s) was not necessary and might be confusing for the consumer. The EU therefore invited China to consider requiring only the name and address of the manufacturer legally responsible for the product and to waive the requirement to provide the name and address of subcontractors.

2.13. Furthermore, the EU sought 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 CFDA. Any requirement for third party verification by a Chinese organisation would be more trade-restrictive than necessary. The EU also considered that the requirements regarding cosmetic claim substantiation should be aligned and compatible with international best practices and provide general criteria and guidance rather than regulate specific wording. Requirements for the publication of detailed claim substantiation reports on a website could be damaging to the intellectual and commercial property rights of a company. Therefore, the detailed efficacy information needed to be accessible only to official control authorities, who had appropriate training and expertise to assess scientific study reports and the compliance of cosmetic claims with legal requirements. Finally, as the notified draft would bring significant changes to the current practices of the cosmetic industry and the competent authorities in China, the EU requested the granting of a transition period of at least 24 months. The EU also invited the CFDA to publish

practical guidance at an early stage during the transition period so as to ensure a harmonised understanding and smooth application of the new measures.

2.14. The representative of Japan, expressing support for the positions of Canada, EU, Korea and the US, recognized that the new draft Administrative Measures on Cosmetics Labelling was designed to greatly strengthen the present cosmetics labelling regulations in China. However, if the proposed measures were implemented, the global cosmetics industry active in the Chinese market, including Japanese firms, would suffer an immense economic blow. In addition, Chinese consumers would also suffer from conspicuous disadvantages.

2.15. The representative of China explained that cosmetic labelling was essential for consumers to understand basic information regarding cosmetic products and that it was one of the most important aspects of cosmetic supervision for most Members. In 2012, the CFDA had drafted the Cosmetics Label Instructions Regulations and Guidance for the Cosmetics Label Instructions (G/TBT/N/CHN/937) to solicit public opinion; however, it had never gone into effect and was now replaced by AMCL. Furthermore, in November 2014, AMCL had been put online to solicit public opinion and the CFDA had subsequently received feedback from domestic as well as foreign cosmetic enterprises and industry associations. China assured Members that AMCL, which was still being drafted, would follow international rules and give full consideration to the valuable inputs from interested parties.

2.2.2.2 China - Banking IT Equipment Security Regulation

2.16. The representative of the United States said that the China Banking Regulatory Commission had on 26 December 2014 issued "Guidelines for Promoting the Application of Secure and Controllable Information Technology in the Banking Sector", including the accompanying Classification Catalogue of Banking Information Technology Assets and Indexes of Security and Controllability. Under the regulations, commercial banks would be required to purchase an increased percentage of information and communications technology (ICT) products to comply with a series of requirements, some of which had a potential to create unnecessary obstacles to trade. The regulations appeared to require government pre-approval for a wide range of commercial ICT and encryption products, including the disclosure of source code and other sensitive design information, which was a matter of enormous concern to industry. Other provisions of the Guidelines appeared to be of concern from a TBT perspective as well. The Guidelines required "tests and certification" to be conducted by state regulators and laid out product requirements that were based on design and descriptive characteristics (e.g. equipment that had intellectual property rights (IPR) owned and/or developed by Chinese-invested enterprises or "indigenous IPR") rather than performance requirements. The guidelines also required source code to be filed for registration with the government banking regulatory body. The US was concerned that aspects of the December 2014 Guidelines went beyond usual practice for the regulation of ICT equipment in the commercial banking sector and asked China to provide its objective and rationale to extend certification and testing requirements to ICT products covered in the regulation. Furthermore, the US requested China to suspend implementation of the regulation, conduct a transparent process, allowing meaningful opportunity for comment and enquiries by all interested stakeholders, and notify the TBT Committee.

2.17. The representative of the European Union, supporting the US statement, said that the regulation was another worrisome development in the area of IT and encryption in China. As with other similar measures, there had been a total lack of transparency, with no opportunity for public comments or publication in an official journal while the guidelines had only been communicated to banks. The guidelines clearly qualified as a technical regulation and contained conformity assessment procedures and hence should have been notified under the TBT Agreement. The EU requested China to abide by its obligations under the TBT Agreement to notify the regulation and postpone its application until consultations had been carried out. The guidelines would require Chinese banks to only procure equipment which incorporated indigenous technology manufactured domestically. With regard to conformity assessment procedures, foreign manufacturers would have to surrender key technologies to the Chinese authorities, putting at risk vital elements of their business. In addition, the scope of products affected was also of concern. As also indicated by European banks operating in China, the IT systems operating in China needed to be compatible with the global infrastructure. Therefore, preventing foreign banks from using foreign technology could lead to security challenges for banking IT systems worldwide. The EU sought clarification on the objective and rationale of the guidelines and also on the relationship between this measure

and another set of Chinese measures in area of IT security, which were the subject of another specific trade concern (IMS item number 294) raised by the EU. The EU asked how the new regulations would coexist with the previous ones and emphasised the importance of international cooperation in this area to develop resilient systems, which deployed the best possible technology globally.

2.18. The representative of Japan stated that the guidelines required that the banking information technology equipment contain indigenous Chinese intellectual property and that the equipment go through assessment procedures and obtain a certification based on a particular set of criteria. Japan questioned the consistency of these requirements with obligations under the TBT Agreement, particularly non-discrimination and refraining from imposing unnecessary trade restrictions. Japan called on China to ensure transparency on this issue as the guidelines had neither been notified to the TBT Committee nor publicised for public comment. Japan also requested that China clarify whether the guidelines were mandatory or voluntary. If the guidelines required that banking technology equipment undergo assessment procedures and obtain certification from the Chinese authorities, then the guidelines would appear to be applied in a mandatory manner. Japan requested details on the conditions of source code disclosure and underlined that it was difficult for companies to disclose their source codes since they contained vital information associated with inter-firm competition. Japan also sought clarity on the State Cryptography regulation which would apply to cryptography modules and on how the new regulation would fit with the existing security regulations such as the Chinese Compulsory Certification (CCC) System, OSCCA regulations, and the Multi-Level Protection Scheme (MLPS).

2.19. The representative of Canada said that while understanding China's desire to minimize threats to its ICT infrastructure, it was of the view that China's approach to "secure and controllable" ICT would decrease, not increase cyber security for China's network and banking ICT infrastructure. Associating himself with the concerns raised by the US, he emphasized that as drafted, China's national cyber security regime and guidelines were far more trade restrictive than necessary to achieve their national security objectives. China's insistence on requirements to divulge and review source code, local content requirements for hardware, software and intellectual property, and mandatory adoption of Chinese encryption processes would violate national treatment obligations under Articles 2 and 5 of the TBT Agreement. Therefore, Canada requested that China explain why it must rely solely on locally sourced products to achieve its national security objectives with respect to secure and controllable ICT and on what grounds foreign-sourced ICT was banned from Chinese networks. In addition, Canada sought further clarifications on how the testing of the foreign ICT products would be undertaken, which criteria would be assessed, and what the specific objective was of requiring the disclosure of intellectual property and encryption with respect to China's stated national security objectives.

2.20. The representative of China reported that the rapid development of the global information technology and financial innovation had brought new challenges to the banking industry that required all Members to strengthen the security of the information network and operational management in the banking system. In 2014, China had issued guidelines for applying secure and controllable information technology to enhance cyber security and construct an IT risk control mechanism in the banking sector. Issuing of such guidelines was consistent with international practice and contributed to the stability of the global financial system. In February 2015, China Banking Regulatory Commission (CBRC) had published a notice online to answer the main concerns of interested parties: With respect to the source codes, the guidelines did not require a full reveal of source codes, but only to keep a file of it. China assured Members that it would give full consideration to opinions of interested parties to finalize the method and process of source code filing. With respect to intellectual property rights, China only required proprietary intellectual property rights, instead of indigenously-developed technologies. The suppliers only needed to provide proofs of independent intellectual property rights or legal proof of origin of their software. Furthermore, the guidelines only requested commercial banks to establish a working mechanism to prevent risks in IT systems and daily operations. This applied equally to both domestic and foreign products and enterprises. The CBRC had met with relevant enterprises and agencies such as USITO, IBM, Oracle and EMC from the US and JEITA from Japan regarding these points and it had also been agreed to build effective communication mechanisms together.

2.21. The representative of the European Union thanked China for its explanation although it did not address questions regarding transparency. He asked for further information on the distinction between "filing" of source code and "disclosure" of source code. In addition, he asked for a

clarification as to whether the requirement for intellectual property (IP) rights from indigenous technology had been waived.

2.22. The representative of China clarified that IP rights did not need to originate in China but that the supplier had to hold IP rights. China was still working on the method for the filing of source code and was willing to work with interested parties on this issue.

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

2.23. The representative of Mexico expressed concerns with respect to the Emergency Technical Regulation No. 088: "Surface tension agents", issued by Ecuador on 22 November 2013 and notified in document G/TBT/N/ECU/117. In particular, Mexico questioned 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/405.

2.24. The representative of Ecuador said that the purpose of Technical Regulation No. 088 on surface tension agents was to prevent risks to human health and safety and the environment, and practices likely to mislead end-users. The regulation was based on Andean Community (CAN) Decision 706 of 10 December 2008 on harmonization of legislation on domestic hygiene products and absorbent personal hygiene products, which was undergoing constant revision. It had been duly notified under the TBT Agreement. Taking into account comments from Members with respect to conformity assessment, Ecuador had amended the regulation 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.

2.2.2.4 Japan – Wood Use Points Programme (G/TBT/N/JPN/471 G/TBT/N/JPN/471/Corr.1)

2.25. The representative of the Russian Federation said that Japan had implemented the Wood Use Points Program (WUPP) as of 1 April 2013 but notified it only on 4 November 2014 in document G/TBT/N/JPN/471. According to the programme, participating consumers who purchase new homes built with a minimum of 50.1% of wood products from selected varieties of conifers would be eligible to receive up to 300,000 Wood Use Points (with an equivalent value in Yen), which could be redeemed through the purchase of specified local products, or alternatively, donated to support certain local economic activities. The WUPP introduced a new conifers classification system, based on the criteria of "growing forest resources", compliance with which was mandatory for participation in the WUPP. Japan had approved a list of conifers for participation in the WUPP, of which 6 species were endemic to Japan and 5 originated from a limited list of WTO Members. Russia traditionally exported wood, *inter alia* to Japan and was therefore concerned about this programme. Since WUPP was a technical regulation within the meaning of Annex 1 of the TBT Agreement, Russia questioned why Japan had not notified Members of the products to be covered by the technical regulation at an early appropriate stage (Articles 2.9.1 and 2.9.2 of the TBT Agreement) and had not allowed a reasonable interval between the publication of the regulation and its entry into force (Article 2.12 of the TBT Agreement). Russia also asked why Japan had not used relevant international standards - Appendices of the Convention on International Trade in Endangered Species (CITES) and the classification of the International Union for Conservation of Nature (IUCN) - as a basis for the technical regulation. None of the standards included conifers in its lists of products subject to trade limitations (Article 2.4 of the TBT Agreement). Furthermore, Russia wondered how WUPP would be consistent with Japan's WTO commitments, specifically the commitment to accord "... treatment no less favourable than that accorded to like products of national origin in respect of all laws, or use" (GATT Article 3.4) and the commitment to accord "... any advantage, favour, privilege ... immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties" (GATT Article 1.1).

2.26. The representative of Japan stated that Japan had explained the Wood Use Points Programme and provided written answers in response to Canada's questions in the context of past meetings of the Council of Trade in Goods. In addition, in light of interest shown and without prejudice to the applicability of the TBT Agreement, Japan had submitted a TBT notification on the

programme (G/TBT/N/JPN/471 and 471/Corr.1), circulated on 4 November 2014. The objective of the programme was, through promoting wood use, to contribute to proper management and conservation of forests, prevention of global warming, and promotion of a recycling-oriented society, as well as to serve for the development of rural areas. In order to achieve this objective in an effective and efficient manner, the eligibility criteria for wood were set out in the programme and some foreign species had also been designated as eligible wood. The program applied both to domestic and foreign wood and ensured that both were treated in a non-discriminatory manner, consistent with the WTO agreements. With respect to timeframe, the entitlement period had ended on 30 September 2014 and no points could be earned for works starting after this date. Furthermore, Japan had published the draft budget for the next fiscal year and it did not contain a similar programme.

2.2.2.5 Russian Federation – Technical regulations on safety of railway transport (TR CU No. 001/2011, No. 002/2011 and No. 003/2011)

2.27. The representative of Ukraine raised concerns regarding technical regulations applied by the Russian Federation on railway transport safety: TR CU 001/2011 On Safety of Railway Rolling Stock, TR CU 002/2011 On Safety of the High-speed Railway Transport and TR CU 003/2011 On Safety of Railway Transport Infrastructure. As a member of the Customs Union, the Russian Federation used two systems of conformity assessment procedures - mandatory certification and conformity assessment – covering a considerable list of products subject to mandatory certification of conformity in the area of railway transport. Ukraine considered this two system approach as overregulation and unnecessarily trade-restrictive, hence in violation of Article 2.2 of the TBT Agreement, which, *inter* alia, stipulated that technical regulations shall not be prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. In particular, Paragraph 9 of Article 6 of TR CU 001/2011, paragraph 3 of Article 6 of TR CU 002/2011 and paragraph 13 of Article 6 of TR CU 003/2011, specified that for the certification, the applicant should be a legal entity (or individual entrepreneur) registered under the laws of the Customs Union member states in their territory, and be a producer or a seller, or, act as foreign supplier under a contract. These requirements provided less favourable conditions for suppliers from other WTO Members than those accorded to suppliers of like products of national origin (e.g. originating in the Customs Union). Hence, these requirements were inconsistent with the provisions of Articles 5.1.1 and 6.4 of the TBT Agreement.

2.28. In addition, she said, the requirement for mandatory registration resulted in additional costs for assessing the conformity of like products originating from WTO Members compared to those of national origin, leading to non-compliance with paragraph 2.5 of Article 5 of the TBT Agreement. This related to the registration of legal entities in the territory of the Customs Union or conclusion of contracts with existing legal entities, registered in the territory of the Customs Union. Other Ukrainian concerns were related to the lack of recognition of equivalent technical regulations according to Article 2.7 and the refusal to negotiate and conclude agreements for the mutual recognition of results of conformity assessment procedures according to Article 6.3 of the TBT Agreement. In November 2013, Ukraine had proposed a relevant draft agreement on mutual recognition of results of conformity assessment procedures; however, the Russian Federation and the Eurasian Economic Commission had insisted on using the mechanism provided for in the Agreement of the Customs Union member states on removing technical barriers in trade with CIS countries that were not Members of the Customs Union as of 17 December 2012. According to the mentioned mechanism, non-Members had to adopt the technical regulations of the Customs Union on an alternative or as single-option basis. Hence, the Customs Union Agreement required that non-members comprehensively adopt technical regulations and conformity assessment procedures of the Customs Union to be able to supply products in its territory. This created unnecessary obstacles to international trade and a technical barrier by nature, as understood in the TBT Agreement. Ukraine requested that these concerns be taken into positive consideration by the Russian Federation in good faith and with a view to ensuring compliance of the Customs Union's technical regulations with the provisions and principles of the TBT Agreement by addressing safety objectives in a less trade-restrictive manner.

2.29. The representative of the Russian Federation said that these technical regulations had been adopted in July 2011, before the accession of Russia to the WTO. Despite the fact that Russia was not a WTO Member at the time, it had provided a very reasonable period of three years between their adoption and entry into force, in full accordance with Articles 2.12 and 5.9 of the TBT Agreement. The decision on the adoption of these technical regulations contained very soft

transitional provisions. Following the entry into force of the technical regulations in July 2014, product certificates already issued were valid until the end of their validity, but not later than 1 August 2016. In addition, the production and circulation on the market of products conforming to previously established specifications was also allowed until 1 August 2016. Moreover, the production and release into circulation of Eurasian Economic Union (EAEU) products that were not subject to mandatory assessment (confirmation) of compliance with mandatory requirements was also allowed until 1 August 2016. In fact, the Russian Federation and the EAEU had provided a five-year period between the adoption and entry into force of the technical regulations to allow time for producers in exporting Members to adapt their products or methods of production to the new requirements. Conformity assessment procedures were the same for domestic and imported products.

2.2.2.6 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)

2.30. The representative of Australia said that in December 2014, the Indonesian Government had issued a regulation limiting imports of beef to prime cuts and some offal and manufactured meat. While the regulation had subsequently been amended in January 2015 to allow imports of secondary beef cuts by state-owned enterprises in limited circumstances, Australia remained concerned that the measure effectively restricted the import of secondary beef cuts and offal. The regulations also imposed a number of requirements - including packaging, labelling and purpose of usage requirements - on imported beef products that did not apply to domestically-produced beef. Australia was concerned that this action by Indonesia unjustifiably restricted trade. Australian industry was already feeling the effects of the regulation, which had been introduced without notice or consultation with trading partners. Australia understood the complexities being faced by Indonesia as it sought to meet its food security goals and was working with Indonesia to help supply food security, including through cooperation to increase capacity in Indonesia's beef industry. Australia encouraged Indonesia to look at alternative policies that were WTO-consistent and that did not restrict high-quality Australian products which were a safe and reliable contribution to Indonesia's food supply. He requested that Indonesia explain in detail the objectives of the regulations and whether it considered that the import restrictions on secondary beef-cuts and offal under the decree met the definition of technical regulation under the TBT Agreement, and if so, on what basis.

2.31. The representative of the European Union shared concerns raised by Australia concerning the Indonesian Regulation, which effectively banned imports of most secondary cuts of meat and would allow only state-owned enterprises to bring them in at times of shortages. The EU asked how Indonesia ensured that these measures guaranteed that products imported from the territory of any Member were treated no less favourably than products of national origin, as required in Article 2.1 of the TBT Agreement and that they were not prepared, adopted or applied with the effect of creating unnecessary obstacles to international trade as required in Article 2.2 of the TBT Agreement. The EU also wondered why Indonesia had not allowed a reasonable interval between the publication of these regulations and their entry into force, in order to allow time for producers in exporting Members to adapt to the requirements of the regulations as required by Article 2.12 of the TBT Agreement.

2.32. The representative of Canada supported the concerns raised by Australia regarding the broad scope of the proposed regulations and the timeliness of the notification. Canada was concerned that the proposed measures might be unduly trade restrictive, and that no time had been provided for comments from trading partners. Canada also questioned the appropriateness of notifying the proposed regulations to the TBT Committee. Measures designed to address food supply and price volatility did not appear to be directly related to TBT objectives. Canada urged Indonesia to provide more clarity regarding its proposed measure and provide sufficient time for comments before bringing these proposed regulations into force.

2.33. The representative of Indonesia said that they were unable to provide detailed responses at the meeting but that they would report back to their capital regarding these concerns. For a preliminary response, he explained that the objective of the regulation was to improve the

distribution chain of meat with a view to ensuring that price in the market reflected actual demand and supply of meat. Indonesia had identified some situations in which there was abundance of meat available (either domestically produced or imported) but without an appropriate price adjustment, due to flawed distribution chains. The provisions stipulated in the regulations were aimed at ensuring a fair market mechanism and preventing unnecessary disruption in the meat supply, which may cause anomalous price increases. Since the 60-day comment period provided for in the notification was still available, he suggested that Members also send written enquiries to the national enquiry point.

2.2.2.7 Mexico – Standard on non-alcoholic and soft drinks

2.34. The representative of El Salvador thanked the Mexican delegation for having attended consultations regarding their concern on the interpretation and implementation of a Mexican standard for juices and non-alcoholic drinks, which had resulted in the customs reclassification of one product exported from El Salvador. Despite the confirmation of El Salvador's classification of the product through laboratory analyses undertaken in Mexico, the Mexican authorities had still not changed their position with respect to the product's classification. El Salvador was of the view that the measure was going beyond what was established by the standard, hindering trade flows into the Mexican market. Therefore, El Salvador was approaching Mexico through various fora, including the WTO, to find a solution to this problem.

2.35. The representative of Mexico said that they had been informed of this concern only a few days earlier, following which bilateral discussions in Geneva and a conference call between authorities in capitals had already taken place. As regards the regional context, no concerns pertaining to Mexico had been raised during the December 2014 meeting of the TBT Committee established under the Free Trade Agreement between Mexico and Central America and which also provided a forum for raising specific trade concerns. Moreover, Mexico was not of the view that the issue involved a measure covered under the TBT Agreement or the TBT Chapter of the Mexico-Central America Free Trade Agreement. The Mexican Government department responsible for the negotiations on market access had explained that the issue involved a discrepancy in tariff classification. The discrepancy arose from the analysis of the physical and chemical characteristics of the product and the difference between "fruit juice based beverages" and "flavoured waters", within the meaning of the international Harmonized System nomenclature. For a proper technical opinion, it was advisable to consult the Explanatory Notes to the Harmonized System. Since the Explanatory Notes did not establish quantitative limits for products of subheadings 2202.10 and 2202.90, reference had been made to the Mexican Standard NMX 439 1983 "Foods, Non Alcoholic Beverages, Beverages and Soft Drinks: Classification and Definitions", which set out the criteria for distinguishing between the various types of beverages. It was not a matter of applying the Mexican standard but of referring to it in order to differentiate between "flavoured waters" and "fruit juice based beverages" and determine the difference between "mineral waters or aerated waters, containing added sugar or other sweetening matter, including flavoured waters" and "other non-alcoholic beverages". According to the results of the analyses carried out by Mexico's Customs Laboratory, the imported products were non-alcoholic fruit flavoured beverages, ready-made for consumption, whose ingredients consisted of water, added fruit juice in a proportion ranging between 2.5% and 4%, sugar (between 3% and 6.1%) and thickeners; therefore, they could not technically be considered as "fruit or vegetable beverages." Similarly, a beverage with a juice content of less than 10% of total product weight could not be said to be a juice based beverage but rather a beverage to which flavouring had been added, or, in other words, a flavoured beverage. In short, this issue was a tariff matter that did not lie within the purview of the TBT Committee and raised a systemic concern because otherwise the distinction between "tariff measures" and "non-tariff measures" would be lost.

2.2.2.8 Canada - Tobacco Reduction (Flavoured Tobacco Products) Amendment Act, 2013 – Bill 206

2.36. The representative of Indonesia said that according the information they had received, the Government of Alberta Province (Canada) would soon enforce "Tobacco Reduction (Flavoured Tobacco Products) Amendment Act, 2013 – Bill 206", an amendment which would prohibit the use, distribution, and sale of "flavoured tobacco products", understood to be tobacco products with a characterising flavour. However, there was an indication that in practice, menthol cigarettes would get an exception to remain traded. The Act, which was going to be applied as of 1 June 2015, would presumably be a barrier for market access of clove cigarettes from Indonesia intended to be

sold in Alberta Province and was likely to set a precedent for other provinces in Canada. In addition, the Act would affect the production of clove cigarettes in Indonesia. The export of tobacco products to Canada had recently dropped dramatically. The exception for menthol cigarettes was a form of discrimination, which contravened one of the basic WTO principles and was similar to the policy issued by the US government, which had later become the subject of a dispute between the US and Indonesia. Indonesia urged Canada (especially Alberta Province) to postpone the implementation of the regulation since it would lead to differences in treatment between clove cigarettes and menthol cigarettes in Alberta Province. Indonesia did not see any scientific evidence for the effectiveness of the policy and suggested that Canada avoid this kind of policy to prevent unnecessary future disputes, similar to that between the US and Indonesia.

2.37. The representative of Canada said that considering the late submission of the specific trade concern, they were not in a position to provide a detailed response. Canada's representative noted Indonesia's concerns and said that he would discuss them with provincial counterparts in Alberta. He added that both the Canadian Government and the Alberta Government were committed to dealing with smoking issues, which the measures in question were designed to address. Furthermore, he indicated that Canada had a very transparent legislative process and that it took its WTO obligations seriously.

2.2.3 Previously raised Specific Trade Concerns

2.2.3.1 India – Pneumatic tyres and tubes for automotive vehicles[2] - IMS ID 133

2.38. The representative of the Republic of Korea expressed his delegation's disappointment with India's lack of response to this concern raised repeatedly by several Members and reiterated concerns regarding the Indian Quality Order on Pneumatic Tyres and Tubes for Automotive Vehicles, in particular the ISI marking fees and the discriminatory bank guarantee on foreign tyre manufacturers. The ISI marking fees were being levied on all tyres with the ISI mark, even on those sold in other overseas markets. Korea was of the view that it was quite unfair and unjustifiable to impose a loyalty, even for the products heading to the other countries' markets. Also, India had mentioned at the previous TBT meeting in November 2014 that there was a possibility that goods sold in overseas markets might eventually land in India at a later date. The bank guarantee of USD 10,000 was intended to protect the interests of the Bureau of Indian Standards (BIS) and would be invoked in case of breach of any condition of the agreement signed between BIS and licensee. However, Korea could not find any legitimate reference to back up India's argument and requested once again that India take this issue more seriously and show a more positive attitude so as to resolve this issue as soon as possible.

2.39. The representative of Japan referred to Clause 10.2 of the revised agreement, according to which tyre manufacturers outside India were required to pay a bank guarantee fee of USD 10,000 per plant. Since this technical regulation would cause unnecessary competitive difference between factories inside and outside India, Japan requested that India consider amending the regulation. Since the TBT Committee meeting in June 2014, Japan had been requesting India to explain whether or not there was an actual case where the bank guarantee was actually used to compensate loses occurred as a result of a breach of the BIS license agreement and also whether or not India required a similar bank guarantee with respect to products other than tyres. At the TBT Committee meeting in November 2014, India had explained that the ISI marking fee was reasonable because it was not imposed discriminately inside and outside India. However, Japan considered that the ISI marking fee itself was expensive compared to other countries. Japan requested India to show evidence that the ISI marking fee was equivalent to or not expensive compared to other countries. Finally, as the EU and Korea had indicated before, it took quite a long time compared to other countries, namely four or five months, to complete the certification procedures. Japan requested India to consider shortening the time spent on certification procedures.

