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Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 17-18 JUNE 2015

CHAIRPERSON: MS ALANA LANZA

Note by the Secretariat[1]

1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in WTO/AIR/TBT/2.

2 ELECTION OF THE CHAIRPERSON

2.1. The Committee elected Ms Alana Lanza (Honduras) as the chairperson of the Committee.

3 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

3.1 Statements from Members under Article 15.2

3.1. The Chairperson reminded the Committee of Members' notification obligation under Article 15.2 of the TBT Agreement and further informed the Committee that the latest list of statements submitted under Article 15.2 of the TBT Agreement were contained in document G/TBT/GEN/1/Rev.14, issued 23 February 2015. She informed the Committee that in total, since the last meeting in March 2015, Ukraine and Sri Lanka had submitted revisions to their original

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

statements. She further informed the Committee that 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).

3.2 Specific Trade Concerns

3.2.1 Withdrawn concerns

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 The Chairperson reported that the following Specific Trade Concerns had been withdrawn from the Agenda at the request of the concerned Member:

a. Chinese Taipei – Amendment to Legal Inspection of Toy Commodities - withdrawn by United States (New).

b. Norway – The Regulation on Limitation in Use of Hazardous Chemicals - withdrawn by the Republic of Korea (New).

c. United States- Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates - withdrawn by China (New).

d. Ecuador- Draft Technical Regulation of the Ecuadorian Standardization Institute (RTE INEN) No.47: Metal Cable Tray, electrical conduit and trunking systems- withdrawn by Mexico (New).

e. European Union – Alternatives to Animal and New Cosmetic Regulations – withdrawn by Canada (Previously raised).

3.2.2 New Concerns

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

3.3. The representative of Argentina said that, prior to this meeting his delegation had requested the European Union to notify this proposed regulation to the SPS Committee, as the issue fell under the SPS Agreement. The proposed measure was however notified instead to the TBT Committee. He said that Argentina was seriously concerned over this new proposed regulation, which intended to amend the current system for the authorization of GMOs, established in Regulation (EC) No. 1829/2003, with a view to allowing EU member states to restrict or prohibit the use of GMOs and genetically modified food and feed in all, or only in parts, of their territory, although such use had been authorized by the European Commission. He recalled that EU member states already had the possibility to prohibit and restrict, at national level, the marketing and importation of biotech products, provided that they produced scientific evidence that such products could pose a risk to health or the environment. However, the new proposal gave EU member states broad scope for discretion, which was inconsistent with the WTO rules, as they would now be able to unilaterally reject the authorizations approved by the European Commission under the current system, without having to provide any scientific proof. This would be a disguised discriminatory, arbitrary and unjustified restriction on international trade.

3.4. He said that according to the text of the proposed regulation, the prohibitions or restrictions applied by EU member states should be based on factors other than those identified in the risk assessment by the European Food Safety Authority (EFSA) for the authorization of GMOs, i.e., factors other than the risk to human and animal health, or to the environment. Argentina recalled that in the past, the EU and its member states had tried unsuccessfully to justify their restrictions on the use of GMOs using science-based arguments, which was why the issue was brought before a WTO Panel in 2003 (*EC — Approval and Marketing of Biotech Products*). This Panel found in 2006 that these restrictions were inconsistent with the SPS Agreement. In order to avoid further contentions being raised in the WTO and additional adverse rulings, the European Commission appeared to be seeking, through the new proposed amendment to Regulation (EC) No. 1829/2003, alternative means of evading its international obligations under the SPS Agreement in this regard. Argentina believed that the measures under the proposed regulation that would enable EU

member states to restrict or prohibit GMOs were similarly incompatible with the WTO rules. This was so because this proposal would create unnecessary obstacles to international trade and would lack proportionality in restricting trade more than what would be necessary to fulfil the objectives sought by the EU member states.

3.5. Argentina considered that if the proposal would be adopted, it would create a high level of unpredictability in international commodity markets by unjustifiably impacting not only producers in the EU, but also those in third countries. This proposed measure would also affect the integrity of the EU's single internal market and free transit within the EU. Although this could be attributed to a competition decision by the EU institutions, it would also adversely affect, either directly or indirectly, Argentina's exports to the EU. Argentina therefore requested the EU not to adopt the notified proposal and instead, to implement, in a timely and proper manner, the current EU legislation on the approval and authorization of the use of GMOs throughout the territory of the EU, thus bringing its regulations into line with the WTO rules.

3.6. The representative of Paraguay said that that this proposal would give EU member states the power to prohibit the use of genetically modified (GM) food and feed after these products have been authorized by the European Commission, including for those that had already been on the market. Many of these products, he said, had been used for a number of years in the European Union without any reports of negative effects to human or animal health or the environment. Under the new proposal, EU member states would not be allowed to use justifications linked to the assessment of risks to health or the environment, which have already been comprehensively addressed in the Commission's authorization decision, based on studies conducted by the European Food Safety Authority (EFSA), and by the EU procedures already available. The new proposed rules would mean, therefore, that the requirement that the measures applied by Members be based on scientific evidence in accordance with the SPS and TBT Agreements would not be met.

3.7. He noted that the EU was the main destination market for Paraguay's agricultural exports, receiving more that 32% of the Paraguayan soya exported worldwide. The entry into force of this EU proposal would therefore unjustifiably restrict trade, as there was no technical or scientific basis to prohibit the use of such soya. It would also weaken the provisions established by EU's own food safety authority and, at the same time, undermine legal predictability in trade. The delegation of Paraguay requested the EU to reconsider the amendment of the existing Regulation and suggested that a similar notification be made to the SPS Committee.

3.8. The representative of the United States said that her delegation was still not convinced by the EU's rationale for notifying this measure to the TBT Committee. For the US, given that the proposed regulation amended an SPS measure (Regulation (EC) No1829/2003), it should have been notified to the SPS Committee pursuant to Article 7 of the SPS Agreement. The US therefore asked the EU to make such notification to that Committee. In this respect, she recalled that the preamble to the amended Regulation specifically stated that its objective was to protect human and animal health, and that this measure was the subject of a WTO dispute regarding its consistency with the SPS Agreement.

3.9. She further observed that this proposed measure would amend the original SPS regulation so as to allow EU member states to implement bans on non-scientific grounds precisely because both the EU and its member states have repeatedly failed to justify such actions with science-based risk assessments. In this respect, she recalled that the 2006 WTO Panel Report in *EC — Approval and Marketing of Biotech Products* found nine EU member state bans to be in violation of Articles 5.1 and 2.2 as well as Article 5.7 of the SPS Agreement. It was therefore clear to her delegation that allowing EU member states to take a "case by case approach" to justifying bans and restrictions was not sufficient to circumvent the grounding in scientific principles and adequate risk assessments required by the SPS Agreement. She also noted that several members of the European Parliament have stated that this proposal appeared to raise serious concerns under WTO rules.

3.10. The representative of Canada questioned whether allowing EU member states to ban the use of GM events that have been deemed safe by the European Food Safety Authority (EFSA) for consumers, livestock and the environment by a vigorous risk assessment, and approved by the European Commission, was compatible with the EU's international trade obligations, especially those under the SPS and TBT Agreements. Furthermore, the proposal appeared to pose a

challenge to the concept of the EU single market and could potentially result in a patchwork of conflicting regulations across the EU. This measure, if implemented by one or more EU member states, would have the potential to cause serious trade disruptions for the EU's international trading partners and would introduce further uncertainty with respect to exports of GM crops to the EU. Furthermore, the use of terms and definitions, such as "use", lacked clarity and would result in further uncertainty for exporters.

3.11. The representatives of Brazil and Chile said that their respective delegations shared the concerns raised by other Members and requested the EU to also notify the proposed measure to the SPS Committee.

3.12. The representative of the European Union explained that the proposed measure would amend the EU legislation on GM food and feed so as to provide a legal basis for EU member states, if they so wished, to take a decision on the use of these products on their territory, subject to certain conditions. This proposal was not a renationalisation of the decision to authorise GMOs. GM food and feed would still remain to be assessed by EFSA in accordance with harmonised science-based criteria, and they would also continue to be authorised at EU level, following an EU decision of authorisation. As such, the proposal would not introduce any restriction or ban. It would only provide the possibility for EU member states, if they so wished, to opt out from the EU decision of authorisation based on overriding reasons of public interest distinct from the assessment of risks to health or the environment. She explained that strict substantial conditions were provided for in the proposal to ensure compatibility with EU law and international obligations, i.e., measures adopted by EU member states shall be based on compelling grounds, could not be discriminatory and needed to be proportionate. The mobility of GM food and feed was thus preserved under the proposal as EU member states could not restrict or ban their free circulation and import but only their use. Further, EU member states would not be allowed to restrict or ban the use of food and feed in case GMOs were present at trace level, or restrict or ban the use of products fed with GMOs.

3.13. She also explained the reason behind the EU's determination that neither the proposal, nor the national measures that could be taken on the basis of the proposal, were SPS measures as defined in Annex A of the SPS agreement. They were not such measures, she explained, because they did not relate to the protection of the life and health of human and animals. In this respect, she noted that the reason why the proposal did not allow EU member States to use compelling grounds which related to the assessment of risks to health and to the environment, was precisely not to interfere with the EU risk assessment. However, for transparency reasons, the EU drew Committee Members' attention both to the fact that this proposal existed and to the fact that it has been notified under the TBT Agreement. She indicated that the final date to submit comments was 90 days, counted from 20 May 2015.

3.2.2.2 Russian Federation – Measure affecting import of Ukrainian food salt

3.14. The representative of Ukraine voiced her delegation's concern regarding a ban of the Russian Federation on imports of food salt produced by Ukrainian State Enterprise *Artyomsol*. She said that the ban was imposed on 26 January 2015 by Russia's Federal Service on Customers' Rights Protection and Human Well-being Surveillance (*Rospotrebnadzor*) under the pretext of violation of legislation in the sphere of sanitary and epidemiological safety. The announced ground for prohibition was an alleged incompliance with the requirements for organoleptic indicators. She said that this measure was introduced suddenly and in a non-transparent manner and that, except for a short notice on the website of *Rospotrebnadzor*, there was no other information officially provided to Ukrainian Authorities. Russia did not provide any official results of examinations or tests, revealing any problem of inconsistency of the Ukrainian products.

3.15. She also noted that the Ukrainian producer in question effectively applied a management system for quality and safety that was in accordance with the requirements under ISO standard 9001:2008 and the quality of the product has been certified by both Ukrainian and Russian authorised bodies. The food salt of the mentioned Ukrainian producer has been exported to Russia for many years. During recent years, export of the salt products to Russia reached 55% of the company's production, more than half of which was food salt. Ukraine believed that the Russian measure was thus not justified and was applied in a non-transparent and unpredictable manner, with a view of creating unnecessary obstacles to trade. As such, this measure was inconsistent with provisions of the Articles 2.1, 2.2 and 5.1 of the TBT Agreement. Ukraine asked Russia to

immediately lift this trade ban and bring the measure in line with the TBT Agreement as well as the commitments Russia has undertaken under its WTO accession.

3.16. The representative of the Russian Federation said that the temporary suspension of imports of food salt produced by Ukrainian enterprise *Artyomsol* was introduced due to the violation of the requirements of consumer protection technical regulations of the Eurasian Economic Union. In 2014, the Russian competent authority – *Rospotrebnadzor* - detected incompliances in food salt produced by *Artyomsol*. The products labels contained false information and the products themselves were not in compliance with the corresponding requirements for purity and iodine content. The label of salt indicated that it was iodized salt with 0.04 mg/g of iodine content according to the technical regulation of the Customs Union "on the labelling of food products". However, laboratory tests had indicated a lower amount of iodine in the salt produced by this Ukrainian producer. Due to this fact, the surveillance at the State Boarder check-points and in retail network was enforced. As of the end of 2014 and early in 2015, there were large-scale detections of such products in the internal market that appeared to be deceptive practice in trade. The results of the tests confirmed incompliance with the existing requirements. Due to such incompliance, on 26 January 2015 Russia introduced a temporary import suspension of the mentioned products into its territory. The measures were imposed with the aim of protecting Russian consumers' right for reliable information on the products, and to prevent deceptive practices in trade, and to maintain, at the appropriate level of protection, the safety and life and health of population in full compliance with Article 2.2 of the TBT Agreement. She stressed that the suspension of imports was a temporary measure covering only one Ukrainian enterprise. It was not therefore a full-fledged import ban of all Ukrainian food salt products. Nevertheless, since the implementation of measure, Ukrainian competent authorities had not taken any steps to establish contacts with its Russian counterparts to resolve this issue. In order to resume the supplies of the products from this Ukraine enterprise to Russia, Ukraine should take steps to start such necessary communication at the bilateral level.

3.2.2.3 China - Registration Fees for Drugs and Medical Device Products

3.17. The representative of Canada expressed his delegation's concern that this measure was published on, and was in force since, 27 May 2015, without being first notified to the WTO. Members did not have therefore any "reasonable interval" between publication and entry into force, as required by Article 5.9 of TBT Agreement. Also of concern to Canada was the fact that China was not providing domestic registration fees for Class II medical devices. And also the fact that China was not providing for national treatment to Class III medical device manufacturers by charging imported medical devices a first registration fee that was more than double the domestic registration fee. Based on the document released, Canada also believed that China failed to provide national treatment to drug manufacturers, with imported drug registration fees being, in most cases, double what domestic drug manufacturers were charged. As a result, China was neglecting its responsibilities under Article III:2 of the GATT 1994 as well as Article 2.1 of the TBT Agreement by failing to provide the same treatment to imported drugs and medical device products as their domestically-made equivalents. Specifically, China was charging new, imported drugs a first-time registration fee of approximately 376,000 RMB for the clinical trial, and 593,900 RMB for the production listing, compared to the 192,000 RMB and 432,000 RMB charged to domestic drug producers, respectively. For registering generic drugs with the CFDA, China charged approximately 367,600 RMB for imported product listings that did not require a clinical trial, compared to approximately 184,000 RMB for domestic equivalents. For generic drugs that required a clinical trial, China charged 502,000 RMB for imported drugs, compared to the 318,000 RMB fee for domestic drug producers. In terms of medical devices, the first registration fee for Class III imported medical device products was approximately 308,800 RMB, whereas domestically made medical device products were only charged approximately 154,000 RMB. Canada asked China to explain why it was using two separate fee structures for domestic and imported drugs and medical devices?

3.18. He also said that Canada has recently learned about the accelerated service being offered by the CFDA to fast-track applications for drugs and medical devices. Canada asked China to confirm whether domestic and foreign firms would be charged the same fast-track fee. Additionally, it appeared that certain innovative imported products would not need to pay registration fees to the CFDA. It was Canada's understanding that the "innovative" definition was based on China's "Green Channel" framework, which has only accepted one imported product as innovative in over a year. Canada asked China to provide clear guidelines as to how it planned to

determine whether a product was innovative or not. Would the same definition of "innovative" be applied to domestic and foreign products alike?

3.19. The representative of the United States associated herself with Canada's concerns with the lack of notification and nature of the fee structure. She said that this final regulation implemented a new fee system for the "evaluation and on-site investigation" for Class II and Class III medical devices. The new scheme was effective immediately, without consultation. Manufacturers of Class III medical devices were now required to pay fees that were approximately twice as high as Chinese producers for the initial registration. China delegated the authority for all Class II registration fees to their provincial governments. The new fee system was broad and affected over 50% of all medical device categories. The US asked China the following questions: (i) why had it delegated registration and the collection of fees for Class II devices to provincial governments? (ii) what would be the criteria used by provincial governments when determining user fees? (iii) why registration fees could be twenty times more costly for foreign manufacturers than domestic manufacturers and disproportionate to the conformity assessment procedures provided? She also said that the U.S. Food and Drug Administration (FDA) did not have user fees to perform any on-site medical device inspections. The FDA did use fees to recover costs associated with evaluations and on-site inspections for generic drug applications under the Generic Drug User Fee Amendments (GDUFA) program, but the U.S. system for calculating user fees was transparent, and GDUFA fees were negotiated with industry in advance of becoming final.

3.20. The US also requested China to notify this regulation to the TBT Committee, so Members would be able to review and comment on the fee structure for inspection and how it was justified. The US further requested China to suspend levying of registration fees until the scheme was notified with at least a 60-day comment period and a reasonable interval for implementation. The US acknowledged that on-site inspections were necessary to promote public health and to ensure that products were safe and effective. The US also agreed that foreign inspections were more expensive. However, the US requested that the fees associated with foreign inspections should also be transparent, non-discriminatory, and reflect input and concerns from the regulated industry.

3.21. The representative of Republic of Korea said that his delegation was of the view that new licence application fees discriminated between national and foreign medical device manufactures. Although Korea understood that on-site audit for medical device originating in a foreign country required additional cost (for example, related to hotel accommodation fees), China's on-site audit fee was more than double compared to those applicable to domestic medical devices. As a matter of fact, on-site audit was not compulsory according to Article 13 of the supervision and administration of medical devices. It was stipulated that on-site audit could be performed as quality inspection on imported medical devices, only if necessary. Korea therefore requested China authority to separate the cost for on-site inspection from the registration fees, which was the general practice performed by many Members, including Korea.

3.22. The representative of China said that before the measure at issue was published, for a long time China did not charge any fees for the registration of medical devices. She said that charging registration fees on drugs and medical devices was a global norm and, in any case, these new Chinese fees were far lower than the international level. China understood that the long interval between the new fee system and the old system (whereby no fees were charged) might have caused some Members to feel the fees have increased. With regard to different registration fee structures for domestic and foreign drug and medical devices, she clarified that the gap only related to the different costs needed for on-site inspection. Between domestic and foreign products, the costs arising from communication, transportation, accommodation and others relating to on-site inspectors could differ greatly. In this respect, she noted that Article 5.2.5 of the TBT Agreement required that any conformity assessment fees on foreign products should be "equitable in relation to any fees chargeable for assessing the conformity of like products of national origin or originating in any other country, taking into account communications, transportation and other costs arising from differences between location of facilities of the applicant and the conformity assessment body." Additionally, it was international common practice to charge differently on domestic and foreign products for on-site inspection. For example, according to the Prescription Drug Use Fee Act (PDUFA), the US FDA required foreign companies to pay USD 15,000 more than domestic ones.

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

3.2.2.4 Chinese Taipei - GMO Labelling

3.24. The representative of Canada said that while his delegation recognised and supported Chinese Taipei's right to implement regulations that provided consumers with adequate information to make informed choices, Canada also believed this objective could be satisfied through less trade restrictive voluntary measures. More specifically, Canada was concerned that mandatory labelling could mislead consumers by not providing them with straightforward meaningful information. Mandatory labelling should be reserved for legitimate health concerns and was not an appropriate tool to address concerns about food quality and fraud. The scientific consensus was that GM products that have been safety assessed and approved were safe for human consumption and therefore should not require additional labelling. More restrictive measures may be counterproductive to Chinese Taipei's efforts to modernise its food regulations and inadvertently create food safety concerns where there were none. The recent trend for TFDA to pre-empt potential political or public reaction through trade restricting regulations was troubling to Canada.

3.25. The representative of the United States said that her delegation shared Canada's concerns as this measure would significantly disrupt the US exports of agricultural products to Chinese Taipei. The US was particularly concerned with the fact that the regulation would lower the labelling threshold to 0.9% from 5.0% and, at the same time, expand the scope of the label to include all processed food products regardless of the presence of foreign DNA or protein. The US also expressed concern with the fact that this measure entered into force on 1 June 2015 instead of 1 January 2016, which was the initial date announced for implementation. Such immediate implementation did not allow time for manufactures to modify their labels.