2.40. The representative of the European Union reiterated their concerns with regard to the Indian Order, which introduced a certification procedure with a mandatory marking for tyres. The EU requested once again that India reconsider its marking fee system, which currently applied to each ISI-marked tyre and not only on those tyres which were actually sold on the Indian market. The EU called for the removal of the royalty fees, which were extremely burdensome and much

[2] G/TBT/N/IND/20, G/TBT/N/IND/20/Add.1, G/TBT/N/IND/40 and G/TBT/N/IND/40/Rev.1.

more restrictive than necessary, or at least for the modification of their calculation to limit them to tyres sold on the Indian market. Furthermore, as already indicated in previous meetings, the EU considered that the USD 10,000 bank guarantee that BIS could use in case of breach of the BIS agreement was both discriminatory and an unjustified practice, because it applied only to foreign manufacturers. India was therefore invited to remove this requirement.

2.41. The representative of India said that most of the issues raised in the meeting had already been explained to interested delegations at many occasions in previous meetings. The "Pneumatic Tyres and Tubes for Automotive Vehicles (Quality Control) Order, 2009", which had been issued on 19 November 2009 and entered into force on 13 May 2011, applied to both domestic and foreign manufacturers. Pneumatic tyres could be imported into India only if they conformed to the specified standards and bore the Standard Mark of BIS. For this purpose, the foreign manufacturers desiring to export their goods to India were required to enter into an agreement with BIS to receive the BIS license, so that they could use the BIS Standard Mark. The foreign manufacturer was also required to furnish a bank guarantee of USD 10,000 in favour of BIS for due compliance of the provisions of the BIS Act, rules and regulations, and terms and conditions of the license. The performance bank guarantee had been deemed necessary in view of a default by a foreign manufacturer in payment of its dues to BIS, which could not be retrieved even after taking up the matter with the Embassy of that country. In case of any violation of the BIS Act or non-payment of the marking fee by a domestic manufacturer, BIS could seek compensation through domestic courts, whereas the Act could not be enforced in foreign countries. The bank guarantee was intended to protect the interests of BIS during the tenure of the license and was invoked only in case of breach of any condition of the agreement signed between the BIS and licensee. It essentially covered any possible loss of revenue for the BIS in cases of non-payment of requisite marking fee dues to BIS and also took care of legal expenses if any. It was also important to bear in mind that the bank guarantee remained with the concerned bank in the form of refundable security and should not be counted as expenditure.

2.42. He explained further that the BIS charged the marking fee on all goods produced and marked with ISI. The marking fee was charged at the same rate to foreign as well as domestic manufacturers and varied from 0.01% to 0.2% of the cost of the product. For example, if the cost of a commercial vehicle tyre was approximately Rs. 20,000, then the marking fee was Rs.2 per tyre, or 0.01%. Therefore, the marking fee could not be considered as exorbitant. Some Members had asked that the marking fee be calculated only on those goods exported to India. He clarified that the marking fee would not be charged in case the manufacturers supplied their goods to other countries without the ISI mark; however, if they covered that supply with the ISI mark, then they were liable to pay the royalty fee to BIS. Moreover, there was a possibility that the goods sold in overseas markets might eventually land in India on a later date. He underlined that it was previously not permitted to supply ISI marked products to any country other than India, and that the entire ISI marked production was required to be supplied to India only. However, as per demand of the international industry, this condition had been relaxed and ISI marked products could now be supplied to any part of world. Preference was given to ISI marked products in many countries, particularly those neighbouring India. As per the feedback received from many companies outside India, they obtained the BIS licence for selling ISI marked products in their country only, and not for exporting to India.

2.43. With respect to the concern that the certification process might take as long as four to five months, he mentioned that the process involved a visit to the applicant's factory to assess its capability as well as testing of samples in an independent lab. Hence, the process could take some time. However, the requests for inclusion of new varieties of tyres in an existing license were processed within two weeks. In response to a query from the previous meeting, he also explained that the license could be renewed for a period of up to two years. As part of the BIS product certification scheme, surveillance was maintained on the performance of BIS licensees through factory inspections, testing of factory samples and market samples. Still, in many cases, renewal of licence had been granted even when no plant inspection had been carried out during the operative period of the licence. As for the additional questions from Japan, they had been addressed during a bilateral meeting and also in writing.

2.2.3.2 India – Drugs and Cosmetics Rules 2007 (G/TBT/N/IND/33) - IMS Item No. 167

2.44. The representative of Canada thanked India for having provided additional clarifications on its Medical Device Regulatory System, in response to their letter sent on October 2014. Nonetheless, Canada remained concerned that India's plans to regulate medical devices might have important economic effects on the Canadian medical device manufacturers and might not be in compliance with TBT obligations. Regarding the Guidance Document on Common Submission Format for Registration/Re-Registration of Notified Medical Devices in India, which came into effect in January 2013, Canada was still very concerned with two of its provisions: the necessity for certificates/licenses to be notarized/attested by the Indian Embassy in the country of origin and the requirement for medical devices to be freely sold in the country of origin. These could be more trade restrictive than necessary given the fact that many Canadian products might be marketed only in jurisdictions other than the country of origin and certificates/licenses issued by leading jurisdictions, including Canada, should not require notarization. He asked whether India had considered less trade restrictive alternatives to pursue its objectives.

2.45. Furthermore, Canada would welcome clarifications with regards to the Performance Evaluation Report requirements for diagnostic kits. In Canada's understanding, the "Consecutive batches" referred to in the Guidance Document referred to release testing, which normally aimed to prevent substandard lots from reaching the market and demonstrate that the device met its specifications. It also provided ongoing/real time monitoring of the manufacturing process. Canada sought confirmation that this type of release testing was what was being referred to in its Guidance Document. Canada also asked whether it would apply to all Notified Diagnostic Kits and whether it needed to be done in India. Canada also welcomed any additional details that India could provide on its future plans for medical device regulation and the status of the Drugs and Cosmetics (Amendment) Bill, 2015, which, as they understood, had not been passed by Parliament yet.

2.46. The representative of the European Union reiterated their request for India, which already allowed the registration certificate number of the brand and the name and address of the registration certificate holder to be labelled by means of stickers, to also allow all aspects of cosmetics labelling, including the list of cosmetic ingredients or any other information relevant for the consumer, to be provided via stickers, which can be attached at customs bonded warehouses. Allowing the information to be provided after imports in customs warehouses was a very important trade facilitating measure that did not jeopardise India's legitimate health and safety objectives. This was particularly relevant for manufacturers that exported small quantities and found it difficult to adapt the labels to different geographical regions requirements.

2.47. Secondly, as already mentioned during the June 2014 meeting of the TBT Committee, the Indian Central Government had amended the legal metrology Packaged Commodities Rules 2011 to require that cosmetic products bear a red or brown dot at the top of the principal display panel for products of non-vegetarian origin and a green dot for products of vegetable origin. In the meantime, the EU had received information that as a result of an ongoing court case, the requirement could be withdrawn following the declaration of the Bombay High Court, allowing producers to decide whether to indicate the red/brown/green dot or not. The EU appreciated receiving further information on this issue. Thirdly, the EU shared the objective of achieving sustainable cosmetics by restricting animal testing for cosmetics ingredients. However, the EU was concerned about India's implementation of its import ban on animal testing for cosmetics ingredients, which did not take into consideration technical possibilities and options of derogations in exceptional circumstances.

2.48. Furthermore, the EU was still concerned with and sought further information on the application of a new importing checklist to check compliance of imported products with the Indian requirements. The EU was informed that through this checklist, India required market operators to provide data and tests that were not provided for in the basic Cosmetics Law of 2010, while the previous checklist used by Drug Controller General of India (DCGI) had been in line with this law as well as the guidance document issued in 2013. Finally, the EU requested India to notify to the TBT Committee the latest draft amendments of the Drugs and Cosmetics Act and of the Drugs and Cosmetics Rules, 1945, which had already been made available for public consultation.

2.49. The representative of the United States associated herself with the comments from Canada and the EU and stated that the US appreciated the bilateral consultation on the Drugs and Cosmetics Rules held earlier during the week. She further requested India to notify the amendments to the TBT Committee and allow for comments from interested Members.

2.50. The representative of India said that there had been no change in the regulatory status regarding the question of allowing stickers to display all labelling information on cosmetics since the previous meeting, during which India had made a statement on this issue (Para 2.81 of G/TBT/M/64/Rev.1). Only the registration certificate number of the brand and the name and address of the registration certificate holder was permitted via stickers. Hence information pertaining to all other aspects of cosmetic labelling, including the list of cosmetics ingredients or any other information for the consumer, was not allowed via stickers under the Drugs and Cosmetics Rules. Furthermore, the current rules did not allow "stickering" for placing brown or green dots at the top of the principal display panel to reflect whether a cosmetic product had a non-vegetarian or vegetarian origin. India had already forwarded replies to the Canadian delegation regarding India's regulatory system on medical devices and was willing to provide further clarification on the matter.

2.2.3.3 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

2.51. The representative of Canada reiterated concerns regarding China's Food and Drug Administration's (CFDA) burdensome approval and registration process for cosmetic products. The lack of progress in approving new ingredients was a serious barrier to trade. According to Canada, the "positive list" approach did not ensure an improvement in safety compliance and was redundant with regulation mechanisms already in place. The "positive list" approach might actually prevent Chinese consumers from accessing safer and more innovative cosmetic products. CFDA's intention to define what was a "new" vs. an "existing" ingredient according to a positive list risked a characterization of thousands of ingredients that were already sold on the Chinese market as suddenly "new". Canada recognized that CFDA published an annual report which outlined the CFDA approval rate of special and non-special imported cosmetics. According to CFDA, 2,494 special cosmetics and 11,726 non-special imported cosmetics were approved in 2013. He asked China to clarify the share of these 2013 approved cosmetics that contained "new ingredients". Domestic cosmetic manufacturers were able to register "new ingredients" without an additional application process, and China applied a different registration process for its domestic cosmetics manufacturers than it did for importers. Streamlining the approvals processes for imported cosmetics and applying the same registration process applied to domestic cosmetic products would create a fair trade environment for the cosmetic industry, consistent with the TBT Agreement.

2.52. The representative of Japan reiterated two specific concerns regarding guidance for application and evaluation of new cosmetic ingredients ("the Guidance"). Firstly, he noted that since the implementation of the Guidance in May 2011 only four new ingredients had been registered, and there remained significant difficulties for export of cosmetic products to China with new ingredients. Japan therefore requested China to accelerate examination of new ingredients. Secondly, the Guidance required safety evaluation data to be submitted for each single molecule isolated from plant extracts and fermented solvents. This requirement was excessive and trade restrictive and this requirement did not feature in the safety evaluation practices for cosmetic ingredients of other countries, such as the United States, the European Union, and Japan. He asked China to revise the Guidance, so that cosmetic manufacturers were able to register new ingredients without the additional process of isolation of new ingredients. Finally, Japan requested clarification from China as to the scientific basis for requiring evaluation of single molecules isolated from a complex ingredient, as well as the product safety risk which could arise in evaluating a complex ingredient without isolation.

2.53. The representative of the European Union reiterated concerns in relation to the pace of progress on the procedure for the authorization of new ingredients. The EU was still of the opinion that the new registration procedure was not delivering with the speed, efficiency and predictability necessary. Given that several new ingredients were developed per year, and that only four had been registered in the last four years, the EU asked how did the new system of ingredient authorisation worked in practice, and whether there were any positive developments that could be shared by Chinese authorities at the meeting. An authorization procedure restricted to only certain

ingredients, such as UV filters, colorants and hair dyes, would be more adequate, as cosmetics were not pharmaceuticals. For the remaining ingredients, which represented the majority of cosmetic ingredients, the safety characterization and assessment should be done under the responsibility of the manufacturer. In this context, the EU suggested two proposals to China: to limit the procedure for registration of new ingredients to priority substances - i.e. higher risk substances - and allow a lighter procedure for lower risk substances; and, to share the safety responsibility for new ingredients between China's Food and Drug Administration (CFDA) and the registrant company for low risk substances. Finally, he noted that EU concerns on the Chinese requirement on the labelling of cosmetics had already been covered earlier in this meeting under the first new STC raised.

2.54. The representative of China reminded the Committee that since the notification of the measure in July 2011, the CFDA offered specialized training and guidance on the difficulties enterprises had met in the implementation of this measure. In addition to cooperation at the governmental level, CFDA had kept bilateral channels open and formed several working groups on this issue with several Members. CFDA had paid great attention to the approval of new cosmetic ingredients. China continued to communicate with experts and industry associations in China and abroad, and was carrying out further research on this issue. In addition, China was seeking effective ways to administrate cosmetics through cooperation with Members. The approval procedure was being carried out in an orderly fashion. By the end of 2014, CFDA had approved 13,511 imported cosmetics applications. China remained available to discuss the issue bilaterally and welcomed further cooperation and valuable inputs from interested parties.

2.55. The representative said that the "inventory of used cosmetics ingredients in China" was still under drafting, and that it was not a "positive list" on cosmetic materials, but only developed to distinguish if one material was firstly used in cosmetics produced or sold in China. The document designed a sole standard on approving new cosmetic materials, to prepare for devolving responsibility of managing imported "normal cosmetic" registrations to provincial level authorities. CFDA had carried out two rounds of public consultation, and industry had added over 10,000 existing materials to the document. Except for the materials banned for safety hazards, all cosmetic materials that had been used on the Chinese market were going to be included in the document. She noted that all materials were to be marked by both their Chinese and INCI name. At the present stage, CFDA was still finalizing the document.

2.56. Regarding the "Adjustment of Cosmetic New Ingredient Registration Management" (G/TBT/N/CHN/1019), China explained it was issued to accelerate the approval procedure of new cosmetic materials through an adjustment on administration level. In addition, China noted that Cosmetics Label Instructions Regulations and Guidance for the Cosmetics Label Instructions (G/TBT/N/CHN/937) was replaced by Administrative Measures on Cosmetic Labelling (AMCL).

2.2.3.4 India – New Telecommunications related Rules (Department of Telecommunications, No. 842-725/2005-VAS/Vol.III (3 December 2009); No. 10-15/2009-AS-III/193 (18 March 2010); and Nos. 10-15/2009-AS.III/Vol.II/(Pt.)/(25-29) (28 July 2010); Department of Telecommunications, No. 10-15/2009-AS.III/Vol.II/(Pt.)/(30) (28 July 2010) and accompanying template, "Security and Business Continuity Agreement") - IMS ID 274

2.57. The representative of Canada reiterated concerns with respect to India's test requirements for telecommunications products. India's in-country security testing regulations for telecommunications products would hinder or possibly shut Canadian exporters out of the Indian market. Canada disagreed with India's blanket approach to testing in the telecommunications sector, and still did not understand why Common Criteria (CC) testing was not appropriate for India's telecommunications framework, given that it was already internationally accepted. Recognition by India of foreign conformity assessment bodies accredited by signatories to the ILAC/IAF mutual recognition agreements (MLAs) to test and certify to India's regulatory requirements would minimize the negative impact on companies wishing to export to India while at the same time providing assurance to India that the recognized conformity assessment bodies were competent. Moreover, allowing accredited foreign conformity assessment bodies to test and certify to India's regulatory requirements would reduce testing costs and allow exporters to bring their products to the Indian market more quickly. He asked India to provide a detailed rationale and justification for deviating from Common Criteria testing.

2.58. The representative of the United States acknowledged India's extension of the implementation date for in-country testing to March 2015, but noted with concern that this date was fast approaching, and there were continued concerns with India's planned security testing of telecommunications equipment. She asked for confirmation as to whether the April 2015 enforcement date would be extended. The US voiced serious and fundamental concerns with the new license amendment regime, especially with respect to the domestic testing requirement in the telecommunications sector. The US continued to disagree with India's premise that domestic testing was either necessary or sufficient to meet India's legitimate security concerns, and noted that India had yet to articulate an explanation of how testing a product in-country in India advanced its security objectives. The testing requirement was difficult to reconcile with India's certification under the Common Criteria Recognition Arrangement (CCRA), by which India had agreed to accept the results of CC tests conducted outside India. Having supported India's CC certification, the US was particularly disappointed to see no change in the revised licensing amendment.

2.59. The representative of the European Union joined Canada and the US in reiterating concern about the imminent entry into force of the information security testing clearance and the related in-country testing requirements. While thanking India for its willingness to engage in discussions with European Industry and with the EU, the EU was of the view that the system was not ready for implementation on 1 April 2015 and asked India to consider further postponement of the measure.. Until then, it was the EU's understanding that a status quo would apply and that foreign test results would continue to be accepted. The EU welcomed confirmation by India at previous meetings that relevant tests would have to be carried out according to international standards, namely the common criteria ISO/IEC 15408 Common Criteria standard, ISO 27000 for information security management systems, and the standards developed by the third generation mobile technology partnership project, 3GPP and 3GPP2, as regards telecom and telecom network elements problems. The EU representative also understood that India was in the process of joining the 3GPP2, a step also welcomed by the EU towards ensuring lasting adherence by India to standards developed by this platform. Test results from laboratories appointed by the Common Criteria Recognition Arrangement (CCRA) would continue to be accepted also beyond 1 April 2015 for the purpose of the required security assurance, which would be in line with India's obligations as a full member of the CCRA. The EU invited India to continue discussing with telecom equipment suppliers to develop working methods and procedures reflecting international practice. As for security aspects of mobile telecom elements which were not covered by the Common Criteria standard, the EU asked that India accept results of qualified foreign laboratories holding accreditation from ILAC MRA signatories beyond 1 April 2015, and that India therefore not require exclusively in-country testing, but instead continue to accept foreign test results as a basis for any certification to be issued in India by appointed certification bodies.

2.60. He. The representative of Japan supported the Canadian, EU and US positions, and confirmed Japan's interest in the Unified Access Service Licence Agreement and requested India to ensure that Indian telecom regulations did not impede market access for foreign industries.

2.61. The representative of India recalled his statements from the previous meeting, and presented some updates on the current state of play. On the issue of whether compulsory in-country testing would start from 1 April 2015, he informed Members that the requisite infrastructure was being planned and therefore the date of entry into force of in-country testing was likely to be extended. With respect to whether test certificates from foreign laboratories such as CCRA and ILAC would be accepted, he stated that the licensees shall induct only those network elements into their telecom network which had been tested as per relevant contemporary Indian or International Security Standards. The standards to be tested against were, for example: for IT and IT-related elements against ISO/IEC 15408 standards; for Information Security Management Systems against ISO 27000 series; for Standards, Telecom and Telecom related elements against 3GPP security standards and 3GPP2 security standards. These tests were to be conducted by any international agency/lab proficient in testing against these standards, such as CC labs in case of ISO/IEC 15480 standards, until 31 March 2015. As from 1 April 2015, the certification was to be provided only from authorized and certified agencies/labs in India. However, this date was likely to be extended.

2.62. He further stated that moving to an authorised nation from a consuming nation for testing under CCRA did not change India's position with regard to the requirement for security testing and certification of telecom equipment from labs located in India due to national security

considerations. As stated earlier, the CC testing was limited to IT and IT-related products, and being a process based testing, largely addressed the issues of commercial security consideration. It did not address the national security issues. Moreover, when an IT product was used in telecom network, it became a telecom network element where functional or operational requirements were governed by 3GPP or 3GPP2 standards. India believed that security testing of telecom equipment with respect to India's Department of Telecommunication's user specification would not be considered an infringement of CCRA. However, in respect of testing of IT products to be used in telecom network which had already been tested under CCRA, leverage would be given to the CC testing and additional tests, if required, would be carried out as per the prescribed systems, processes and standards.

2.63. India reiterated that in-country security certification testing of telecommunications equipment had been mandated due to the fact that in the modern age, telecommunications equipment was vulnerable to the spyware and malware attacks. He said that network element wide test requirement would be part of the guidelines for in-country testing. Finally, he informed Members that the TSDSI (Telecommunications Standards Development Society of India), an Indian Telecom SDO, was already an organizational partner of 3GPP.

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

2.64. The representative of Canada expressed concern with China's overall regulatory approach in the information technology sector, in particular, that it 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.

2.65. The representative of the European Union requested that a link be established between this specific trade concern and the new specific trade concern raised on China - Banking IT Equipment Security Regulation. The EU requested clarification on the relationship between the guidelines for the banking sector and the existing framework for information security products. The extent, for instance, to which the commercial encryption regulation of the Office of State Commercial Cryptography Administration (OSCCA) would be relevant for the implementation of the guidelines for equipment procurement by banks. In addition, the EU inquired about the extent to which banking was considered as critical infrastructure, and whether the Multi-Level Protection Scheme would be relevant for the implementation of the guidelines.

2.66. The EU noted that the revision of the OSCCA regulation on commercial encryption products had been on the agenda of the State Council legislative office for several years. He requested an update on the process and the content of the revised regulation, and when the measure was going to be notified to the TBT Committee. He requested an update on the implementation of the Multi-Level Protection Scheme (MLPS) in light of the new cyber security strategy being implemented by China. In this respect, he emphasised the importance of ensuring transparency, predictability for market access, and the need for a clear system of enhanced international cooperation to ensure compatible regimes enhancing security without hindering trade in commercial products, while contributing to the attainment of legitimate objectives.

2.67. The representative of Japan reiterated support for the positions of Canada and EU on this issue, and said that Japan was concerned in particular with the various schemes and regulations within China on information security, and how they could negatively affect trade of information security products.

2.68. The representative of China informed the Committee that the Regulation on Commercial Encryption Products had been listed in the 2015 Legislation Plan of the State Council of China, and currently the Regulation was being drafted in line with the Legislation Law and Rules on Formulation of Administrative Laws of China. China said that OSCCA would undertake scientific evaluations and public consultations to ensure openness in the legislation process. On the MLPS, China suggested Members to refer to the minutes of the previous meeting.

2.2.3.6 Russian Federation – Draft on Technical Regulation of Alcohol Drinks Safety (published on 24 October) (G/TBT/N/RUS/2) - IMS Item No. 332

2.69. The representative of the United States appreciated Russia's notification of this measure to the WTO, and for Russia's exclusion of the proposed circulation procedure from the most current version of the draft text. However, the US remained concerned about several other provisions that were present in the original draft, notified by Russia in December 2012. Specifically, the proposed definition of whiskies, and the requirement that they be aged for no less than three years. The US also remained concerned that alcoholic beverages still required an expiration date. Additionally, she noted concerns outlined in previous US comments with respect to the standards for production facilities, and several conformity assessment procedures and their applicability to foreign manufactures. She requested that Russia clarify that these requirements would not be applicable to producers already subject to controls by US authorities. In this vein, she recalled the previous statement by Russia that the 2012 draft was substantially modified in December 2013. In the interest of enhancing transparency and mitigating any undue burden for exporters of alcoholic beverages to Russia, she requested that Russia notify its latest draft of this technical regulation and provide an additional comment period for stakeholder input.

2.70. The representative of Mexico reiterated concerns with this measure, and recalled that his delegation had sent written comments to Russia in December 2011 and April 2012, but had not yet received any formal responses. The concern was expressed for the first time in the Committee in March 2012, and had been reiterated in all the subsequent TBT Committee meetings. The issue was the lack of information on the state of preparation of the technical regulation on the safety of alcoholic beverages. In this respect, Mexico requested the Russian Federation to provide information on the state of progress on the elaboration of the regulation and the current state of play with regard to its final adoption. He also asked Russia to explain how the comments of the Mexico were taken into account in relation to the final text of the regulation, and to provide a formal response to those comments.

2.71. The representative of the European Union requested an update on the status and timeline for adoption of this draft technical regulation, notified in 2012 and scheduled to be finalized before the end of 2014. The EU recalled detailed written comments in 2013, and reiterated in subsequent meetings of the TBT Committee. Russia had explained in previous TBT Committee meetings that most of the EU comments regarding wine and beer would be taken on board in the revised draft technical regulation on alcohol products safety. However, the EU noted that the revised text had not yet been notified under the TBT Agreement, nor had it been published. The EU asked whether Russia intended to re-notify the revised text to the TBT Committee, given that it would likely include substantial changes as compared to the text notified in 2012. A re-notification would give WTO Members a possibility to analyse how their comments have been taken into consideration.

2.72. The representative of Australia voiced continued concerns with elements of Russia's technical regulation on the safety of alcoholic drinks and requested an update on the status of the measure. Both Australia and Russia shared the commitment to adopt internationally accepted standards for alcoholic products as recommended by the International Organisation of Vine and Wine (OIV), and to avoid creating unnecessary obstacles to trade in wine. He once again suggested that Russia consider adopting the OIV list of approved additives and processing aids, as set out in the "International Oenological Codex" and the "International Code of Oenological Practices". Australia remained concerned about the legal status of wines which conformed to the health warning statement under the previous legislation, and were in circulation at the time the draft regulation entered into force. He asked that Russia introduce a six-month transition period for these products to enable industry sufficient time to implement the stated labelling requirements. On the issue of wines which used an Australian geographical indication (GI) in their description and presentation, he asked whether Russia had considered his delegation's request that wines labelled with an Australian GI be considered as a "protected geographical indication" under the new technical regulations, and that the relevant exemptions from the regulations relating to wines with a "protected geographical indication" be applied. He also reminded Russia of concerns over the requirements relating to the bottling location of wines which included a GI in their description and presentation. He enquired whether the Customs Union regulations required such wines to be bottled within the boundary of the GI stated in the description and presentation of the wine.

2.73. The representative of the Russian Federation underscored that these concerns were raised previously, and invited Members to refer to the answers provided during past TBT Committee meetings. Russia continued to work on the draft on the Technical Regulation of Alcohol Drinks Safety, and assured Members that it would take into account all constructive comments and proposals, and welcomed further cooperation with all the parties on this matter.

2.2.3.7 Republic of Korea – Regulation on Registration and Evaluation of Chemical Material (G/TBT/N/KOR/305) - IMS Item No. 305

2.74. The representative of the United States encouraged Korea to develop a strong definition of confidential business information (CBI) and include at least the possibility of protecting the specific chemical identity, composition, and uses, while respecting the legitimate government interest in allowing for reporting of generic chemical names, and for providing adequate hazard information to downstream users. K-REACH should include additional provisions preventing any disclosure of CBI. Korea should tighten the definition of "hazardous substance" so as to avoid confusion and an overly broad application that would de facto prevent claims of CBI for any substance. The US considered that the phrase "other chemical substances that either pose or raise the concern of hazard or risk" should be deleted from the definition. She encouraged Korea to give greater consideration to stakeholder requests to delay the implementation date in light of the issues that had been raised. She asked that the role of the Korean Chemical Manufacturers Association (KCMA) be defined and that there be a level playing field for both domestic and foreign registrants.

2.75. The representative of Japan was concerned that products containing approximately 500 hazardous substances, not less than 0.1% by weight and not less than 1 ton per year in total, had to be notified to the authority of the production, sales and import of them. Japan understood that the enforcement decree included an exception that in some cases the notification could be delayed until 30 April of the next year. However, chemical industries would still have the heavy burden of examining 500 hazardous substances through supply chains all at once. Japan reiterated its request for Korea to introduce the regulation in a stepwise manner according to the priority of hazardous substances.

2.76. The representative of the Republic of Korea informed the Committee that this measure had entered into force on 1 January 2015. With regard to the US concerns on CBI, he reiterated what had been said at the November meeting, that this type of information was defined in the "Unfair Competition Prevention and Trade Secret Protection Act" and that the Ministry of Environment would decide what specific chemical identity, composition and uses could be considered CBI, taking into account commercial value of information and business activity. Therefore, information designated as a CBI during the registration process would be considered strictly confidential upon request. Information shared in the supply chain was limited to safety issues such as risk posed by chemical substances, limited usage and precautions. Concerning the list of existing chemicals subject to registration, he said this list was in the final legislative process and would soon be notified to the WTO so as to give Members the opportunity to comment and to inform that there would be a three-year grace period from the date of entry into force of notice. Concerning the request to tighten the definition of "hazardous substance", the representative said that regretfully this would not be possible as Korea had undertaken considerable consultation with both domestic and international stakeholders prior to the very recent entry into force of this Act. So as to enhance transparency and ensure better understanding of measures, guidelines for Acts and Decrees were been prepared in English. Finally, he assured Members that other issues raised would be relayed to the competent authorities and that Korea would continue to cooperate on a bilateral level.

2.2.3.8 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 Item No.328

2.77. The representative of the United States noted that toy safety was an objective shared by many Members. However, her delegation still considered certain aspects of Indonesia's toy regulatory regime to be considerably more restrictive than those adopted by other Members and, specifically, more restrictive than necessary to achieve the objective of protecting human health. In this respect, the US continued to have concerns related to laboratory accreditation, testing frequency, sampling, documentation, and substance restrictions as well as the requirement to

have a bilateral MRA in place by April 2016. Despite efforts by both the US Government and other trading partners, as well as the toy industry coalition, few of these concerns were addressed prior to the regulation coming into force at the end of April 2014. The US was particularly concerned that the increased costs and decreased quantity and variety of safe toys from compliant companies due to these restrictive requirements would cause consumers to look for alternatives in the grey market, thereby decreasing consumer safety. The US looked forward to receiving a copy of the revised technical guidance as well as the list of MOI-approved international labs.

2.78. The representative of the European Union expressed his delegation's view that the technical working group that was being formed in the Indonesian Ministry of Industry could be a good tool for industry to collaborate with the Ministry with a view to finding viable solutions to amend Decree No. 24 so as to eliminate the current discriminating, unnecessary burdensome conformity assessment requirements contained therein (tests on every imported batch as compared with tests of samples taken from the production line every 6 months for domestic products). The EU asked Indonesia to provide further updates with respect to such revision initiatives. The EU also sought clarification on the application of the current two year grace period concerning the acceptance of foreign tests by laboratories accredited by ILAC MRA signatories. The EU asked whether this two year period applied individually to each lab as from the date of appointment or, rather, this was linked to the entry into force of the decree. The EU believed that there should be scope for acceptance of results from tests conducted by foreign laboratories on a permanent basis in view of the current capacity constraints in Indonesia, even beyond the grace period.

2.79. The EU also said that the inconsistencies stemming from the fact that in Indonesia toys were subject to two separate sets of labelling requirements: a toy specific one (Decree No. 24), and a general one (the revised general labelling requirements discussed separately under STC IMS ID 436).

2.80. These combined requirements meant that toys had to be handled manually twice: before shipment, according to the general requirements for labelling in Indonesian language, and after importation, in order to meet the specific labelling requirements under the toy regulation. It was the EU's understanding that the Ministry of Industry and the Ministry of Trade were responsible for managing this set of requirements. The EU expressed its willingness to work together with Indonesia in aligning to this requirements and eliminating the inconsistencies.

2.81. The representative of Japan associated himself with the US and the EU and reiterated his delegation's previous request for Indonesia to revise its measure so as to make it consistent with TBT Agreement obligations, in particular by not being more trade-restrictive than necessary.

2.82. The representative of Indonesia said that, as stated in previous meetings, the Mandatory SNI for toys products was still valid and there was no updated information regarding the implementation of this regulation. Regarding concern on the differences in sampling criteria between domestic products (which was every 6 months) and imported products (for every shipment), Indonesia explained that this treatment was based on the consideration that the domestic production capacity was of around 5,000 pieces of toys every 6 months, while imported products could exceed 5,000 pieces in one shipment. This was also based on the fact that Indonesia was a developing country where most toy producers were SMEs with low production capacity. Regarding testing procedure, Indonesia explained that the mandatory toy regulation stated that test results issued by foreign testing laboratories listed in the Mutual Recognition Agreement (MRA) under APLAC/ILAC scheme were accepted. Furthermore, foreign testing laboratories accredited by their respective accreditation bodies could be recognized provided that the countries where the laboratories were based had a bilateral agreement (MOU) on technical regulations with the Indonesian Government and the laboratories were appointed by the Indonesian Ministry of Industry. Indonesia has granted 2 years of grace period for the result to be recognized. However, this kind of special treatment during this grace period could only be extended beyond the period if the government of the country where the laboratories were based already had a mutual recognition agreement with the Indonesian Government.

2.2.3.9 India - Food Safety and Standards Regulation - Food labelling requirements - IMS ID 298

2.83. The representative of the European Union said that India's ad hoc guidelines of January 2014 note that only India specific food labelling requirements (such as vegetarian/non vegetarian logos) and the name and address of the importer could be affixed by the importer by means of stickers in customs warehouses. However, in most economies in the world food products could be labelled by means of stickers, provided that they are accurate and not easily detachable. This was a very important trade facilitating practice that, while duly protecting the consumer, at the same time allowed producers to serve different regions with different language requirements without having separate production lines. Given the foregoing, the EU considered India's labelling practice to be: (i) too burdensome; (ii) not in compliance with Article 2.2 and 2.4 of the TBT Agreement; and (iii) not in accordance with the Codex Standard for the labelling of pre-packaged foods (CODEX STAN 1 1985). According to this Codex Standard: ''If the language on the original label is not acceptable, to the consumer for whom it is intended, a supplementary label containing the mandatory information in the required language may be used instead of relabelling''. This standard also stated that: ''in the case of either relabelling or a supplementary label, the mandatory information provided shall be fully and accurately reflect that in the original label.'' The EU therefore asked India to bring its implementing guidelines in line with Codex so as to allow all type of labelling information - and not only the Indian specific one - to be provided by stickers (for example at customs bonded warehouses). This 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 way.

2.84. The EU also noted that some specific parts of Indian food regulations were not in line with Codex standards (for instance, olives and whole-wheat pasta). In this respect, the EU asked if India intended to bring amendments to the India Food Regulations any time soon in order to bring them closer to Codex standards. Additionally, with respect to alcoholic drinks, the EU noted that currently the Indian legislation required that the labels of alcoholic drinks contained the full list of ingredients. As for food, the EU continued to request that India accept stickers providing such information. Finally, given that the Indian Food Safety and Standards Authority was preparing a technical regulation on alcoholic drinks as well as an update of allowed food additives, the EU asked India what were the envisaged timeframes for notifying these measures to the WTO.

2.85. The representative of Australia expressed continued concerns with India's food standards and their enforcement by the Food Safety and Standards Authority of India (FSSAI). He noted that Australia had previously supported the efforts of FSSAI to harmonize Indian food standards with CODEX standards, a process that began in early 2013 and was due to be finalised in 2014. Australia had provided extensive information to FSSAI about Australian food standards and their enforcement. Australia asked India to inform: (i) when the process of harmonisation of India's food standards with Codex would be finalised; (ii) whether India was planning another review of its standards; and, if so, (iii) whether India would consider the issues raised by WTO Members and whether this review would be through finalisation or extension of the Codex harmonisation process, or a separate review.

2.86. The representative of Canada echoed the concerns expressed by the previous delegations.

2.87. The representative of India informed the Committee that there was no change in the regulatory status since the last meeting of the Committee and referred Members to the statements made by India on that occasion, as reflected in the minutes of that meeting (Para 2.124 and 2.125 of G/TBT/M/64/Rev.1). He also stated that additional issues raised would be communicated to the regulatory authority in the capital for response.

2.2.3.10 European Union – Draft Implementing Regulations amending Regulation (EC) No. 607/2009 laying down detailed rules for the application of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products (G/TBT/N/EEC/264, G/TBT/N/EEC/264/Add.1) - IMS ID 345

2.88. The representative of the United States recalled her delegation's previous concerns and requested the status of the applications submitted by the US wine industry over four years ago. The US noted that some of its suppliers that currently used the terms referred to in the EU

measure had been unable to ship their products. The US was also concerned with the lack of transparency in the application process for the use of traditional terms. This process continued to undermine US exports of wine to the EU.

2.89. The representative of Argentina associated himself with the statement of the US and reiterated his delegation's concerns with the unjustified delay in resolving this long standing STC. By providing EU member states with the exclusive right to use certain traditional expressions, in each of their respective languages, the European measures restricted the right of third countries to use these same expressions on their labels, seriously affecting Argentine exports of wine to the EU. Argentina argued that because traditional expressions were indications of quality, they would fall under the TBT Agreement and not under the TRIPS Agreement. Consequently, these expressions could not be registered as IP nor confer any exclusive rights for their use. This measure therefore constituted clear and flagrant discrimination against Argentina and any other producing country that wanted to place wines bearing traditional expressions such as "Reserva" and "Grand Reserva" on the European market. Thus, the EU measure was not adopted to protect consumers from being misled nor to guarantee the characteristics wines may have when associated with such expressions, considering the existence of multiple definitions for each one of these terms, all of them accepted by the EU through different mechanisms . This measure was not therefore consistent with the TBT Agreement.

2.90. In spite of being WTO inconsistent, and in order to help find a practical and constructive solution to avoid the barriers posed by the EU legislation, Argentina reported that in 2009 it submitted its file for the approval of terms "Reserva" and "Grand Reserva". After various exchanges, this dossier was then approved in March 2012 by the European Commission's Wine Management Committee. Although the substantive procedure was completed in March 2012, the final formal step, namely the adoption of the Argentine dossier by the College of Commissioners and its publication in the Official Journal of the EU, had not yet been taken. The substantive procedure took two years and seven months, from July 2009 until the approval of the dossier in March 2012, while the delay to comply a single administrative act of a formal nature had already reached three years, from March 2012 to March 2015. It was striking that the delay to finalize merely formal administrative acts had exceeded the time taken to end the substantive procedure that approved the dossier. It was not coherent that only one formal act required more time than the total amount of acts of the process, during which Argentina had also responded to objections by different entities and supplied additional information in response to requests from the EC for clarifications regarding its documentation. He added that recently a new internal ad hoc group of DG-AGRI was revising all requests for recognition of traditional expressions, which could result in further delays for the final approval of the Argentine requests. Argentina insisted that such delay was doubly unjustified: neither had the process been concluded in a reasonable period of time, nor had a reasonable explanation been given for the delay. This delay constituted in and of itself an obstacle to trade and left Argentine wine in a disadvantageous position in relation to their other competitors that had access to such expressions. Argentina urged the EU to find a prompt solution, having asked them so through bilateral, multilateral and plurilateral channels, where several notes were sent to the EU by the World Wine Trade Group, to date without success. To this end, Argentina asked the EU, once more, to eliminate these unjustified restrictions on the Argentine exports of quality wines, taking the final formal step towards the approval of the Argentine requests, namely, to include the Argentine dossier in the agenda of the next meeting of the College of Commissioners and to publish the corresponding final ruling in the Official Journal of the EU.

2.91. The representative of the European Union explained that an internal assessment on traditional terms has been carried out within the EU with stakeholders and experts from the EU member states (in accordance with Article 114(3) of Regulation n^{o} 1308/2013 establishing a common organization of the markets in agricultural products). This consultation, which was still ongoing, included the conditions and specificities under which these traditional terms could be used on the labels of products from third countries. The possible derogations, based particularly on minimum requirements for production methods and controls under product specifications of the wines concerned, have been covered by this discussion. Nevertheless, no final conclusions had been reached yet. The EU would continue to make the necessary efforts to bring new elements in its current policy on protection of traditional terms and their indication on the labels of wines in order to accommodate trade partners' concerns. In this respect, he noted that the concerns raised by the US and Argentina had been taken into account in the assessment process currently carried

out in the EU. The procedures under consideration (whether from EU member states or third countries) would be taken once this evaluation would be finalized.

2.2.3.11 Chile – Proposed amendment to the Food Health Regulations, Supreme Decree No. 977/96[3] - IMS ID 370

2.92. The representative of Canada said that, while his delegation supported Chile's policy objective of promoting healthy dietary choices in reducing obesity and related NCDs, it nonetheless encouraged Chile to consider a less trade restrictive labelling regime to achieve this goal, in particular since this measure deviated from international standards, was not based on science and was likely to be more trade restrictive than necessary.

2.93. The representative of the United States said that, while her delegation strongly supported Chile's public health objectives of reducing obesity and related NCDs, it was nevertheless concerned with various aspects of the proposed measure, such as the "warning" element of the icons, the prohibition on health claims and complementary information for products that carry icons, and the short implementation timeline. She also noted that the proposed measure may have a significant impact on trade. She urged Chile to explore less trade restrictive labelling measures that would include flexibility in the placement or shape of the icon, and reflect consumer information based on common serving sizes, which would help consumers achieve a balanced and healthy diet. She also requested an update on Chile's rulemaking schedule, given recent leadership changes in its Ministry of Health. In this respect, she noted that Chile had not provided a response to the comments and questions the US sent on August 2014 (including on the basis for the nutrient limits), and that Chile had not provided a recent opportunity to discuss our concerns bilaterally, despite repeated requests.

2.94. The representative of Mexico reiterated concerns with regard to the proposed amendment to the Food Health Regulations, Supreme Decree No. 977/96, issued by Chile and notified to WTO Members in document G/TBT/N/CHL/282. This concern was first raised in March 2013 and reiterated at several Committee meetings. Mexico's full statement is contained in document G/TBT/W/406.

2.95. The representative of the European Union reiterated the views his delegation expressed in previous meetings, in particular in November 2014. While fully supporting Chile's ultimate objective of fighting obesity and NCDs, it nonetheless disagreed on how such objective could be best met. He asked Chile to take a different approach, which was the one the EU embraced: to recognise the importance of the relationship between diet and health, while at the same time empowering consumers to make informed choices based on factual information. The EU also recalled the specific concerns it had expressed previously with this measure, in particular regarding: (i) the lack of scientific basis for the definition of the maximum levels for the concerned nutrients; (ii) the absence of international guidelines backing up the requirements in the measure; and (iii) doubts as to whether this measure was proportional and effective.

2.96. The representative of Australia said his delegation supported Chile's right to implement measures to provide consumers with information to make appropriate dietary choices and reduce the risk of diet-related NCDs, provided that such measures were implemented in a WTO-consistent manner. In this respect, Australia suggested that there were other measures available to Chile to promote consumer health (also been envisaged by other Members, including Australia), and which could achieve Chile's objective. Australia also thanked Chile for having clarified that the warning label would no longer take the form of an octagonal "STOP sign" but would instead be a coloured hexagon and that its size would be established in relation to the size of the total area of the products. Australia was particularly pleased that Chile has changed the proposed front of pack labelling requirement based on suggestions by other Members. However, Australia also noted that this labelling scheme was still mandatory for some food categories, including some dairy foods. However, there were some inconsistencies between the requirements for imported and domestic product. Finally, Australia noted that Chile has extended the original date of entry into force to 30 June 2015.

2.97. The representative of Brazil reiterated its concerns about the new Chilean labelling requirements on food products, particularly regarding the adequacy between the purposes and the

[3] G/TBT/N/CHL/219, G/TBT/N/CHL/219/Add.1, G/TBT/N/CHL/221, G/TBT/N/CHL/282

methods adopted. The measures seemed more trade restrictive than necessary to fulfil the objectives. Brazil was closely following developments on this issue. He thanked the Chilean delegation for their constructive bilateral discussion.

2.98. The representative of Costa Rica associated herself with concerns expressed by the previous delegations.

2.99. The representative of Guatemala reiterated the concerns her delegation has expressed in previous meetings and requested Chile to explain how the measure's thresholds on nutritional content, the position, colour and dimensions of the description in the form of a black and white stop sign on labelling, could reduce the level of obesity amongst Chilean consumers. She also asked how these requirements reflected the norms established in the Codex Alimentarius for food labelling.

2.100. The representative of Chile said that the Supreme Decree No. 977/96 had been notified to the WTO as G/TBT/N/CHL/282 on 22 August 2014 and that this notification replaced all previous notifications and their addenda. The deadline for comments was 22 October 2014, and Chile received 28 sets of comments (12 from WTO Members and 16 from the private sector), which were transmitted to the relevant regulatory body. A public consultation was also held on the proposed amendment, to which over 300 comments were received from interested parties, including civil society and the private sector. The Chilean Government had also engaged in a nationwide dialogue on the relevance and significance of the regulation. Chile noted in this respect that although no final version of the regulations has yet been adopted, the process has reached its final stage. Chile explained that the adoption of the measure, which has been delayed due to internal circumstances, would take place in the near future. Chile assured Members of its intention to take all reasonable measures available to meet its obligations under the TBT Agreement, and to respond to all queries and provide information to trading partners and WTO Members.

2.2.3.12 India – Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order, 2012[4] - IMS ID 367

2.101. The representative of Canada voiced his delegation's continuing concern that this measure could hinder or possibly shut Canadian exporters out of the Indian market due to delays in registration and testing. So as to minimize the negative impact on companies wishing to export to India while at the same time providing assurance that the recognized conformity assessment bodies were competent, he suggested that India recognize foreign conformity assessment bodies accredited by signatories to the ILAC and IAF MLAs to test and certify to India's regulatory requirements. This approach would reduce testing costs and allow exporters to bring their products to the Indian market more quickly. He noted that substantive amendments to the Order, such as those with respect to marking and labelling requirements, should be notified to the Committee.

2.102. The representative of the United States reaffirmed her delegation's continuing concerns with the measure. She said that the Compulsory Registration Order (CRO) domestic testing requirements would only slow progress toward achieving the goals of "Digital India" thus inhibiting the likelihood of success as disruptions to the ICT equipment supply chain would persist and exacerbate with the expansion of products brought under the measure's scope. India's requirement for foreign products to retest to an Indian standard that was already tested to an identical international standard was a clear example of how India's CRO posed unnecessary restrictions. Regarding the requirement that testing be conducted solely in labs domiciled in India, she recalled previous interventions on this issue.

2.103. She noted that BIS-approved labs adhere to the mutual recognition principles as a member of the IECEE CB Scheme toward reciprocal approval of tests performed at IECEE CB accredited labs located outside of India. In this regard, she suggested that appointed labs should only require a product sample unit to conduct verification testing if the labs could not resolve a suspected non-compliance issue from information exchanges between the Certification Body issuing the CB Test report and/or the manufacturer. This would provide immediate relief to manufacturers and allow India's labs to learn how to correctly perform necessary testing. BIS should also remove the expiration date from the test report. No other national certification agencies have expiration dates on their test reports. She further stressed that accordance with

[4] 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

international best practices for testing and certification of IT and electronics equipment would help jumpstart Digital India's efforts and the Indian Government should work on collaborative consultations with industry and other stakeholders to come into alignment. This should promote the development of an MRA, proposed during Secretary Sharma's visit in January 2015 to institute international best practices for testing of telecom equipment.

2.104. She also noted the US' concern with the burdensome over-labelling and regulation by FAQs. In this respect, she requested that the list of products under the HSE exemption should be broadened to include all products that were not for the consumer market and posed little risk to average consumers. She noted the US industries' trade concerns with, and asked India to explain the rational of, the expanded list of products covered by the CRO as of November 2014. Such an expanded list would create similar problems as those under the original product scope, including testing delays. These requirements involved multiple approvals for a single device without a resulting increase in product safety. It was also the US' understanding that that a market surveillance programme would be launched. She hoped that this program would be notified to the TBT Committee with a reasonable comment period. In this respect, the US asked if batteries that were part of a larger product would be included in this testing as companies were struggling to give clarity to their suppliers due to ambiguity over what batteries needed to be tested.

2.105. The representative of the European Union reaffirmed his delegation's views that the registration process was burdensome and that the in-country testing requirements were unnecessary. The EU noted that the new expanded compulsory registration scheme included fifteen new product categories, including mobile phones and some of their key components. This new scheme was published in India's official Gazette on 13 November 2014, entering into force 6 months later, on 13 May 2015. In this respect, the EU asked if this new scheme would be notified to the Committee and if it would only be applied once Members comments had been taken into account. The EU understood from the last TBT Committee that work was ongoing towards streamlining the registration process and that a technical advisory committee had been set up under the Department of Electronics and Information Technology of the Ministry of Communications and Information Technology. The EU therefore requested an update on any improvement to the registration process in terms of shorter times for processing applications and the possibility of having one product registration number per product model rather than per each factory making the product. This was particularly important for factories streamlining registration procedures and for products with a short lifecycle for which the current delays in obtaining registration in the best of cases were 45 days, having an adverse effect on the ability of product suppliers to timely market those products within the useful lifecycle of such products.

2.106. The EU noted that another point of concern was the validity of test reports. Currently, the validity period was limited to ninety days, which meant that an application for registration had to be submitted within ninety days of obtaining the test report. The EU considered this to be unduly restrictive and that, in principle, it was unnecessary to have the time limitation. If it predated ninety days, it would still cover products where the safety properties and design had not changed since the original test had been carried out. Thus, once registration has been obtained, the validity of the registration should not be subject to a time limitation, in particular the currently applicable short time limitation of two years. The EU said that products which had not undergone any design change in safety properties should have a special dispensation whereby renewals would be fast-tracked and would not need to undergo a fresh procedure to obtain new registration. The EU expressed appreciation for the flexibilities introduced with regard to labelling arrangements - in particular for products with very small physical dimensions - and encouraged India to continue working with the industry to find practical solutions on a product-basis. The EU emphasised the potential of minimising burdens for foreign suppliers by accepting test reports generated under the IECEE CB scheme or foreign laboratories with adequate accreditation. It encouraged India to maintain this possibility on a permanent basis for this measure.

2.107. The representative of India noted that the October 2012 Requirement for Compulsory Registration included fifteen categories of electronics items, which were based on their compliance to specified safety standards. Under this measure, both domestic and foreign manufacturers/importers/sellers/distributors of the notified goods must conform to the specified standards. Industry needed to get goods tested with laboratories recognized by BIS, which, on meeting requisite standards, would grant a unique registration number. A self-declaration of conformity mark on their products in a prescribed manner was necessary, followed by the registration number. In November 2014, the Schedule of this new scheme had been expanded to

include 15 more products. Provisions of the compulsory registration scheme shall apply to these products also on expiry of six months from the date of publication of notification in official Gazette, except for sealed secondary cells and batteries mentioned in serial no. 20 of the Schedule for which the provisions would apply on expiry of nine months. This expansion of product coverage has been done in due consultation with all stakeholders, and the standards notified are either adopted international (IEC) standards or based on them. The draft Gazette notification has also been on DeitY's website for public opinion before it was finalized providing opportunity to any stakeholder to comment. The comments received had been duly considered before issuance of the Gazette notification.