3.26. She also noted that the US exported processed foods to Chinese Taipei, including alcoholic beverages, amounting to approximately USD 659 million in 2014. US exports of genetically engineered (GE) products, and/or products derived from GE plants, amounted to an estimated USD 2 billion in 2014. These amendments imposed significant burden on producers, exporters and importers of food containing GE ingredients. Increased cost for food to Chinese Taipei consumers could cause companies to exit the market. The US therefore requested Chinese Taipei to return to its former labelling regulation of a 5.0% threshold for labelling of food where introduced DNA or protein may be present. The former regulation worked well in addressing consumers' needs. On the other hand, the more stringent threshold for labelling and the immediate implementation date created an obstacle to trade for a wide variety of food products - from bulk commodities such as corn and soya bean to processed foods products - and would have a negative impact on domestic food processing industries. Since the presence of authorised GE ingredients in food products did not pose a human health risk in comparison with the conventional foods on a categorical basis, there was no scientific evidence for these amendments and hence they would raise unjustified food safety concerns among the public.

3.27. The representative of New Zealand said that her delegation considered that the labelling requirement promulgated through the regulations could be confusing to consumers and could therefore result in unjustified concerns. When applied to food that was highly refined and where processing removes all transgenic DNA and transgenic protein, the labelling requirements could raise unnecessary consumer concerns and potentially desensitize them to labels regarding GMOs. Consumers may not readily appreciate the difference between food derived GMO that no longer contained transgenic DNA or transgenic protein, on the one hand, and food that did not contain these proteins, on the other hand.

3.28. The representative of Chinese Taipei explained that on 24 December 2014 the Ministry of Health and Welfare was granted the authority to modify the regulations. This was promulgated on 22 December 2014, including with respect to highly refined foods, which now should be labelled to protect the consumers' rights. According to that motion, the Ministry announced three regulations

which were: (i) a draft amendment on labelling requirements for pre-packaged foods containing ingredients of genetically modified organisms (GMOs); (ii) a draft amendment on labelling requirements for food additives containing ingredients of GMOs; and (iii) a draft amendment on labelling requirements for unpackaged food containing ingredients of GMOs. As from 26 February 2015, for food that used GMOs during manufacturing processes although the final product did not contain transgenic DNA fragments or transgenic protein, the new rules require that these products should display either of the following statements: (i) "*this product is made of GMOs, but this product does not contain any transgenic DNA fragments or transgenic proteins*"; or (ii) "*this product's raw materials contain GMOs, but this product does not contain any transgenic DNA fragments or transgenic proteins*". The authority had already held technical expert meetings to discuss labelling of highly refined foods with no transgenic DNA fragments or transgenic proteins. Based on the conclusions reached after such meetings, on 29 May 2015 the authority announced the three regulations described above. These regulations would be notified to the WTO very shortly. For foods that used GMOs directly during manufacturing process although the final product did not contain transgenic DNA fragments or transgenic proteins, one of the following pieces of information was required to be labelled on the product: (i) "*genetically modified, with genetic modification or used genetically modified organisms [the name of a particular organism]*"; or (ii) "*this product is made of genetically modified organism [name of a particular organism], but do not contain any transgenic DNA fragment or transgenic proteins*" or "*this product's raw materials contain genetically modified organisms [name of particular organism], but do not contain any transgenic DNA fragment or transgenic proteins*", or (iii)"*this product do not contain any transgenic DNA fragments or transgenic proteins but it is made of genetically modified organisms [the name of a particular organism]*", or "*this product does not contain any transgenic DNA fragments or transgenic protein but with genetically modified organisms [the name of a particular organism]*".

3.2.2.5 Chinese Taipei - Additional labelling standard of prefecture of origin for foods from Japan

3.29. The representative of Japan expressed his delegation's concerns with Chinese Taipei's import restrictions on Japanese foods for radionuclides. He noted that Chinese Taipei had recently strengthened its import restrictions, such as requiring certification of testing results of radionuclides and certification of prefectures of origin. In addition, in the TBT area, Chinese Taipei's Food and Drug Administration (TFDA) issued its public announcement, dated 15 April 2015, requesting that the foods originating in Japan should, inter alia, indicate their prefectures' name of origin by a product label and sticker, and also a notice at stores and restaurants. He noted that these requirements were only imposed on Japanese products. Japan considered that this TDFA requirement to indicate the prefectures' name of origin on each product would fall under the scope of TBT Agreement. Japan asked Chinese Taipei to clarify whether this requirement was mandatory or voluntary. He said that Japan's concerns with these measure stemmed more precisely from the following two reasons: (i) the fact that this measure may give consumers in Chinese Taipei the negative impression that Japanese foods were less safe than those from other countries; and (ii) the fact that this measure may cause negative effects on the trade of Japanese foods by putting additional burden, such as additional cost or record keeping, imposed on distributers, retailers and restaurants. He also said that Chinese Taipei and Japan were closely engaged in bilateral consultations with a view to finding a mutually acceptable solution to this matter as Chinese Taipei was one of Japan's most important trade partners.

3.30. The representative of Chinese Taipei said that food products produced in certain areas in Japan were still subject to certain import management regulations. The purpose of the requirement for the attested documents was to validate the area of production. There were several false declarations of origin and forgery of labels recently happened in Chinese Taipei and because of these violations Chinese Taipei had no choice but to implement the requirement to inspect the declaration of the origin of food products from Japan. Concerning the measure announced on 16 April 2015, he responded to Japan that this measure was voluntary in nature.

3.2.2.6 Sweden - Chemical Taxation for Certain Electronics

3.31. The representative of the Republic of Korea thanked the European Union for, but was still not convinced by, the explanation the EU gave Korea bilaterally that the measure at issue – a Swedish tax scheme on chemicals enforced on certain electronics using flame retardants – was not a TBT measure. Korea's understanding was that this measure imposed specific taxes on certain

electronic products using brome, phosphorus, chlorine additive flame retardants as well as brominated and chlorinated reactive flame retardants. However, in situations where there would not be appropriate substitutes for these chemicals this regulation would lead to significant barriers to international trade. Korea believed that Sweden should have therefore notified and published this regulation in accordance with TBT transparency rules, especially those under Articles 2.9.1 and 2.11. Korea also noted that under Annex 1 of the EU's Low Voltage Directive, electronic and electric products must be designed to protect human, animals and property. In achieving this objective, flame retardants had normally been used in the process of manufacturing of products to ensure safety in case of fire. Thus, the imposition of taxes on brome, phosphorus and chlorine, which were the basic elements of flame retardants, could be a serious obstacle in achieving the safety of these products. Korea therefore asked Sweden to take into account these points when implementing the measure at issue.

3.32. Korea further recalled that Section 3 of 15.1 in the regulation – titled "Proposed Rule of Tax on Certain Electronics" – specified 13 products subject to the taxation scheme. However, it was very difficult to comply with the regulation due to the ambiguous scope of the regulated flame retardants. Korea asked Sweden to provide a detailed list of all regulated substances, including CAS registration numbers. Korea also noted that under 3.2.6 – titled "Differentiation through Tax Deduction" – products not containing brome, phosphorus or chlorine additive flame retardants would be provided a 50% tax deduction. The measure also provided that products that did not contain brome, phosphorus and chlorine additive flame retardants, or brome, chlorine reactive flame retardants, would be eligible for a 75% tax deduction. As it was very difficult to figure out which substances fell under one of these categories, Korea requested Sweden to provide the substance list and detailed guideline for tax deduction eligibility.

3.33. Finally, Korea submitted that, although it was well known that phosphorus flame retardant was a substitute for brome and chlorine flame retardants developed as part of halogen-free movement of the flame retardant industry, it seemed unreasonable and controversial that phosphorus flame retardant itself was regulated under this Swedish regulation. Considering that phosphorus flame retardants were relatively less harmful to human and environment, Korea requested Sweden to reconsider the inclusion of this particular substance as among those regulated by the measure.

3.34. The representative of the European Union informed the Committee that the Swedish Government was currently conducting consultations on this matter, which might be subject to future legislation and that, at this stage, only a so-called "inquiry report" had been finalised. He also said that Sweden was currently examining this "inquiry report" in order to decide whether to draft legislation in this field. He explained that this report proposed two new excise duty regimes: an excise duty on certain electronic products and an excise duty on PVC floor, wall and ceiling coverings. Therefore, the possible future legislation did not seem to fall under the definition of technical regulation and/or conformity assessment procedure as defined in the TBT Agreement and it was therefore not necessary to notify it to the TBT Committee.

3.2.2.7 Brazil - Draft Ordinance Act Nº. 374, 27 November 2014 (Portaria SDA/MAPA 374/2014) Establishes quality requirements for wine and derivatives of grape and wine, G/TBT/N/BRA/613

3.35. The representative of the European Union noted that some provisions of this draft measure differed from the recommendations of the International Organisation of Vine and Wine (OIV), of which Brazil was a Member. Some of these differences would oblige EU wine producers to modify their labels and therefore entail higher production costs. In particular, the draft measure departed from the relevant OIV recommendations as well as Codex standards with regard to a minimum content for indicating on the label the grape variety of lower share (this minimum content was 15% under the relevant OIV Recommendation while under the draft Brazilian measure it was established at 25%), and also with regard to a requirement to classify wine according to colour. In this respect, the EU recalled that Article 2.4 of the TBT Agreement called for use of international standards and asked Brazil to indicate the reasons for these diverging requirements.

3.36. The EU was also concerned with the draft measure's provisions on sugar content of these products, for which OIV Recommendations also existed. She noted that the draft measure, together with an earlier decision of February 2014 ("*Decreto No. 8.198*"), was not in line with these OIV Recommendations, and was now creating problems at import point, in particular for

sparkling wines. The EU asked Brazil to clarify to what extent the draft measure would apply to wines imported from the EU, considering their "tipicity" (Article 52 of the *Decreto No. 8.198*). The EU said that it would welcome an interpretation of the draft measure in conjunction with the text of *Decreto No. 8.198* so as to clarify applicable rules.

3.37. The EU further asked Brazil to provide clarification with respect to the analytical parameters diverging from the OIV Recommendations, including on ashes and alcohol content. The EU was also concerned with the fact that the use of caramel would be only allowed in liquor wines, and not in other wine-derived distillates. Additionally, the EU was concerned with: (i) the prohibition of the terms "dry" or "reserve" on the label of grape and wine derivatives; (ii) the high levels of alcohol and wine content in sangria; (iii) the misleading use of the term "*moscato*", as well as the evocations of certain names protected in the EU, such as "*conhaque*", "*grappa*" and "*champanha*".

3.38. The representative of Brazil said that up until 27 January 2015, a 60-day public consultation period was held on the proposed measure. A number of comments and suggestions were made, both from various governments and the private sector, including from the EU. All comments were consolidated and were currently under appreciation of the relevant authorities. He also informed that the Brazilian Ministry of Agriculture would hold a public hearing on this subject and interested parties that have contributed to the public consultation would be able to attend. The date of this public hearing would be communicated in due course. Finally, since this TBT notification referred to a proposed measure subject to public consultations, consequently the measure under discussion had not produced any affects whatsoever in the trade of wine and derivatives of grape and wine.

3.2.2.8 France – Ban on BPA in toys

3.39. The representative of the United States said that, while her delegation recognised that this issue was still an ongoing legislative process, the US would nonetheless like to raise some concern with an amendment to France's Health Framework Law (No. 2302). This amendment, which was currently under discussion in the French Senate, would impose a complete ban on the presence of *bisphenol-A* ("BPA") in toys. She asked if France has assessed the legal compatibility of the ban in toys with the European Toy Safety Directive and the Treaty for the Functioning of the EU. Given the functioning of the internal market, the US was of the view that this measure could cause significant trade disruptions. The US asked the EU to explain whether France intended to notify the implementing measures to the WTO if the ban were to be adopted. The US also asked whether France had undertaken a trade impact assessment and, if so, whether a copy of what had been considered could be provided.

3.40. The representative of the European Union informed the Committee that the French Parliament was currently examining a draft Law on the Modernisation of the French Health System. In this context, the possibility of introducing a ban on BPA in toys was being discussed. However, the legislative process was still ongoing and there was no stable text yet. Specifically, following the first reading of the proposal adopted by the National Assembly (*Assemblée Nationale*) on 14 April 2015, the text would now have to be examined by the Senate. The EU therefore considered any discussion on this matter in the TBT Committee to be premature at this stage.

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

3.41. The representative of the United States was concerned that an Indonesian revised draft regulation – Technical Requirements of Telecommunication Devices and Set Based on Long-Term Evolution Technology Standard (KOMINFO) – which established technical specifications for 4G LTE products, including certification, conformity assessment and mandatory local content requirements, might create unnecessary obstacles to trade. Although US stakeholders were included in domestic public consultations, the US expressed concern that the draft regulation had not been notified to the TBT Committee. It appeared that the regulation would come into effect prior to the finalization of the revision of its counterpart regulation – Ministry of Industry Regulation (MOI) 69/2014 – on the method of calculating local content. Given that the ability of companies to comply with the KOMINFO draft measure depended on the MOI revision, the issuance of the draft before the MOI's revision was completed would create confusion. The US was also concerned that the KOMINFO draft would come into effect the day the regulation was

promulgated and leave companies no time to adjust to the new requirements. The KOMINFO draft required compliance with the European Telecommunications Standards Institute (ETSI) 3GPP TS 36.104 (version 11.7.0, release 11). Accredited and approved facilities had to test compliance with the ETSI standard. It was unclear to the US whether there were additional testing requirements that would have applied to devices and how those testing requirements related to previously established testing requirements for cell phones. The US also requested further information on the testing and certification requirements contained in the two appendices to the draft regulation, and how those requirements related to two other previously established regulations. The US thus urged Indonesia to delay adoption of the KOMINFO draft until its notification to the TBT Committee and further consultation could take place. The US also asked Indonesia to indicate when the regulation would be finalized and to consider a workable timeframe.

3.42. The representative of Canada shared the US' concerns with respect to Indonesia's intention to introduce local content requirements for smartphones using 4G/LTE technology as it could pose a significant barrier to trade. Canada asked for clarification on whether the new local content requirements were going to be notified to the WTO and what process they would follow so as to take Members' concerns into account (Article 2.9.2 of the TBT Agreement). In addition, Canada asked Indonesia to provide a justification for its approach and the objectives of the local content requirements. Canada also inquired whether Indonesia had considered a less trade restrictive means for accomplishing the measure's objectives. Like the US, Canada also requested that Indonesia provide Members with an indication of when the regulations might be finalized and to delay their adoption or entry into force until such time as consultations had taken place.

3.43. The representatives of Japan and Australia associated themselves with the US and Canada's concerns, in particular those related to transparency.

3.44. The representative of the European Union associated himself with the concerns of previous delegations, in particular their request that the draft regulations be notified to TBT Committee and that their implementation be postponed until such notifications have been carried out and other WTO Members and their stakeholders had the opportunity to analyze and comment on them. The EU referred to the requirement of the draft regulations that testing had to be carried out in Indonesia by laboratories accredited and approved by the Indonesian Administration. In order to avoid an unnecessary repetition of tests, the EU invited Indonesia to accept the results of tests carried out outside Indonesia in properly accredited laboratories, considering the global nature of mobile communication equipment markets and the availability of global agreements for accreditation of laboratories. Finally, as the draft regulation required compliance with a specific standard, the EU invited Indonesia to consider ways to update the references to that standard in a manner that kept pace with the fast technological evolution in the sector. Thus, rather than making a reference to a dated version of a standard, it could have referred to the most recent available version to reflect the latest technological innovations.

3.45. The representative of Indonesia explained that enhancing Indonesia's participation in the global value chain required strengthening the local industry in that sector. They were formulating the ministerial decree as they sought to ensure certainty in that sector and to increase confidence among stakeholders. They undertook the process through collaborating with the private sector and fostering the participation of international players by means of a transparent public consultation process. Indonesia assured the Committee that the draft would take into account all inputs and concerns from every stakeholder and would be in line with international rules and standards as well as WTO provisions. As to the question of whether Indonesia intended to notify the measures to the WTO, the representative said that he took note of this question but was unable to answer it at this juncture.

3.2.2.10 Turkey - Toy Communique 01/2015

3.46. The representative from the United States said that toy inspection measure required that every import shipment of toys be detained in order for three or four representative samples be taken from each "stock keeping unit" (SKU) in the shipment that had to be sent to a laboratory for phthalates and flame retardant testing. Turkey also tested for azo dyes in plastic toys, even though they were not found in plastics. Typically, a toy shipment contained numerous SKUs. In addition, importers would have to certify that the subject imports conformed to Turkey's toy safety regulations. Customs then would issue a registration number valid only for that shipment and would also have to be presented to customs at the port with a US$38 processing fee (100

Turkish Liras). Moreover, the "CE marking" was already required for conformity assessment procedures according to the EU Toy Safety Directive, which Turkey had adopted. US toy companies reported that the measure resulted in heightened costs and time delays. The US said that US toy importers were incurring a US$60 testing fee per item, or approximately US$380 per truck load, plus detention charges. Further, Turkish authorities took 3-4 weeks to conduct the required laboratory tests while shipments had to wait at the port. The US was concerned that the measure had the following negative effects of: (i) discriminating against imports; (ii) creating unnecessary obstacles to trade; (iii) being more trade restrictive than necessary; and (iv) treating companies with a track record of compliance unfairly. The US said that in their various bilateral meetings the Turkish authorities, although there were sentiments from them that they were willing to resolve the issue, there had been no progress and the US had not received any responses to their follow-up enquiries. The US stressed the need to resolve the issue before September 2015 to avoid significant market disruptions and therefore requested suspension of the measure until a more reasonable measure could be developed and implemented for toy testing in Turkey.

3.47. The representative of Turkey said that Turkish import controls subjected toy products to risk analysis under the "Risk Based Trade Control System" (TAREKS). As import controls were carried out electronically and on a risk basis, only risky products were subjected to safety and conformity checks. In this regard, inspections were conducted as physical checks and controls, including document/marking checks. Products were sent to accredited laboratories for testing only when there was doubt concerning product safety in terms of Communiqué 2015/10. She also noted that the relevant Communiqué was republished at the beginning of every year and contained neither legislative change nor additional technical requirements in connection with import checks for toys. As the Communiqué did not impose any new testing requirements on toy imports, Turkey was of the opinion that the measure did not have to be notified to the WTO or allow time for comments. Turkey suggested that the US concerns might rather have been related to the procedures at Customs to verify the accuracy of the importers declarations. In this respect, she explained that Turkey faced serious toy safety issues in its domestic market. The Ministry of Customs and Trade implemented strict verifications to ensure coherence between the domestic market and border procedures. Given the risk associated with toy products, Turkey was confident that similar practices have been applied by both developed and developing countries to ensure consumer health, safety and protection in the framework of legitimate objectives. Turkey emphasized that they accorded national and foreign companies equal treatment as all firms were subject to the same rules and procedures when placing their products on the Turkish market, and were thus in accordance with the principle of non-discrimination embedded in the TBT Agreement as well as GATT 1994). However, he said that Turkey undertook to consider the concerns of the US carefully and to maintain their internal consultation process with the Ministry of Customs and Trade in this regard.

3.2.2.11 Norway – Draft amendments to the Tobacco Control Act and the Tobacco Labelling Regulations relating to Standardised Tobacco Products

3.48. The representative of Indonesia appreciated Norway's intention to pursue a public health policy by protecting its citizens from the negative effects of tobacco consumption. Nevertheless, Indonesia was of the view that the enactment of such a policy should be undertaken in a manner that would not be more restrictive than necessary. Moreover, the proposed amendments were not consistent with Article 2.2 of the TBT Agreement as well as with several provisions of the TRIPS Agreement. Indonesia stressed that multiple researchers, using different analytical approaches and data sets, had failed to find any empirical evidence that plain packaging measures reduced prevalence 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 had a positive impact on consumer behaviour. Plain packaging had failed to bring about the declines in tobacco prevalence predicted by Members who adopted this measure. As Indonesia was currently in a dispute on a similar issue against Australia, Indonesia urged Norway, as well as other Members in the process of adopting similar measures, to postpone their proposals until this dispute was solved. Additionally, Indonesia invited Members to evaluate alternative measures which were more effective in achieving the health objective at issue and, more importantly, consistent with the WTO covered agreements.

3.49. The representative of Dominican Republic joined Indonesia's request to Members which were considering the adoption of plain packaging measures to wait until the dispute was resolved.

3.50. The representative of Zimbabwe voiced concerns with the proposed measure. Zimbabwe's full statement is contained in document G/TBT/W/421.

3.51. The representative of Cuba said that while her delegation acknowledged Member's right to enact health measure, it nonetheless joined Indonesia's request to Norway to suspend the adoption of its plain packaging measure until the Australia dispute was resolved.

3.52. The representative of Canada expressed support for Norway's decision to propose this measure and said that his delegation was following with interest the ongoing international developments regarding plain packaging of tobacco products and how such measures interacted with both international trade and public health. He referred to the problem of tobacco use in Canada and around the world. In Canada alone, 37,000 people died annually from tobacco use and it was Canada's leading cause of preventable death and disease. He also noted that tobacco products were the only goods subject to a legally-binding health treaty, the World Health Organization Framework Convention on Tobacco Control (WHO FCTC). Canada invited Members to consider the complete economic picture regarding tobacco control, including whether tobacco might be a net economic drain for many countries.

3.53. The representative of Australia reiterated its support for the decision by other WTO Members to adopt mandatory plain packaging of tobacco products and welcomed Norway's decision to have undertaken a public consultation process. The important steps made by Norway in tobacco control demonstrated that efforts to delay the adoption of tobacco plain packaging measures had not been successful. In Australia's view, tobacco plain packaging was not about the destruction of intellectual property rights. The measure prevented the use of packaging to advertise and promote a product that caused significant damage to public health. Australia expressed its firm 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. Australia's plain packaging measure was a legitimate public health measure and it was consistent with Australia's obligations under the WTO covered agreements. The measure was endorsed by leading public health experts, as well as the WHO, and it was supported by extensive peer review research, reports and studies. Even though Australia was currently defending the measure in the WTO, it would be inappropriate for complainants in the WTO dispute underway against Australia to invoke these proceedings in an attempt to delay or discourage other Members from adopting their own similar legitimate tobacco control measures.

3.54. The representative of Uruguay expressed support for Norway's decision on this particular measure and reiterated its position regarding the consistency of measures on tobacco and the right of Members to adopt measures to protect public health.

3.55. The representative of New Zealand expressed support for Norway's decision to have undertaken a public consultation process. She also stated that there was an extensive and growing body of international research establishing that plain packaging formed part of a comprehensive tobacco control programme which would contribute to the objective of protection of public health. To date, there was no credible evidence showing otherwise. The TBT Agreement recognised the fundamental right of Members to implement non-discriminatory measures necessary to protect public health and provided appropriate flexibilities for Members to do so. New Zealand believed that it was possible for Members to implement a tobacco plain packaging regime that was consistent with the WTO covered agreements.

3.56. The representative of Norway welcomed the interest of other Members in Norway's recent proposal. She then explained Norway's long history in tobacco control. In 1973, the Parliament adopted the first Tobacco Control Act, which banned tobacco advertising, established an age limit for the sale of tobacco and mandated health warnings. A national tobacco control strategy for the period 2013-2016 was launched in February 2013. The strategy was focused on protecting children and young people from the negative effects of tobacco. The strategy's long term vision was a tobacco-free future in order to protect and promote public health. With this in mind, the government launched a public consultation on standardised tobacco packaging in March 2015. The consultation process was both transparent and inclusive. In May 2015, the draft measure was notified to this Committee in accordance with Norway's TBT obligations. A consultation paper explaining the issue in detail was included as part of the notification. The documents outlined the government's policy objectives and referenced the scientific evidence regarding the effectiveness of standardised packaging.

3.57. Norway believed that there was strong evidence that standardised packaging, as part of a comprehensive tobacco control programme, would contribute to the objective of a tobacco-free generation/society and would improve public health. Details of this evidence were set out in Norway's consultation package and interested Members were encouraged to examine it. It was scientifically documented that tobacco, when used as intended, caused death and disease. Indeed, smoking was the single largest cause of preventable death and disease in Norway, with approximately 6,600 Norwegians dying each year from smoking-related illnesses. The proposed legislation formed the latest strand of comprehensive tobacco control legislation. Amongst other measures, Norway implemented smoke-free legislation, total bans on tobacco advertising and display of tobacco products at points of sale. In addition, all tobacco products placed on the market should carry combined text and graphic health warnings.

3.58. Norway also explained that the draft legislation at issue was aimed at restricting the promotion of tobacco products to further reduce the smoking prevalence in Norway by: (i) discouraging uptake of tobacco use by young people; (ii) encouraging and supporting tobacco users who wanted to quit and prevent relapse; and (iii) reshaping social norms and attitudes around tobacco use to promote health and wellbeing. More specifically, the draft legislation was aimed to reduce the attractiveness of tobacco products, especially for young people, by removing the advertising effect of the package design. In developing its proposal on plain packaging, Norway closely examined the consistency of the proposal with its obligations under the WTO agreements, including the TBT Agreement. In this respect, Norway recalled that Article 2.2 of the TBT Agreement explicitly provided that the protection of human health was a legitimate objective. WTO Members may thus take measures to protect such objective, provided that these measure were not more trade restrictive than necessary to fulfil their objective(s). In Norway's view, the proposal on plain packaging was in line with WTO rules, including those in the TBT Agreement. Further, plain packaging was also a recommended measure under the WHO FCTC, to which Norway was a party. These obligations included, for instance, the introduction of measures to prevent initiation, to promote and support cessation and to decrease the consumption of tobacco products. Articles 11 and 13 of the WHO FCTC, as well as their implementing guidelines, explicitly advised the parties to that Convention to introduce plain packaging as a measure to achieve the objective of protecting public health. It was Norway's firm view that the WHO FCTC and the relevant WTO agreements were mutually supportive, and that it was possible to implement measures intended to regulate the packaging of tobacco products in line with both sets of binding obligations.

3.59. Finally, with respect to calls for its legislative process to be put on hold while the disputes against Australia were resolved, Norway said that such disputes should not have any bearing on Members adopting their own measures in favour of public health. The Norwegian national consultation process was closed on 9 June 2015 and the period for comments under the WTO notification rules, was until 90 days after the date of notification (18 May 2015). All comments received, both nationally and by WTO Members, would be studied by the Norwegian authorities.

3.60. The representative of Mexico said that the proposed measure from Norway had certain similarity with other measures adopted by other WTO Members. He also indicated that Mexico would continue to follow closely the developments in the various bodies of the WTO for cases such as this one, initiated against Australia.

3.61. The representative of the World Health Organization (WHO) stated that the use of all types of tobacco posed substantial risks to human health. Additionally, health, social and economic costs associated with tobacco use were greater in developing countries. Tobacco plain packaging was one of a number of complimentary measures to reduce the demand for tobacco products. Evidence from well-qualified, respected and credible sources suggested that plain packaging would make restrictions on advertising, prohibitions on misleading packaging and health warnings more effective. It was reasonable to expect prevalence of tobacco use to decline as a consequence of this measure, an expectation that was consistent with the early evidence from Australia. The body of empirical evidence was further supported by guidelines to Articles 11 and 13 of the WHO FCTC. The WHO concluded its intervention by requesting that all previous statements by the WHO on tobacco plain packaging be included in the record of this meeting.[2]

[2] The representative of the WHO made a statement during the November 2014 meeting of the TBT Committee (G/TBT/M/64/Rev.1, para 2.33), the full content of which is contained in G/TBT/GEN/175.

3.2.2.12 China – Technical Specification for Natural Rubber

3.62. The representative of Indonesia noted that at the previous meeting held in March 2015, her delegation conducted a bilateral meeting with China regarding the issue of technical specification for natural rubber and delivered official comments to the Chinese TBT enquiry point. In this respect, China had not provided a response to their comments. Indonesia also informed the Committee that many Indonesian natural rubber exporters had encountered barriers to trade since January 2015. In Indonesia's view, these barriers were caused by the imposition of customs and excise policy on the importation of natural rubber, specifically rubber TSNR under HS heading 4001. The policy required exporters to submit custom clearance documents, such as phytosanitary certificates, quality certificates from government, SPPSNI (Chinese translation version) or SPPSNI (Indonesian/English bilingual version). In addition, the required documentation was costly and lengthy to complete. Indonesia recalled Article 2.2 of the TBT Agreement, which stated that Members shall ensure that technical regulations should not be prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacle to international trade. The policy was not brought to the attention of the public so Indonesia requested China to notify the measure to the TBT Committee. Finally, Indonesia asked China to harmonise its custom clearance documents, as it would assist Indonesian exporters to comply with such requirements.

3.63. The representative of Malaysia supported Indonesia's statement regarding China's Technical specification for natural rubber. As Malaysia was one of the major exporters of natural rubber, his delegation had concerns with the potential negative effects that this could have on Malaysian exporters. Although Malaysia acknowledged China's right to introduce measures based on legitimate objectives, Malaysia joined Indonesia's request to China to notify the measure to other Members in accordance with relevant provisions of the TBT Agreement.

3.64. The representative of China thanked Indonesia and Malaysia for their interest in this measure. Since China had bilaterally received Indonesia's concerns, China kept continuous information exchange with Indonesia and requested more information to clearly identify the measure and the competent authority responsible for it. Unfortunately, China did not find that there was such a technical specification for natural rubber. She therefore invited Indonesia and Malaysia to work with China to better understand and address their concerns.

3.2.3 Previously Raised Concerns

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

3.65. The representative of Japan requested that India consider amending the regulation at issue given that Clause 10.2 of the revised agreement required tyre manufactures to pay a US$ 10,000 bank guarantee fee per plant, causing an unnecessary competitive difference between factories within India and those outside. During previous bilateral discussions, India had agreed to try to consider reducing the bank guarantee fee. He had also asked if India would consider withdrawing this bank guarantee fee. Japan had questioned whether the fee was at a uniform rate given that India had said that the bank guarantee fee applied to all products in India, including those of foreign manufacturers. He requested an update from India on this question. On ISI marking, Japan considered the fee to be expensive in comparison with other countries and asked that India show evidence of how the ISI marking fee was equivalent or cheaper than those of other countries. He said there was also no improvement in the lengthy certification process, which still took four or five months, much longer than in other countries. Japan asked India to at least consider shortening the procedures for first licences, by simplifying the necessary application documentation.

3.66. The representative of the European Union reiterated concerns it had raised in previous meetings about the certification procedure with a mandatory marking for tyres. He referred Members to his statement made at the previous TBT Committee meeting[3] and highlighted in particular the EU's request that India align its procedures to international practices and remove the obligation to pay a marking fee per marked tyre and to eliminate the discriminatory bank guarantee requirement.

[3] G/TBT/M/65, para. 2.40.

3.67. The representative of India said that as most of the concerns were not new and had been sufficiently explained in both previous Committee and bilateral meetings, he requested that interested Members refer to the minutes of the previous meeting.[4] For the new questions, he said his delegation would forward them to capital for response.

3.2.3.2 India – Drugs and Cosmetics Rules 2007, G/TBT/N/IND/33 (IMD ID 167)

3.68. The representative of Canada raised the following two specific concerns with two provisions in the Guidance Document on Common Submission Format for Registration/Re-Registration of Notified Medical Devices in India, namely: (i) the necessity for certificates/licenses to be notarized/attested by the Indian Embassy in the country of origin; and (ii) the requirement for medical devices to be freely sold in the country of origin. Canada believed that these provisions caused unnecessary barriers to trade for the following two reasons: (i) many Canadian medical devices were marketed outside the country of origin; and (ii) requiring notarization of official government certificates/licenses from reputable jurisdictions was a burdensome regulatory requirement with no obvious benefit. Canada also continued to have concerns with the Guidance Document on Common Submission Format for Registration/Re-Registration of Notified Diagnostic Kits in India and referred Members to questions raised at the previous TBT Committee meeting.[5] Finally, on country of origin labelling of medical devices, Canada understood that the Drugs and Cosmetics (Amendment) Bill, 2015 had not yet been passed by the Indian parliament and requested an update from India on when the final draft of the bill would be notified to the TBT Committee.

3.69. The representative of the European Union requested India to allow information to be displayed via stickers, attached at customs bonded warehouses, for all aspects of cosmetics labelling, including the list of cosmetic ingredients or any other information relevant for the consumer, and not only the India-specific information, as was the current practice. He also requested an update on the state of play on the ongoing court case at the Bombay High Court concerning the Indian Central Government amendment to the legal metrology Packaged Commodities rules 2011 requiring cosmetic products to bear a red or a 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. Regarding the animal testing ban, established by Regulation 148C (Ban on animal testing of cosmetics), in force since May 2014, and Regulation 135B (Ban on import of cosmetics tested on animals), in force since October 2014, the EU requested clarification on the following two issues: (i) whether the ban applied only to new ingredients (i.e. ingredients tested on animals after the ban entered into force); and (ii) whether the ingredients that had been tested on animals for purposes other than cosmetics (e.g. for pharmaceuticals) could still be used in cosmetics. Finally, he requested India to notify the latest draft amendments to the TBT Committee.

3.70. The representative of India informed the Committee that India was seeking to align itself with international trends in this field by defining medical devices as distinct from drugs. He explained that, in order to follow international best practices, a separate chapter had been proposed in the draft Drugs and Cosmetics Amendment Bill 2015 for regulating medical devices. The draft bill had been placed in the public domain, consultations involving all stakeholders had been undertaken and comments and suggestions had been taken into account. On the concern for the need for notarization or attestation of certificates by the Indian embassy in the country of origin, he said this was required so as to prevent the submission of fabricated documents. The requirement for medical devices to also be sold in the country of origin ensured that safety and efficacy had been evaluated by national regulatory authorities.

3.71. Concerning the performance evaluation report requirements for diagnostic kits, he said the purpose of this requirement was to ensure quality of devices as per the national standards prescribed at the time of registration. Each batch of imported notified in-vitro diagnostic medical device kits ("IVD kits") had to undergo testing at the National Institute of Biologicals ("NIB") before release into the Indian market. In reply to the question of whether stickers were allowed on cosmetic products, he said there was no change in the regulatory status since the previous meeting. In this respect, he invited interested delegations to consult the minutes of the November

[4] G/TBT/M/65, paras. 2.41-2.43.
[5] G/TBT/M/65 paras. 2.44-2.45.

2014 TBT Committee meeting.[6] Similarly, on the requirement for products to bear a brown dot or green dot to reflect whether the product had non-vegetarian or vegetarian origins, there was no change in the legal status since the last meeting and the present rules did not allow this information on stickers. In response to the concern on the prohibition on the import of cosmetics tested on animals, the Indian representative reported that the Drugs and Cosmetics Rule 1945, as amended on 21 May 2014, prohibited testing on animals within the country. Rule 1945 was further amended on 13 October 2014 so as to also prohibit the import of cosmetics tested on animals. India believed that this was in line with EU's own policy. Concerning the issue of the checklist, raised in the previous TBT Committee meeting, he said that, in view of the concerns on the quality of the imported cosmetics, this checklist had been amended so as to add clarity on the data or documents required for evaluation. This checklist was based on the provisions of the existing Drugs and Cosmetics Rule 1945 and did not require generating any new data prior to submission.

3.2.3.3 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)

3.72. The representative of Japan reiterated the following two specific concerns with the "Guidance for Application and Evaluation of New Cosmetic Ingredients". Firstly, he requested that China accelerate the registration process of these products as only four new ingredients had been registered to date and there continued to be significant difficulty in exporting cosmetic products with new ingredients. Secondly, Japan again asked China to revise the requirement to submit the data for each single isolated molecule, in particular given that no explanation has been given on the scientific grounds for making such a requirement. Japan also raised a new concern about the disclosure of information. More specifically, Japan was concerned that companies were obliged to provide detailed information on manufacturing process, the reaction process and conditions of reaction. In some cases, this information appeared on the CFDA's website. While some improvements had been made, Japan requested that further action be taken so as to ensure that a company's confidential information not be disclosed.

3.73. The representative of the European Union reiterated concerns it has raised during previous meetings, and in particular with respect to the pace of progress in the new ingredients authorization process. The EU was of the opinion that the new registration procedure did not deliver in an efficient and predictable manner. He referred the Committee to the statement delivered at the previous meeting of the Committee.[7] In particular, he recalled the proposals that: (i) the authorization procedure should be limited to the procedure for registration of new ingredients when it concerned priority substances - i.e. higher risk substances – and to allow a lighter procedure for lower-risk substances; and (ii) to share the safety responsibility for new ingredients between China's Food and Drug Administration (CFDA) and the registrant company.

3.74. The representative of China said that the CFDA had 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 formed several working groups with several Members. CFDA was also in contact with experts and industry associations, both within and outside China, so as to ensure that research was carried out. China would keep the bilateral channel open and welcomed interested parties to continue to cooperate with China and put forward valuable inputs.

3.2.3.4 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)

3.75. The representative of Canada reiterated concerns regarding India's test requirements for telecommunications products. As stated in previous meetings, his delegation believed that India's in-country security testing regulations for telecommunications products would hinder or possibly shut exporters out of the Indian market. Canada disagreed with India's blanket approach testing in

[6] G/TBT/M/64/Rev.1 para 2.81.
[7] G/TBT/M/65, para 2.53.

the telecommunications sector and did not understand why Common Criteria (CC) testing was not appropriate for India's telecommunications framework, given that it was already internationally accepted. Canada believed that allowing accredited foreign conformity assessment bodies to test and certify to India's regulatory requirements would reduce testing costs and permit exporters to bring their products to the Indian market more quickly. Canada appreciated India's explanation given at the previous TBT Committee meeting, but remained unconvinced that deviating from CC testing would enhance the security of these products. He requested that India provide an explanation of where this alternative approach might improve security.

3.76. The representative of the European Union asked India to confirm whether the new requirements had been postponed beyond 1 April 2015. It was the EU's understanding that until the new requirements entered into force the status quo would continue to be applied, with foreign test results being accepted and suppliers continuing to be allowed to self-certify their products. Following the entry into force of the new requirements, the EU understood that testing would be based on relevant international standards, as clarified by India in previous meetings. Concerning the security aspects covered by the Common Criteria Recognition Agreement ("CCRA"), test results from laboratories approved by CCRA members would be accepted with no additional in country testing, whereas other security aspects not covered by common criteria would not require any in country testing. He requested India not to require any in country testing as this did not add any value in terms of enhanced security and suggested that India instead accept test results of qualified laboratories holding accreditation from ILAC MRA signatories. Those test results could be the basis for certificates to be issued in India by certification bodies approved by the Indian authorities. He looked forward to continued discussion between India and interested WTO Members so as to ensure that the new requirements, when implemented, would reflect best international practice.

3.77. The representative of the United States requested that India explain why the proposed revised telecommunications security regulations dating from May 2011, and subsequent updates, had not yet been notified to the WTO. She requested that they be notified as soon as possible so as to give Members and interested stakeholders adequate opportunity to comment. While noting the date for in-country testing had been extended, there had been no formal announcement of such extension. The US urged India to remove the in-country testing requirement from the proposed regulation, as such a requirement added significant additional costs for manufacturers. Given India's certification under the CCRA, India had agreed to accept the results of CC tests conducted outside its territory. These tests were sufficient for the US and many other markets and she therefore asked that India explain why they were not sufficient for the Indian market and why further in-country testing requirements were necessary for national security reasons. She encouraged India to allow telecommunications service providers to determine from whom to source, based on each company's ability to address any security concerns. This approach promoted market competition and, as a result, more secure products. A less trade restrictive approach would also contribute to India's domestic economic growth in the telecoms sector. She encouraged India to accept international testing standards and sought India's assurance that test reports under the CCRA and 3GPP standards would be accepted regardless of whether the tests were performed in India or in accredited laboratories outside of India.