2.108. He recalled that some delegations had suggested that India should accept test reports issued under the IECEE CB scheme or by the labs accredited by ILAC MRA signatories, and also limit domestic testing only in cases of suspected non-compliance of products. There was no change in the regulatory system and referred interested delegations to India's statement made in the previous Committee meeting. On a related concern of allowing foreign labs to perform the requisite testing, he noted 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 Mutual Recognition Agreement with BIS. The BIS has so far signed MRAs with national standard bodies of three Members: Israel, Sri Lanka and Pakistan and therefore, it was not possible to process applications from labs based elsewhere. Concerning the suggestion that tests should only be repeated if there was a change in design and components that affected safety properties, he explained that retesting was required in case there was a change in design. However, in case of a change in components of the product, only relevant safety tests could be performed at BIS-recognized labs. For a revision of a standard or amendment to the existing standard, testing was required only for the additional or modified safety requirements. Recently, Amendment No. 1 was issued to IS 13252(Part-1):2010 and would be implemented by 31 May 2015. BIS has issued guidelines for implementation on 3 December 2014, available on BIS website (http://www.bis.org.in). In terms of these guidelines, only one sample of any base model out of all registered models would require testing for few additional or modified requirements. An undertaking was required by the manufacturer for self-declaration that they have implemented the Amendment No. 1 and all the models covered under their registration conformed to IS 13252(Part-1):2010 including amendment No. 1.

2.109. He also noted that some delegations had expressed a need to expand the validity period of test reports beyond the existing level of 90 days. In this matter, he explained that there was no change in the status since previous Committee meeting. The period of 90 days for submission of test reports to BIS was defined in the BIS Rule for registration and was considered adequate. However, there was a development with respect to the validity of registration. The Policy Advisory Committee (PAC) had decided to increase the validity period of registration from one year to two years, and that all registrations granted previously for one year shall be valid for two years. This decision was available on BIS website. Concerning the issue on registration per product and not per factory, he explained that the matter of single registration for multiple factories was under active consideration of the PAC. For this purpose, a list of criteria has been recently drafted and placed on DeitY's website for comments, which would be duly considered by the PAC before finalizing the criteria.

2.2.3.13 Peru – Act to Promote Healthy Eating Among Children and Adolescents – IMS ID 383

2.110. The representative of Canada said that while his delegation supported Peru's objective of reducing obesity and other non-communicable diseases (NCDs), there were concerns that this measure may deviate from international standards and be more trade restrictive than necessary to achieve its objective. Canada asked Peru to clarify whether the proposed regulations were based on international standards and sound science. He asked whether Peru had considered less trade-restrictive alternatives. For instance, the Codex guidelines on health claims and nutritional labelling could be used as the basis for alternative approaches that could provide similar information to consumers without the cost of mandatory product relabelling. He requested an update on the Health Ministry's evaluation process of comments received, and enquired whether a new draft would be developed. He asked Peru to indicate when these regulations would enter into force and encouraged Peru to provide a transition period to allow industry time to adjust to any new labelling requirements.

2.111. The representative of the United States expressed concern that nutritional labelling was only mandatory when either a voluntary claim was made or a consumption warning was required. She said that mandatory nutrient declaration for all food and alcoholic food would give consumers the most complete information to make dietary decisions as all foods contribute to daily nutrient consumption, unless nutritionally insignificant. She asked if Peru had considered alternative approaches. Nutrition panels could be regarded in a negative way by consumers if only the least healthy foods displayed nutrition information. Targeting only certain foods for nutrition labelling could make it more difficult for consumers to identify healthier foods, and stifle industry innovation to make food healthier. In the event that Peru amended the nutrient content levels notified under Resolution 231, she requested that Peru: (i) provide an opportunity for comments; (ii) provide an explanation for such a determination; and (iii) and extend the timeline for implementation. She also noted that the notification indicated that they considered the World Health Organization/Pan American Health Organization (WHO/PAHO) recommendations, as well as the guidelines issued by the Codex Alimentarius, in determining whether foods were high in the nutrients of concern. As the guidance from these bodies varied, she asked which specific guidance Peru has taken into consideration as the basis by which they determined the levels were appropriate for their population. As the Act did not define font, size, colour or placement of the advisory statement, she asked whether Peru was considering supplemental symbols, icons or pictorial representation of an advisory statement. Additional documents would be helpful in enabling US industry to comply with the regulations. She requested an update on Peru's timeline for the development of the guidance. She stressed the need for an extended period for compliance which would help reduce the costs associated with label design and label stock supply and rotation. Typically countries allowed a much longer time period for compliance when label redesign was required. For example, FDA issued two proposed rules in March 2014 (G/TBT/N/USA/893 and G/TBT/N/USA/894) that would, if adopted, require major changes to US pre-packaged food labels. The FDA proposed a compliance period of two years from publication of the final rule, whereas there was than the 180 days allowed for compliance under Peruvian measure.

2.112. The representative of Colombia said his delegation had already provided comments on the measure and hoped to continue to raise this matter also within the framework of their sub-regional area, the Andes region.

2.113. The representative of Costa Rica shared the concern raised by Canada and the US and inquired whether the Peruvian Ministry of Health had reviewed and processed comments from Members and asked whether there would be a new version of the regulations and if it would be published.

2.114. The representative of Guatemala reiterated its concerns raised in previous meetings regarding this measure and asked Peru to provide more feedback regarding the internal process of the regulation.

2.115. The representative of Peru reported that the situation had not changed much since the last TBT Committee. The Ministry of Health was still evaluating the comments that had been provided within the timeframe. He said they were still looking at how the regulation could avoid being trade restrictive. The final regulation would come into force, as required, six months after its publication.

2.2.3.14 Indonesia – Ministry of Health Regulation 30/2013 on the inclusion of sugar, salt and fat content information, as well as health messages on the label of processed foods (G/TBT/N/IDN/84) - IMS ID 389

2.116. The representative of Canada said that while his delegation supported Indonesia's objective of reducing the risk of non-communicable diseases (NCDs), it had concerns that the proposed measure could have a significant impact on trade and could be more trade restrictive than necessary. He asked whether the requirement for the inclusion of a message identifying certain risks in relation to the quantity of sugar or fat ingested per day was necessary to achieve Indonesia's policy objective. Could Indonesia provide any scientific evidence supporting the use of such measures, and identify on which international standards the measure was based? He noted that Indonesia indicated at the November TBT Committee meeting the possibility of accepting test results from other laboratories, including in the country of origin. He asked Indonesia: (i) to provide more information as to when it planned to address this issue; (ii) to provide an update regarding when it planned to announce which food categories would be required to carry the

mandatory labelling for sugar, salt and fat; (iii) to indicate when the regulation would enter into force and the transition period for industry to adjust.

2.117. The representative of the United States said that the Decree lacked clear guidance on how to implement and comply with the new labelling regulations. While Indonesia had allowed three years for compliance from the original publication date, companies were not in a position to start compliance until the additional guidance was made available. She requested a more definite timeline for when the Ministry of Health would issue further technical guidance for implementation. There were concerns with Indonesia's lack of acceptance of test results from laboratories other than those accredited by KAN or that have a MRA with KAN. She urged that test results from laboratories using appropriate or recognized methodologies be recognized. The US, for example recognized the appropriate method in the official methods of the Association of Analytical Communities (AOAC) International. Less trade restrictive approaches, such as following a process of random sampling and testing of products in commerce, could ensure the accuracy of label information for the vast majority of food and beverages. Finally, she asked Indonesia to confirm whether the total diet study was completed and to inform which food categories would be required to carry the mandatory labelling for sugar, salt and fat.

2.118. The representative of the European Union reiterated previous concerns and asked that the implementing provisions for this Regulation, which would address product coverage in detail, be notified in draft form with sufficient time for comments. He reiterated in particular its concerns with respect to the mandatory warning message on salt, sugar and fat content that would have to be included on the label of all processed food products. The EU invited Indonesia to consider whether the objectives of the Regulation could be achieved with less trade-restrictive means. The EU asked for clarification on the following outstanding issues: the way of placing of nutrition information and related health warning, testing methods for nutrition levels and the conduct of risk assessment related to non-communicable diseases. Like the US, the EU was interested in learning about the results of the total diet study by the Indonesian Ministry of Health with the aim to determining types of food included in the high risk and low risk classifications.

2.119. The representative of Australia said that while his delegation recognised and supported Indonesia's right to implement measures to provide consumers with information so as to make appropriate dietary choices and reduce the risk of diet-related NCDs, it also considered important that such measures would not be more trade-restrictive than necessary to achieve these objectives. While Indonesia would be one of the first countries in the world to implement a mandatory scheme for foods containing sugar, salt and fat, he noted that other countries were currently considering other less-restrictive measures available to promote consumer health. He asked Indonesia to clarify why it considered a mandatory health message on processed foods as the only option available to achieve its aim for public health and informed consumer choice. He noted in this respect that the Codex Alimentarius Guidelines on Nutrition Labelling (CAC/GL 2-1985) set out the principles for nutrition labelling on an international level. One principle 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." The application of a mandatory health message reflecting to levels of specific critical nutrients would not therefore be consistent with this principle. Australia also requested information on whether Indonesia would allow stickers containing the health message to be applied to the labels of processed foods after importation, and before being placed on the market to comply with the Decree. Australia was concerned that foreign companies importing food products would need to produce a separate label for Indonesia, thus resulting in extra costs and delays in bringing products to market. Australia further noted that the proposed nutrition declarations must be based on tests carried out by accredited labs and sought clarification on what methods would be used for the tests verifying the nutrition declarations and whether tests performed by foreign laboratories, or in-house laboratories of companies would be accepted. Australia also asked whether this proposed requirement would be enforced for both domestic and imported products and how compliance would be tested.

2.120. The representative of Indonesia said that the technical guidance that was being prepared to implement the measure would include inter alia the food categories to be covered by the measure. These implementing regulations would be notified to the WTO. He also confirmed that in 2014 the Ministry of Health conducted a study on total diet focusing on individual food consumption survey. This particular survey has accommodated the information on average weight

of food, and the percentage of people who consume food according to food category and nutrition intake, specially energy, protein, carbohydrate, fat and sodium content. Regarding the conformity assessment procedures, he explained that the Regulation required that testing of sugar, salt and fat contents and other quality parameters must be conducted by laboratories accredited by the Indonesian National Accreditation Body (KAN) or by other competent institutions that have Mutual Recognition Arrangement (MRA) with KAN. Laboratory test result must be provided when producers were to register or re-register at National Agency for Food and Drug Control (BPOM), or when they re-formulate ingredients of the products. The possibility to accept test results issued by other laboratories or laboratories of the country of origin would be addressed at a later stage.

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

2.121. The representative of Canada raised concerns with the European Union's departure from internationally accepted risk assessment practices. The EU proposal was a hazard-based approach that created a level of uncertainty among exporting countries, and had the potential to disrupt international trade and increase costs for producers and consumers. Canada had submitted comments during the consultation process underscoring the importance of considering a risk-based approach over a hazard-based approach. He asked when these comments might be reviewed, and once the EU had assessed all comments received, what the next steps would be. He also voiced concern with the potential application of default MRLs to Canadian exports under the hazard-based approach and requested clarification on the interplay between Regulation 1107/2009 and Regulation 396/2005 in that regard.

2.122. The representative of Argentina shared the concern raised by Canada regarding the process proposed by the EU on defining criteria at the European level for the identification of endocrine disruptors. In spite of sharing the legitimate concern for the potential effect on the environment and public health of substances that may have endocrine disrupting properties, Argentina was of the view that any decision made by the EU on this topic must respect agreed multilateral principles, and in particular the WTO Agreements on SPS and TBT, without creating unnecessary obstacles to trade. The future regulation to be adopted by the EU should be based on science, avoiding unjustified negative impacts on international trade, in particular for developing countries that produced raw materials. He urged the EU to conduct the entire process in a transparent manner, allowing comments to be submitted throughout.

2.123. The representative of the United States thanked the EU for publishing its "Public Consultation on Defining Criteria for Identifying Endocrine Disruptors (EDs) in the Context of the Implementation of the Plant Protection Product Regulation and Biocidal Products Regulation". The US had provided comments on 16 January 2015. While 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 the EU roadmap did not identify the scientific evidence considered when developing each option, nor was there any explanation of why the evidence led to the selection. The roadmap only broadly noted that it convened expert groups and commissioned an EFSA scientific opinion. While the Roadmap identified Member State impact assessments and provided links to them, there was no explanation of what aspects of those assessments were considered relevant. She noted that the roadmap appeared to have broad implications for the registration of pesticides and chemicals globally and could thus affect other EU legislation. She asked the EU to provide answers on a number of questions: Could the EU provide information on which existing EU measures were likely to be affected by each of the options and what were the next steps envisaged for regulating endocrine disruptors; If the EU would consider other approaches such as those based on the weight of scientific evidence or any others raised during the public consultation, and if so would Members have an opportunity to comment on them. Concerning the public consultation being convened in early June, she asked for additional information on the scope and how interested parties might participate. Could the EU provide additional information on which chemicals would be included in the impact assessment and the methodologies the EU used in determining which chemicals would be included? Given the significant trade impact and the uncertainty regarding what approaches the EU was considering, she requested that the EU continue to inform the Committee and all stakeholders of developments so as to assure them that their views were being considered during the regulatory development process.

2.124. The representative of the European Union reiterated the intention to carry out a comprehensive impact assessment to analyse different options for defining criteria for the identification of endocrine disruptors and their corresponding health, socio economic and environmental effects. In this context, the European Commission published in mid June 2014 a roadmap setting out the scope of such impact assessment and the policy options that would be assessed. He explained that at least two studies supporting the impact assessment were needed. The first one had already started and would assess the chemicals that might be identified as endocrine disruptors under each of the various options for the criteria. As part of this impact assessment process, on 26 September 2014 the European Commission launched a public consultation on the definition of criteria for identifying endocrine disruptors in the context of the implementation of the EU's plant protection products regulation and the biocidal products regulation. This public consultation ended on 16 January 2015. The responses received to the public consultation were published on 2 February 2015. An analytical report of the responses would be provided in due course. This factual, quantitative report would feed into the work for the impact assessment whose outcome would not prejudge or constitute the announcement of any position on the part of the European Commission, but would allow the Commission to take an informed decision as regards further EU legislative work as appropriate. He said the European Commission would organize a conference in June 2015 informing Member States, MEPs, third countries and stakeholders about the on-going impact assessment. Only when the impact assessment was concluded, would the European Commission present proposals for introducing criteria to identify endocrine disruptors in the EU's plant protection products regulation and biocidal products regulation. The criteria might also have an impact on other pieces of EU legislation. Pending the new criteria, interim criteria were applicable both in the biocidal products and in the plant protection products regulations. Finally he said the EU would notify the new proposal to the WTO, allowing third parties comments to be duly taken into account.

2.2.3.16 Ireland - Proposal to introduce standardised / plain packaging of tobacco products in Ireland (G/TBT/N/IRL/1, G/TBT/N/IRL/1/Add.1) IMS ID 380

2.125. The representative of Malawi expressed her delegation's concerns regarding the consistency of the proposed measure with the TBT and TRIPS Agreements. She also requested Ireland to abstain from any tobacco plain packaging legislation until the WTO disputes lodged against Australia's plain packaging measures had been concluded. Malawi's full statement is contained in document G/TBT/W/401.

2.126. The representative of Zimbabwe associated her delegation with the concerns raised by Malawi and reiterated concerns raised at the previous Committee meeting. Zimbabwe's full statement is contained in document G/TBT/W/403.

2.127. The representative of Guatemala, speaking also on behalf of the Dominican Republic, said while they shared the policy objectives of Ireland on public health and tobacco control; they had concerns with regard to the proposed legislation and requested that Ireland consider less trade restrictive alternative measures that would effectively achieve its legitimate objectives.

2.128. The representative of Nicaragua said that this was a significant concern that had been raised in various meetings. He requested that the intervention made by his delegation at the TRIPS Council and included in the minutes of that meeting, also be referenced in the minutes of this meeting.[5]

2.129. The representative of Australia reiterated their strong support for the decision by Ireland to legislate for the mandatory plain packaging of tobacco products and in particular welcomed the passage of the Public Health (Standardised Packaging of Tobacco) Bill 2014 through the Irish Parliament. The important steps made by Ireland in tobacco control demonstrated that efforts to delay the adoption of tobacco plain packaging measures in a number of countries had not been successful. Australia would continue to support Ireland in its development and implementation of its tobacco plain packaging measures. Australia firmly believed that Members had the right to implement measures necessary to protect public health, while complying with relevant international treaty obligations, including the TBT Agreement. Tobacco plain packaging was a legitimate measure designed to achieve a fundamental objective: the protection of human health. The adoption of tobacco plain packaging measures was a policy choice endorsed by leading public

[5] IP/C/M/78/Add.1

health experts as well as the World Health Organization and was supported by extensive credible peer reviewed research, reports and studies. Australia's own tobacco plain packaging measure, currently being litigated in the WTO, was consistent with Australia's obligations under the WTO Agreements. Concerning Malawi's reference to the dispute that involved Australia, he said it was inappropriate for complainants in these disputes to invoke those proceedings in an attempt to delay or discourage other Members from developing or implementing their own legitimate tobacco control measures.

2.130. The representative of Norway reiterated comments already delivered in the TBT Committee and other fora, in that public health and tobacco control were topics of particular interest to Norway. It was Norway's opinion that it was within the right of each WTO Member to adopt measures in order to protect public health as long as the measures chosen were consistent with WTO agreements. It was clear that tobacco control policies and preventive measures such as the standardised packaging had the legitimate objective of protecting public health. She stated that together with many other WTO Members, who were party to the WHO Framework Convention on Tobacco Control (FCTC), they took their obligations under the said convention seriously. These obligations included, among others, introduction of measures to prevent initiation, to promote and support cessation and to increase consumption of tobacco products. Packaging and labelling were subjects of Article 11 and 13 of the FCTC and the latter explicitly advised the parties to the Convention to introduce plain packaging as a measure to achieve the objective of protecting public health.

2.131. It was Norway's firm view that the FCTC and the relevant WTO Agreements were mutually supportive and that it was possible to implement measures that were in line with both sets of binding obligations. Her delegation strongly supported Ireland's efforts to reduce smoking, and appreciated the bold action taken by the Irish Government. On 17 March 2015, the Norwegian Government launched public consultation on standardised packing of tobacco products, which would be duly notified to the TBT Committee. In conclusion, she said Norway shared Australia's view that ongoing DSB cases should not have any bearing on measures adopted by Members in favour of public health.

2.132. The representative of Ukraine said that while her delegation shared Ireland's policy objectives related to public health protection and tobacco control, there were concerns over the proposed legislation. She encouraged Ireland to consider less restrictive trade measures and urged Members who had plans to implement tobacco plain packaging measures to await the conclusion of the dispute on the Australian plain packaging measure.

2.133. The representative of Cuba shared concerns raised by other Members and called on Ireland to abstain from implementing measures pending the outcome of the proceedings against Australia.

2.134. The representative of Nigeria supported the statements made by Malawi, Zimbabwe, Ukraine and Cuba. As previously stated in the TBT Committee, Nigeria did not oppose Ireland's legitimate objective of protecting human health, but had concerns with the proposed measure. If the standardised tobacco plain packaging measure proposed by Ireland came into law, it would remove the ability of tobacco manufacturers to use trademarks on their products. As a significant producer of tobacco leaves, her delegation was concerned about the broader systemic implications and its practical commercial consequences on the national economy. Nigeria fully supported any form of regulation based on evidence, but in this case there was no proof that plain packaging of tobacco products would be effective in discouraging smokers, rather it was Nigeria's opinion that it would exacerbate the situation. She noted that the proposed regulation was inconsistent with the EU obligations under the TBT and TRIPS Agreement. Her delegation looked forward to receiving more information on the status of the proposed measure and the future intentions of Ireland in light of the numerous concerns raised by Members.

2.135. The representative of New Zealand registered its support for Ireland's decision to enact legislation requiring plain packaging for tobacco and tobacco products. He said that there was an extensive and growing body of international research which established plain packaging as part of a comprehensive tobacco control programme that would contribute to the objective of improving public health. New Zealand had not seen credible evidence that proved otherwise. The TBT Agreement recognised the fundamental right of Members to implement non-discriminatory measures necessary to protect public health and that it was possible for Members to implement a

tobacco plain packaging regime that was consistent with all of the WTO obligations including the respective obligations under the TBT Agreement.

2.136. The representative of Uruguay reiterated comments made at the TBT Committee and other fora within the WTO in favour of the legitimacy of generic packaging measures under the WTO Agreements. Many WTO Members were party to the FCTC and had adopted such measures. Article 11 of the FCTC required the adoption and implementation of effective measures with regard to the packaging and labelling of tobacco products. His delegation believed that the principles of public health fell within the competency of individual states and as such could legislate in the public interest. These principles were reiterated in the FCTC Punta del Este Declaration and other such declarations. Therefore measures taken by Members were consistent with both WTO and WHO commitments.

2.137. The representative of Canada supported Ireland's proposal to introduce standardised plain packaging for tobacco products. Canada followed with interest the ongoing international developments and held that such measures were in line with both international trade and public health. As a pioneer in the packaging labelling requirements for tobacco products, such requirements were a core component of the right to regulate in the public interest. As the discussions moved forward, he said Members might want to consider the complete economic picture regarding tobacco control and whether tobacco was actually a net economic gain to many countries.

2.138. The representative of Indonesia supported Malawi's concerns and referred Members to its concerns reflected in the minutes of the previous Committee meeting (G/TBT/M/64/Rev.1)

2.139. The representative of the European Union thanked delegations for their comments on the Irish Public Health (Standardised Packaging of Tobacco) Bill 2014 which had been enacted in March 2015 with orders for commencement to be signed by the Minister for Health. The transitional periods for the Act were in line with those set out in the EU Tobacco Products Directive i.e. May 2016 and would fully apply from May 2017. As already noted in previous meetings, the European Union reiterated that tobacco products had recognised harmful effects on human health. In that sense, Article 2.2 of the TBT Agreement included the protection of human health as a legitimate objective. The Agreement also recognised that any measure pursuant to this legitimate objective must not be more trade restrictive than necessary and create unnecessary obstacles to international trade. It should also be noted that Article XX(b) of the GATT 1994 emphasised the importance of public health by justifying measures "necessary to protect human … health". The legislation was in response to packaging design strategies developed by tobacco companies in recent years which were clearly aimed at young people, including young women. This Act formed the latest strand of a comprehensive range of tobacco control legislation already in place in Ireland which included a ban on smoking in the workplace, a ban on tobacco advertising and sponsorship, a ban on the display of tobacco products in shops and a requirement for all tobacco products to be stored within a closed container. In addition, all tobacco products placed on the market had to display combined text and graphic health warnings. Certain types of sale promotions were prohibited and selling tobacco products to those under 18 years of age was also forbidden. Legislation prohibiting the smoking of tobacco products in vehicles where children were present was enacted in December 2014 and would enter into law in 2015.

2.140. The EU explained that, in addition to the Public Health (Standardised Packaging of Tobacco) Act 2015, Ireland notified an explanatory memorandum that detailed the rationale of the measure and its expected health impacts, a regulatory impact analysis and several scientific studies on the impact of plain packaging on smoking prevalence. In parallel with the WTO notification, Ireland had also notified the measure to the European Commission in accordance with internal EU requirements for notification of draft national technical regulations under Article 8 (1) of Directive 98/34/EC and under Article 24 (2) of the Tobacco Products Directive 2014/40/EU. Ireland received detailed opinions and comments from some EU Member States on the draft measure within the framework of the internal notification procedure. These were analysed, considered and responded to by the Irish authorities. Comments received from WTO Members under the WTO TBT notification procedure, were being equally examined and written replies would be provided.

2.2.3.17 Ecuador – Resolution establishing the "General conformity assessment framework for Ecuador" and the "Handbook of procedures to be observed prior to all stages of the customs clearance, marketing and market surveillance of manufactured, imported and marketed goods subject to Ecuadorian technical regulations[6] - IMS ID 398

2.141. The representative of Canada was concerned with the burdensome nature of Ecuador's conformity assessment policy and practice requirements, and local practice for conformity acceptance. He described the difficulties faced by a Canadian company to ship potato products to Ecuador. These included the certificate of conformity to regulatory requirements (general and including technical regulations INEN 085 and 022) that had to be supported by a verification checklist to demonstrate compliance with compositional regulatory requirements, a verification checklist to demonstrate compliance with food labelling requirements (technical regulation: INEN 022), a compliance report to demonstrate the actual lab analysis on key quality parameters and a certificate of plant compliance to GMPs. Once all of these documents were compiled (more than 16 pages), the exporter was advised that they needed to be notarized and legalized through the Ecuadorian consulate or through a client in Ecuador. This process took a number of days to complete and became quite disruptive because of the number of people involved. Products were required to be segregated at the warehouse level until all documents were prepared which further complicated operations. However these necessary documents appeared to be redundant given that while a sanitary registration was required, other documents required appeared to be used to guarantee quality and compliance. He suggested that a certificate of conformity could be sufficient instead. He asked if there had been any recent changes to the policy or process that might alleviate concerns of importing companies and if it was possible to have a clear template for importing companies that would help ensure conformity while reducing the duplicate nature of some of the documents and processes.

2.142. The representative of Brazil highlighted some concerns regarding the resolution establishing the "General conformity assessment framework for Ecuador" and the "Handbook of procedures to be observed prior to all stages of the customs clearance, marketing and market surveillance of manufactured, imported and marketed goods subject to Ecuadorian technical regulations". He asked if Ecuador could clarify whether international standards were taken into account, and if so, which ones. In some cases, exporters were experiencing difficulties in identifying accredited test laboratories and accredited certification bodies. The significant bureaucracy in the acceptance of tests made outside Ecuador, the lack of transparency in the procedures for complying with the new product requirements, and the procedures for the acceptance of "manufacturer's declaration of conformity" were burdensome and bureaucratic. Therefore, the measures seemed more trade restrictive than necessary. Specifically, on the "General conformity assessment framework for Ecuador", he sought clarification on transitional provision four and on how this provision relates to Article 2.1 of the TBT Agreement. He thanked Ecuador for the constructive bilateral discussions which had taken place and looked forward to continued engagement.