3.78. The representative of Japan supported the Canadian, EU and US positions and confirmed Japan's interest in the new Unified Access Service Licence Agreement. She requested that India ensure the telecommunications regulations did not impede market access for foreign industry. On the statement delivered by India at the previous TBT Committee meeting, she raised the following points: (i) concerning the suspension of compulsory in country testing, whether India could inform the Committee if a date had been set for when this suspension would be lifted; (ii) India stated that the testing based on common criteria was limited to IT and IT related products, and telecommunication work was governed by other standards. Therefore, security testing of telecommunication equipment did not infringe CCRA. However, telecom devices were included in the scope of CCRA security certification. The CCRA provided that any products certified in a CCRA member state based on the common criteria could be accepted by the other member states without re-evaluation of telecommunications device security. Japan had therefore a concern that telecommunications device security by India would impose a heavy burden on telecommunication device industry. The framework of CCRA had been promoting the development of security requirement based on the common requirement for telecommunication devices. India should therefore utilise CCRA; and (iii) India had stated that the additional testing would only be carried

out on IT devices which had already undergone CCRA evaluations and she requested that India not impose this excessive burden of a repeated security evaluation on industry.

3.79. The representative of India confirmed that the compulsory in-country testing obligation had been postponed until such a time as the required infrastructure was in place and no date had yet been set. Regarding the concern on security testing of equipment, he reiterated that the CC testing did not suffice as it was process-based and was used for certifying only the claims of the vendor about the security features incorporated in the product without certifying that there were no other vulnerabilities. The Common Criteria certification did not address national concerns on the security requirements of telecom networks. Telecom equipment was tested against 3rd Generation Partnership Project (3GPP) standards for operational requirements, but 3GPP did not have security standards for telecoms equipment. Only in 2014, 3GPP created SA3 sub-group to work out the security standards for telecom equipment. He also explained that the requirement for mandatory testing was meant to address national security concerns. It could not be considered a trade barrier as it was applicable to all the manufactures or vendors irrespective of source of procurement including domestic manufacturers. As clarified in the past, India would rely on international standards as much as possible. IT product testing carried out against the CC process would be leveraged without necessarily repeat testing. However, some additional test could be conducted if required in the interest of nation. He noted that different countries had different approaches to dealing with security testing of telecom equipment, including equipment sourced from specific countries or companies being banned. In some EU member states, equipment was being tested against domestic standards and in the UK equipment procured from Chinese vendors had to be tested at a laboratory established in the UK, where staff underwent security screening by the UK Government.

3.2.3.5 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)

3.80. The representative of Canada was particularly concerned that China's regime for regulating the information technology sector was overly burdensome and trade restrictive. While Canada recognized China's need to address security concerns, it was important to avoid duplicating conformity assessment testing. Canada felt that China's approach to regulating IT security lacked coordination domestically and ran counter to well-established best practices. He requested that China explain the relationship between the OSCCA and the MLPS in more detail.

3.81. The representative of the European Union associated his delegation with the comments made by Canada. This very comprehensive Chinese regulatory framework, he said, required very cumbersome conformity assessment procedures and discriminated against foreign product suppliers and products incorporating foreign technology vis-à-vis products incorporating domestic technology. He once again requested an update on the state of play on the revision of the OSCCA regulation on commercial encryption products. He also requested that China elaborate on the relationship between OSCCA regulation and MLPS and on the notion of critical infrastructure, which created a lot of uncertainty with regard to the implementation of the MLPS. He emphasised the importance of ensuring transparency, predictability for market access and the need for enhanced international cooperation in this area in order to ensure compatible regimes which harness security without hindering trade in commercial products.

3.82. The representative of Japan reiterated its support for the positions of Canada and the European Union. Japan was paying particular attention to the various schemes and regulations within China and how these could negatively affect trade in information security products. At the previous meeting of the Committee, China had made a statement that there would be an opportunity for public comment during the revision of the OSCCA. She requested that this process be opened up in a broader manner towards stakeholders including Japan.

3.83. The representative of China thanked delegations for their continued interest in the measure and said as there were no further updates on the issues raised. Members should thus refer to the minutes of previous meetings.

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

3.84. The representative of the European Union invited the Russian Federation to update the Committee on the status and timeline for adoption of this draft technical regulation, which had been notified in 2012. The EU had submitted detailed comments in writing in 2013, many of which, according to the Russian delegation at previous meetings, had been taken on board and would be reflected in the revised draft technical regulation. She asked when this revised text might be notified to the TBT Committee so as to allow Members the opportunity to analyse how their comments were taken into account.

3.85. The representative of Australia said his delegation remained concerned with certain elements of this technical regulation. He requested an update on the status of the draft regulation and the implementation time-frame. Australia would prefer a six-month transition period for regulations relating to wine so as to allow industry sufficient time to implement any labelling requirements.

3.86. The representative of the Russian Federation thanked the EU and Australia for their comments but said these concerns had been replied to during previous TBT Committee meetings. The draft technical regulation was still being developed. In May 2015, the Eurasian Economic Commission ("EEC") sent a corrected text of the technical regulations to the governments of Eurasian Economic Union member states, which took into account many of the comments and suggestions of stakeholders and WTO Members. Once approved, the new draft would be publicly available on the EEC website. Once published, the new draft would be put forward for adoption by the Council of the Eurasian Economic Union. This was not expected to be before the third quarter of 2015 and a transition period for implementation would follow.

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

3.87. The representative of the United States asked Korea to confirm that this regulation would be amended by the second half of 2015 and that stakeholders' engagement would continue throughout the process. Confirmation was also requested as to whether the Ministry of Environment ("MOE") was considering further protection of companies' confidential business information ("CBI") by allowing direct reporting and the use of concentration ranges rather than exact composition percentages. Concerning the request that the definition of "hazardous substances" be tightened, the US understood a public notice had been issued in December 2014 regarding the list of chemicals equivalent to the MOE's definition of hazardous chemicals and looked forward to receiving a copy of the public notice. Confirmation that "hazardous substances" under K-REACH were limited only to those regulated chemicals and no other was also requested. The US encouraged Korea to continue working with stakeholders to ensure that CBI claims were not unintentionally prohibited. She said that the US chemical industry urgently needed more specific guidance on all products that would be classified under the biocides group under K-REACH implementation and looked forward to these documents being provided as soon as possible. The US supported a strong definition of CBI that included at least the possibility of protecting the specific chemical identity, composition, and uses, while respecting the legitimate government interest of allowing reporting of generic chemical names, and providing adequate hazard information to downstream users and that the Ministry of the Economy continued to consider provisions that prevent any compromise of CBI. Finally, she asked for confirmation that the Korean Government might consider delaying implementation as such a delay would allow greater consideration to industry requests in light of the practical issues raised and would allow industry stakeholders adequate time to implement all of the necessary changes to K-REACH's broad and complicated scope.

3.88. The representative of Japan said that, concerning the Notification of Product Containing Hazardous Substances (Article 32), Japan understood the aim of reporting products which contained hazardous substances so as to protect consumers and the environment. However, as stated at the previous meeting, the obligation to investigate hazardous substances contained in products through supply chains all at once placed a heavy burden on industries. Japan requested that Korea introduce the regulation in a stepwise manner, according to the priority of hazardous substances, taking into account its hazards, usages and exposure situation. Additionally, with respect to the "Information Provision of Downstream User or Seller by Manufacturer or Importer

(Article 38 of the Enforcement Rule)", Article 38 Paragraph 2 of the enforcement rule (ministerial decree), Japan considered that the information on manufacturing volume and import volume was not necessary to ensure safety of downstream users or sellers and was considered confidential information by manufacturers. Japan request that manufacturing volume and import volume be omitted from the information with which manufacturers or importer had to provide.

3.89. The representative of Australia said the implementation of this regulation was being monitored with interest. It was necessary to ensure regulatory quality in terms of predictability, transparency and adequate stakeholder consultation and recognized there had been significant consultation on this matter. It was also important to ensure the implementation of adequate checks and balances so as to protect commercial-in-confidence information from such registration and evaluation processes. Australia looked forward to receiving and reviewing further notifications on the regulations in future.

3.90. The representative of the Republic of Korea informed the Committee that his government had collected comprehensive opinions from all interested parties and stakeholders. There was now the intention to amend the regulation so as to resolve the challenges that stakeholders may face. This would be done by taking the following steps: (i) by simplifying the document requirements; (ii) by clarifying targets of the report; and (iii) by removing the redundant period. Regarding the reporting obligation, Korea explained that foreign manufactures and producers could not be entitled to report directly because they were not the legal representative in Korea. However, in accordance with the first clause of Article 49, in a case where a foreign manufacturer or producer designated a Korean representative (with legal entity in Korea as a legal agent), they would be able to do direct reporting in lieu of the foreign manufacturer or producer. Further detailed guidelines could be provided if necessary on this matter. On Japan's suggestion that Korea implement this measure on a stage-by-stage basis, he said that according to the law regarding hazardous chemical substances, this was not a new detail as it had been already regulated under the law for some time. He also said that the Korean Government would hold forums and discussion groups in response to Members' concerns, in particular on trade secret protection. The guidelines were being continuously supplemented and the reinforcement of the protection of CBI was also being done. There was also a 3-year grace period from 1 January 2015 for implementation.

3.2.3.8 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 ID 328)

3.91. The representative of the European Union recalled concerns with regard to conformity assessment procedures introduced by Decree No. 24 and asked if there was a plan to review the toy safety decree in order to create a level playing field as regards conformity assessment procedures. He said that the EU understood that the Ministry of Industry in Indonesia had approved some foreign laboratories and therefore required confirmation on what a laboratory needed to demonstrate in order to be approved as well as the timeline for approval, noting that the 2-year grace period would expire in mid-April 2016. He further said that Indonesia should consider making the current arrangement under the 2-year grace period a permanent arrangement in order for results from tests conducted by foreign laboratories which were adequately accredited by ILAC MRA signatories under international standard 17025 to be accepted on a permanent basis.

3.92. With regard to labelling requirements, he said that the EU had pointed out in the past to the existence of two separate sets of requirements: (i) one related to general labelling; and (ii) others stemming from Decree No. 24. These requirements resulted in the affixing of the label at different points in time and different places, hence handling the product twice in the country of exportation and after importation. The EU thanked Indonesia for recently providing a written reply to its concerns and requested Indonesia to clarify the extent to which, as stated in its reply, the general labelling requirements for toys had been coordinated with the specific requirement under the toy safety decree in order to avoid unnecessary burden for toy manufactures. Indonesia was requested again to streamline those requirements.

3.93. The representative of the United States said that she was concerned that Indonesia's toy regulatory regime included aspects that were more restrictive than those adopted by other Members. She stated her delegation's concerns related to lab accreditation, testing frequency, sampling, documentation, and substance restrictions, as well as the requirement to have a

bilateral MRA in place by April 2016. She said that they were informed that Indonesia was no longer recognizing any additional laboratories under the current process and that few concerns were addressed prior to the regulation coming into effect in April 2014.

3.94. The representative of Japan said that several requirements of the Indonesian toy regulation would be more trade-restrictive than necessary. Regarding foreign testing laboratories of SNI certification, she expressed strong concern with the requirement of a Mutual Recognition Agreement (MRA) with Indonesia after two years of the enforcement. She requested information on any changes of the toy regulation, in particular with a view of revising it in order to be consistent with the obligations under the TBT Agreement.

3.95. The representative of Indonesia stated that the objective to implement the Mandatory SNI for Toy safety was to protect human health and that foreign testing laboratories listed in the MRA under APLAC/ILAC scheme were still acceptable. Based on the Ministry of Industry regulation No 18 of 2014, there were 25 international laboratories that had been registered. She said that testing frequency per shipment was still valid and the 2-year grace period could only be extended if the government of the country where the laboratories conduct the testing had an MRA with the Indonesian Government. Indonesia had conducted market surveillance in order to prevent unsafe toys in the grey market.

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

3.96. The representative of the European Union recalled that the Codex Standard for the labelling of pre-packaged foods (

3.97. STAN 1-1985) stated that ''*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 re-labelling*". She additionally recalled that this standard also said that ''*in the case of either re-labelling or a supplementary label, the mandatory information provided shall be fully and accurately reflect that in the original label*.'' She further said that in most economies, food products could be labelled by means of stickers, provided that those were accurate and not easily detachable. She requested India to bring its implementing guidelines in line with the Codex standard and to allow all type of labelling information. She also requested confirmation that India was in the process of amending specific parts of the Indian food standards to bring them further in line with the Codex standards. She also welcomed the fact that the Indian Food Safety and Standards Authority was preparing a specific technical regulation on alcoholic drinks and one on food additives, and that India was in the process of launching a public consultation process. She requested the timeframes for notifying the draft regulations to the WTO TBT Committee and assurances that regulators from other WTO members would have the opportunity to comment on those regulations.

3.98. The representative of Switzerland requested information on why it was not possible to provide translated information to consumers by means of stickers instead of only industry specific supplementary information.

3.99. The representative of the United States sought an update on the status of India's efforts to better align their domestic requirements with international standards. She requested India to provide the timeline for the publication of the amended FSSAI Rules. The US was concerned about how India planned to define whiskey and further requested India to provide the expected timeline for notification of the requirements to the SPS and TBT Committees.

3.100. The representative of Australia sought an update on: (i) the anticipated date for the harmonisation of India's food standards with Codex; (ii) the proposed date(s) for India's next review of its food standards; and (iii) whether these would occur in parallel or simultaneously. He also asked India to inform the time at which the process of harmonisation of its food standards with Codex would be finalised and to inform whether India was planning another review of its standards. He also requested information on whether India had considered the issues previously raised by WTO Members and if so, if the process would be through finalisation or extension of the Codex harmonisation process, or a separate review.

3.101. The representative of Canada shared the concerns expressed by other Members and looked forward to receiving India's responses to these concerns.

3.102. The representative of India said that there was no change in the regulatory status since the previous Committee meetings and referred delegations to its statement made in the Committee meeting of November 2014.[8] He also said that Codex did not prescribe that the labelling requirement could be met through additional sticker(s) and that the core information regarding, for instance, product ingredients, composition, nutrition values, and best before dates, could only be provided by the manufacturer and no one else. He explained that the label had to be an inseparable part of the container/package. He further said that permitting additional stickers as a means of information from any other source, or even the manufacturer, was likely to compromise the sanctity of information, which was the basic requirement for a consumer to make informed choices. With regard to harmonization of regulations with Codex, he said that the standards that were being formulated by the Food Safety and Standards Authority of India were increasingly harmonized with international standards. However, India had to consider harmonisation in view of its own ground realities and local requirements or adaptations.

3.2.3.10 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 (IMS ID 345)

3.103. The representative of Argentina said that the fact that this trade concern has been flagged almost continuously over the past six years by several Members reflected not only the protection granted by the EU to this specific sector - to the detriment of wine producers from other regions - but also the clear lack of progress in finding a solution. He said that the situation had affected the entry into the EU market of high quality and differentially priced wines from Argentina, thereby placing Argentine wine exports at a disadvantage compared with those of certain competitors from EU countries with access to European consumers who preferred wines identified and labelled as of a high quality. He said that the EU legal regime was inconsistent with the obligations under the TBT Agreement, including those prohibiting discrimination, as these traditional expressions were indications of quality that fell under the TBT Agreement and not under the TRIPS Agreement. He said that the multiplicity of definitions for each term accepted by the EU showed that the objective of the EU policy was neither to protect consumers from being misled nor to preserve the characteristics that wines may have when associated with those terms.

3.104. He then recalled that, despite its position that the EU legal regime was inconsistent with the TBT Agreement, and in order to reach a practical and constructive solution, Argentina submitted in 2009 its dossier for approval of the terms "*Reserva*" and "*Gran Reserva*". He said that Argentina responded to the objections raised and supplied additional information in response to requests from the European Commission for clarifications. He reported that Argentina's dossier was discussed and examined by the European Commission Wine Management Committee in March 2012 and since then Argentina has been awaiting completion of the final steps. He said that the situation was incoherent as the substantive process lasted two years and seven months, while the formal administrative decisions had still not been adopted after more than three years (since March 2012). He noted that a new ad hoc group within the Commission's Directorate General for Agriculture and Rural Development was currently reviewing all the requests for recognition of traditional terms and that, further delaying the final approval of Argentina's requests. He noted that Argentina had expected a favourable solution at a multilateral, plurilateral and bilateral level despite not receiving a positive response or a valid explanation to justify EU's delays. He concluded by saying that the delay in resolving the issue was unjustified and requested the EU to lift the restrictions so as to include the item on the agenda of the next meeting of the College of Commissioners for adoption and publication of the relevant regulatory act in its Official Journal.

3.105. The representative of the United States said that this EU measure would severely restrict the ability of non-EC wine to use common or descriptive and commercially valuable terms, on the grounds that those terms were traditional to European wines. She said that this was a concern particularly when some of these terms did not have a common definition across all EU member states. She noted that some US suppliers which currently used these terms remained unable to

[8] G/TBT/M/64/Rev.1, Paras. 2.124 and 2.125.

ship their products to the EU. The US did not understand why some countries had already been granted permission to use some traditional terms, while other countries, including the US, continued to wait on their applications for years. She reported that in a conversation with the Commission on 8 June 2015, the Commission stated that it was not acting on the applications pending the completion of a review of the regulations and simplification of the entire process. She suggested that the existing applications be reviewed while the simplification process was ongoing. She also said that while her delegation appreciated that the European Commission shared information and solicited feedback, this process still lacked transparency as not all necessary information on the comment procedures has been provided. She thus requested the EU to inform the time at which it would publish information about its review of the traditional terms regulations and notify the simplification process to the WTO. The EU had not responded to the WWTG's October 2014 letter and that the Commission had declined an invitation to speak on the issue of applications at the 30 April 2015 WWTG Intersessional meeting in Brussels.

3.106. The representative of the European Union said that an internal assessment on traditional terms had been carried out within the EU with stakeholders and experts from its member states. The consultation was still ongoing and included conditions and specificities under which the traditional terms at issue could be used on the labels of products from third countries. She stated that the possible derogations, based particularly on minimum requirements for production methods and controls under product specifications of the wines concerned, had been covered by the discussion and that no conclusion had been reached. The EU would continue to make 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. She informed the TBT Committee that the concerns raised by Argentina and the US had been taken into account in the assessment process currently being carried out in the EU and that the EU continued to be open to discussion with trade partners bilaterally.

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

3.107. The representative of Canada said that while his delegation supported Chile's policy objective of promoting healthy dietary choices, reducing obesity and related non-communicable diseases (NCDs), his delegation remained concerned that these regulations, notified on 19 August 2014, contained the following flaws: (i) they deviated from international standards; (ii) they were not be based on science; and (iii) they were likely to be more trade restrictive than necessary. He thus urged Chile to consider a less trade restrictive alternative to achieve its policy goals. He recalled that Canada had submitted written comments in October 2014, but had yet to receive a response from Chile. As the Decree appeared to be with the "*Contraloría General de la República de Chile*" (General Comptroller Office of the Republic of Chile - CGR) for approval, he also requested an update on status of the measures and the timelines for their implementation.