2.143. The representative of Ecuador informed the Committee that Item 17 of the assessment framework guaranteed Ecuadorian citizens' right to safety, security, protection of human and animal life, and protection of the environment. The Inter-ministerial Committee on Quality of Ecuador was, according to article 9.1 of the law on the Ecuadorian System of Quality, established as the body in charge of formulating the policies on the basis of which products would have to comply with technical regulations and conformity assessment procedures before they were traded. The Inter-ministerial Committee on Quality of Ecuador established resolutions 001, 002 and 005 with guidelines for the trading of products in accordance with the requirements of the technical regulations, and how they would be applied. Ecuador was of the view that the guidelines could not constitute trade restrictions as they sought to establish effective mechanisms to make it possible to evaluate compliance with the requirements. In any event, prior to placing products on the market, producers who were subject to technical measures had to submit a conformity certificate or an inspection that showed that there was compliance with the technical regulation that had been made available by the conformity body. The procedure is electronic for domestic and foreign products.

[6] G/TBT/N/ECU/44, G/TBT/N/ECU/44/Add.1, G/TBT/N/ECU/44/Add.2, G/TBT/N/ECU/44/Add.3.

2.2.3.18 Russian Federation – Measure affecting import of Ukrainian confectionary products - IMS ID 399

2.144. The representative of Ukraine reiterated concerns raised continuously since March 2013 with regard to the ban on the import of Ukrainian confectionery products into the Russian Federation. Despite efforts to reach a settlement, the relevant Russian authorities continued to act in a discriminatory and non-transparent manner. Ukraine still awaited Russia's written replies to the questions submitted such as: A request for scientific information, including laboratory test results with regard to products banned for importation since 29 July 2013 and 5 September 2014; Official detailed clarification and justification of keeping the ban and explanation as to the compliance of the measures with Articles 2.1 and 2.2 of the TBT Agreement; and Official results of the inspection of Ukrainian factories that was conducted in October 2013. She reminded the Committee of Russia's proposal at the November 2014 meeting concerning bilateral consultations at the level of competent authorities of both countries and looks forward to such consultations.

2.145. The representative of the Russian Federation explained that the suspension of imports of confectionary products was introduced because of labelling non-compliance under the technical regulation of the Customs Union on the labelling of food products, adopted on 9 December 2011. In July 2013, the Russian regulating authority Rospotrebnadzor had detected that the labelling of confectionary products produced by Roshen contained false information and were not in compliance with the requirements. In 2014, further non-compliance was detected in a whole range of Ukrainian companies, highlighting a decline in surveillance by the Ukrainian competent authorities. The measures introduced by the Russian Federation were in compliance with WTO rules, particularly with the provisions of the TBT Agreement – to protect Russian consumers' right to reliable information about the products, and to prevent deceptive practices. He considered Ukraine questioning Russia on the principle of national treatment to be unjustified, as these technical regulations applied equally to Russian producers. Following consultations in December 2013, Ukrainian authorities had recognized that there had been non-compliance in Ukrainian products with the EAEU technical regulation requirements, and arrangements were made to rectify this. To date, Ukrainian authorities had still not undertaken the measures agreed upon so as to allow products onto the Russian market. In the meantime, other Ukrainian products were also found to be non-compliant with the conformity requirements. He said the competent authorities would continue discussions on a bilateral basis in order to avoid further restrictions.

2.2.3.19 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 [7]- IMS ID 411

2.146. The representative of Canada said that while Canada supported Ecuador's objective of reducing the risk of non-communicable diseases, they were concerned that Ecuador's requirement for the inclusion of a graphic system indicating the concentration of various nutritional components in food products could deviate from international standards. He asked what scientific evidence was behind the categories for levels of concentration of nutritional components. Canadian industry had reported some market access challenges with respect to demonstrating compliance with the requirements of this regulation. The multiplicity of documents needed to prove that products were in conformity with the Ecuadorian regulation was overly burdensome and time-consuming. He looked forward to hearing Ecuador's views concerning this new regulation and its impact on trading partners.

2.147. The representative of the United States raised concerns regarding the overly burdensome and duplicative process to demonstrate conformity with labelling elements. These included a label review as part of the Sanitary Food Registration process and a certificate to demonstrate compliance with Ecuador's commodity standards. These requirements did not appear to add value in ensuring the safety of the products in question. She said US suppliers continued to encounter difficulties complying with the certificate of conformity requirements and reported that they had been unable to self-certify through use of accreditation with ISO standards. US suppliers had to provide per lot or per shipment laboratory tests from an OAE accredited lab, in addition to self-certification, thereby undermining the use of self-certification. While Suppliers should have records available if audited, there should be no need to produce them with every shipment. She asked Ecuador to provide an update on recognizing third party testing. Concerning the choice to declare

[7] 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.

total fats versus saturated fats, Codex had established a NCD-NRV for saturated fat; however, no such recommendation existed for total fats. Further, in the last amendment, the reference to WHO/FAO as a basis for determination of nutrient content limits had been deleted. She noted that Codex has not established an NCD-NRV for sugar. The US and other WTO Members had enquired as to the basis for the nutrient content limits, but no national level research had been supplied to support the determined levels. Regarding the mandatory requirements, she reiterated the US position that for foods derived from genetically modified organisms that had been found to be substantially equivalent to conventional counterparts, mandatory "Contains Transgenics" labelling could create an erroneous impression that the product was less safe than conventional products. Genetically engineered products that had been evaluated through risk-based safety assessments in accordance with international guidelines, such as through the Codex Alimentarius Commission, should not require different labelling. She said that in addition to confusing consumers, such labelling might also increase costs to industry, consumers, and government authorities. Rather than a mandatory labelling requirement, a voluntary approach would allow for consumer choice and encouraged Ecuador to reconsider its mandatory approach to biotech labelling. Concerning Articles 5.2 and 5.3 of the measure notified in G/TBT/N/ECU/19/Add.8, on the proposal to base its biotech labelling requirement on a 0.9% threshold, she asked for clarification of how this threshold would be calculated. She sought confirmation that the measure would exempt foods which did not contain transgenic protein or DNA, such as highly processed products, from genetically engineered crops; foods which may be produced using genetically engineered processing aides; and foodstuff derived from animals fed with genetically engineered feed.

2.148. The representative of Mexico reiterated concerns regarding Resolution No. 116, in particular the "certificate of recognition" requirement that applied to a range of products. He also raised concerns with Ecuador's draft first revision, PRTE INEN 022 (1R), of the Ecuadorian Standardization Institute Technical Regulation entitled "Labelling of processed and packaged food products", notified to WTO Members in document G/TBT/N/ECU/19/Add.8. Mexico's full statement is contained in document G/TBT/W/407.

2.149. The representative of Brazil sought clarification on whether the technical regulation was based on an international standard and if so, which one. The signs to be displayed on products followed a system of coloured bars to indicate the amount of certain ingredients and Brazil asked Ecuador to clarify the technical criteria they had adopted and whether Ecuador had considered less trade restrictive measures to fulfil the same objective. Concerning the required labelling on genetically modified organisms and threshold of 0.9%, he asked what criteria or international standard had been followed in that regard.

2.150. The representative of Guatemala was concerned that the speed of implementation and the lack of prior notification of the measure. While the regulation was derived from Codex Alimentarius, there was a clear departure from it in that it was not science based, was stricter than necessary, and other less trade restrictive measures had not been considered. Foodstuff could be characterised as good or bad on the sole basis of the nutritional content because of a number of inherent nutritional characteristics. Even when exporters sought to comply with the various measures, the necessary conditions for compliance were not available. Therefore the necessary procedures to assess conformity were not available. In conclusion, given the uncertainty that foreign exporters had to deal with, he asked that Ecuador reconsider the design and the scope of the measure.

2.151. The representative of Costa Rica said they had a number of concerns regarding the sign to be placed on the label on the basis of a sodium, fats and sugars content, as prescribed under RTN 022. Food products that were processed and packaged had to comply with resolution 14413 of 22 August 2014. He reiterated that they considered the system Ecuador had relied upon was not based on scientific evidence. There were also concerns with the requirements for the list of products with transgenic ingredients. He questioned the scientific substantiation of that proportionality against what was in Article 2.2 of the TBT Agreement. He requested clarification on how the terms were dealt with under the final regulation and supported the concerns raised by other delegations.

2.152. The representative of the European Union joined other delegations' concerns on the Ecuadorian Technical Regulation 022 which imposed nutrition food labelling obligations comprising "high in" warnings and a traffic light warning system. While fully sharing Ecuador's public health objectives regarding the provision of adequate nutritional information to consumers, the EU

doubted that the approach taken in the notified draft was the best way to achieve those objectives or that it was proportional to the aim pursued of enabling consumers to make an informed choice in order to foster effective competition and consumer welfare. The representative recalled previous interventions recorded in the minutes on the lack of proportionality of the measure, its departure from Codex guidelines and the use of the "high in" warnings of the previous meeting of this Committee (G/TBT/M/63).

2.153. The representative of Ecuador recalled what had been stated previously in the TBT Committee in that Resolution No. 116 neither created nor introduced technical regulations, but rather incorporated and withdrew subparagraphs subject to the Certificate of Recognition requirement and was clearly an administrative measure for the purposes of customs control. She stated that each regulation established, *inter alia*, its scope of application, its date of entry into force, and its conformity assessment mechanisms, and all had been notified to the TBT Committee. The Resolution only provided for the submission of a supporting document with the customs declaration as part of an internal administrative procedure, and consequently, it was not a technical regulation. Resolution No. 116 could not be considered a restriction to trade, as it was consistent with multilateral regulations.

2.154. On the Regulation RTE022 "Food Labelling", Ecuador reported that the Ministry of Health conducted a National Survey on Health and Nutrition in 2012, which showed Ecuador's epidemiological profile was on an upward trend in the number of non-communicable diseases affecting all segments of the population, regardless of age, place of residence or socio economic level. This inspired the Ecuadorian Government to develop policies geared towards the prevention of chronic diseases, which meant ensuring that people had access to appropriate, clear, accurate and non-misleading information on the content and characteristics of food. Hence the Sanitary Regulations for the Labelling of Processed Foods for Human Consumption, which provides that "any food processed for human consumption shall comply with Ecuadorian Technical Regulation RTE INEN 22 on the labelling of processed and packaged food products. There shall also be a system of horizontal colour coded bars (…)". The reference framework for the Sanitary Regulations was the international resolutions reaffirming the decisions adopted by the World Health Assembly, to promote the implementation of the WHO Global Strategy on Diet, Physical Activity, and Health by introducing policies and measures designed to promote healthy diets and to encourage the implementation of all of the WHO recommendations for the promotion of food and non-alcoholic beverages for children, including food with a high content of saturated fats, trans fatty acids, free sugars or salt and by fostering policies that favour the production of food conducive to a healthy diet and that facilitate access thereto. Besides the measure was notified to the WTO on 12 March 2014 and a number of comments were received from Member, chiefly relating to the positioning of the label, the prohibition on the use of children and animals in advertising, and the use of self-adhesive labels, amongst others.

2.155. On the other points raised, she stated that the distinction between the terms "food" and "processed food" referred to in the Sanitary Regulations was based on international and national standards: the General Standard for the Labelling of Pre Packaged Foods (CODEX STAN I 1985), and Article 259 of Ecuador's Organic Law on Health; The definition of the health claim referred to in the Sanitary Regulations corresponded to the definition contained in the document "Guidelines for Use of Nutrition and Health Claims" (CODEX CAC/GL 23 1997). She said evidence of the importance to consumers and their preference and understanding of graphical labelling of the kind used by Ecuador was based on a variety of studies, including a Full Regulatory Impact Assessment in the United Kingdom showed that traffic light labelling had led consumers to make more healthy choices. A study conducted in New Zealand in 2014 assessed the impact on consumer choice in relation to a selection of processed foods of four different types of food labelling, and showed that traffic light food labelling was the best way of communicating the nutritional content of processed foods. Similarly, a systematic review of 38 scientific articles assessing the impact of front of pack labelling on consumers revealed that participants identified the healthier options more easily when the label appeared on the front of the package. Furthermore, she stated that Ecuador was complying with indicator 3.3.1 of the Pan American Health Organization's Plan of Action. Ecuador considered that there were enough technical and scientific arguments to justify the need for the measure and as part of its comprehensive public policy, the Government of Ecuador was also developing other strategies to promote healthy nutrition.

2.2.3.20 France – Recycling Triman Mark: "Draft Decree on a common set of symbols informing the consumer about recyclable products subject to a system of extended producer responsibility associated with waste sorting instructions" (G/TBT/N/FRA/153) - IMS ID 420

2.156. The representative of Canada acknowledged that France's proposed labelling scheme for products was based on environmental considerations. There were, however, a number of questions following the recent amendments to the TRIMAN regulations, published on 26 December 2014. Canada was of the view that environmental and safety labels on products should be clear and comprehensible for the consumer. Internationally developed and recognized symbols for recycling of products, such as the green dot recycling compliance logo and Möbius recycling marker, had been used effectively for many years. He asked that France confirm that manufacturers could place the TRIMAN mark on their product websites so as to satisfy the marking requirements under the regulation. He noted that the 26 December 2014 amendments included a reference to the equivalency of other recycling marks from other European Union Member States and asked that France confirm that this also applied to internationally developed and recognized recycling marks that were used by some of those Member States. He asked for clarification on whether France would accept products bearing recycling marks used by other European Union Member States in lieu of the TRIMAN mark from WTO Members who are not European Union Member States, in accordance with its most favoured nation obligations under Article 2.1 of the TBT Agreement

2.157. The representative of the European Union informed the Committee that the decree introducing a recycling symbol (the so called 'TRIMAN logo') had been published on 26 December 2014 and entered into force on 1 January 2015. According to the adopted decree, the waste sorting instructions, which had to contain at least the recycling symbol ('TRIMAN logo'), had to be affixed, preferably on the product, but could be affixed on the product packaging, accompanying product manual or on any supporting media (including dematerialised forms).

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

2.158. The representative of the European Union requested the Russian authorities to provide an update on the timeframe for the adoption of the amendments notified under notification G/TBT/RUS/29. The Russian authorities had informed the TBT Committee during the last Committee meeting that the amendments were still under development and that the estimated date for adoption was January 2015 at the earliest, with an expected entry into force in July 2015. He asked whether the adoption did happen in January 2015 and for confirmation that the foreseen timing for the entry into force of the amendments in July 2015 was still valid. He also requested that the final adopted text be made available.

2.159. The representative of the Russian Federation said that timeline for the implementation of the technical regulation revealed the need for changing certain requirements applied under the measure. Such amendments to the technical regulation were developed and accordingly notified as required by the TBT Agreement. The comments received were being considered and the draft amendments to the technical regulation were under development. The amendments would most likely be adopted in April 2015, and accordingly enter into force in October 2015. Until then, the amendments to the current version of technical regulation were to be applied.

2.2.3.22 India – Labelling for Canola Oil – IMS ID 413

2.160. The representative of Canada reiterated concerns relating to the Food Safety and Standards Authority of India (FSSAI) import clearance notice that the product must be labelled and marketed as "Imported Refined Rapeseed Oil - Low Erucic Acid". He stated that India's decision to apply such labelling requirements directly affected exports, marketing and sales of canola oil in India. 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. Moreover, the requirements differed from the international standard, namely the relevant guidelines recommended by Codex Alimentarius. The Bombay High Court had ruled in favour of an importer, by issuing a stay order against the FSSAI labelling guidelines for "canola oil" and this had been upheld by the Supreme Court. A final ruling was yet to be issued by the Bombay High Court and he requested India to provide information on the status and possible next steps. He

encouraged India to consider an alternative measure that would follow Codex Alimentarius guidelines, and not create an unnecessary barrier to trade.

2.161. The representative of Australia remained concerned with the requirements 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). This was an unnecessary labelling burden for Australian exporters of refined "canola oil" to India and the term "canola oil" was often used to describe domestic products that were available for local sale in India. He said that India's Plant Quarantine Order 2003, which outlined India's import quarantine requirements for plants and plant products, allowed the use of the alternative terms "rape and canola". Australia supported FSSAI's initiative of harmonising India's food standards with Codex that commenced in early 2013.

2.162. The representative of India stated that there was no change to the regulatory status since the last TBT Committee meeting and requested concerned delegations to refer to the statement at that meeting which was reflected in paragraph 2.206 of G/TBT/M/64/Rev.1.

2.2.3.23 Egypt – Bottled water - IMS ID 421

2.163. The representative of Turkey reiterated its ongoing concerns on the export of bottled water to Egypt. Exporters from Turkey were unable to obtain import permission from Egypt's Ministry of Health Supreme Committee for Water as the periodic control of the source could not be maintained based on Egyptian Standard No. 2007/1589. Bilateral efforts including an invitation for the technical committee to visit Turkey in April and a meeting request with the relevant Egyptian authorities in October 2014 had not been replied to. Turkey had received a letter from the Ministry of Trade, Industry and SMEs in which requirements for putting bottled water into the Egyptian market were explained but these procedures were, in Turkey's view, only for domestic producers as the Supreme Committee did not grant permission to Turkish firms. He again posed the following questions: (i) what were the requirements for exporting bottled water to Egypt; (ii) from which countries did Egypt allow importation of bottled water; (iii) how did the Egyptian authorities maintain periodic control of the source of the bottled water coming from these countries; and, (iv) whether they conducted inspection visits, or required test reports or certificates. Turkey reiterated its readiness to invite a technical committee from Egypt to conduct inspection visits and control the water source if this was the requirement applied by Egypt to its trading partners. Egypt's current policies and practice were contrary to the principle of non-discrimination and also constituted an unnecessary obstacle to international trade in violation of Articles 2.1 and 2.2 of the TBT Agreement. He invited Egypt to cooperate with Turkey to find a mutually satisfactory solution and recalled Egypt's existing obligations under WTO Agreements in general, and the TBT Agreement in particular.

2.164. The representative of Egypt said that five bilateral meetings had been held with the Turkish delegation on the side-lines of the TBT Committee between July 2013 and November 2014. At these meetings, Egypt had confirmed the necessity for companies to abide by the Egyptian Standard No. 2007/1589 to export bottled water to Egypt. This standard was publicly available at the Egyptian Organization for Standardization website[8] and at their Headquarters in Cairo. A copy of the standard had been provided to the Turkish delegation in November 2014.

2.165. Regarding Turkey's concerns on the conformity of the Egyptian Standard with Codex standards and WHO guidelines and on the work being undertaken to update the standard, she said that the Egyptian Standard for "Bottled Water (other than Natural Mineral Water)" was in conformity with the relevant Codex Alimentarius Standard No. 227/2001 and the WHO Guidelines Reference Vol – 1 – 2006. Updating the current standard did not imply that it was not in accordance with international standards but was rather a reflection that the country was keen to adhere to the latest scientific research and risk assessments published by these organizations. Both developed and developing countries had similar practices to ensure consumer health safety and protection through continuous or periodic revision of standards. Public health and safety regulations remained a priority for Egypt. The prerequisite to export bottled water applying the HACCP system with an EU reference had been removed but applying HACCP was still otherwise

[8] www.eos.org.eg

mandatory for companies seeking to export bottled water to Egypt pursuant to Ministerial Decree No. 50 of 2008.

2.166. Egypt reconfirmed that equal treatment was accorded to both national and foreign companies equally as long as the companies were in compliance with the Egyptian Standard No. 2007/1589. In 2012, the Egyptian authorities had suspended 13 Egyptian bottled water companies due to their non-compliance with the Standard. Since October 2013, all companies requesting permission to export bottled water to Egypt, including Turkish companies, were advised by the Supreme Committee of Water of the Ministry of Health to comply with the Egyptian Standard. Moreover, the Egyptian authorities had provided the Turkish delegation with the requirements and procedures needed to obtain prior permission for commercially developed water resources. After completion of this step, conducting regular checks and inspection visits to the water sources would apply. More than 50 foreign companies, including Turkish ones already present in Egypt, were registered with the Ministry of Health for exporting natural mineral water to the Egyptian market. No Turkish company had requested permission to export bottled water since October 2013. Egypt believed that it was in compliance with Article 2.1 of the TBT Agreement and that compliance with the Egyptian standard was not more trade restrictive than necessary as it was vital to protect human health and safety.

2.2.3.24 United Kingdom – Proposal to introduce plain packaging of tobacco products (G/TBT/N/GBR/24) - IMS ID 424)

2.167. The representative of Malawi expressed her delegation's concerns regarding the consistency of the proposed measure with the TBT Agreement. She also requested the United Kingdom to abstain from any tobacco plain packaging legislation until the WTO disputes lodged against Australia's plain packaging measures had been concluded. Malawi's full statement is contained in G/TBT/W/402.

2.168. The representative of Indonesia appreciated the attention given by the United Kingdom to the harm of consuming tobacco products. However, in Indonesia's view, the proposal submitted by the UK Government related to plain packaging of tobacco products violated Article 2.2 of the TBT Agreement and also several provisions of the TRIPS Agreement. Studies by researchers, using different analytical approaches and data sets, had failed to find empirical evidence that plain packaging measures were reducing the prevalence of smoking in the general population or among youth. After nearly two years of plain packaging implemented by one Member, there was no available survey evidence that plain packaging was having a positive impact on consumer behaviour. Plain packaging had failed to bring about the decline in tobacco prevalence. As Indonesia was currently in a dispute on a similar issue against Australia, he urged the UK to postpone their proposal until this dispute was solved.

2.169. The representative of Australia reiterated its delegation's strong support for the decision by the UK to legislate for the mandatory plain packaging of tobacco products. Australia welcomed the passage of the UK's regulations for standardised packaging by the UK Parliament, which it understood would come into force in May 2016. He said that the decision followed the assessment of evidence of positive public health impacts of standardised packaging, including the findings of an independent review. Moreover, the important steps made by the UK in tobacco control demonstrated that efforts to delay the adoption of tobacco plain packaging measures in a number of countries had not been successful. Australia would continue to support the development and implementation of the UK's tobacco plain packaging measures. In the interest of time, he requested that the issues highlighted by his delegation on Ireland Plain Packaging measures, also be considered for this specific trade concern.

2.170. The representative of Guatemala said that it supported the legitimate objectives pursued by the UK related to public health and tobacco control. However, Guatemala had concerns about the proposed legislation and urged the UK to consider less restrictive alternative measures that effectively achieved its legitimate objectives.

2.171. The representatives of Zimbabwe, Nicaragua, Nigeria, New Zealand, Norway and Uruguay requested that their comments delivered under Ireland – Proposal to introduce plain packaging, also be taken into account for this specific trade concern.

2.172. The representative of the European Union stated that the UK's Draft Regulation on "Standardised Packaging of Tobacco Products" was notified on 3 September 2014 (G/TBT/N/GBR/24). The UK Government had tabled the standardised packaging regulations in Parliament with the intention that these regulations be debated before the end of March 2015, would apply to the whole of the UK, and enter into force at the same time as the EU Tobacco Products Directive in May 2016. Tobacco products had recognised harmful effects on human health. Article 2.2 of the TBT Agreement included the protection of human health as a legitimate objective and it was also recognised that any measure pursuant to this legitimate objective must not be more trade restrictive than necessary and create unnecessary obstacles to international trade. It was also noted that Article XX (b) of the GATT 1994 emphasized the importance of public health by justifying measures "necessary to protect human […] health". The UK Regulation aimed at restricting the promotion of tobacco products to further reduce the smoking prevalence in the UK by: (i) discouraging uptake of tobacco use by young people; (ii) encouraging and supporting tobacco users who want to quit; and (iii) reshaping social norms and attitudes around tobacco use to promote health and wellbeing. He added that the measure would be latest in a comprehensive range of tobacco control legislation already in place in the UK. Under existing legislation, there was already a ban on advertising tobacco products to the general public, a ban of tobacco sponsorship to sports and cultural events; and companies were forbidden to give free samples of tobacco. Furthermore, pictorial warnings on tobacco products were required in the UK and the sale of tobacco products from vending machines was prohibited. As from 2015, tobacco displays in all shops would be prohibited.

2.173. He explained that the UK had also made available, through the TBT notification, an explanatory memorandum that detailed the rationale of the measure and its expected health impacts, an impact assessment and several scientific studies on the impact of plain packaging on smoking prevalence. In parallel with the WTO notification, the UK had also notified the measure to the European Commission in accordance with internal EU requirements. The UK had received detailed opinions on the draft measure from some EU member states which were analysed and considered by the UK authorities. As regards the comments received from WTO Members, he said that these were equally examined and written replies would be provided.

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

2.174. The representative of Canada said that its concerns had been expressed in a letter to Thailand's enquiry point on 27 May 2014 and at previous TBT Committee meetings. His delegation appreciated that comments from trading partners had been taken into account and that Thailand could consider a different approach to the graphic warning labels. Concerns remained about the proposed measures that prohibited the use of wine labels that contained: images of athletes, artists, singers or cartoons; and messages affiliated with activities such as sport, music and contests. Some terms and definitions lacked clarity and could result in uncertainty for wine exporters. For example, some Canadian wine labels could breach Clause 2 (2) and Clause 3 (1-4 and 6) of the proposed rules as they portrayed depictions of athletes, artists and singers or other artistic depictions which could be considered "cartoons". Canadian wine labels were not intended to appeal to children or promote irresponsible alcohol consumption. There was no correlation between the sale of products labelled with sport or cartoon-like images with an uptake in youth or irresponsible drinking. He recognized Thailand's right to implement regulations to protect consumer health and safety, and provide consumers with adequate information to make informed choices. Canada was, however, concerned that Thailand's proposed labelling 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. He asked if Thailand had any studies to suggest such labelling requirements would help achieve its policy objectives and whether it had considered any less trade restrictive alternatives. Canada and Thailand participated in the APEC Wine Regulators Forum to discuss regulatory cooperation and trade facilitation where the spirit of the group was to eliminate unnecessary technical requirements and impediments to the trade of wine.