3.108. The representative of Mexico reiterated its concerns, noted in document G/TBT/W/406, regarding the amendments to Supreme Decree No. 977 in respect of the labelling of food products. Like Canada, Mexico was aware that a version therein, dated 16 April 2015, was currently with the Comptroller's Office. Mexico was concerned about the measure's possible infringement of Articles 2.4 and 2.2 of the TBT Agreement as well as Article 20 of the TRIPS Agreement. Mexico asked Chile to inform the current status of this measure and its technical content. Mexico also asked Chile to inform the basis for its determination of the amounts beyond which foods were considered to contain excessive salt, sugar and fat. It also request that Chile modify the classification of foods, which made a distinction between solid and liquid foods, so as to take into account international parameters and ensure food would instead be classified according to the category to which it belonged.

3.109. The representative of the European Union recalled the concerns expressed at the previous TBT Committee meeting regarding notification G/TBT/N/CHL/282. The EU had submitted written comments with respect to this notification and would welcome a written reply from Chile. He also requested an update on the status of the measure and an explanation on how the concerns of WTO Members were being taken into account by Chile.

3.110. The representative of the United States said that her delegation strongly supported Chile's public health objectives of reducing obesity and related NCDs, and appreciated the extensive

bilateral engagement on Chile's nutrition labelling regulation. The US recognized that the finalization of the regulation was imminent as a draft had been signed by the President of Chile and was now in the "*Contraloría General de la República de Chile*" (General Comptroller Office of the Republic of Chile - CGR) for legislative review. However, guidance was requested regarding where the process stood as the US was concerned that the final regulation would contain elements which could affect as much as US$250 million in exports annually.

3.111. With respect to the substantive provisions, the US noted that the version of the regulation being currently considered required a "stop-sign" shaped icon on the front of pre-packaged foods that exceeded certain thresholds of saturated fat, sugar, sodium, or calories. Recognizing that there was no single correct approach to nutrition labelling, US industry was concerned about the nature of this requirement, as it may constitute an obstacle to international trade. She asked if Chile had considered a less-trade restrictive approach. The US was also disappointed that Chile did not adopt a product/category-based methodology for determining whether labels were required based on serving sizes of a typical daily consumption diet. She highlighted that a 100g or 100ml portion for all foods did not reflect typical daily consumption of many foods (such as butter, gum or white bread), and would likely mislead consumers, since many nutrient-dense foods may have to bear warning icons. The US positively recognized that Chile would allow health claims and trademarks on foods that must bear icons. Such information would provide positive information on foods where the nutrient content of saturated fat, sugar, calories and salt had either been reduced, or the food was a good source of other nutrients that could be useful in reducing the incidence of disease. She said this would provide incentive to industry to reformulate and make foods healthier.

3.112. The US also expressed its belief that a single extended period for implementation and compliance with nutrient threshold-based labelling requirements was needed, preferably 2 years from the date the final regulation was published. Staggered phase-in periods would raise costs for industry by requiring multiple label changes. Her delegation planned to monitor the impact of Chile's requirements on US pre-packaged food exports. She asked if Chile was considering an evaluation of the regulation after 18 months and, if so, whether the evaluation process could be explained and the results shared with trading partners.

3.113. The representative of Australia expressed his delegation's support for 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. He appreciated, in particular, the clarification provided by Chile on issues such as the form of the warning label on packaging. Australia was also pleased that Chile had changed the proposed front-of-pack labelling requirement based on suggestions by Australia and other Members. However, he noted that the labelling scheme was still mandatory for some food categories, including some dairy foods. There were also some inconsistencies between the requirements for imported and domestic products. Noting that Chile had extended the date of entry into force to 30 June 2015, Australia looked forward to working with Chile and receiving further notifications on proposed amendments.

3.114. The representative of Guatemala reiterated concerns expressed over this measure and requested Chile to respond to the issues raised by Guatemala in writing. Information on the status of the measure and the intended implementation procedure was also requested.

3.115. The representative of Brazil reiterated the importance of providing information on the scientific basis of the Chilean measure as well as the international standard that was taken into consideration in accordance with Article 2 of the TBT Agreement.

3.116. The representative of Costa Rica stated that the Chilean measure required special labelling and imposed restrictions with regard to advertising. Costa Rica believed these requirements could violate Chile's obligations under the TBT and TRIPS Agreements. Furthermore, comments made during the public consultations did not appear to have been taken into account. Costa Rica was concerned in particular with the measure's possible significant impact on trade as a result of the imposition of warning message, the application of thresholds for certain foods without consideration of portions, and the limitation of trademarks. He believed that the current description with regard to colour codes and nutrient content did not comply with the TBT Agreement, especially with respect to the absence of a scientific basis and lack of conformity with international standards (i.e. Codex guidelines).

3.117. The representative of Colombia said that his delegation had submitted written comments and requested a written response from Chile.

3.118. The representative of Chile said that on 16 April 2015, Chile's Minister of Health and the President of the Republic issued and signed Decree No. 13. On 20 April, this Decree was brought before the "*Contraloría General de la República de Chile*" (General Comptroller Office of the Republic of Chile – CGR). He explained that the CGR was a body independent from the Executive Power, which was in charge of examining the legality of measures such as Decree No. 13. On 16 June 2015, Decree No. 13 was withdrawn from CGR so that certain modifications requested by this body could be introduced and CGR would then be able continue the legality review process, which was expected to be completed by the end of June 2015.

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

3.119. The representative of Canada remained concerned with the Electronics and Information Technology Goods Order of 2012 as it could hinder or possibly shut Canadian exporters out of the Indian market due to delays in registration and testing. He again suggested that India recognize foreign conformity assessment bodies accredited by signatories to the ILAC and IAF to test and certify to India's regulatory requirements. This would minimize the negative impact on companies wishing to export to India while providing assurance that the recognized conformity assessment bodies were competent. Allowing accredited foreign conformity assessment bodies to test and certify would reduce testing costs and allow exporters to bring their products to the Indian market more quickly. Noting that the Bureau of Indian Standards (BIS) required a mutual recognition agreement (MRA) to accept tests results from non-BIS laboratories, even if they were ILAC- or IAF-accredited, Canada asked for the rationale for requiring an MRA and for details about the scope of these agreements. Finally, he noted that substantive amendments to the Order, such as those with respect to marking and labelling requirements, should be notified to the TBT Committee.

3.120. The representative of the European Union said that his delegation continued to regard the compulsory registration scheme for electronic products to be excessively burdensome. Since the last Committee meeting, India had notified the expansion of the compulsory registration scheme to fifteen new product categories in notification G/TBT/N/IND/47. However, this notification was made only after publication of the expansion order. He appreciated that India had extended the date of entry into force for seven of the fifteen categories until 13 August 2015, whereas for the remaining eight, the entry into force remained 15 May 2015. The EU invited India to postpone the entry into force for all fifteen categories until it had reviewed the comments received from WTO Members.

3.121. Concerning the EU's request for streamlining the registration process, he expressed his delegation's appreciation with the fact that a technical advisory committee had been set up, under the Department of Electronics and Information Technology of the Ministry of Communication and Information Technology, to look into possible improvements to the process. The EU sought confirmation that this committee was actively considering allowing one product registration number per product model in cases of multiple factory locations under the responsibility of the same manufacturer and when the product was sold under the same brand. The EU also believed that consideration should be given to a shorter processing time for applications, especially for some products with a short life cycle. The EU requested acceptance of test reports generated under the IECEE CB scheme or by laboratories which were accredited to ILAC MRA signatories. On validity of the test report, he reiterated that there was no reason, in principle, to limit this validity to ninety days in order for the application for registration to be filed with product safety characteristics that had not changed. Finally, with respect to the validity of registration, the EU believed that the limit of two years should be interpreted flexibly if the product had not undergone any safety property changes.

3.122. The representative of the United States appreciated the continued interaction on the implementation of the Compulsory Registration Order (CRO). She recalled that at the March 2015 TBT Committee meeting, India had stated that the validity period of registration was increased from one to two years, and that registration for multiple factories was under active consideration by the Policy Advisory Committee. She welcomed any updates that India could provide on these

developments. Furthermore, feedback received from US industry indicated that the registration renewal form was currently being reviewed, and she encouraged India to ensure that only information necessary for renewal was required in the form. The US also appreciated that in the past, India had reviewed and expanded the list of products under the High Specialized Equipment exemption and urged that this list be further broadened to include all products that were not for the consumer market and posed little risk to average consumers. For example, products that were IT products installed, operated, and maintained by professionals trained to manage the product's inherent safety risks.

3.123. The US also stressed that, despite positive engagement, it continued to have serious concerns with the CRO's requirement that foreign products be retested to an Indian standard that was identical to an international standard, particularly when the products had already been tested to that international standard. She viewed this as an example of how India's CRO posed unnecessary restrictions. Noting India's explanation that under the BIS Rules, items covered by the CRO were required to be tested at a lab in India recognized by the BIS or at a lab covered under an MRA with BIS, the US stated that as a member of the IECEE CB Scheme, India already effectively had an MRA with other members of this scheme. The US, therefore, did not understand the reason for requiring an additional MRA on the top of the existing agreement India already had with IECEE CB Scheme members. The US thus again requested India to recognize test results from accredited labs located outside India. In addition, the US requested that appointed labs 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 test report and/or the manufacturer. This would provide immediate relief to manufacturers and allow India's labs to improve testing. She noted India's response that the expiration of test reports within 90 days was adequate, but assured India that such an expiration period was not deemed adequate by industry, and that this practice did not align with international norms as no other national certification agencies had expiration dates on their test reports. The US, therefore, requested India to eliminate this expiration period.

3.124. The US further noted that a limited amount of time was provided between India's March 2015 notification and the entry into force of the expanded list of 15 products subject to the CRO requirements. She requested that additional time be provided for traders to comply with these newly notified requirements. The US also encouraged India to continue its collaborative consultations with industry and other stakeholders to bring its safety testing regime into alignment with international best practices for testing and certification of IT and electronics equipment as this would help jumpstart "Digital India" efforts.

3.125. The representative of Switzerland asked why low risk electronic products - such as LED lamps, mobile phones, cash registers and power banks - were submitted to compulsory registration. He recalled that India was requesting in-country testing for these products and that foreign test results were not recognised even if carried out by laboratories working under IECEE CB schemes. He said that such conformity assessment appeared to be more restrictive than necessary and, this respect, he drew India's attention to the fact that Article 5.1 of the TBT Agreement provided a strong case for less burdensome procedures for low risk consumer products. He also noted that tests were valid for 90 days only and were to be renewed every two years. India had not yet provided an explanation for this restrictive practice. Switzerland again invited India to accept conformity assessment based on IECEE CB schemes.

3.126. The representative of India noted that most of the concerns raised had been explained in previous meetings. As there was no change in the regulatory status, he requested interested delegations to refer to India's statement contained the minutes of the last TBT Committee meeting in March 2015.[9] He further said that the single registration for multiple factories was under active consideration by the Policy Advisory Committee ("PAC"), which had recently approved a list of criteria. The scheme for single registration was being prepared by the BIS and the Department of Electronics and Information Technology ("DeitY") and would be placed on the BIS website for stakeholders' consultations before finalization. He added that DeitY had initiated surveillance for notified goods and samples were being picked up from the manufacturer's location. India stated that the surveillance provisions formed part of the initial CRO under Gazette Notification No. 1975 of 3 October 2012, which came into force on 3 July 2013 and hence no separate notice period for surveillance was required.

[9] G/TBT/M/65, paras. 2.107 to 2.109.

3.127. India provided clarifications on cells and batteries covered by the new Order. Sealed secondary cells and batteries containing alkaline or other non-acid electrolytes for use in portable applications were covered under compulsory registration. These cells or batteries needed to be separately registered even if used in other products. He added that if the battery was an integral part of the host product and non-detachable, it would be tested as part of the host product and a separate registration for the battery in such a case was not required. In response to a query on the addition of new models to already registered and existing series, he clarified that as per the series guidelines up to ten models would constitute one series. More models could be added to a registered series up to a count of ten in the series, provided the new models complied with the series criteria. Concerning marking/labelling on cells, he said that BIS had already notified labelling requirements for the self-declaration mark under the compulsory registration scheme vide Order No. BIS/DGO/(405)/2014, dated 31 July 2014. Paragraph 7(vi) of the Order clarified that where the products were too small in size and the statement could not be marked on the product, the same could be done on the packaging and accompanying documents. Finally, he took note of the additional concerns raised and which had not been clarified in previous meetings, and said that these would be forwarded to capital for a suitable response in due course.

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

3.128. The representative of Canada said that while his delegation supported Peru's objective of reducing obesity and other NCDs, there were concerns that this measure may deviate from international standards and be more trade restrictive than necessary to achieve its objective. Since final technical parameters for sugar, salt and fat levels in food were published on 18 April 2015, he asked how Peru had established these levels and whether they were based on international standards. He stressed in this regard that existing 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. Canada asked how food warning labels were to be affixed to products and whether these labels could be affixed at a customs bonded warehouse in Peru prior to entering the market. Additionally, Peru had failed to provide explicit instructions on how products were to be determined to be "high" in sugar, salt or fat and on the type of enforcement mechanisms to be used to ensure that products were properly labelled. He requested Peru to provide details on the product certification process and the post-market enforcement mechanisms. Finally, he asked 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.

3.129. The representative of Mexico shared the concerns expressed by Canada and recalled concerns expressed on previous meetings. In particular, Mexico referred to the "Regulation that establishes the technical parameters for non-alcoholic food and beverages with respect to their sugar, salt and fat contents". He asked Peru to explain the basis for the regulation in accordance with the first sentence of Article 2.4 of the TBT Agreement, in particular on how Peru defined technical parameters and what was the rationale behind the division of foods into liquids and solids. He also asked on which international standard Peru had used as a basis for the differentiation and establishment of the parameters, as well as the basis for the exceptions in the application of those technical parameters that were included in the Regulation. Finally, he requested Peru to elaborate on the next steps for implementation of this measure.

3.130. The representative of the United States said that her delegation was monitoring the development of Peru's regulations to implement the Healthy Eating Act. While the US supported Peru's public health objectives of reducing obesity and related NCDs as well as the objective of encouraging healthy eating, concerns remained over the potential impact of the Act and the recently notified Supreme Decree on US pre-packaged foods exported to Peru (amounting to USD 258.7 million in 2014). In terms of process concerns, she noted that Peru had committed to allow trading partners to comment on nutrient content limits in the Supreme Decree. The US, therefore, urged Peru to notify Supreme Decree 007-2015-SA, establishing technical parameters for labelling the content of sugar, salt and saturated fat in pre-packaged foods and beverages, which was published domestically on 18 April 2015. She added that the US had submitted an enquiry point request for notification of this measure on 24 April 2015.

3.131. With respect to the scope of labelled foods, the US stated that nutrition panels were a valuable tool for consumers in making informed choices and encouraged labelling for all

pre-packaged foodstuffs. She added that Codex and the WHO Global Action Plan for the Prevention and Control of NCDs advocated nutritional labelling of all pre-packaged foodstuffs. The US was concerned that nutritional labelling was only mandatory when either a voluntary claim was made or a consumption warning was required. She asked if Peru had considered alternative approaches as nutrition panels may be regarded by consumers in a negative way if only the least healthy foods were required to display nutrition information. Targeting only certain foods for nutrition labelling could make it more difficult for consumers to identify healthier foods. In contrast, mandatory nutrition declaration for all foods and non-alcoholic beverages gave consumers the most complete information to make dietary decisions because all foods contributed to daily nutrient consumption, unless nutritionally insignificant.

3.132. The US also asked Peru to explain whether the consumption warning, as specified in the Act, would apply to significantly more foods and non-alcoholic beverages than those specified in notification G/TBT/PER/59. With respect to nutrient limits, Peru's proposed threshold for the amount of sodium would require a consumption warning and nutrient facts panel that was significantly lower than what would correspond with the Codex NRV-NCD of 2000 mg/day. She asked Peru to clarify how it determined and chose the proposed limit, rather than the Codex NRV. The US also noted that while Codex had not established a nutrient reference value for sugar, the WHO recommended that no more than 10% of calories come from free sugars. She asked Peru to clarify the basis by which it established the per-portion nutrient content limit for sugar. Noting that Peru's nutrient content limits notified in G/TBT/PER/59 more closely aligned with typically consumed portions, the US asked Peru to explain why it determined an across-the-board nutrient threshold based on 100 gram, or 100 millilitre, amounts was appropriate for its population. For example, a 100 gram portion was well over a typical serving and daily consumption of butter, gum or white bread. Recognizing that Codex also allowed for the use of serving sizes if the number of servings contained in the package was stated, the US asked if Peru would instead consider using thresholds based on actual serving sizes of more specific food types that would vary to reflect the consumption patterns of the Peruvian population. Furthermore, she asked why Peru had not provided for labelling putting the "consumer advisory" into the context of daily dietary consumption, especially for foods where the customary portion consumed was typically larger or smaller than the 100g/ml baseline or where the food may provide other valuable nutrients.

3.133. With respect to compliance guidance, the US noted the comments submitted to Peru on 18 August 2014, and asked whether Peru was considering supplemental symbols, icons or pictorial representation of an advisory statement associated with nutrient thresholds. Additional guidance 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 reiterated the importance of an extended period for compliance, which would help reduce costs associated with label design and label stock supply and rotation. Typically, countries allowed a 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 the Peruvian Resolution 30021 allowed only 180 days for compliance.

3.134. The representative of Guatemala reiterated the concerns raised by her delegation at previous meetings. She was particularly concerned that Peru had published the regulation on 18 April 2015 with no scientific or technical basis for the values therein. She requested Peru to provide clarifications on the regulation and the issues raised by Guatemala in its previous written comments.

3.135. The representative of Costa Rica said that his delegation supported the concerns raised by the previous delegations. While his delegation shared the health concerns associated with obesity and NCDs, the necessity of implementing any health measure in this area must be justified by technical and scientific information. Costa Rica considered that Peru's Supreme Decree 007-2015-SA lacked such necessary technical and scientific justification. He recalled that this Decree implemented the first transitory provision of "*Ley 30021*" (Law 30021) on the promotion of healthy eating for children and adolescents. This first transitory provision of this Law called for the establishment of technical requirements for determining whether a food product contains high levels of sugar, sodium and saturated fat. However, Decree 007-2015-SA did not comply with the mandate of Law 30021 that it was supposed to implement given that the values established therein cannot be considered as being "high" just because they were based on a

document called "*Recommendations from a Pan American Health Organization Expert Consultation on the Marketing of Food and Non-alcoholic Beverages to Children in the Americas*."[10] Costa Rica noted that this document was not clearly endorsed by all members of the Pan American Health Organization ("PAHO"). Instead, this was a document merely based on personal opinions of the participants. Additionally, Costa Rica considered that the "food values" expressed therein did not comply with relevant international "food codes" for they lacked scientific basis and were not based on international standards. That was to say, they did not show any scientific basis linking the nutritional characteristics of a specific food with health risks related to obesity/overweight and other NCDs. Finally, he expressed his delegation's concern that this Peruvian labelling scheme would affect consumers by not only creating confusion, but also by considerably contributing to the increase in informal supply of food products and beverages that were not produced under known health standards.