2.175. The representative of the United States expressed concerns with Thailand's recently adopted measure on alcoholic beverage labelling. The US had submitted comments on the original text notified by Thailand and noted that many of these comments were not reflected in the measure adopted on 25 December 2014. The US supported Thailand's desire to address public

safety and health concerns related to excessive alcohol consumption, but requested the opportunity for further consultation to define a less trade restrictive solution. She emphasized that the measure, as written, would cause confusion for exporters, as its vague and unclear language was open to misinterpretation or different interpretations by various government officials, which could result in unnecessary obstacles to trade, including impediments to new entrants into the market. She urged Thailand to reconsider this measure, taking into account the comments provided. Given the need for guidance on how the measure would be implemented, Thailand should allow for adequate transition periods to facilitate industry's adjustment to the new labelling scheme. The US understood that Thailand was now reviewing alternative labelling measures and requested clarification on what options were being considered. She asked for confirmation that Thailand was considering disbanding the National Alcohol Policy Committee. Given the roll of this committee, she asked who would ensure that policies took all stakeholder input into account.

2.176. The representative of Mexico expressed his delegation's concerns regarding the consistency of the proposed measure with the TBT Agreement and its effect on trade in alcoholic beverages. The measure could also violate the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). Mexico's full statement is contained in G/TBT/W/408.

2.177. The representative of the European Union reiterated concerns regarding the Regulation on "Criteria, Procedures and Conditions for Labels of Alcoholic Beverages" (B.E 2558/2015) notified by Thailand on 28 March 2014 and published in the Royal Gazette on 22 January 2015. His delegation regretted that none of the issues previously raised had been properly addressed in the final act. There remained concerns about the strict labelling requirements proposed in the notified draft and its departure from international standards. Referring to Article 2.4 of the TBT Agreement, the EU invited Thailand to clarify the reasons for a deviation from the definition of a label and a container as provided in the text of CODEX STAN 1-1985. Regarding Clause 2 and 3 of the adopted regulation, the EU was concerned that the lack of clarity in the provisions of the notified draft relating to messages on labels may lead to inconsistent interpretations by economic operators. He requested Thailand to explain how it intended to interpret and enforce these clauses. The administrative complexity of the label approval process, to be dealt with by two separate government agencies, and the short implementation deadlines for compliance constituted serious market access barriers. Lack of information regarding implementation and the transition period was a concern. He requested Thailand to provide appropriate guidelines for implementation, to extend the transition period to one year, and to allow the sale of all products existing in the market until stocks had been exhausted.

2.178. On a positive note, the EU said that the use of graphic health warnings was not part of the recently adopted regulation, but remained concerned about its possible introduction in the future. He requested further clarification on the status of this proposed measure and welcomed Thailand's commitment, at the last meeting, to notify the TBT Committee. He requested Thailand to take into consideration less trade restrictive measures or, failing this, to clarify on which basis and evidence Thailand considered that different, less costly and burdensome alternatives than the indication of a graphic health warning, would be insufficient to address the objective pursued.

2.179. The representative of Australia recognised the right of governments to take measures necessary to protect public health and the Thai Government's efforts to address a legitimate concern through its proposed labelling regulation for alcoholic beverages. He, however, sought clarifications on the impact of the proposed regulation for importers and was concerned that Clause 2 and 3 could cause uncertainty for importers as to whether certain labels were consistent with the regulation. In Clause 2 (1-2), it was unclear what constituted an "unfair message to consumers" and what terminology on labels would be prohibited under the regulation. He asked if descriptions of the taste and quality of wine would be permitted or considered to "indirectly persuade consumption". Would descriptors such as "finest", "premium" or "prestige" and images associated with a brands heritage such as a mountain or vineyard still be permitted? In Clause 3 (4), he said that the definition of a "cartoon" was unclear and asked if, for example, artistic drawings and illustrations that were well-established elements of the trademark would be prohibited under these measures. Moreover, the label approval process appeared to be administratively burdensome, as importers/manufacturers required the approval of two government agencies. What were the responsibilities of these agencies in the process? Given the ambiguity in the application of these provisions, and the importance of providing certainty to commercial parties who needed to design, print and affix new labels in order to comply with the

Thai requirements, Australia requested the Thai Government to provide further details on these aspects of the regulation.

2.180. The representative of Thailand said that the regulation on "Alcoholic beverages control, rules, procedures and condition of labels of alcoholic beverages" was notified as G/TBT/N/THA/47 and had been presented in the Royal Gazette on 22 January 2015. The regulation would be fully implemented in March 2015. Products which were imported before March would be allowed to be sold until 22 August 2015. The National Committee on Alcoholic Beverages Policy (NCABP) was taking into account all concerns received from all stakeholders and was also carefully considering how to deal with the pictorial labelling obligations that must be fulfilled. Thailand assured Members that it would provide further details through the notification process without delay and would convey the concerns raised to the relevant authorities.

2.2.3.26 Indonesia – Regulation of Minister of Trade No. 10/M-DAG/PER/1/2014 concerning Amendment of Regulation of Minister of Trade No. 67/M-DAG/PER/11/2013 concerning Affixed Mandatory Label in Indonesian Language for Goods (G/TBT/N/IDN/85) - IMS ID. 436

2.181. The representative of the European Union said that the EU continued to have concerns with the burdensome, time-consuming and costly compulsory registration procedure for sample labels as a precondition for obtaining the labelling certificate (SKPLBI). The EU had raised this concern during the last TBT Committee meeting and sent written follow-up comments on 13 November 2014. The EU considered that the objectives of consumer protection and of prevention of fraud or malpractices could be achieved through a general requirement for local manufacturers and foreign manufacturers/importers to submit a sample label for information to the Indonesian authorities prior to first placing of a product on the Indonesian market. The requirement for permanently affixed labels through engraving, embossing and the like, and the correlated prohibition to affix labels in the form of stickers while products were still in the Indonesian customs was excessively constraining for many products and not in tune with market reality for globally traded products.

2.182. Concerning the requirement that labels for automotive spare parts sold directly to consumers must adhere firmly to the product or packaging unless a letter of exemption from the mandatory labelling in the Indonesian language was obtained, the EU pointed out that international practice did not require, in addition to the homologation markings, specific printings on tyres themselves. The EU invited Indonesian authorities to consider that automotive spare parts, and in particular tyres, with a marking attesting conformity to UNECE regulations be accepted on the Indonesian market without further requirements at customs. Further labelling requirements could apply at the point of sale to the general public without requiring any marking on the product itself, for example by affixing labels to the packaging of tyres or by providing the required information by signs, brochures or other similar ways. Finally, he reminded the Committee that the EU had already raised concerns on the application of labelling requirements for toys, in relation to G/TBT/N/IDN/64 - Technical Guidelines for the Implementation of the Adoption and Supervision of Indonesian National Standards for Obligatory Toy Safety (STC IMS Item no. 328).[9]

2.183. The representative of Japan urged Indonesia to ensure that the regulation was not more trade restrictive than necessary.

2.184. The representative of Indonesia said that the Regulation of the Minister of Trade concerning affixing label in Bahasa Indonesia language was to protect consumers from unclear or wrong interpretation of information. It replaced the previously notified regulation (G/TBT/N/IDN/47). The principles of the regulation were: (i) non-discrimination for domestically produced and imported goods traded in the domestic market; (ii) affixing label in Bahasa Indonesia to be clear and easy to understand; (iii) labelling must be fixed (permanent) for goods and packaging as using sticker was not allowed; (iv) the label would contain information or clarification regarding the identity of the good and business; and (v) information on how to use or a danger symbol or warning sign must be included for items related to safety, health, security and the environment. Goods which were sold in bulk and packaged directly in front of the consumers

[9] 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)

and imported goods as classified in the regulation were exceptions to the regulation. Some types of products were also exempted from this regulation, such as basic materials for production processes, products in bulk, temporary imported products and several other categories. Exemption was also given to producers, trademark holders, general importers and suppliers of automotive products who submitted a letter of exemption to the Directorate of Consumer Empowerment of the Ministry of Trade. Indonesia welcomed bilateral discussion with Members on more specific aspects of the regulation.

2.2.3.27 China – Regulations for the Supervision and Administration of Medical Devices (Order No. 650 of the State Council)[10] - IMS ID 428

2.185. The representative of Canada remained concerned about China's Order No. 650 of the State Council "Regulations for the Supervision and Administration of Medical Devices" which was broad and confusing and could have far reaching effects on the medical device industry in China and foreign suppliers of medical devices. Canada recognized that China had issued a number of implementing measures with respect to Order No. 650 in the past months. However, several elements of the regulatory framework remained unclear and worrisome.

2.186. Specifically, regarding Article 13 of Order No. 4 and Article 15 of Order No. 5, he understood that the new requirement was that imported products for which registration or listing applications were being made should have obtained market approval from the country (region) where the applicant's business registration was or the product was produced. Canada requested clarification on this new interpretation and on which types of document were now required. Such a requirement would be an issue for Canadian exporters who may not necessarily seek regulatory approval domestically. Could applications be made for Canadian-originating medical devices or in-vitro diagnostic products which received approvals in other leading jurisdictions, such as the US or EU, but which were not approved in Canada? If not, could a Canadian company registered in a country for which it had received approvals, such as the US or EU, for its Canadian-originating medical devices or in-vitro diagnostic products that was not approved in Canada, be considered?

2.187. In addition, Canada noted that under Order No. 4 and Order No. 5, China required the applicant to provide registration inspection samples of Class II and III medical devices and in-vitro diagnostic products. Canada was concerned that this form of duplicative type testing was unnecessary and burdensome with regard to imported devices that had already been approved in other markets. He further noted that Article 22 of Order No. 4 stated that clinical trials should be conducted for Class II and III medical devices. However, it was not clear whether foreign clinical trial data was acceptable or whether the trials must be conducted in China. It was Canada's understanding that Class II and III medical devices had to pass a quality test under the "effectively operated quality assurance system" before applying for clinical trial. Could China confirm this new procedure and provide further information on this quality test and the standards being tested. Further information was also requested on the "effectively operated quality assurance system" and on whether foreign labs could provide this testing. Article 35 of Order No. 5 specifically stated that, for in-vitro diagnostic products, a focused clinical evaluation should be conducted in China. Canada was concerned that this constituted an unnecessary and duplicative clinical trial requirement for exporters of in-vitro diagnostic products that had received prior regulatory approval in other leading foreign jurisdictions, including Canada. This requirement would result in additional time and expense being incurred by Canadian medical device exporters wishing to enter the Chinese market.

2.188. Canada was also concerned with the suggested registration fees that would discriminate against foreign manufactures. According to documents released in the media, domestic manufacturers would benefit from preferential registration fees. He hoped that China would implement registration fees that were aligned with its WTO obligations. China was asked indicate when an official price list would become available and also when a final combined catalogue of medical devices would be released.

2.189. The representative of the European Union reiterated its concerns on the Chinese regulations regarding medical devices notified in G/TBT/N/CHN/1022-1026 and 1029 and subsequently raised at the TBT Committee in June and November 2014. He noted that Order No.

[10] 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.

650 established that clinical trials were required for the registration of Class II (moderate) or Class III (higher risk) medical devices in China. Article 17 of Order No. 650 stated that if the safety and effectiveness of the medical device could be proven by using the data obtained from the clinical trial of similar products or during clinical applications, then the product was exempted from clinical trials and listed in a catalogue. Therefore, the EU understood from Order No. 650, that medical devices not listed in the catalogue would have to be the subject of clinical trials to be conducted in China. The EU was still concerned that the draft lists of Class II and Class III devices which would be exempted from clinical trials were limited. Moreover, the regulatory mechanism to update such lists tended to lag significantly behind the pace of innovation in the medical technology sector. The EU, therefore, requested that the China Food and Drug Administration (CFDA) put in place a robust system that allowed swift updates of the exemption catalogues, as needed. The EU was also concerned that for products not listed in the catalogues, duplicative and redundant clinical trials would have to be conducted in China. Due consideration needed to be given to studies which have taken place outside of China, especially where studies had been conducted in a jurisdiction which, like China, was a member of the International Medical Device Regulators Forum (IMDRF). In most cases, the results of studies would be valid across populations and would not need to be repeated or may only require smaller bridging studies to ensure that the original data was relevant for China. The EU reiterated the importance of avoiding any duplication of clinical trials which would cause additional delays in placing products on the Chinese market without any added benefit. The EU remained concerned regarding the requirement for registration of medical devices in the country of origin. He failed to understand the rationale for the requirement, as all medical devices marketed in China (whether already registered in the country of origin or not) needed to comply with comprehensive Chinese authorization requirements.

2.190. Concerning the Electromagnetic Compatibility (EMC) testing, the EU reiterated its request that CFDA accept test reports from foreign laboratories accredited by bodies that were members of ILAC, as an alternative to in-country testing in China. The EU stressed that the registration certificate should exclude potentially confidential "Product Technical Requirements" documentation. Finally, the EU requested that Chinese authorities provide a three year transitional period as the new provisions introduced major changes. Further guidelines detailing the relevant processes would also be welcome.

2.191. The representative of the Republic of Korea said that overseas manufactures could produce medical devices for export rather than for the domestic market due to national regulations, medical environment or for other reasons. However, the notified regulation (G/TBT/N/CHN/1026 and 1029) required foreign exporters to submit a marketing certificate authorized in their country of origin for approval in China. Such a requirement would create additional delays to enter the Chinese market without any added patient benefit. He requested that China exclude this requirement for imported medical devices. Furthermore, he understood that Chinese authorities required notarization of the marketing certificates. Korea asked that China exclude the marketing certificates authorized by the government of the country of origin from the registration requirement for imported medical devices and avoid the requirement of a Chinese version of marketing certificates. Concerning the registration fees, Korea had been informed by domestic industry that the Chinese authorities were finalizing regulations on registration fees for medical devices. Korea asked China to notify the measures so that manufacturers and stakeholders could submit their comments and concerns.

2.192. He noted that the Chinese standard on Electromagnetic Compatibility (EMC) was identical to the IEC standard but China did not accept test reports issued by internationally accredited laboratories that abided by the IEC standard. This would lead to unnecessary duplication of testing and additional delays and costs for foreign exporters as medical devices imported to China were already tested in accordance with the IEC standard. Therefore, Korea requested China to accept, for approval of overseas medical devices, the test reports which were from internationally accredited laboratories or were internationally recognized test reports tested consistently with China's technical requirements.

2.193. The representative of China said that the Regulations for "Supervision and Administration of Medical Devices" categorized medical devices according to the level of risk with Class I, II and III from low to high risk. For administration, Class I medical devices only needed to be filed, while Class II and III devices had to be registered. In manufacturing, again Class I medical devices only had to be filed, while Class II and III devices needed to be examined and approved by CFDA. Concerning business operations, there was no special limits set by CFDA on Class I medical

devices, but Class II medical devices needed to be filed and Class III medical devices licensed. She said that notifications G/TBT/N/CHN/1022-1026 and 1029 were drafted to enforce the Regulations. Before implementation, CFDA had held specialized training to help enterprises and organizations understand these measures. She added that CFDA had communicated directly with relevant foreign and domestic enterprises and associations and had taken comments into account, including those received from the EU and US chambers of commerce in China. Comments from all Members, interested parties and stakeholders would continue to be taken into account.

2.2.3.28 Ecuador – Draft Technical Regulation of the Ecuadorian Standardization Institute (PRTE INEN) No. 189: "Labelling of alcoholic beverages" - IMS ID 433

2.194. The representative of Canada noted that the new customs regulation on spirits imports covering whisky, vodka, tequila and rum had been approved on 9 August 2013, published in the official registry on 23 September 2014 with entry into force 30 days later. As this regulation would apply to imports only, it might be in violation of Article 2.1 of the TBT Agreement. The proposed requirement for the labels to be affixed in the country of origin was also of concern. The standard practice in the internationally traded spirits industry was to apply, in the country of production, generic front labels providing mandatory information and to affix, in the import market, other market specific information on the back or secondary label. He said that the regulation could be more trade restrictive than necessary to fulfil its objective and requested that Ecuador explain how it complied with Article 2.2 of the TBT Agreement and whether a less trade restrictive alternative had been considered. He also asked if comments from Members would be taken into account and whether Ecuador would notify any amendments to the regulation.

2.195. The representative of the United States expressed her delegation's concerns regarding the requirement included in the regulation for a certificate of conformity and referred to their remarks on Ecuador's general framework for conformity assessment (G/TBT/N/ECU/44, Addenda 1, 2, 3). With respect to the standard, she noted that it requires the name of the importer of alcoholic beverages to 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. What was the status of the possible revision of the measure to be less trade restrictive, given the potential added costs to any alcoholic beverage producers exporting to Ecuador? Finally, noting that many countries allow country-specific label changes in customs bonded warehouses, what was the reason for not allowing this common international practice. She strongly encouraged Ecuador to incorporate specific language allowing for such practice.

2.196. The representative of Mexico reiterated his delegation's concerns with the fact that the measure did not provide for any possibility of labelling or relabelling in the primary area of the product and with the requirement that the name of the Ecuadorian importer be affixed on the label. These requirements could be in contravention of the TBT Agreement, specifically Article 2.2, as it was debateable whether this measure constituted the least restrictive alternative to fulfil the legitimate objective pursued. He requested that the requirement of a label of origin with the name of the importer in Ecuador be removed, and that Ecuador replies to the comments formally submitted by Mexico on 2 July 2014.

2.197. The representative of the European Union shared the concerns expressed by other delegations. He noted that the EU had submitted comments on 1 July 2014 and was still awaiting a reply from Ecuador. He expressed concern about the fact the regulation required the name of the importer to appear on the front label. He asked Ecuador to reconsider whether such a requirement was necessary as this information did not seem to be addressed to consumers nor did it seem to be justified. He also expressed concern regarding the requirement that the labelling of alcoholic products must be done in the country of origin and that labelling or relabelling was not allowed in a primary customs area. Such obligation would create serious burden and costs for EU manufacturers who would need to print and affix different labels for the Ecuadorian market only, constituting an important obstacle to international trade. He thus invited Ecuador to consider allowing labelling with stickers at customs warehouses prior to import. This proposal was a widely accepted way to proceed and would allow Ecuador to comply with its policy objectives. Additionally, he requested Ecuador to clarify the rationale behind the requirement for imported products to obtain a certificate issued by an accredited conformity assessment body and to explain why self-certification was not an appropriate option in order to achieve their policy objectives. Could Ecuador clarify the relationship between this technical regulation and Resolution No. SENAE-DGN-2013-0300-RE relating to post entry control of imported alcoholic beverages, and how this

technical regulation would apply to products that were already on the Ecuadorian market prior to its entry into force. The representative of Chile shared the concerns raised by other Members on the proposed draft regulation. He reported that their concerns had already been communicated in writing to Ecuador. He thanked Ecuador for their willingness to have bilateral discussions in which Ecuador was able to clarify the issues.

2.198. The representative of Ecuador said the aim of the draft technical regulation 189 on labelling of alcoholic beverages was to protect human health and safety, and prevent deceptive practices. The measure applied to both domestically produced and imported beverages. Both regulation 189 and resolution 300 were being analysed nationally and WTO Members would be informed as soon as a decision was adopted.

2.2.3.29 China - Safety Requirement for Lithium Ion Cells and Batteries used in Portable Electronic Equipment (G/TBT/N/CHN/1016) IMS ID 425

2.199. The representative of the Republic of Korea noted that many Members adopted technical regulation on lithium ion cells and batteries which were harmonized with international standards. Korea had also enforced similar technical regulation concerning safety of lithium ion cells and batteries. However, many of China's test requirements for their safety regulation did not correspond with either the current IEC62133 or its draft revision. He requested that China harmonize those requirements with international standards. Concerning Article 11, he asked that China eliminate the requirement from the National Standard or exclude it from mandatory requirements since the safety requirement for system protection circuit could be complied by portable electronic equipment manufacturers rather than cells and batteries manufacturers. Korea would continue to work together with China so as to find a reasonable solution.

2.200. The representative of China said that as lithium batteries were the cause of many injuries and even death, China had drafted a national standard safety requirement in order to protect consumer's health and safety. An ad hoc working group established in 2008 developed this standard. The working group consisted of more than 40 lithium producers and science research institutes, both domestic and abroad, including many foreign enterprises. After three years of in-depth discussion and industry surveys, and three rounds of requests for comments, a final version of the draft standard was formulated. She said that, due to a different scope of application, the Chinese standard did not directly correspond to IEC62133. It adopted the relevant criteria of IEC62133, when appropriate, and improved the IEC standard according to the characteristics of the lithium battery. A number of proposals based on this Chinese standard had been adopted by the IEC, which illustrated its effectiveness. The Chinese standard, based on the relevant international standard, did not violate any TBT Agreement provision or principle.

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

2.201. The representative of Canada expressed his delegation's concerns regarding the requirement to register each product model with a unique registration number present on its packaging. Such requirements were not found in any other country and presented a significant burden for toy manufacturers. The registration scheme was intended to improve product traceability and to reduce fraud related to the "G" mark, but toy manufacturers had in place traceability measures that rendered such requirement unnecessary, as evidenced by toy safety regimes maintained by Canada, the US, the EU and other Members. He strongly encouraged the Gulf Cooperation Council (GCC) members, through the GCC Standardization Organization (GSO), to allow registration numbers to be assigned to each manufacturer rather than to each model. He also expressed concern regarding differences in interpretation of regional technical regulations by GSO members, such as labelling requirements for affixed labels or imprinted labels and the requirement of additional random testing on previously assessed products. The lack of consistency encumbered compliance and market access. He observed that GSO required testing for the "G" Mark on toys, but there was little information on how labs outside of the gulf region could be accredited to apply such tests and asked GSO to provide guidance on the matter. Finally, Canada remained interested in the progress of standards harmonization of GCC members and on the notification process. He asked whether a protocol for a single notification from the GSO had been considered to replace separate GCC country notifications. Canada looked forward to receiving a response to the letter sent on this matter in 2014.

2.202. The representative of the European Union thanked the Kingdom of Saudi Arabia for the useful bilateral meeting and for the information that had been provided. He expressed his delegation's support for harmonisation efforts being made within the Gulf region, including towards setting up a single notification process for the region, and said the EU was willing to exchange experience and provide any clarification regarding the EU's own experience with technical harmonisation in the toy safety or other sectors, as this may help ensuring more uniform implementation across the region. A single notification process would certainly be a positive development, specifically on the toy issue. He noted that, to the EU's understanding, a guide document on the registration process was being prepared and that input from foreign industries was welcomed. This would provide flexibility concerning registration and would streamline the procedures as well as address the main concerns raised so far by industry, as outlined by Canada. The EU would relay the information to its stakeholders and invite them to work with the technical committee preparing such guide document. During the bilateral meeting the EU had also shared concerns regarding additional duplicating conformity assessment procedures in some Gulf countries. Saudi Arabia had explained that the procedures should not be seen as duplicative conformity assessments but rather as market surveillance tests that were not a condition for introducing toys in the Gulf market. The EU took this information on face value and would confirm it on the ground. The EU had received confirmation at the bilateral meeting that foreign tests results would be accepted and requested Saudi Arabia to confirm this to the TBT Committee.

2.203. The representative of the Kingdom of Saudi Arabia thanked Canada and the EU for their positive remarks regarding the technical harmonisation efforts undertaken by Saudi Arabia and other GCC member states through the GSO. He noted that the single notification effort was driven by the points raised by Canada and the EU. He reported that Saudi Arabia had established a dialogue with the TBT Committee to streamline and coordinate notification efforts by GSO members. Regarding the requirement on fixing the 'G' mark, he explained that the mark had to be affixed as indicated in clause 6 of the technical regulations on GCC marking. However if it was not possible considering the nature of the product, the mark had to be placed or affixed on the container if any, or on the enclosed documents. On the issue of duplicative conformity assessment requirements, he assured delegations a certificate of conformity was not required, but rather a certificate from a third body recommending that all documents were authentic.

2.2.3.31 Russian Federation – Measure affecting import of Ukrainian dairy products - IMS ID 426

2.204. The representative of Ukraine shared her delegation's concerns regarding the import ban on dairy products imposed by the Russian Federation. The measure was still being applied in a non-transparent manner with a lack of cooperation and constructive communication from the Russian Federation in resolving the trade concern. Ukrainian producers were still unaware of the specifics of the technical regulation. The requested laboratory tests results of Ukrainian dairy products conducted by the relevant Russian authorities had still not been received. The most efficient way to resolve the market access problem was a clear understanding of where and to what extent Ukrainian dairy products presumably did not meet Russian regulations requirements. In this regard, she asked the Russian Federation to provide, in writing, scientific justification for the measure, including the laboratory tests results.

2.205. The representative of the Russian Federation said that the temporary import restriction of certain Ukrainian enterprises' dairy products was introduced due to lack of conformity with the labelling and identification requirements established by technical regulation from the Russian Federation and the Eurasian Economic Union (EAEU). Distribution within the territory of the Russian Federation of food products that were not in compliance with the provisions of the technical regulation was prohibited. The prohibition to import dairy products concerned only some enterprises and was not a ban on all Ukrainian dairy products. She further noted that in order to resume product supply, Russia urged the competent authorities responsible for safety and quality control of exported products, as well as for consumer protection activities, to start bilateral consultations. The earlier competent authorities started the bilateral work the sooner Ukrainian products would be back in the Russian market.