3.136. The representative of Peru reported that Law 30021 was promulgated on 17 May 2013 to promote healthy eating among children and adolescents. This law established in its first complementary provision the technical parameters for determining whether processed foods and non-alcoholic beverages had a high sugar, sodium and saturated fat content, and also provided for the gradual reduction and eventual elimination of trans-fats. These parameters were specified in a draft regulation (Decree 007-2015-SA), notified to the TBT Committee on 20 May 2014 (G/TBT/N/PER/59), with a 90-day comment period, which expired on 31 July 2015. On 18 April 2015, Peru published the final version of such regulation. Regarding the timeframes for the implementation of this Decree, she said that, although the final version of this regulation had been already published, this was but only one of the various other components of Law 30021. This law, in fact, contained numerous other components, including the promotion of nutrition education and the implementation of a monitoring study of nutrition and obesity, which would have to be developed in a comprehensive manner by an inter-sectoral commission created for such purpose. As the consideration of these elements was still pending before that multi-sectoral commission, she explained that it was difficult to stipulate, in the short term, a date for the entry into force of "Ley 321". Consequently, stakeholders had a reasonable period of time to adapt their products to the new requirements. With regard to the basis supporting the nutritional parameters established in Decree 007-2015-SA, Peru stressed that they were based on recommendations from a consultation made to experts from PAHO on the promotion and advertisement of foodstuffs and non-alcoholic beverages targeting children. These recommendations were ratified by the "Plan of Action for the Prevention of Obesity in Children and Adolescents" during the "53rd Directing Council of the PAHO" and the "66th Session of the Regional Committee of WHO for the Americas." Peru also stated that, in any event, the nutritional levels established in Decree 007-2015-SA took into consideration the parameters established by the *Codex Guidelines on Nutrition Labelling*.

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

3.137. The representative of the United States said that, while strongly supporting the strengthening of public health and environmental protection by properly identifying, understanding, and regulating the use of plant protection products that may have endocrine disrupting properties, the US had been raising concerns with the EU process for identifying endocrine disruptors for several years. The US submitted extensive comments on the EU Public Consultation on Defining Criteria for Identifying Endocrine Disruptors (EDs) in January 2015 and also participated in the EC conference on the impact assessment criteria to identify endocrine disruptors, which took place on 1 June 2015. While the US was pleased to hear Commissioner Andriukaitis stressing in his speech at that conference that the Commission would do its "best to be open and transparent," that event concluded with no notable outcomes or indication of any specific actions the EU would undertake in response to the consultations that were held on that occasion. As emphasized in the past,[11] the US was concerned about the lack of transparency and urged the Commission to consider publishing a report, including outcomes of the conference and next steps. Further, none of the options outlined by the EU in its roadmap appeared to take risk into consideration, as required under WTO obligations. The proposal, as drafted, could thus impact billions of dollars of trade worldwide and potentially result in the withdrawal a large number of substances, as well as the products that contain them, from the EU.

[10] http://iris.paho.org/xmlui/handle/123456789/3594.
[11] See G/TBT/M/65, para. 2.123.

3.138. The representative of Canada said that his delegation had presented the potential trade impacts of ED regulations in the EU at a conference organized by DG SANTE in Brussels on 1 June 2015. While awaiting the outcome of the roundtable and the release of the preliminary report of the Commission, Canada renewed its request for further clarifications on the interplay between Regulations 1107/2009 and 396/2005. Canada believed that moving to a more restrictive hazard-based cut-off criterion would raise concerns over how maximum residue limits under Regulation 396/2005 would be established and renewed. Canada shared the EU's objectives of ensuring food safety and a safe environment. However, Canada also considered that a risk-based approach, as opposed to a hazard-based one, would equally achieve this objective, while also ensuring that global agricultural trade remained unimpeded. In fact, the EFSA Scientific Committee had reached a similar conclusion in its 2013 Scientific Opinion on the hazard assessment of endocrine disruptors, stating that "EDs can be treated like most other substances of concern for human health and the environment and be subject to risk assessment and not just hazard assessment". The EU's hazard-based approach could thus disrupt trade in food and feed and unnecessarily create a level of uncertainty among exporting countries, while increasing costs for agricultural and agri-food stakeholders in both the EU and exporting countries such as Canada.

3.139. The representative of Australia indicated that Australia had provided a submission to the European Commission's endocrine disruptor impact assessment public consultation process in January 2015. As the EU worked towards developing any new policy for endocrine disruptors, it was important to ensure that the new or amended regulations were no more trade-restrictive than necessary to fulfil the EU's legitimate objective. In addition, if the proposed new regulation was not in accordance with an international standard, the proposal would need to be notified to the WTO so that Members had adequate time to provide inputs. He requested an update on the outcomes of the public consultation process and the EU's plans to take forward the endocrine disruptor review.

3.140. The representative of New Zealand said that her delegation continued to follow with interest the evolution of the EU's regulatory approach to endocrine disruptors and thanked the EU for the opportunity to submit comments during the public consultation process.

3.141. The representative of the European Union said that, as mentioned in previous meetings**,** the EU had initiated a comprehensive impact assessment that would analyse different options for defining criteria for the identification of endocrine disruptors and their corresponding health, socio-economic and environmental effects, once incorporated in different pieces of EU legislation. In this context, the European Commission had published, in mid-June 2014, a roadmap setting out the scope of the impact assessment, and presenting the policy options that were being assessed. At least two sequential studies supporting the impact assessment were needed. The first one had started and would assess which chemicals might be identified as endocrine disruptors under each of the various options for the criteria. The second one would assess the socio-economic, health and environmental impacts of the incorporation of the various options for the criteria into the relevant legislation. A public consultation on the definition of criteria for identifying endocrine disruptors in the context of the implementation of the EU's regulations on plant protection products and biocidal products had been carried out between September 2014 and January 2015 to collect information relevant to the impact assessment. The responses received under such consultation were published on 2 February 2015 and an analytical report of the responses would be provided by the Commission by the summer of 2015. The factual and quantitative report would feed into the work for the impact assessment, the outcome of which would not prejudge or constitute the announcement of any position on the part of the European Commission. Instead, it would allow the Commission to take an informed decision as regards further EU legislative work, as appropriate.

3.142. She also informed the Committee that the Commission had organized a series of roundtable meetings between April and May 2015 as well as a public conference on 1 June 2015, informing EU member states, MEPs, third countries and stakeholders about the ongoing impact assessment. Detailed information about the impact assessment as such, including the web-stream and the presentations given at the conference, was available on the website of DG SANTE.[12] The European Commission would present proposals for new criteria to identify endocrine disruptors in the EU's plant protection products and biocidal products regulations only after the conclusion of the impact assessment. She added that the criteria might also have an impact on other pieces of EU legislation. Pending the new criteria, interim criteria were applicable in both the biocidal products

[12] http://ec.europa.eu/health/endocrine_disruptors/events/ev_20150416_en.htm.

and plant protection products regulations. The EU would notify the new proposal to the WTO in order to allow third parties' eventual comments to be duly taken into account.

3.2.3.15 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)

3.143. The representative of Canada said that while supporting Indonesia's objective of reducing the risk of non-communicable diseases (NCDs), his delegation was concerned about Indonesia's regulatory proposal requiring labels for all processed and fast foods containing sugar, salt and fat. Presenting total values of these nutrients and including a health warning on the labels could have a significant impact on trade and was likely to be more trade restrictive than necessary. Canada had concerns about how this nutritional information would be placed on the product and whether this information could be affixed after importation of the good but before it was placed on the market. Canada also questioned whether Indonesia's requirement to include a message identifying certain risks in relation to the quantity of sugar or fat ingested per day was necessary to achieve its policy objective and asked whether Indonesia could provide any scientific evidence supporting the use of such measures and also identify on which international standards they would be based. Referring to Indonesia's statement at the March 2015 TBT Committee meeting[13] regarding the possibility of accepting test results from other laboratories, including from the country of origin, he asked that Indonesia provide an update on the acceptance of test results from accredited laboratories that used internationally recognized and appropriate methodologies. In addition, he asked Indonesia to provide a timeline as to when it would announce which food categories would require the mandatory labelling for sugar, salt and fat, when the regulation would enter into force and what the transition period for industry to adjust would be. Furthermore, as Indonesia had indicated that technical guidance for this regulation was being prepared, he asked for an update on the status and expected publication date of such technical guidance and also encouraged Indonesia to notify further amendments to the regulation.

3.144. The representative of the European Union reiterated her delegation's concerns with regard to the Indonesian Ministry of Health regulation, issued on 16 May 2013, introducing a mandatory health warning message on sugar, salt and fat content on the label of all processed food products. The EU was also interested in seeing the results of the total diet study undertaken by the Indonesian Ministry of Health with the aim of determining types of food to be included in high risk and low risk classifications. As reiterated in previous occasions, the EU looked forward to the issuance of implementing provisions for the regulation, addressing product coverage in detail as well as providing further technical guidance. The EU requested that both measures be notified to the TBT Committee while still in draft form so that Members were provided with sufficient time for comments. In particular, the EU wished to receive clarification and detailed information on three issues: (i) on how nutrition information and related health warnings would be placed on the label, on testing methods for nutrition levels and on the conduct of risk assessment related to NCDs; (ii) on the possibility for Indonesia to accept test results issued by laboratories other than the ones accredited by the Indonesian National Accreditation Body (KAN) or by other competent institutions having a Mutual Recognition Arrangement (MRA) with KAN; and (iii) on the possibility to place stickers after importation, and before the placement of the products on the market in Indonesia, for instance, in customs warehouses, as an alternative to labelling in the country of origin.

3.145. The representative of the United States noted that the Decree of the Indonesian Ministry of Health (MOH) lacked clear guidance on how to implement and comply with the new labelling regulations. While Indonesia allowed three years for compliance from the original publication date, companies were not in a position to work towards compliance until the additional guidance was made available. Therefore, the US requested a more definite timeline as to when the MOH would issue further technical guidance for implementation, as promised during previous discussions in the TBT Committee, especially since the measure had already entered into force. In addition, the US disagreed with Indonesia's lack of acceptance of test results from laboratories other than those accredited by, or having an MRA with, KAN, and continued to request recognition of test results from laboratories using appropriate or recognized methodologies, especially given the level of risk associated with nutritional information and other labelling elements. In the case of the US, for example, they recognized the appropriate method from the Association of Analytical Communities (AOAC) International. Furthermore, the US encouraged Indonesia to take into account less trade

[13] G/TBT/M/65, para. 2.120.

restrictive approaches, such as following a process of random sampling and testing of products in commerce, which could ensure the accuracy of label information for the vast majority of food and beverages. Finally, the US indicated its continued interest in the findings of the total diet study, which Indonesia had conducted and referred to during the previous TBT Committee meeting.

3.146. The representative of Australia said that his delegation recognized and supported Indonesia's right to implement measures to provide consumers with information to make appropriate dietary choices and reduce the risk of diet-related NCDs, consistent with WTO obligations. Indonesia would be one of the first countries in the world to implement a mandatory scheme for foods containing sugar, salt and fat. He asked for clarification as to why Indonesia considered that a mandatory health message on processed foods was necessary. In this respect, he recalled that the Codex Alimentarius Guidelines on Nutrition Labelling (CAC/GL 2-1985) set out the principles for nutrition labelling at the international level. One of these principles was that "the information should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product". The application of a mandatory health message referring to levels of specific critical nutrients was not consistent with this principle. Australia sought clarification on how the risk assessment of products would be undertaken with respect to NCDs and whether Indonesia would define the size and location of the mandatory health message on the package.

3.147. Furthermore, he expressed his delegation's belief that the justification behind the mandatory labelling statement seemed to be inconsistent with current nutritional advice. In Australia, for instance, dietary advice no longer included a recommendation to moderate total fat content in the diet. The most recent evidence supported by the latest Dietary Guidelines for Australians, published in 2013, advised limiting the intake of saturated fat but not total fat. Rather, Australia used other forms of nutrition labels, such as the mandatory declaration of key nutrients through a Nutrition Information Panel and voluntary nutrient content and health claims, and encouraged nutrition information on food labels supported by effective and sustained nutrition education to address the rising levels of NCDs. In this regard, Australia supported the requirement for sugar, salt and fat content to be indicated on the label of processed foods as part of the nutrient information panel, which was a mandatory requirement in many countries.

3.148. He also said that, according to the information Australia had, nutrition labelling was regulated under Indonesian law but applied only to nutritionally fortified and functional foods. As the Decree at issue did not address the specific requirements for nutrition labelling, Australia noted that the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985) required nutrient labelling to be expressed as "g" or "kcal" per 100 g or per 100 ml, or per package if it was just one portion. Therefore, Australia suggested maintaining consistency with Codex Standards when developing these requirements. In addition, Australia 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. Furthermore, Australia noted that the proposed nutrition declarations needed to be based on tests carried out by accredited labs and sought clarification on the methods that would be used for the tests verifying the nutrition declarations and whether tests performed by foreign laboratories, or in-house laboratories of companies, would be accepted. Australia also sought clarification on whether the proposed requirement would be enforced for both domestic and imported products and how compliance would be tested. Finally, Australia noted that this Indonesian Decree was published in the Official Gazette on 16 April 2013 and would enter into force three years after promulgation. Noting that the Decree was only notified to the WTO on 13 January 2014, he encouraged Indonesia to notify any further amendments and guides on the operation of the Decree to the TBT Committee. Referring to Indonesia's statement from the previous TBT Committee meeting regarding an implementing Decree, he requested that this other Decree be notified to the TBT Committee in a timely manner so as to allow WTO Members sufficient time to provide comments.

3.149. The representative of Mexico observed that this trade concern was similar to others raised during the meeting, where Members had called for further transparency regarding food labelling measures. His delegation was also interested in receiving updates on the measure and providing comments.

3.150. The representative of Indonesia said that the implementing regulation of the Ministry of Health No. 30 (2013), which was being discussed with stakeholders internally, would, as stated in the previous meeting, cover some criteria regarding the types of processed food categories as well testing and other technical requirements. The implementing regulation would be notified after the conclusion of the discussions on the draft. For further details, he suggested that comments be summited to the Indonesia TBT Enquiry Point.

3.2.3.16 Ecuador – Resolution establishing the "General conformity assessment framework for Ecuador" and the "Handbook of procedures to be observed prior to all stages of the customs clearance, marketing and market surveillance of manufactured, imported and marketed goods subject to Ecuadorian technical regulations, G/TBT/N/ECU/44, G/TBT/N/ECU/44/Add.1, G/TBT/N/ECU/44/Add.2 G/TBT/N/ECU/44/Add.3 (IMS ID 398)

3.151. The representative of Canada said that burdensome documentary requirements and local practices had made Ecuador's current conformity assessment system unwieldy for importers. As Canada had stated at the March 2015 Committee meeting, in light of comments received from the industry,[14] Ecuador's conformity assessment requirements had multiple levels of redundancy that created impediments to trade. Several verification checklists, additional compliance reports, as well as local notarization requirements were needed for individual shipments of potatoes, for example. These burdensome and redundant requirements created extended delays in processing at importation and increased costs to importers. Canada was of the view that a sanitary registration and a certificate of conformity would be sufficient to ensure the quality and compliance of products. The multiple requirements did not appear to provide any additional level of safety, security, protection of human and animal life, or protection of the environment, but rather seemed to be more trade restrictive than necessary to meet the Member's objectives. Canada welcomed information from Ecuador on any steps being taken to mitigate these impediments to trade.

3.152. The representative of Ecuador reiterated her delegation's position that the resolution was necessary to ensure compliance with measures related to security, the protection of human, animal and plant life, the preservation of environment, and the protection of the consumer. As per Article 9.1 of the Law on the Ecuadorean Quality System, the Inter-ministerial Committee on Quality was responsible for developing policies to define products that had to comply in a compulsory manner with technical regulations and conformity assessment procedures. In this context, Resolutions 001, 002, 005 of the Inter-ministerial Committee amended Resolutions 9 and 10 of the National Quality Council, which established guidelines regarding the implementation of each technical regulation. Therefore, the measures did not constitute a barrier to trade. On the contrary, they sought to establish efficient mechanisms, allowing for the assessment of compliance with the requirements established in technical regulations, via a certificate of conformity assessment or inspection together with its recognition certificate. Similarly, domestic producers of goods subject to technical regulations needed to submit a certificate of conformity or inspection from an accredited or designated body to the Sub-secretariat for Quality of the Ministry of Industry and Productivity. The procedures for imported as well as domestically produced goods were conducted electronically.

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

3.153. The representative of Canada said that his delegation supported Ecuador's objective of reducing the risk of non-communicable diseases (NCDs) and acknowledged Ecuador's efforts at the previous meeting to provide references to some of the scientific basis for adopting their approach. Nevertheless, he questioned the scientific evidence behind the established categories for the level of concentration of nutritional components. In addition, Canada still had concerns regarding the burdensome nature of the conformity assessment procedures. Specifically, Canada had received industry complaints on the requirement to provide a verification checklist to demonstrate compliance on a per shipment basis. Canada believed that, alternatively, adequate data

[14] G/TBT/M/65, para. 2.141.

management coupled with periodic audits was a less burdensome method of achieving the same objective. Canada was concerned that the regulation was already having an impact on trade and that it might be more trade restrictive than necessary. Canada welcomed Ecuador's views concerning the restrictive elements of their law and whether they were trying to improve the product certification process.

3.154. The representative of Mexico reiterated his delegation's concerns expressed in previous Committee meetings, which were also contained in document G/TBT/W/407. He asked Ecuador to provide information that would justify technical regulation RTA INEN 022, which was possibly in violation of Articles 2.2 and 2.4 of the TBT Agreement and Article 20 of the TRIPS Agreement. Mexico was particularly concerned that the nutritional labelling was not based on the nutritional intake of daily dietary requirements, regardless of whether they were processed food or not. Mexico was also concerned about the compatibility of Ecuador's conformity assessment procedures with the obligations of the TBT Agreement.

3.155. The representative of the European Union said Ecuador's Technical Regulation 022 on the labelling of processed and packaged food products imposed nutrition food labelling obligations comprising "high in" warnings and a traffic light warning system. While the EU fully shared 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 these objectives and was proportional to the aim pursued, which should be to empower consumers to make an informed choice in order to foster effective competition and consumer welfare. Recalling the EU's previous interventions,[15] she underlined her delegation's concerns regarding the lack of proportionality of the measure, its departure from Codex guidelines and the use of the "high in" warnings.

3.156. The representative of the United States recalled the US's previous interventions requesting that Ecuador suspend its implementation of Resolution 116 in order to allow Members to comment on the measure and provide specific information on how Ecuador could take the least trade restrictive approach to its conformity assessment procedures. Reiterating this request, the US asked that Ecuador provide formal justification in a TBT notification concerning the legitimate objective achieved by the institution of this technical regulation not already fulfilled by other pre-market import requirements. Since the last TBT Committee meeting, the US had been working bilaterally with Ecuador to outline concerns and suggestions regarding Resolution 116 and looked forward to a response to these recommendations.

3.157. Regarding Technical Regulation of the Ecuadorian Standardization Institute RTE INEN No. 022 on the labelling of processed and packaged food products, recalling previous interventions, she reiterated that requiring multiple certificates to demonstrate conformity of labelling elements - in addition to a label review as part of the Sanitary Food Registration process and a certificate to demonstrate compliance with Ecuador's commodity standards -, was overly burdensome and duplicative and would, in any case, add no value in ensuring the safety of the products in question. US suppliers had continued to encounter difficulties coming into compliance with the certificate of conformity requirements and had reported that they had been unable to self-certify through use of accreditation with ISO standards. In addition, US suppliers had been asked to provide per lot or shipment lab tests from an Ecuadorean Accreditation Organization (OAE) accredited lab in addition to self-certification, which undermined the use of self-certification. Suppliers needed to have records available if audited, but should not need to produce them with every shipment. In this context, she asked for an update on Ecuador's progress in recognizing third party lab tests.

3.158. The US also asked Ecuador to inform the basis for requiring an advisory statement on foods based on their "natural" content, noting that no international guidance existed for the determination of "natural" content of foods. Regarding the mandatory requirements to label food and beverage products with the statement: "Contains Transgenics", the US recalled its long standing position that for foods derived from genetically modified organisms that had been found to be substantially equivalent to conventional counterparts, mandating such labelling could create an erroneous impression that the product was less safe than conventional products. Rather than a mandatory labelling requirement, a voluntary approach would allow for consumer choice without

[15] G/TBT/M/65, para. 2.152.

creating concerns in the eyes of the consumer that such products were unsafe. Therefore, the US encouraged Ecuador to reconsider its mandatory approach to biotech labelling.