2.2.3.32 European Union – Proposal for a Directive of the European Parliament and of the Council amending Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic (COM(2013) 195 final) (G/TBT/N/EU/109) - IMS ID 434

2.206. The representative of the United States noted that EU's regulatory objectives for adjusting truck length requirements was to increase fuel efficiency and the reduction of greenhouse gas emission of trucks. Her delegation applauded the removal of truck length restrictions. She noted the requirements that vehicles benefitting from removal of these restrictions offered increased fuel efficiency and maintained vehicle safety. She expressed her delegation's concern that these requirements do not become barriers to trade. She asked the EU to consider flexibility on maximum turning radius, before entry-into-force. There were options for dealing with the issue of turning radius other than through restrictive rules on goods. Road signage or rules related to road use could effectively address concerns related to vehicle routing. Long haul trucks need not have access to all roadways to provide major environmental and economic benefits to EU citizens. Additionally, the benefits of aerodynamic improvements increased with road speed and aerodynamic long haul trucks could improve shipping efficiency if routed along major highway corridors where turning radius was least problematic. Preventing sales based on turning requirements only pertinent to local roadways was therefore unnecessarily restrictive.

2.207. The representative of the European Union thanked the US for their renewed interest in the amendment of Directive 96/53/EC. The European Commission proposal had been adopted on 15 April 2013 and had been subsequently forwarded to the European Union co-legislators. The European Parliament had recently adopted the final text and it was expected that the Council would follow shortly. The initial proposal of the Commission allowing for a derogation on the maximal length of cabs and trailers would be maintained. This length extension would be allowed only if certain aerodynamic and safety criteria were met and, in any case, vehicles would still be subject to the requirement that vehicles or vehicles combinations in motion must be able to turn within a swept circle having an outer radius of 12.5 metres and an inner radius of 5.3 metres (Article 1.5 of Annex I of current Directive 96/53/EC). He noted that no modification of such requirement was foreseen in the near future. This criterion had been defined taking into account the size of the existing infrastructure in the EU and some Member States already had difficulties coping with vehicles complying with this requirement as their infrastructure were not always large enough. Splitting the turning circle requirement of point 1.5 of the Annex according to different types of infrastructures was not envisioned, as vehicles or vehicle combinations would use all types of infrastructure during their life time and should consequently be suitable for all. Specific length limitations already existed (Article 7 of directive 96/53/EC) for certain areas such as villages, national parks or mountains, but those needed to be limited as much as possible.

2.2.3.33 Ecuador - Equivalence Agreement N° 14.241 with the European Union regulations - IMS ID.453

2.208. The representative of the United States reminded Ecuador of their notification obligations as a WTO Member and the need to notify Agreement No. 14 421 and Resolution 042-2014 to the WTO. She expressed concerns regarding the fact that Ecuador had not provided information on which EU standards and regulations were equivalent or what products were verified under Agreement No. 14 421. The Technical Report issued on 30 May 2014 proposed the adoption of European rules in order to help the Ecuadorian industry. She enquired how European standards and regulations would help more than other international standards and other examples of regulation from other WTO Members. She also asked how other WTO Members would have the opportunity to engage in a similar equivalence agreement.

2.209. The representative of Mexico expressed his delegation's concerns regarding the consistency of Agreement No. 14 241 and Resolution 042-2014 with the TBT Agreement. He noted that Mexico had submitted a number of questions at the TBT Committee meeting of November 2014, but no replies had been received. Mexico's full statement is contained in document G/TBT/W/404.

2.210. The representative of Brazil said his delegation shared the concerns raised by other delegations, in particular regarding the consistency of the provisions of the Agreement no. 14.241 with Article 2.1 of the TBT Agreement.

2.211. The representative of Ecuador informed the Committee that Ecuador had established a mechanism allowing for the recognition of equivalence to EU technical regulations. The mechanism applied to the standards and quality levels maintained by the EU on products marketed in Ecuador and subjected to technical regulations before conformity assessment. She explained that the agreement sought to include policies that could possibly retain products of a higher quality for the benefit of the population of Ecuador as well as implementing controls and quality analysis of imported goods within the framework of Ecuador's national and international laws. All Members had a legitimate right to undertake such action. She noted that Agreement 14.241 regulated the conformity equivalence of standards and quality level for products emanating from the EU and explained that the agreement did not establish details regarding the various products. The TBT Agreement set forth a possibility of evaluating the recognition of equivalence of conformity to facilitate trade between different parties. She emphasised that the agreement had only recognised the equivalence of technical regulations and evaluation procedures, in a non-automatic manner, for the products to be subjected to the Ecuadorian technical regulations and to those emanating from the EU, as allowed under 2.7 and 6.1 of the TBT Agreement She also denied that the mechanism could in any way bring discrimination against products from non-EU countries since the arrangement was fully justified by the TBT Agreement. As was the case with all WTO Members, Ecuador had a right to consider and evaluate the possibility of subscribing in future agreements of mutual recognition in order to address concerns in this area.

2.2.3.34 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

2.212. The representative of Switzerland thanked the Kingdom of Saudi Arabia for notifying and providing delegations with an official translation of its regulation. However, he concerns regarding the Saudi Arabian Ministerial Council Decree "on the sale and marketing of energy drinks" of 3 March 2014, the objective of which was food safety and the proposed entry into force was 21 January 2014. He recalled that the decree contained several restrictions on sales, advertisement and marketing, as well as product labelling in the form of a mandatory statement. The mandatory statement for so-called "energy drinks" required a compulsory warning as follows: "This product has no health benefits, having more than 2 cans a day could lead to health damages". It also contained warnings related to several groups such as youth and athletes. The warnings were to be put on the product itself as well as on refrigerators, dedicated exclusively to energy drinks and separated from other food products. He noted the interval of only 15 days between the end of the comment period and the entry into force and recalled in particular Art. 2.12 of the TBT Agreement, which required that, except in urgent circumstances, a reasonable deadline for adaptation should be allowed. He asked how Saudi Arabia intended to allow producers to adapt and to confirm the date of entry into force of the measure. Switzerland shared Saudi Arabia's intention regarding public health, but reiterated that certain specific questions remained unanswered on why it was decided to go beyond relevant Codex standards on nutrition, and why it was decided to ignore standards on claims, that request a sufficient body of scientific evidence providing truthful and non-misleading information. Saudi Arabia should inform the Committee on the substance that allegedly raised food safety concerns that justify the measure.

2.213. Based on available information, he expressed his delegation's belief that the decree, which went further than relevant international standards, required negative warnings linked to unspecified food safety concerns, as well as far-reaching restrictions on sales, seemed more trade restrictive than necessary and imposed high costs on producers. His delegation was willing to continue engaging bilaterally with Saudi Arabian authorities and encouraged them to report to the Committee on the status of the regulation.

2.214. The representative of the European Union, thanked the Kingdom of Saudi Arabia for its notifications of the measures regulating the labelling and marketing of energy drinks, but requested a written reply to his delegation's submission. He noted that the latest notified draft contained an obligation for energy drinks' cans to contain the statement "warning of the harmful effects of energy drinks" preceded by the word "WARNING!" along with the following health warning: "This product does not have any health benefits; consuming more than two cans per day may negatively affect your health; this warning concerns people such as pregnant and lactating women, those who are less than sixteen years old and suffering from heart diseases, high blood pressure and diabetes patients, people allergic to caffeine and athletes during exercise". He asked Saudi Arabia for information on the studies and risk assessment conducted showing that energy

drinks had "harmful effects" on health. He also asked for information about the scientific grounds on which Saudi Arabian authorities stated that "consuming more than two cans per day may negatively affect" human health and that energy drinks had specific effects on people "who are less than sixteen years old' and "athletes during exercise". In this regard, he noted the Scientific Committee on Food adopted in 1999 an Opinion on Caffeine, Taurine and Glucuronolactone as constituents of so-called "energy" drinks, which did not provide grounds to establish such warning labels. The European Food Safety Authority had recently published a draft scientific opinion on the safety of caffeine updating the previous opinion in light of new scientific evidence. The draft opinion was open to public consultation until the 15 March and, to date, did not provide grounds to establish such warning labels. He asked that Saudi Arabia explain the rationale for imposing labelling requirements stating that energy drinks did "not have any health benefits" and recalled the international Guidelines on Nutrition Labelling (CAC/GL 2-1985), according to which "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'. He noted that the notified draft prohibited "advertising of any energy drink or promotional campaigns for any energy drink via any readable, audible or visible media organ, or by any other means" and that it also prohibited "sponsoring any sport, social or cultural event, or taking any procedure leading to promotion" and the "free distribution of energy drinks to consumers of all age groups". It also prohibited "the sale of energy drinks in restaurants and canteens in government facilities; education and health facilities; halls and public and private sports clubs". He asked Saudi Arabia to provide information on any impact assessment carried out in relation to the measures, and in particular on the envisaged effects of these restrictions on the sale, advertising and sponsoring of energy drinks.

2.215. The representative of the Kingdom of Saudi Arabia thanked Members for their interest in the matter. He confirmed that bilateral discussions to explain Saudi Arabia's position were held with delegations where discussions were focused on Saudi Arabia's GSO technical regulation on energy drinks and that the revised regulation would most likely be produced before the end of 2015. His delegation would keep Members updated on the matter and written responses would be forwarded to respective delegations in due course.

2.2.3.35 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

2.216. The representative of Mexico referred to paragraph 2.39 of the previous minutes (contained in document G/TBT/M/64/Rev.1) and asked that these be considered as part of the record for the current meeting. In addition, he considered that Brazil's proposal (as contained in the draft resolution) could be contravening fundamental principles of the TBT Agreement, including conformity with international standards, by failing to consider the existence of a widely accepted international nomenclature for the ingredients of cosmetic products (INCI nomenclature). Mexico was also concerned that the distinction being made between products from the European Union and imports from Brazil's other trading partners (specifically those of the Latin American region) was in violation of the most favoured nation (MFN) principle. Thus, Mexico had formally submitted comments on 19 January 2015 requesting Brazil:

a. to explain why the INCI nomenclature system was not accepted given that it was globally recognised by regulators as well as by the main product manufacturers and raw material producers;

b. to provide justification of the benefits of translating the names of product ingredients into Portuguese considering that these products used a large number of raw materials with highly complex technical names that lay consumers were not familiar with and would be incapable of distinguishing between;

c. to revoke the provision in question, or, if appropriate, to modify the wording so as to allow, explicitly, for the use of the International Nomenclature of Cosmetic Ingredients (INCI). It was noted that Mexico allowed the of the International Nomenclature of Cosmetic Ingredients in the technical regulation on labelling of such products (NOM 141 SSA1/SCFI 2012 - Labelling of Pre Packaged Cosmetic Products Health and Commercial Labelling which had been in force since 2012); and,

d. to explain the rationale of the measure and the reasons why it was necessary to translate the product ingredients in relation to the legitimate objective pursued by Brazil, bearing in mind the INCI nomenclature.

2.217. The representative of the European Union reiterated concerns sent to Brazilian authorities on 19 January 2015. He said that the Brazilian authorities intended, by the notified draft, to introduce obligatory labelling requirements that list in Portuguese all ingredients of the product formulation on the labels of personal hygiene products, cosmetics and perfumes marketed in Brazil. The EU asked Brazil to consider accepting the internationally used International Nomenclature of Cosmetic Ingredients known as INCI instead of requiring the list of ingredients in Portuguese.

2.218. The EU believed that using INCI had various benefits. For instance, the names helped users to identify products with ingredients they knew they were sensitive to. Scientists and dermatologists were also assured that information would be referenced by a uniform name, eliminating the possibility of confusion or misidentification from the use of multiple names for the same material. The INCI names had been adopted by many countries worldwide, including the EU. Indeed, according to the EU Cosmetics Regulation, all cosmetic products sold in the EU had to display a complete ingredients list using identical terms across the whole EU. Ingredient names had, by law, to be those listed in the INCI dictionary.

2.219. The representative of Canada supported the comments made by Mexico and the EU.

2.220. The representative of Brazil referred to the minutes of the last meeting. On process, he noted that notification G/TBT/N/BRA/608 referred to a draft measure regarding the requirement of describing the chemical composition of personal hygiene products, cosmetic products and perfumes in the label of the product in Portuguese. A public consultation period had been opened for 120 days, until January 2015. The Brazilian Health Surveillance Agency (ANVISA) had received a number of contributions from interested parties and it was currently examining them. The measure would then be notified to the Committee. As had been previously explained, according to the Brazilian Consumer Protection Code, consumers in Brazil had the right to receive clear and appropriate information regarding the products and services available to them. The proposed regulation 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. This ruling was being appealed but, while there was no decision, it had to be implemented.

2.221. With respect to the measure itself, he said that it was important to clarify that the proposed measure did not affect the use of the International Nomenclature of Cosmetic Ingredients (INCI) nomenclature. The current legislation determined that the description of ingredients on personal hygiene products, cosmetic products and perfumes had to follow INCI. The proposed measure aimed at providing the same information in Portuguese *in addition*. ANVISA was currently analyzing ways to facilitate compliance, such as the possibility of providing the information on outer boxes or leaflets, in case of small products. The proposed measure also contained references to information on Portuguese names for the ingredients. Once the new regulation was approved, a transitional period would be granted for both domestic and foreign manufacturers to adapt.

2.2.3.36 China - National Standard of the P.R.C., Safety Technical Specifications for Children's Footwear - IMS ID 444

2.222. The representative of the European Union noted that his delegation had sent comments on 5 December 2013 and received a reply from the Chinese authorities on 31 October 2014 answering all of the concerns of the EU except for one, which the EU had raised in its follow-up written comments of 14 January 2015. The notified draft set up five categories of odour ratings for new footwear for children, and the corresponding testing requirements. The odour ratings set up in the notified draft seemed to go beyond health and safety concerns and bore many aspects related to the quality of the product. In the EU's opinion, odour was, per se, not harmful or necessarily an indication of risks to human safety and the environment as perfectly safe materials could emit a strong odour (e.g., rubber and soap) whereas very dangerous materials could generate no odour. The EU considered that the testing procedure for unpleasant odours based on the olfactory sense

was not an accurate or precise enough practice for measuring the shoe's potential risks to humans or to the environment. Therefore, the EU suggested that Chinese authorities reconsider this requirement and remove the odour testing and rating requirements of the notified draft. Should the requirement be maintained, the EU requested further information on the implications of the test operator's finding on the odour rating. And, in this context, the EU would appreciate further information on whether such an odour rating would have to be labelled on the product - and whether the specific odour rating entailed a prohibition or any restriction on the marketing of the product in China.

2.223. The representative of China thanked the EU for its interest in its odour rating requirement for children's footwear (China Light Industry Standard QB/T 2880-2007 "Children's Leather shoes"). This was the first standard which defined odour ratings for Children's leather footwear. Six years of implementation showed, in practice, the odour ratings was effective and easy to operate, it had played a positive role in leading enterprises to use green materials in the current level of science and technology. During the odour test, the tester's operating time was very short and at a certain distance away from the shoe, so it was less likely to cause injury - there had, to date, been no report of any injury to the testers. The average result was given by three or more testers, which could reduce the chance of subjective judgement.

2.224. China said that human olfactory determination methods similar to the method in GB 30585 were commonly used in the international levels. For example, European Standard EN 13725: 2003 adopted the physiological human sense in dynamic olfactory, used for the determination of odour concentration of air quality. On textiles, Oeko/Tex Standard 100 specified the test reference of odour is SNV 196 651 in which the procedure of the test was the method of human olfactory; and, SNV 196 651 had been practiced for quite a long time and still worked. In addition, other industries such as car production (e.g., the US standard SAE J 1351) also used human olfactory method to determine the odour in the car.

2.225. On labelling, China said that the odour rating did have to be labelled on the product and in China the product standard reference needed to be labelled. In China's experience, low price and low quality shoes were more likely to fail the odour test. Moreover, in China's view, the application of this standard could guide production companies to actively use green and environmental materials, and could also be useful for parents to avoid buying children's shoes which emitted strong odour.

2.2.3.37 Russian Federation – Measure affecting imports of Ukrainian juice products - IMS ID No. 439

2.226. The representative of Ukraine reiterate her delegation's concern regarding the ban on imports of all Ukrainian juice products, including baby food, to the Russian Federation, which had been enacted on 29 of July 2014 by the Federal Service on Customers' Rights Protection and Human Well-being Surveillance (Rospotrebnadzor). She reminded the Russian delegation about the request for information and clarifications which had been sent about eight months ago, on 15 August 2014, to the TBT/SPS Enquiry Point of the Russian Federation in accordance with provisions of Articles 10 and 2.5 of the TBT Agreement. No response had been received from the Russian Federation.

2.227. Ukraine considered that the ban imposed by the Russian Federation was discriminatory in that it accorded treatment less favourable than that accorded to like products of national origin, and to like products originating in other countries. It was thus not justified, was applied in a non-transparent and discriminatory manner and created unnecessary obstacles to trade. As such it was inconsistent with provisions of Articles 2.1, 2.2 and 5.1 of the TBT Agreement. Ukraine welcomed the proposal from the Russian Federation presented at the TBT Committee meeting in November 2014 concerning bilateral consultations at the level of the competent authorities of both countries and looked forward for such consultations.

2.228. The representative of the Russian Federation said her authorities had introduced restrictions to the supplies of juice products, produced in Ukraine, towards which necessary conformity confirmation procedures had not been provided. Despite this the products had been labelled with a Single market circulation sign for the Eurasian Common Economic Space, an action that represented a violation of the legislation of the Russian Federation and Eurasian Economic

Union legal acts. The large-scale detection of such products in the internal market circulation appeared to constitute deceptive practice. For the restriction to be lifted, the Russian Federation called on the competent authorities of Ukraine to participate in bilateral consultations.

2.2.3.38 Russian Federation – Measure affecting imports of Ukrainian beer products - IMS ID No. 440

2.229. The representative of Ukraine reiterated her delegation's concern regarding the ban on import of Ukrainian beer products to the Russian Federation. The grounds for this prohibition had initially been announced as non-compliance with legislation on consumers' rights protection, in particular, labelling requirements. She said that the measure was applied in a non-transparent and unpredictable manner. The ban had been in force for seven months and the Russian Federation had not taken any concrete steps contributing to its lifting. Ukraine considered that the ban was discriminatory in nature, that it accorded treatment less favourable than that accorded to like products of national origin and to like products originating in other countries. Moreover, the measure created unnecessary obstacles to trade. It was thus inconsistent with provisions of the Articles 2.1, 2.2 and 5.1 of the TBT Agreement. The representative of Ukraine reminded the Russian Federation about its request for providing written official clarification and justification for the measure and the manner in which it was is applied in terms of the provisions of the Article 2 of the TBT Agreement. It was noted that the Russian Federation, at the November 2014 Committee meeting, had made a proposal for bilateral consultations at the level of competent authorities to discuss possible ways of solving the problem.

2.230. The representative of the Russian Federation said that the suspension of certain beer products and beer-containing beverages produced by some Ukrainian enterprises had been introduced in the Russian Federation due to a violation of technical regulation requirements in the consumer protection area, more specifically due to non-compliance with labelling requirements. Numerous cases had been detected and the measure had been introduced to prevent deceptive practices and to maintain the appropriate level of protection for human life and health, and safety. As such, the measure did not contradict the obligations of the Russian Federation under the articles 2 and 5 of the WTO TBT Agreement. Russia stressed that the suspension encompassed only certain Ukrainian enterprises that produced beer, and was not a ban to import into the territory of the Russian Federation of *all* the beer products from Ukraine. In order to resume the supplies of the products from these Ukrainian enterprises he reiterated the Russian call to the competent authorities of Ukraine responsible for the quality and regulation of such products to engage in consultations. Russia remained ready to assist in this regard

2.2.3.39 Ecuador - Draft Technical Regulation of the Ecuadorian Standardization Institute (RTE INEN) No. 047: "Metal cable tray, electrical conduit and trunking systems" (G/TBT/N/ECU/53/Add.2) - IMS ID 454

2.231. The representative of Mexico reiterated those concerns set out in paragraph 2.67 of document G/TBT/M/64/Rev.1 (the November 2014 meeting of the Committee) and asked that these be considered as part of the record for the current meeting. He noted that the Ecuadorian technical regulation established packaging requirements for metal cable tray, electric conduit and trunking systems, including the requirement to indicate the country of origin and the name of the importing company. Mexico considered that, on the basis of Article 2.1 of the TBT Agreement, this requirement could be discriminatory and produce protectionist effects, since it applied solely to imported products. Moreover, the requirement was different from the one normally specified for this type of product and this entailed an increase in product costs. The Regulation also established that products with the Ecuadorian Standardization Institute (INEN) seal of quality were not subject to the requirement of a certificate of conformity for marketing purposes; this seal was only issued for Ecuadorian products, and this, on the basis of Article 5.1.1 of the TBT Agreement, could have a discriminatory effect on imported products.

2.232. Taking into account the provisions of Article 2.4 of the TBT Agreement, Mexico considered that the products covered by the technical regulation in question needed to be governed essentially by the provisions of International Electrotechnical Commission (IEC) Standard No. 61537, "Cable tray systems and cable ladder systems for cable management", rather than Ecuadorian Technical Standard INEN 2486, which did not have product safety tests as its main objective.

2.233. He noted that the manufacturer or distributor was required to obtain a raw material conformity certificate; in other words, the raw material certificate had to be appended to the conformity certificate for the finished product. This would imply the establishment of requirements that would be in breach of Article 5.1.2 of the TBT Agreement, as they would generate unnecessary duplication given that the finished product certificate was the document that best served to guarantee that the raw material was suited to the type of product and that it also met the specific manufacturing standard. In view of the foregoing, Mexico had formally submitted comments to Ecuador on 25 July 2014, along with the following requests:

a. to give consideration to all the comments submitted by Mexico as regards compliance with the principles of non-discrimination and proportionality governing technical regulations and conformity assessment procedures, and the preparation of technical regulations in accordance with international standards, as laid down in the TBT Agreement;

b. to eliminate the specific packaging requirement for imported products and to make the necessary change to ensure compliance with the principle of non-discrimination provided for in the TBT Agreement;

c. to take international standard IEC 61537 as a basis for fulfilling the objective pursued by Technical Regulation No. 047, and if this was not deemed appropriate, to provide the necessary justification. In this regard, it was requested that Ecuador revisit the making compliance with Ecuadorian Technical Standard NTE INEN 2486 compulsory (for the reasons set out above);

d. to eliminate the exemption from the requirement of a conformity assessment certificate for products with the Ecuadorian Standardization Institute (INEN) quality seal, because of its discriminatory basis; and,

e. to eliminate the requirement for presentation of a raw material conformity assessment certificate, or if Ecuador maintained that requirement, to provide justification for its inclusion among the requirements under this regulation.

2.234. The representative of Ecuador said that the purpose of technical regulation 047 was to prevent risks to the health and safety of persons while at the same time avoiding any prejudice to final users. Ecuador explained that the regulation had its basis on various international standards such as IEC 61537, ANSI/UL 568 O NEMA VE1 Y NEMA VE2, ISO 9227, UL 568, EN 50085, IEC 60529, IEC 62262. Ecuador further elaborated that the technical regulation had been notified in accordance with the TBT Agreement and that the regulation demonstrated the conformity of the product with various mechanisms including the presentation of the declaration of first part. The representative of Ecuador concluded by saying that her authorities had taken into account comments made by Members and had revised the regulation as far as it related to the product regulation and the labelling of the product.

2.2.3.40 Ecuador - (PRTE INEN) No. 111: Energy efficiency. Clothes dryers. Labelling - IMS ID 455[11]

2.235. The representative of Mexico expressed concern about the above-mentioned regulation. Mexico's full statement is contained in document G/TBT/W/409.

2.236. The representative of the United States supported the concerns raised by Mexico.

2.237. The representative of Ecuador said that the objective of the measure was to provide energy efficient products which would both improve the environment as well as their quality. Ecuador reported that the Ministry for Electricity and Renewable Energy tried to have commercialized products with high energy efficiency and have a system that promoted awareness amongst consumers. This action combined standards and labels with the intention to enable

[11] G/TBT/N/ECU/152, RTE INEN 005 (G/TBT/N/ECU/1/Add.4) INEN 036 (G/TBT/N/ECU/39/Add.3) INEN 047 (G/TBT/N/ECU/53/Add.3) INEN 072 (G/TBT/N/ECU/87/Add.4) INEN 077 (G/TBT/N/ECU/95/Add.4) INEN 091 (G/TBT/N/ECU/125/Add.1) INEN 109 (G/TBT/N/ECU/184/Add.1) INEN 196 (G/TBT/N/ECU/226/Add.1).

consumers to reduce energy consumption and increase energy efficiency. Ecuador would take into account all comments made by Members with regard to the conformity assessment of the technical regulation to try to facilitate the presentation of a statement which would solve any problems encountered by Members.

2.2.3.41 Israel - Resistance to ignition of mattresses, mattress pads, divans and bed bases (G/TBT/N/ISR/666, G/TBT/N/ISR/666/Add.1) - IMS ID 440

2.238. The representative of the European Union reminded the Committee that in November 2014, Israel had provided information that the entry into force of the notified draft was suspended due to on-going court proceedings at the Israeli Supreme Court. He asked Israel to provide an update on the current status of the notified draft especially as, according to the information received by the EU, while the Supreme Court case was still on-going, it however seemed that the standard was made mandatory as from 16 February 2015 by the Israeli Ministry of Economy. He requested Israel to consider recognising other relevant standards such as EN 597-1 and that the Israeli standard SI 5418 be a voluntary standard.