3.159. The representative of Costa Rica reiterated his delegation's concern with regard to the measure in question and requested an update on the status of the measure and on how Ecuador had taken trade concerns raised into consideration.

3.160. The representative of Guatemala reiterated her delegation's concerns as expressed in previous meetings regarding the lack of transparency and respect of timelines for the development of this measure, which could be an obstacle to trade. Ecuador had indicated that the objective of the measure was to overcome obesity in its population. However, the labelling requirements prejudiced food as the only cause of the problem. In addition, the regulation deviated from Codex guidelines. Furthermore, there was no scientific evidence indicating that the regulation was apt to achieve its objective. She urged Ecuador to reconsider the design and scope of the measure.

3.161. The representative of Ecuador said that, as indicated in previous meetings, Resolution 116 did not create any new obligatory technical regulations. She underlined that all technical regulations in Ecuador established their scope of application, entry into force and mechanisms for conformity assessment and were notified to the TBT Committee in line with the transparency provisions of the TBT Agreement. Resolution 116 only provided for the presentation of a supporting document together with the Customs Declaration as part of an internal administrative process. Therefore, it was not a technical regulation and did not constitute a trade barrier inconsistent with the TBT Agreement.

3.162. With respect to regulation RTA INEN 022, she explained that the Ministry of Health's national study on health and nutrition, conducted in 2012, had revealed an increase in NCDs among the Ecuadorean population, independent of their age or socio-economic status. Therefore, policies had been established to prevent such diseases and to raise awareness of consumers regarding the content and characteristics of foods. In addition, Ecuador was complying with paragraph 3.3.1 of the "Action Plan for the Prevention Obesity in Children and Adolescents" of the Pan American Health Organization (PAHO), which had established that a "number of countries that have norms in place for front-of-package labelling that allow for quick and easy identification of energy-dense nutrient-poor products and sugar sweetened beverages, which take into consideration Codex norms."[16]

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

3.163. The representative of the European Union requested further information concerning the timeframe for the adoption of amendments notified under G/TBT/N/RUS/29. The EU asked Russia to confirm the information given at the previous meeting of the TBT Committee that the amendments were still under development and that the estimated date for adoption was April 2015 at the earliest, with entry into force expected in October 2015. The EU also requested to receive the final adopted text once available.

3.164. The representative of the Russian Federation explained that the actual implementation of the original technical regulation had revealed the need to change certain requirements. Draft amendments to the technical regulation had been developed and duly notified. While Russia was interested in the rapid adoption of the amendments, it had been delayed due to the accession of two new members to the Eurasian Economic Union, with whom amendments needed to be coordinated. Regarding the timeline, while it was difficult to provide a specific date, it was expected that the amendments would be approved in a few weeks. The current version of technical regulation would be applied until the adoption of the amended version.

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

3.165. The representative of Canada reiterated concerns relating to the Food Safety and Standards Authority of India reaffirming India's position that this product must be labelled and marketed as: "Imported Rapeseed - Low Erucic Acid Oil (Canola Oil)." He said that the labelling

[16] http://www.paho.org/hq/index.php?option=com_docman&task=doc_view&Itemid=270&gid=28890&lang=pt.

requirements directly affected exports, marketing and sales of canola oil in India. Canada expressed concern that these changes to India's labelling regulations were not notified to the WTO and could be more trade restrictive than necessary to achieve India's legitimate objective of food safety. Moreover, the requirements differed from the international standard, namely the relevant guidelines recommended by Codex Alimentarius. Canada was encouraged by a Bombay High Court ruling, upheld by the Supreme Court of India, which issued a Stay Order against the FSSAI's labelling guidelines for canola oil in favour of an importer. 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 to the currently enforced labelling requirements for canola oil that would not unnecessarily create a barrier to trade.

3.166. The representative of Australia sought an update on the status of the measure and said that Australia remained concerned over the regulation's requirement that the use of the term "canola oil" was only permitted as a secondary term. His delegation believed that this regulation contradicted the Codex Alimentarius Standard for named vegetable oils, which permitted the use of synonym descriptors for "rapeseed oil", including "canola oil" (Codex Standard 210 - 1999, section 2.1.16). 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. They also requested an update to the legal proceedings on the matter, further to the Supreme Court decision of January 2015.

3.167. The representative of India informed the Committee that there was no change in regulatory status since the previous meeting. Therefore, the concerned delegations were requested to refer to the statements made by India in the Committee meetings of November 2014.[17] In addition, India maintained that the labelling requirement for "Canola Oil" was strictly as per Section 2.1.16 of Codex STAN 210-1999, wherein it was specified as "Rapeseed oil – low erucic acid (low erucic acid turnip rape oil; low erucic acid colza oil; canola oil) is produced from low erucic acid oil – bearing seeds of varieties derived from the Brassica napus L., Brassica rapa L. and Brassica juncea L., species." India would therefore have had no objection if the Label mentioned "Canola Oil" as "Rapeseed Oil - Low Erucic Acid (Canola)". India objected in the event that a product was labelled only as "Canola Oil" without a mention of the source, that is, "Rapeseed Oil". The FSSAI had maintained that it had no issues if "Canola Oil" was mentioned in parenthesis under "Rapeseed Oil – Low Erucic Acid", as mentioned in the Codex.

3.2.3.20 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 (IMD ID 427)

3.168. The representative of Canada reiterated concerns his delegation had expressed at previous TBT Committee meetings as well as through a letter sent to Thailand's enquiry point in May 2014. Canada understood that the regulation entered into force in March 2014 and thus remained concerned about the measure's prohibition of the use of wine labels that contained: (i) images of athletes, artists, singers or cartoons; and (ii) messages affiliated with certain activities, such as sport, music and contests. Some of the terms and definitions in the regulations lacked clarity and could therefore result in uncertainty for wine exporters. For example, some Canadian wine labels portrayed depictions of the prohibited and other artistic depictions which could be considered to be "cartoons" and, consequently, be also considered to be in breach of the regulations, if imported into Thailand. He said that Canadian wine labels were not, however, intended to appeal to children or promote irresponsible alcohol consumption. Moreover, Canada had not witnessed any evidence that the sale of products with the prohibited labelling increased youth or irresponsible drinking.

3.169. Given the forgoing, he said that while Canada recognized Thailand's right to implement regulations to protect consumers' health and safety and provide them with adequate information to make informed choices, Canada was nonetheless still concerned that these 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. In this respect, he asked Thailand to point to studies suggesting that such labelling constraints would help achieve

[17] G/TBT/M/64/Rev.1, para 2.206 (see also G/TBT/M/65, para 2.161).

Thailand's policy objectives. He also asked whether Thailand had considered any less trade restrictive alternatives to achieve these policy objectives. He noted in this respect that Thailand could be considering a different approach to the graphic warning labels. He further inquired whether Thailand would be issuing an implementation guidance document.

3.170. The representative of Mexico thanked Thailand for the responses to its comments, received on 11 June, but noted that the answers provided by Thailand were still unclear, so his delegation's concerns persisted, in particular regarding confusing language of some provisions of the technical regulation. He urged Thailand to consider Mexico's request, contained in communication G/TBT/W/408, in the sense that, when preparing and adopting this measure, it should apply the proportionality principle contained in Article 2.2 of the TBT Agreement, be in accordance with international standards, where those standards exist, as provided in Article 2.4 of the TBT Agreement, and give due consideration to comments from trading partners' comments on the final version of the technical regulation.

3.171. The representative of the European Union associated herself with the statements made by Canada and Mexico, and reiterated her delegation's 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. She also noted that an additional notification was submitted on 27 April 2015 and that the measure entered into force on 22 April 2015, with a transitional period of 6 months for compliance with the new requirements. The EU thanked Thailand for having provided clarifications and asked for information on the absence of an approval process for labels in the Act and for Thailand to confirm that information. The EU regretted that most of the issues previously raised had not been properly addressed in the final Act. There remained concerns about the strict labelling requirements proposed in the notified legislation and its departure from international standards.

3.172. 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. In this respect, she noted that Thailand had removed the definition of "label" and added the definition of "packaging materials". The EU expressed its concern that the wording of the definitions was too broad and it was thus open to different interpretations. Regarding Clauses 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 could lead to inconsistent interpretations by economic operators. She requested Thailand to explain how it intended to interpret and enforce these clauses, in particular Clause 2(2), that dealt with messages that directly or indirectly persuaded the consumption of, or made claims on the benefit or quality of, an alcoholic beverage. Thailand had clarified that cartoon images that had been registered as trademarks of alcoholic beverages prior to the enforcement of the legislation were not prohibited. However, the EU remained concerned that specific terms linked to the ageing or maturation process related to the conditions, quality or characteristics of the product could be considered contrary to the notified provisions. The EU also believed that the administrative complexity of the label approval process and the short implementation deadlines for compliance constituted serious market access barriers and again requested Thailand if it could allow the sale of all products existing on the market until stocks were exhausted. The EU also invited Thailand to provide appropriate guidelines for implementation and to extend the transition period to one year. The EU also inquired whether there was any mechanism of appeal for decisions taken on the label approval process. The EU welcomed that graphic health warnings were not part of the adopted regulations, but as Thailand's reply of 11 June 2015 said that warning pictures were still under consideration, the EU remained concerned about their possible introduction. The EU requested clarification on the outcome of these considerations and the status of this proposed measure, in particular, regarding the notification to the TBT Committee to which Thailand had committed itself during their previous meetings. The EU reiterated requests that Thailand take into consideration less trade restrictive measures, or failing this, to provide clarification on which basis and evidence they consider that different, less costly and burdensome alternatives, than the indication of a graphic health warning, would be insufficient to address the objective pursued.

3.173. The representative of the United States said that they had submitted comments on the original text notified by Thailand as G/TBT/N/THA/437 in March 2014 and noted that many of these comments were not reflected in the final measure. The US supported Thailand's desire to address its valid public safety and health concerns related to excessive alcohol consumption, and requested further consultation to define a solution that addressed this concern without restricting

trade unnecessarily. In this respect, she pointed out that the Act's vague language was open to misinterpretation and there was no technical guidance on how it would be enforced. She also requested that Thailand delay implementation of the measure until such guidance was provided. Such delay was particularly important because the lack of implementing guidance could lead to significant market access issues for US exports of alcoholic beverages to Thailand.

3.174. The representative of Australia recognized the right of governments to take measures necessary to protect public health, including the Thai Government's efforts to address a legitimate concern through its proposed labelling regulation for alcoholic beverages. He noted that the regulation entered into force on 15 April 2015 and that importers/manufacturers had until October 2015 to comply with the provisions. Importers and suppliers required guidance to ensure compliance and Australia understood that the Thai Government planned to provide such guidelines and undertake consultations to assist industry in the development of labels in accordance with the new requirements. He welcomed a timeframe for the release of these guidelines. However, Australia still remained concerned that Clauses 2 and 3 could cause uncertainty for importers as to whether certain labels were consistent with the regulation. For instance, in Clause 2 (1-2) it was unclear what constituted an "unfair message to consumers" and what terminology on labels was prohibited under the regulation. He asked if, for example, descriptions of the taste and quality of the wine would be permitted. He asked whether certain descriptors (such as "finest", "premium" or "prestige") as well as certain images associated with a brands heritage (such as a "mountain" or "vineyard") would still be permitted. He said that the definition of a "cartoon" in Clause 3 (4) 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, he considered that the label approval process appeared to be administratively burdensome, as importers/manufacturers required the approval of two government agencies. He enquired, in this respect, what the responsibilities of these agencies in the process were.

3.175. The representative of South Africa associated himself with Australia's statement, including the concern about the label approval process and provisions in Clauses 2 and 3. South Africa would send their comments to the TBT enquiry point in due course.

3.176. The representative of Chile shared the concerns of the previous delegations and said that although labelling of alcoholic beverages could seek legitimate objectives, such as protecting public health, it had to be as least trade restrictive as possible.

3.177. The representative of New Zealand acknowledged and supported Thailand's right to introduce new regulations to address specific public health concerns. He reiterated that the new labelling requirements that had been notified in April 2015 were unclear, subjective, and open to interpretation, thus leading to uncertainties and, ultimately, to making the measures unnecessarily trade restrictive. He asked for clarity on the definition of several terms in the regulations and whether there would be an appeal process if a company would choose to challenge a decision made by the Alcohol Control Committee. The regulation provided that labels used prior to the date of enforcement could continue to be used for a period of a 180 days after entry into force. However, New Zealand was concerned that this period was inappropriate for alcoholic beverages with a longer shelf life. He requested continued engagement with stakeholders so as to clarify the process, implementation and enforcement and that the transitional grace period be extended until implementation guidelines were issued.

3.178. The representative of Thailand thanked representatives for their comments. Thailand's full statement is contained in document G/TBT/W/422.

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

3.179. The representative of Canada remained concerned that the labelling requirements contained in Ecuador's customs regulation as published in the official registry in September 2013, and the related technical regulation notified on 8 April 2014, were more trade restrictive than necessary. The requirement that the labelling of products had to be done in the country of origin was a concern. The standard practice in the internationally traded spirits industry was to apply generic front labels in the country of production that provided mandatory information and to affix,

in customs bonded warehouses in the import market, other market-specific information on the back or secondary label. He asked why Ecuador did not allow this standard practice and how deviating from it was necessary to achieve its objective of protecting human health and preventing deceptive labelling. The regulation also required that the name of the Ecuadorian importer be included on the label that had to be affixed in the country of origin. He asked whether previous concerns in this respect have been taken into account in revising the measure, as Ecuador had indicated it would. He noted that the customs regulations published in 2013 were not notified to the WTO and hoped that any updates on this issue would be forthcoming and transparent.

3.180. The representative of Mexico reiterated his delegation's concerns over the draft technical regulation and the fact that the proposed measure requested labelling at origin and did not provide for any possibility of labelling or relabelling in a primary customs area. He recalled that one of the labelling requirements (to include the name of the Ecuadorean importer in the label) was established in a Resolution of Ecuador's Customs National Service, dated 9 August 2013. In this regard, he also requested the removal of the requirement to indicate the name of the importer in Ecuador in the labelling affixed at origin. Finally, he said that any updates on the issue would be appreciated.

3.181. The representative of the European Union shared the concerns expressed by other delegations and asked for a reply to the comments the EU submitted to Ecuador on 1 July 2014. He recalled their previously expressed concerns with: (i) the obligation to state the name of the importer in the front label; (ii) the requirement that the labelling of alcoholic products shall be done in the country of origin, not allowing labelling or re-labelling in a primary customs area; and (iii) the need to undergo certification by a conformity assessment body in order to verify compliance with labelling requirements. He asked Ecuador to clarify the relationship between this technical regulation and Resolution No. SENAE-DGN-2013-0300-RE that related to post-entry control of imported alcoholic beverages, and also how this technical regulation applied to products that had already been placed on the Ecuadorian market on its entry into force.

3.182. The representative of the United States expressed her delegation's concerns regarding the requirement included in the regulation for a certificate of conformity. The regulation required that the name of the importer of alcoholic beverages be placed on the exported product in the country of origin, with no flexibility for placement in customs bonded warehouses via the use of supplementary labels, including stickers. She noted that Ecuador had previously informed that they were reviewing the comments received with the possibility of revising the measure so as to be less trade restrictive. The US inquired as to the status of this review, given the potential added costs to any alcoholic beverage producer exporting to Ecuador. In view of the fact that many countries allowed country-specific label changes in customs bonded warehouses, she asked why Ecuador did not allow this common international practice and encouraged them to accept and to incorporate specific language allowing for it in existing and future norms and standards.

3.183. The representative of Chile expressed concern and requested Ecuador to provide an update on this matter.

3.184. The representative of Ecuador explained that the rationale behind Resolution No.300 of the National Customs Service of Ecuador SENAE-DGN-2013-0300-RE, "Resolutions Back Control of Imported Alcoholic Beverages" on labeling for these products, was to avoid illegal imports and fraud due to the lower prices of these products in neighbouring markets. With regard to PRTE 189 on the basis of the objectives set out in the TBT Agreement, this project had the objective to protect the health and lives of people and prevent practices that may mislead consumers on alcoholic beverages. This regulation established requirements for the labeling of liquor to be sold in Ecuador, without any distinction between drinks. Ecuador received several comments on the draft regulation which was notified in 2014 to the WTO. She said that the regulation was still being analysed and did not have a commencement date and assured Members that they would be informed of the date when it was determined.

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

3.185. The representative of Canada thanked China for the clarification they provided on Order No. 650 of the State Council "Regulations for the Supervision and Administration of Medical Devices". Canada considered that certain aspects of that regulation were still adversely affecting Canadian manufacturers of medical devices. He noted, in this respect, that China's "Medical Device Registration Fee Schedule" was put into force without any notification to the WTO and that China failed to provide Members with a "reasonable interval between the publication of requirements concerning conformity assessment procedures and their entry into force", as required by Article 5.9 of the TBT Agreement. He repeated his delegation's previous request for a status update on Article 13 of Order No. 4 and Article 15 of Order No. 5. It was his understanding that before an imported medical device could be registered, or its applications listed, the product had to have obtained market approval from the country (region) where the applicant's business was registered, or where the product was produced. Canada requested clarification on this new interpretation and on the types of documents that were required. Canada believed that such a requirement would be a problem for Canadian exporters who may not necessarily seek regulatory approval domestically. For example, could applications be made for Canadian-originating medical devices, or *in vitro* diagnostic products, which have received approvals in other leading jurisdictions, such as the US or EU, but were not approved in Canada? Moreover, the Orders required duplicative clinical trials. As China was a member of the International Medical Device Regulators Forum (IMDRF), due consideration to clinical results from other Members of this regulatory body would be preferable. In lieu of requiring a new clinical trial, China could have considered requiring a "bridge study" to ensure that the original data was relevant to China. Requiring a complete, duplicative clinical trial could lead to additional delays and costs for foreign exporters of medical devices without any added benefit. He therefore asked China to confirm whether clinical trial results from jurisdictions that were members of the IMDRF were acceptable.

3.186. In addition, Canada asked for clarification on Article 17 of Order No. 650, specifically as it related to the catalogue of products exempt from requiring China-based clinical trials. There was a limited list of exempted products and it lacked an effective regulatory mechanism to update and remain relevant with recent trends in the medical technology sector. He therefore inquired whether China was developing a system that would allow for prompt updates to the catalogue. If the list was not updated to include more relevant exemptions, costly and unnecessary clinical testing would be required for foreign exporters without any added benefit. He also asked if China could indicate when a final combined catalogue of Medical Devices would be released.

3.187. Canada also understood that Class II and III medical devices also had to pass a quality test under the "effectively operated quality assurance system" before applying for a clinical trial. He thus asked China to confirm this new procedure and provide further information on that quality test and the standards being tested. He asked if it was the same as the product inspection required as part of the registration approval process. He also requested further information on the effectively operated quality system and whether foreign labs could provide that testing. In addition, Canada noted that 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 Canadian exporters of *in vitro* diagnostic products that had received prior regulatory approval in other leading foreign jurisdictions, including Canada. This duplicative requirement would result in additional time and expense being incurred by Canadian medical device exporters wishing to enter the Chinese market.

3.188. Canada was also concerned with the Electromagnetic Compatibility (EMC) testing that was required by Chinese regulators in order for a medical device to be registered. The EMC standard that China used was identical to the one issued by the International Electrotechnical Commission (IEC), of which China was a member. However, China had not accepted test reports issued by internationally accredited laboratories that abided by the IEC standard. Canada requested that China, in an effort to limit duplicate testing and unnecessary costs, accept test reports that were consistent with China's technical requirements although they originated from internationally accredited laboratories.