2.239. The representative of Israel said that this standard on resistance to ignition of mattresses, mattress pads, divans and bed bases was not yet mandatory. The date on which the standard would be mandatory had been delayed again for a period of one year. He explained that the Israeli standard was an adaptation of the British standard BS 7177 in relation to parts pertaining to mattresses for domestic use. Since it was expected that the British standards would be revised, the revision would have an effect on the open flame resistance test. The Ministry of Economy had initiated a risk assessment survey on the impact of mattresses containing flame retardants with regard to public health and safety against the risk of open fire ignition of unprotected mattresses.

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

2.240. The representative of China reported that despite considerable expenses and resources, since 2009, not a single Chinese-manufactured security smartcard chip had been granted Common Criteria EAL4+ Certificate by EU member states. In addition, no Chinese company had become a member of CC-related standard organisations, though many Chinese companies had submitted their applications for the membership of CC-related standard organisations such as JIL Hardware Attack Subgroup. She urged the EU member countries involved in CCRA to grant Chinese companies membership and to process Chinese manufacturers' applications for CC approval of security chips on an equal footing and in a timely manner.

2.241. The representative of the European Union said that encryption for national security was limited to a few sectors closely linked to national security matters and that the required level of certification for different commercial applications was set by the market. Certification schemes were voluntary and neither the EU nor its member states imposed mandatory cryptography standards or conformity assessment procedures as a condition for access to the EU market. It was up to individual companies to ensure secure transmission of data over their systems and networks and procure equipment with the most appropriate technology available to meet their needs. Hence, the EU failed to see the relevance of China's concerns under the TBT Agreement. Nonetheless, the EU reiterated its invitation to China to detail the concerns with supporting evidence and its willingness to further discuss these issues bilaterally. The EU then highlighted some key differences and approach in this area between the EU and China. Unlike in China, where encryption certification for commercial products was mandatory, the European voluntary certification schemes and related supporting European standards were based on international standards for security evaluation, in particular the common criteria standards and global practices. Some Chinese companies were able to claim EAL certificate in the EU while no foreign companies had ever received a commercial encryption licence from OSCCA. There was an absence of an equal level playing field as Chinese companies enjoyed far better conditions for access to the market, including voluntary encryption certification in the European Union, and opportunities to participate in standardisation work. The EU would like to see a rebalancing of the situation.

2.242. The representative of China regretted that they had not received enough information from the EU. He said that they had requested the EU to provide a list of the evaluation and certification bodies involved in the CC certification but had not received such information. They had observed

that a lot of governmental bodies were involved in processing and issuing CC certificates in EU member states and at the EU level, the EU Commission required its private banking industry to ensure that its information security system was secure. In view of the above, it was China's opinion that China and EU were taking similar actions.

2.243. The representative of the European Union explained that it had not refused to provide the information requested by China but as the request was received only a few hours before the meeting commenced, it was just not possible to compile the information. On the legal issues of the coverage of the TBT Agreement, the EU was of the view that it was important to read terms in context of everything that had been said about certification bodies, be they governmental bodies or non-governmental bodies, and in any event qualified by the chapeau of Article 5 ("where a positive assurance of conformity … is required"). According to the EU, the conditions set out in Article 5 had not been fulfilled in this case and the argument being put forward in this particular case was not relevant to TBT.

2.244. The representative of China responded by urging EU colleagues to recall that on the margins of the November 2014 meeting, China had already bilaterally provided clear and plentiful information to the EU, including on the refusal of the EU member states to accept and process China's CC certification applications. With regard to the coverage of the TBT Agreement, China responded that Article 5 (assessment of conformity by central governmental bodies) and/or Article 8 (assessment of conformity by non-governmental bodies) of the TBT Agreement explicitly indicated the relevance of the TBT Agreement to CC certifications carried out in the EU member states.

2.2.3.43 European Union – Limits for hexavalent chromium in toys (2009/48/EC) - IMS ID 449

2.245. The representative China raised concerns with the existing and proposed limit values for hexavalent chromium ("chromium VI") in toys or toy components in the EU toy safety directive 2009/48/EC. The EU toy safety directive sets the limit values of chromium VI for three types of toy materials as 0.02mg/kg, 0.005mg/kg, and 0.2mg/kg respectively, which were even more stringent than those in drinking water as specified in the WHO Guidelines for Drinking-water Quality or foodstuffs as prescribed in Members' national standards. He requested the EU to provide scientific evidence, including children's physiological absorption data, to justify such stringent limit values for chromium VI in toys or toy components placed on the EU market.

2.246. Regarding the EU Scientific Committee on Health and Environment Risks (SCHER) proposal for a revision of the existing limit values for chromium VI in the current EU toy safety directive, he requested the EU to provide information on the recent developments. The EU did not specify testing method for migration limits from toys or components of toys in dry, brittle, power-like or pliable material, or migration limits in liquid or sticky toy material. The stringent requirements of the EU and the absence of testing methods and the extremely expensive testing continued to cause great difficulties for exporters of toys to the EU, both from China and other Members. He requested the EU to adapt its requirements regarding migration limits of chromium VI to the current technological level of the toy industry and the existing conformity assessment capability. He further requested the EU to lower its requirements on migration limits of chromium VI to a level not higher for foodstuff or drinking water.

2.247. The representative of the European Union said that the current limits in Directive 2009/48/EC were to provide a high level of protection of children from exposure to chromium VI, as there were other sources of exposure such as drinking water and the air. The current limits were based on science and there was evidence that they were not only technologically feasible and achievable by industry but were also detectable according to available testing methodologies. The EU representative referred to his statement at the previous meeting for relevant background information regarding the European Commission's request to SCHER. The final Opinion of SCHER was published on 10 February 2015. The draft Opinion had been open for public consultation and comments were carefully considered and taken into account before issuing the final opinion. On the basis of the risk assessment Opinion on the toxicologically safe limits (calculated on the basis of a risk of one cancer occurrence in a million), the European Commission, as part of its risk management tasks, would consider whether the current migration limits for chromium VI needed to be revised. The evaluation would take into account available technology in the industry and available testing methodologies for the detection of chromium VI in toys. If the Commission

decided to propose a revision of the current limits, any such proposal would timely and duly notified in accordance with the TBT Agreement's notification procedures.

2.2.3.44 Ecuador – Cosmetic products (G/TBT/N/ECU/116) - IMS ID 417

2.248. The representative of Mexico said that RTE INEN No. 093 stipulated, in respect of cosmetics covered by the technical regulation, that the "marketing, retailing and/or import thereof were subject to submission to the National Health Authority of the mandatory sanitary notification (NSO), along with, inter alia, technical information (product information file, including the cosmetic product safety report) and the NSO identification code for cosmetic products issued by the National Health Authority". Ecuador could be infringing Article 2.2 of the TBT Agreement, on the basis of available scientific and technical information, as it was not necessary to request a safety assessment report for such products.

2.249. He explained that the technical regulation also stipulated that cosmetics were to be manufactured in accordance with the good manufacturing practice requirements established in Ecuadorian Technical Standard NTE INEN ISO 22716. This could involve further violation of Article 2.2 of the TBT Agreement, because globally, good manufacturing practice certification tended to be voluntary. The regulation required labelling and any instructions for use and disposal, as well as any other manufacturer's information, to be in Spanish. This requirement could be inconsistent with Article 2.2 of the TBT Agreement, as individual product names and the International Nomenclature of Cosmetic Ingredients (INCI) could not be translated into Spanish, since they were personal names. The measure could infringe Article 5.1.1 of the TBT Agreement as regards access to Ecuador for Mexican products, since, according to information from the Mexican cosmetics industry, there were no cosmetics certifying body in Ecuador that could issue the "certificate of conformity of products and systems". He requested Ecuador to give consideration and respond to the comments submitted by Mexico with respect to compliance with the principle of proportionality. He also requested information on the analysis that had been conducted by Ecuador on available alternatives in support of the decision to enforce the ISO 22716 guidelines. He further requested information regarding compliance by the bodies accredited to issue the "certificate of conformity of products and systems". Could Ecuador explain the urgent problems which arose or threatened to arise, which led it to adopt the "emergency" technical regulation. Would Ecuador consider allowing a transitional period to allow for comments and possible adjustments to the measures prior to adoption?

2.250. The representative of Brazil had concerns with the measure due to the lack of accredited test laboratories and accredited certification bodies. Products imported from the EU had preferential treatment under Agreement 14.241, as discussed in a previous STC. He sought clarification from Ecuador regarding developments on the availability of the necessary infrastructure.

2.251. The representative of Ecuador said that technical regulation RTN 093 for cosmetic products was based on a decision of the Andean Community regarding legislation for cosmetic products and also Annex 2 of the Good Manufacturing Processes for the Cosmetic Industry in the Andean Community. Ecuador would take into account all comments made by Members with regard to conformity assessment of the technical regulation to try to facilitate the presentation of a statement which would solve problems encountered by Members.

2.2.3.45 Ecuador – Certification of Ceramic Tiles II - IMS ID 419

2.252. The representative of Brazil said that the new regulation of certification of ceramic tiles posed significant difficulties for Brazilian exporters. Ecuador did not accept manufacturer's declaration of conformity nor Brazilian third-party certification. Brazilian procedures for third-party certification on ceramic tiles were established by the Brazilian Institute of Metrology (INMETRO) and products had to comply with the relevant Conformity Assessment Procedures, which were updated in 2014. He requested that Ecuador accept certification of conformity issued by INMETRO's accredited certification bodies.

2.253. The representative of Ecuador said comments by Members had been taken into consideration and that the regulation had been modified with regard to labelling and

demonstration of the conformity. The Service of Ecuadorian Accreditation accepted the accreditation of AENOR and INTERTEK for the technical regulation.

2.2.3.46 Ecuador - Proposed Motor Vehicle Safety Regulatory Requirements (RTE INEN 034)[12] IMS ID 409

2.254. The representative of the United States said that while her delegation supported the automotive safety and environmental protection objectives pursued by the measure, it was nonetheless puzzled by the unusual way used by Ecuador to notify a significant revision of its technical regulation for vehicle safety through several addenda. A full notification of the third revision of this measure would have been more transparent, and in line with notification obligations under the TBT Agreement. US industry had offered comments to the sixth Addendum on 8 November 2013, and requested INEN to continue acceptance of self-certification to US Federal Motor Vehicle Safety Standards and US Environmental Standards. These comments were however never acknowledged or replied to by Ecuador. What was the scientific evidentiary basis for concluding that, despite a long history of accepting certification to FMVSS as meeting its domestic safety requirements, FMVSS no longer met its public safety requirements? Why were stakeholders not afforded the opportunity to provide data to demonstrate the effectiveness of FMVSS in achieving Ecuador's desired safety outcomes? The regulation finalized in October 2014 had substantially disrupted trade of autos and trucks from the US to Ecuador. Furthermore, with the adoption of UNECE standards exclusively in Ecuador, the introduction of new vehicles developed to FMVSS would be delayed until versions designed to UNECE requirements were developed, presuming US automotive companies intend to design new versions accordingly. This could have a significant impact on trade, in particular since the majority of vehicles imported by Ecuador were models that did not have UNECE versions. She requested that Ecuador reconsider the final regulation, and include acceptance of US FMVSS and US EPA automotive requirements.

2.255. The representative of Mexico said that this topic was of particular concern because, apart from the fact that formal comments were submitted to Ecuador on 12 November 2013, bilateral meetings have been held with the Ecuadorian Government, where the main concerns were expressed and reiterated. Despite this dialogue and these efforts, Mexico's observations were not incorporated in the most recent publication of the technical regulation. Mexico's full statement is contained in document G/TBT/W/410.

2.256. The representative of Brazil shared the concerns raised by the US and Mexico and expressed his delegation's view that a number of requirements under the new technical regulation seemed to be more trade-restrictive than necessary to fulfil the stated objectives, and that this measure was conceived only taking into account the requirements established by UNECE. Other international standards established to fulfil the same objectives, followed by other countries, had not been considered. Products that met high standards of safety and quality were not allowed on to the Ecuadorian market, despite being based on international standards. The new measure also did not allow for "self-certification" for automotive products. He requested Ecuador to accept such certificates, which was line with practices followed in many other countries and also in the region. Also, due to the number the changes required for complying with the new technical regulation, Brazil also requested an extension of the transition period allowed for manufacturers.

2.257. The representative of the European Union requested Ecuador to clarify the timeline for the implementation of the new regulations. He then provided some general comments about efforts for international harmonisation in the motor vehicle sector. International harmonization, when based on a high level of human health, safety and environment protection, played an important role in trade relations in this sector. Within the EU, the motor vehicle industry was the second largest manufacturing sector being traded after machinery. It was undeniable that the most effective instrument for international harmonisation in the motor vehicle sector was the UNECE's "1958 Agreement", which grouped 58 countries globally. The "1958 Agreement" allowed for the development of international standards in the form of UN regulations, and their technical requirements are recognized as sufficient for achieving the high level of protection of human health, safety and the environment desired by the participating countries. Such regulations were also applied by countries other than its contracting parties. This international harmonisation was

[12] G/TBT/N/ECU/32, G/TBT/N/ECU/32/Add.1, G/TBT/N/ECU/32/Add.2, G/TBT/N/ECU/32/Add.3, G/TBT/N/ECU/32/Add.4, G/TBT/N/ECU/32/Add.6.

also the basis of a robust system of mutual recognition among these 58 contracting parties and was therefore a powerful instrument for trade facilitation.

2.258. The EU noted that these reasons supported the view that harmonization in the motor vehicle sector should be promoted and that Members should participate in such efforts within the limit of their resources, as stated in Article 2.6 of the TBT Agreement. Thus, a domestic regulatory approach in the vehicle sector that recognised the relevance of, and expressed a commitment to be aligned with, these UN regulations would be, in the EU's view, fully consistent with the spirit and the letter of Articles 2.4 and 2.5 of the TBT Agreement. With regard to conformity assessment, he said that it was clear that different options could be envisaged. In this respect, it was important to be aware that the administrative and judicial capabilities to enforce and perform an effective market surveillance system clearly played a role in the choice of the most appropriate conformity assessment procedure. These factors must be taken into account when a Member needed to make a choice between various conformity assessment procedures, such as self-declaration /supplier's declaration system or type-approval system. This is recognised in Article 5.1.2 of the TBT Agreement, which underlines the need that conformity assessment procedures should give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking into account the risks non-conformity would create. The EU has been operating a "type-approval system" for the motor vehicle sector for many years. This conformity assessment option has shown to be an efficient way to manage and enforce the high risk associated with motor vehicles and has allowed for a rational use of public resources by the EU.

2.259. The representative of Ecuador reported that Ecuador had recently adopted a new series of safety standards for vehicles within the framework of the measure at issue. This was a first step towards signing the 1958[13] and 1998[14] Agreements of the UNECE.[15] They were adopting standards under the UNECE's "58' Agreement". Ecuador stated that it had encountered in the technical standards of the UN, international standards that had been developed on the basis of a system that was created for the UNECE's "World Forum for Harmonization of Vehicle Regulations (WT.29) and also contracting parties provided the guarantees required to regulate the safety of vehicles and protection of its citizens. Ecuador said that the system they had opted for sought to ensure that vehicle production would be safe throughout the production cycle of each model. WT.29 was an open forum where the contracting parties were able to discuss the regulations and provide updates on the standards that were coming into force. International vehicle manufactures present in Ecuador offered models in other markets that complied with the minimum standards of the Ecuadorian measure at issue (RTE INEN 034) and other standards which were far more demanding. Open dialogue had been maintained from the outset of developing this measure, leading to inputs by manufacturers, importers and assembling companies that had subsequently aligned their models to comply with the new Ecuadorian standards.

2.2.3.47 Russia - Alcoholic Beverages Storage Technical Conditions Order Number 59n - IMS ID 372

2.260. The representative of the United States noted that importers of US distilled spirits products continued to have issues obtaining the necessary "activity" license from FSR, and even when such licences were granted, the storage requirements mandated by the regulation were difficult to meet and inconsistent with international standards. She urged Russia to revise this regulation and to take into account its obligations under the TBT Agreement, particularly in relation to consistency with international standards and the restrictiveness of its conformity assessment procedures.

2.261. The representative of the European Union supported the US comments and considered that the licensing system set out by this order was complicated, burdensome, trade restrictive, non-transparent and in some cases impossible to comply with. He noted that EU exporters of alcoholic beverages were particularly concerned with the approaching renewal of the necessary "activity"

[13] "Agreement concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions," of 20 March 1958.

[14] "Agreement Concerning the Establishing of Global Technical Regulations for Wheeled Vehicles, Equipment and Parts which can be fitted and/or be used on Wheeled Vehicles", of 25 June 1998.

[15] A presentation on these Agreements made by the UNECE to the TBT Committee during a "Workshop on Regulatory Cooperation between Members", held back-to-back with the Committee's regular meeting, is available at: https://www.wto.org/english/tratop_e/tbt_e/docs_wkshop_nov11_e/s3_f_1_unece_e.ppt.

license by the Federal Service for Alcohol Market Regulation due in 2015 as they continued to encounter serious difficulties in meeting the alcoholic beverages storage conditions, which were inconsistent with international standards. For example, under the Order number 59n it was not possible to store jointly alcoholic and non-alcoholic products intended for the formation of gift sets. The EU asked Russia to consider revising Order number 59n in light of its obligations under the TBT Agreement so as to ensure that the licensing system would be transparent and the technical conditions for storage of alcoholic drinks in line with international standards.

2.262. The representative of the Russian Federation said that in accordance with Federal Law No. 171-FZ "On state regulation of production and turnover of alcohol drinks" it was necessary to obtain a licence for the production and turnover of alcohol products (including those for warehousing). He clarified that this was not an import licensing requirement, but instead an activity licence. Order 59n established qualification requirements for the organization, which would carry out the activities of the warehouse of alcohol drinks, but not requirements for the product, process or production method. This order was therefore not a technical regulation and, in any case, these qualification requirements were neither burdensome, nor applied on a discriminatory basis. Russia intended to clarify the need to preserve these qualification requirements and would inform interested WTO Members.

2.3 Exchange of Experiences

2.3.1 Preparation of the 7th Triennial Review

2.263. The Chairman provided a report, on his own responsibility, on the First Thematic Session on the Seventh Triennial Review. The report, he said, was intended to capture the main points that he discerned from the discussions during the 17 March 2015 meeting as well as facilitating Members' future deliberations on the Seventh Triennial Review. The full report is contained in document JOB/TBT/125 (dated 25 March 2015).[16] He reminded Members that, in line with the mandate in Article 15.4 of the TBT Agreement, the Committee was scheduled to complete the Seventh Triennial Review on 4-5 November 2015. Members were thus encouraged to come forward with any submission they intended to make **before 1 June 2015**, in good time before the next thematic session, to be held on 16 June 2015.

2.264. The representative of the United States informed the Committee that her delegation was exploring the idea of contributing a document for the Triennial Review discussing the possibility of having more robust discussions on the notification of regional technical regulations.

2.265. The representative of the European Union said that conformity assessment would be a good topic to develop in the 7th Triennial Review. He said that the European Union was working on some ideas building on what had been discussed in the thematic sessions. He said that the topic could cover: how to design efficient conformity assessment solutions capable of meeting regulators' needs without imposing unnecessary burdens on manufacturers; the role of accreditation in the assessment of the competence of conformity assessment bodies; mechanisms to facilitate the acceptance of conformity assessment results generated in other Members. The EU was also considering a submission on transparency.

2.266. The representative of Japan stated that Japan was considering making a proposal relating to conformity assessment procedures. Details were still under consideration.

2.267. Reverting to some of the discussion held during the thematic session, the representative of Ecuador said that his delegation had some doubts about the utility of the document submitted by Mexico. Ecuador was of the view that, since a paper relating to the same subject was about to be approved (on good regulatory practices), it might be premature to develop directives or guidelines on the same subject, and therefore was against the proposal from Mexico. In response, the representative of Mexico referred to the discussion held during the thematic session and reflected in the Chairman's report (JOB/TBT/125) and noted that the delegation of Mexico was, of course, willing to discuss the matter further in the future.

[16] At the time of the meeting a draft hard copy was provided at the back of the room for Members. The version later circulated takes into account comments provided by Members on that draft.

2.268. On the Swiss proposal, Ecuador stated that considering that the Triennial Review was about the implementation of the TBT Agreement, discussion needed to be limited to measures that sought a legitimate objective in terms of the policies of Members and not in certain other areas mentioned by other Members. The representative of Chile said that while he was in favour of the thematic sessions in general, his delegation was against the proposal from Switzerland.

3 TWENTIETH ANNUAL REVIEW

3.1. The Committee adopted the Twentieth Annual Review of the Implementation and Operation of the TBT Agreement as contained in G/TBT/36. The Committee took note of document G/TBT/CS/2/Rev.21 containing a list of those standardizing bodies that have accepted the Code of Good Practice since 1 January 1995.

4 TECHNICAL COOPERATION ACTIVITIES

4.1. The Secretariat provided information on the TBT Advanced Course which had taken place from 9-20 March. It featured a new component which was that each participant, with the guidance of coaches had developed an action plan to address a specific implementation challenge in their country. Participants were expected to report back periodically on the implementation of the action plans and the Secretariat envisaged inviting them back to Geneva for a follow up session in 2016, for which the Secretariat would request the necessary funding in the context of biannual TA plan. A document containing information on the Secretariat's technical assistance activities was made available.[17]

4.2. The representatives of Chinese Taipei, Chile, Ukraine, Trinidad and Tobago and Peru thanked the Secretariat for the technical assistance activities that had been held.

5 UPDATING BY OBSERVERS

5.1. The representative of the Gulf Standardization Organization (GSO) thanked the Committee for granting GSO observership[18] status. He said that GSO was a non-profit organisation that served as an umbrella organisation for the GCC standards, meteorology, conformity assessment and accreditation. It was a regional standardisation organisation although it was a sub-regional organisation by ISO designation that worked under the umbrella of the Gulf cooperation council, GCC for the Arab states of the Gulf. GSO members were the United Arab Emirates, Kingdom of Bahrain, Kingdom of Saudi Arabia, Oman, State of Qatar, State of Kuwait and Yemen with the headquarters based in Saudi Arabia where it had administration and financial autonomy. The GSO had already issued more than sixteen thousand standards and technical regulations covering various economy sectors. GSO would work towards achieving the objectives of the TBT Agreement by using and promoting the use of international standards, guidelines and recommendations where they exist for the protection of human health safety and the environment within the Gulf region.

5.2. The representative of the IEC informed the Committee that the full report on the IEC activities for developing and industrialising countries was available on their website.[19] Since January 2015, affiliate countries participating in the IEC free programme for developing countries, had a new leader. Since the last TBT Committee meeting, Haiti and Mongolia had established a national electro technical committee and Mongolia and Bhutan had upgraded to affiliate plus. The mentoring programme for affiliates was going strong with two new partnerships being in the final stage. The first ACAS e-learning modules were launched on 18 March 2015. IEC would hold two IEC EX events, one in Poland in April 2015 with the collaboration of UNECE, and the other in Ghana, upon the request of the AFSEC in July 2015.

5.3. The representative of the OIML reminded the Committee that OIML's main role was to develop model technical legislation, covering measurements and measuring instruments used when legal proof was needed. This work was conducted by experts from OIML member states and corresponding members who worked in project groups. One of the many focuses was the development of the operating procedures for this technical work. This had become a much more

[17] G/TBT/GEN/171/Rev.2.
[18] Ad hoc observership status.
[19] http://www.iec.ch/about/globalreach/.

open and transparent development procedure and through the website, all early stages of the work could be completed by a much more consensus based procedure even though as an inter-governmental treaty organisation there were restrictions for the final approval. Work was also under way to improve support for developing legal metrology infrastructures in developing countries. 20 May 2015 was World Meteorology day and the theme for this year was "measurement and light" as UNESCO had designated 2015 as the International Year of Light and Light-based Technology.

5.4. The Committee took note of information provided by the representatives of the Codex Alimentarius Commission[20] and UNECE.[21]

6 OTHER BUSINESS

6.1. The Chairman said that in line with the fax he had sent on 6 March 2015, he recalled that the Secretariat was exploring the possibility of organising an anniversary event for the TBT Committee on 6 November 2015. There would be numerous events in 2015 to mark the 20th Anniversary of the WTO. This event could be an opportunity to share with a wider audience various issues the Committee had worked on since the establishment of the WTO. The Secretariat, in cooperation with the incoming chairperson and in consultation with the Members would develop a draft outline of the programme for the TBT Committee's consideration.

6.2. The representative of India agreed with the proposal to use the opportunity of TBT@20 to look back and take stock of what had been achieved in the past twenty years and his delegation would like to be involved in further development of the programme. While the suggestion was to have the workshop open to public; it would be useful for Members to consider further the nature of participation. On the proposed content, his delegation had reservations on "review of issues which members have considered in some depth over the years." While it was a good idea to highlight success, he said it was not appropriate to deliberate in a public event, those issues which the Committee deliberated in depth but could not reach a consensus on. His delegation had sensitivity on some issues such as economic benefits of international standards being deliberated in the proposed forum. The programme should be developed carefully, taking into consideration all Members' sensitivities.

6.3. The Chairman asked the Secretariat to prepare a draft programme.

7 DATE OF NEXT MEETING

7.1. The next regular meeting of the Committee is scheduled for 17-18 June 2015. It will be preceded by a thematic session to be held on 16 June 2015.

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[20] G/TBT/GEN/177.
[21] G/TBT/GEN/178.