3.189. The representative of the Republic of Korea said that the fact that China did not accept test reports issued by internationally accredited laboratories would lead to unnecessary duplication of testing. This would, in turn, result in additional time and cost for exporters, since medical devices imported to China were already tested by internationally accredited laboratories. He requested that China accept test reports issued by internationally accredited laboratories or internationally recognized test reports which had been made using the criteria contained in China's regulations. In addition, some medical device exporters manufactured products specifically for export as the regulations and medical environments differed between the country of origin and the importing country. That was why China's requirement that a foreign exporter had to submit manufacturing and marketing certificates authorized in their country of origin to obtain an approval in China was untenable. This requirement created additional delays when entering the Chinese market and thus became a non-tariff barrier to trade. He requested that the Chinese authorities removed the said registration requirement and continued to collaborate on this matter, and find a reasonable solution as soon as possible.

3.190. The representative of the European Union reiterated his delegation's previous concerns over the Chinese regulations regarding medical devices notified in G/TBT/N/CHN/1022-1026 and 1029. He noted that Order No. 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 nonetheless 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's Food and Drug Administration (CFDA) put in place a robust system allowing swift updates of the exemption catalogues, as needed.

3.191. 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 thus causing additional delays in placing products on the Chinese market without any added benefit. Due consideration needed therefore 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 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. 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. The EU also said that further guidelines detailing the relevant processes would be also welcome.

3.192. The representative of China said that notifications G/TBT/N/CHN/1022-1026 and 1029 were drafted to enforce the "Regulations for the Supervision and Administration of Medical Devices". Before it was implemented, CFDA held specialized training to help relevant enterprises and organizations understand these measures. The CFDA also communicated directly with relevant foreign and domestic enterprises and associations on these measures and fully considered comments received from Members, including those from the EU and the American Chambers of Commerce in China. China welcomed all Members to contribute to these measures and undertook to take comments from all stakeholders into account. She explained that sale certifications in the country of origin ensured the safety and effectiveness of medical devices and protected Chinese citizens. A list of medical devices exempt of clinical trial had been issued in catalogues of exemptions, 488 Class II and 79 Class III.

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

3.193. The representative of Canada expressed his delegation's concern regarding the requirement to register each product 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. Canada questioned whether any consideration had been given to the possibility of assigning registration numbers to each *manufacturer* rather than each *model*. Such process, which had been proven efficient in other countries, such as Canada, the European Union, the United States, would accomplish the measure's objectives without undue burden to toy manufacturers. In Canada's view, the measure was not precise enough for several reasons. First, there were differences in the 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. Second, regarding third-party certification, it was unclear which third party was being referred to. Third, the possibility of having an exemption allowing toy manufacturers to put a web address on their instructions manual with a link to materials in Arabic was not entirely clear. Canada asked whether these three uniformity issues had been clarified and if not, if there was any intention of providing an update on this matter. Finally, regarding testing, Canada was of the view that the measure lacked clarity on required tests for the "G" Mark on toys sold in the GCC. Finally, Canada requested the Kingdom of Saudi Arabia to provide more information about possible accreditation of laboratories outside the Gulf region.

3.194. The representative of the Kingdom Saudi Arabia stated that most of the issues raised were explained in the previous meeting.[18] He also noted that his delegation would appreciate if in the future new specific trade concerns could be sent in written form so as to facilitate full responses.

3.2.3.24 Ecuador – Proposed Motor Vehicle Safety Regulatory Requirements (RTE INEN 034) (IMS ID 409)

3.195. The representative of Canada echoed the concerns that were raised at the previous meeting by the US, Mexico and Brazil.[19] This included concerns with the lack of scientific evidence provided by Ecuador with respect to its conclusion that vehicles built in accordance with US Federal Motor Vehicle Safety Standards (FMVSS) no longer met their public safety requirements. In Canada's view, this regulation was more trade-restrictive than necessary to fulfil the stated objectives as the measure only took into account the requirements established by UN Economic Commission for Europe (UNECE) standards. Other international standards established to fulfil the same objectives, followed by other countries, had not been considered. As most of the motor vehicles manufactured in Canada were built in accordance with the FMVSS, Ecuador's shift to UNECE standards and its refusal to accept US safety standards was a matter of concern for Canada. US vehicle safety standards, and by extension Canadian safety standards, provided the most stringent performance and outcomes with respect to vehicle safety. Consequently, Canada strongly encouraged Ecuador to continue to allow the use of FMVSS and EPA standards.

3.196. The representative of Mexico reiterated the concerns contained in G/TBT/W/410, in particular, the possible failure to conform to Articles 2.4 and 5.1.2 of the TBT Agreement. Mexico's main concerns focused on the short deadline for the entry into force of the measure and the requirement for third-party certification. In Mexico's view, third-party certification in the automobile sector should be exceptional as it was an internationally-regulated sector, in which vehicles were usually certified in their country of origin. Therefore, Mexico expressed concerns with the need to submit a conformity certificate issued by a particular accredited body. Mexico also shared Canada's concern regarding the refusal to consider other international vehicle-safety standards and requested Ecuador to take due account of the comments that had been presented, so as to introduce the relevant changes in the technical regulation.

3.197. The representative of the United States said that, while her delegation supported the automotive safety and environmental protection objectives pursued by the measure, the US was nonetheless puzzled by the unusual way that Ecuador notified a significant revision of its technical regulation. 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 accepting self-certification of FMVSS and US Environmental Standards. These comments were however never acknowledged or replied to by Ecuador. The US thus asked: 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?

[18] G/TBT/M/65, para. 2.203.
[19] G/TBT/M/65, paras. 2.254-2.258.

Why stakeholders were not afforded the opportunity to provide data to demonstrate the effectiveness of FMVSS in achieving Ecuador's desired safety outcomes?

3.198. She stressed that this regulation, which was 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 in accordance with FMVSS would be delayed until versions designed to UNECE requirements were developed, presuming US automotive companies intended 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 therefore requested Ecuador to reconsider the final regulation and include acceptance of US FMVSS and US EPA automotive requirements.

3.199. The representative of the European Union requested Ecuador to clarify the timeline for the implementation of the new regulation. He encouraged Ecuador to manage the transition to the new regulatory framework for vehicle safety in such a way that it would minimise any possible and unintended trade disruptions. This implied allowing adequate time for producers in exporting Members to adapt the design of their vehicles and their production lines to the new requirements in accordance with Article 2.2 of the TBT Agreement. The EU recalled their statement at the last TBT Committee meeting about the benefits of international harmonisation in the motor vehicle sector.[20] International harmonisation, when based on a high level of human health, safety and environmental protection, was a powerful instrument for trade facilitation. In this regard, the harmonisation activities undertaken by UNECE's World Forum for Harmonisation of Vehicle Regulations (WP.29), most notably UNECE's 1998[21] and 1958[22] Agreements, were an effective way to address technical barriers to trade in the automotive sector. Harmonised technical requirements developed under those agreements provided significant economic benefits by reducing compliance costs which would otherwise arise from the need to comply with different sets of national requirements. The 1958 Agreement added to the benefits of technical harmonisation the advantages of a system of mutual recognition of approvals of vehicle systems, parts and equipment. Additionally, both agreements were also seen as instruments of empowerment and technical development for emerging and developing countries that decided to join them.

3.200. Reacting to the EU's points, the representative of the United States noted that there was no consensus among WTO Members that the UN regulations adopted pursuant to the 1958 Agreement were "international standards", according to the six principles of the November 2000 TBT Committee Decision.[23] In particular, the standard development process for the UN Regulations raised questions with respect to their consistency with the principles set out in paragraphs 8, 9 and 10 of that Decision. In contrast, the 1998 Agreement appeared to better reflect the principles of the TBT Committee Decision. Nevertheless, the US was of the view that at the present time there was no international standard for the majority of automobile safety standards.

3.201. The representative of the European Union underscored the importance of global harmonization in the motor vehicle sector, particularly with respect to trade facilitation. Additionally, he stated that the UNECE was the only global forum engaged in this matter and therefore, the benefits derived from this work should be recognized regardless of the qualification of UNECE regulations as "international standards". In the EU's view, the work undertaken by the UNECE should be supported and developing countries should be encouraged to participate in this work.

3.202. The representative of the United States agreed on the importance of international harmonization and hoped that developing countries could participate in the process of the 1998 Agreement.

[20] G/TBT/M/65, paras. 2.257-2.258.

[21] "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.

[22] "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.

[23] G/TBT/9, 13 November 2000, para. 20 and Annex 4.

3.203. The representative of Ecuador said that her delegation had incorporated the UNECE regulations for harmonisation of vehicles and noted that this system provided security for the entire lifecycle of each model. She then stated that a consolidated international forum should be held that that would duly discuss regulations and adopt the best forms of standards. Vehicle manufacturers present in Ecuador offer models in other markets that comply with either the minimum requirements of the RTE034 or even more stringent requirements. In Ecuador's view, the development of the technical regulation at issue led to important cooperation amongst importers and manufactures. The period of implementation was constantly being assessed by the Ecuadorian authorities so that the time periods were feasible. Consequently, Ecuador informed the Committee that there was a new transition period until October 2015 and therefore Ecuador would be accepting self-certification until October 2015.

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

3.204. The representative of the Republic of Korea noted that many Members adopted technical regulations on lithium ion cells and batteries which were harmonized with international standards. Korea had also enforced a similar technical regulation. However, many of China's test requirements for their safety regulation did not correspond with either the current IEC62133 or its draft revision. In the previous TBT Committee meeting, Korea raised concerns regarding the inconsistency between the proposed regulation and international standards.[24] Nevertheless, the proposed regulation was adopted and published on 5 December 2014 without any revision. He requested China to harmonize those requirements with international standards and to take into account the discussions under the IEC. Concerning Article 11 of the measure, he encouraged China to eliminate the requirement from the National Standard, or exclude it from mandatory requirements, since the safety requirement for system protection circuits could be complied with by portable electronic equipment manufacturers rather than cells and batteries manufacturers.

3.205. The representative of China said that, as lithium batteries were the cause of many injuries and even deaths, China had drafted a national standard safety requirement in order to protect consumer's health and safety. This standard was developed by an ad hoc working group established in 2008. This 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 discussions, 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. While it adopted, when appropriate, the relevant criteria established under IEC62133, the Chinese standard also improved the IEC standard according to the characteristics of the lithium battery. In fact, a number of proposals based on this Chinese standard had been adopted by the IEC itself, which illustrated its effectiveness. The Chinese standard, based on the relevant international standard (IEC), did not therefore violate any TBT Agreement provision or principle.

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

3.206. The representative of Mexico reiterated concerns that were expressed in the last Committee meeting[25], in particular that this measure might not conform to Articles 2.2 and 5.1.1 of the TBT Agreement. He asked Ecuador whether they had considered alternative measures to facilitate compliance with the conformity assessment procedures.

3.207. The representative of Ecuador explained that the measure was based on certain Andean regulations on the harmonization of legislation on cosmetic products, as well as Annex 2 of the good manufacturing practices within the Andean Community for cosmetics. She then stated that although they had amended the measure to facilitate compliance with regard to conformity assessment procedures, her delegation would take into account the comments made by Members.

[24] G/TBT/M/65, para. 2.199.
[25] G/TBT/M/65, para. 2.248.

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

3.208. The representative of Canada expressed concerns regarding Brazil's proposed regulation requiring the translation of cosmetic ingredients into Portuguese for labels of cosmetics and personal care products. Canada believed that this regulation could be more trade-restrictive than necessary given the available alternatives. The "International Nomenclature for Cosmetic Ingredients" (INCI) was an internationally recognized standard for disclosure of ingredients on cosmetic product labels, which Canada, the US, the EU and Japan fully endorsed. As Canada, Japan and the EU were multilingual jurisdictions, Canada believed that this framework was the most effective in conveying information to consumers and health care providers. By adopting a harmonized ingredient labelling regime, Brazil would help reduce the costs associated with developing country-specific original packaging, along with allowing a more streamlined inventory management system for foreign producers of cosmetics and personal care products. Canada also noted that Brazil, as a recent Steering Committee member of the "International Cooperation on Cosmetics Regulation" (ICCR), Brazil was encouraged to pursue technical regulations that would "minimize barriers to trade", instead of creating new ones. Canada hoped that Brazil would evaluate the possibility of using the INCI system for their disclosure of ingredients on cosmetic product labels, leaving the translation to Portuguese as a voluntary option. In this respect, Canada recalled that the Brazilian "National Health Surveillance Agency" (ANVISA) was previously in support of adopting the INCI system for the disclosure of ingredients on cosmetic product labels. However, Brazil was required to adopt a mandatory Portuguese regulation following a Federal Court decision. Consequently, Canada requested Brazil to provide an update on the status of this court case. Additionally, Canada asked whether Brazil had the intention of notifying any new and future developments.

3.209. The representative of Mexico reiterated concerns on the draft technical regulation[26], in particular, for the reasons outlined by Canada with respect to the translation into Portuguese and the non-use of INCI nomenclature. He then noted that in the last meeting, Brazil indicated that they would study the comments submitted by Members, including those from Mexico. He therefore requested Brazil to provide an update of the current status of their analysis and asked if Brazil was planning to use the INCI nomenclature or eliminate the requirement of translation into Portuguese.

3.210. The representative of the European Union referred to the information provided by Brazil during the last TBT Committee.[27] At that time, Brazil indicated that alternative measures were being explored regarding the mandatory indication of labelling requirements in Portuguese. For example, allowing the Portuguese language label on stickers, secondary packaging or leaflets. Therefore, the EU requested Brazil to provide an update with respect to the current state of play of these alternative measures.

3.211. The representative of Brazil reiterated her delegation's statement during the previous Committee meeting.[28] She noted that since that meeting there had been no further updates on this issue. Finally, she explained that 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.

3.2.3.28 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)

3.212. 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 and noted that her delegation had submitted comments on these notifications. She then explained that in the previous Committee meeting the EU conveyed to Saudi Arabia an invitation to share the scientific studies and the risk assessment with respect to the measure at issue.[29] The EU renewed this

[26] G/TBT/M/64/Rev.1, para. 2.39 and G/TBT/M/65, para. 2.216.
[27] G/TBT/M/65, paras. 2.220-2.221.
[28] G/TBT/M/65, paras. 2.220-2.221.
[29] G/TBT/M/65, para. 2.214.

invitation and encouraged Saudi Arabia to update the Committee on the current status of these measures. Finally, the EU requested Saudi Arabia to provide a written reply to their latest submission.

3.213. The representative of Switzerland reiterated concerns with regard to the measure at issue. He then thanked the Kingdom of Saudi Arabia for notifying the measure and for the good bilateral discussions. Switzerland recalled that the measure contained several restrictions on sales, advertisement and marketing, as well as product labelling in the form of a mandatory statement. Switzerland was of the view that although the measure had entered into force, the GSO could still review it. While Switzerland shared Saudi Arabia's public health objectives, it nonetheless reiterated that certain specific questions remained unanswered on why Saudi Arabia decided to go beyond relevant Codex standards on nutrition and why it also decided to ignore standards on claims that requested a sufficient body of scientific evidence providing truthful and non-misleading information. In addition, Switzerland asked Saudi Arabia to reflect on the question of whether negative warnings linked to social groups, such as "youth", "athletes" or to use "during exercise", were really necessary. Switzerland asked Saudi Arabia to explain the expected impact from such unique measure and whether alternatives were considered.

3.214. The representative of the Kingdom Saudi Arabia stated that the measure was not designed to prevent or limit the importation of energy drinks, but rather to control the consumption of such products in a manner that ensured the protection of human health. It was a known fact that Gulf countries were leaders in the prevalence of health diseases, such as high blood pressure and diabetes. The main ingredients of energy drinks were caffeine, taurine and inositol. The labelling requirements were meant to inform the consumer in a clear and transparent manner about the ingredients so as to enable them to make informed decisions regarding the consumption of such products. Saudi Arabia stressed that the entry into force of the measure was delayed more than once in response to the concerns of WTO Members. Finally, he informed the Committee that the GSO Technical Committee would continue working on revising the Gulf energy drinks technical regulation and the GCC Members would notify the Committee on this issue as it unfolds.

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

3.215. The representative of Mexico reiterated the concerns outlined by his delegation in document G/TBT/W/409. He reported that consultations with various stakeholders had revealed that there were still some pending processes with regard to these technical regulations. Mexico expressed particular concern with regard to how conformity assessment procedures were being carried out. Certificates were requested per batch or per type, and he questioned if this was compatible with Article 5.1 of the TBT Agreement. Finally, he asked Ecuador to explain how it had taken into consideration the comments made by Mexico at the last Committee meeting.

3.216. The representative of Ecuador underscored that the objective of the measure was to promote energy efficiency and environmental protection. The Government of Ecuador had issued Resolution No. 111, among others, to ensure that relevant products on the Ecuadorian market were highly energy efficient. These measures involved a combination of regulations and a labelling system, with the intention to provide information enabling consumers to reduce energy consumption and increase energy efficiency. In line with the scope of application, in particular Resolution No. 111, which covered clothes driers, products would have to comply with the requirements on energy efficiency. She noted that Ecuador was currently implementing an energy efficiency policy related to this matter. She reiterated that electrical products would need to comply with the requirements as established by the national authority, which required that the products be labelled in terms of class of energy efficiency performance. In response to the concerns expressed by Members, Ecuador explained that it had already made amendments to the technical regulations to facilitate compliance with the requirements.

3.2.3.30 Ecuador – Certification of Ceramic Tiles II, G/TBT/N/ECU/31 G/TBT/N/ECU/31/Add.4, G/TBT/N/ECU/31/Add.5, G/TBT/N/ECU/31/Add.6, G/TBT/N/ECU/31/Add.7 (IMS ID 419)

3.217. The representative of Brazil reiterated his delegation's previous concerns with the Ecuadorian technical regulation on ceramic tiles, as recently modified. In general, he said the measure did not seem to be in compliance with Articles 2.2, 2.5, 2.7 and 6.1 of the TBT Agreement. He noted that the Ecuadorian technical regulation had led to significant reduction of Brazilian exports in 2013, and to a complete disruption of exports in 2014 and the first half of 2015. At the same time, Ecuador continued to import ceramic tiles from other trading partners. Brazil also expressed concern with what it considered to be very burdensome procedures for obtaining product certification. An example of such procedures was the requirement to have a marking engraved on the back of each tile, instead of being signalled on the carton, as was the usual industry practice. Regarding the information that can be placed on the carton, stickers were not allowed, which imposed further difficulties. Another new requirement that Brazil also considered problematic was the need to perform tests for each shipment, instead of testing products according to their types. He said that, according to industry, the cost of sampling and lab testing as well as inspection and the issuance of certificate of conformity, now fell on each shipment. Moreover, warehousing costs had also risen since the process now took four months as opposed to just 45 days.

3.218. The Brazilian representative also reported that exporters continued to encounter problems due to the lack of accredited laboratories as the only accredited lab available for Brazilian exporters was not able to cater to the demand. Tests were made in third countries, since this laboratory maintained only commercial facilities in Brazil. Moreover, Ecuador did not accept manufactures' declaration of conformity, nor Brazilian third party certification. The fact that other countries were able to export to Ecuador raised additional concerns on possible discriminatory aspects of this measures. Brazil reiterated the request that Ecuador accept certificates of conformity issued by certification bodies accredited by the Brazilian Institute of Metrology (INMETRO).

3.219. The representative of Ecuador informed that Technical Regulation RTE INEN 033 entered into force on 7 October 2008 as a binding requirement for ceramic tiles of domestic or imported origin marketed in Ecuador. She stressed that Ecuador had taken into consideration comments from Members – in particular the concern expressed by Brazil – and had modified the regulation with regard to labelling and conformity assessment procedures. She noted, in this respect, the fact that Ecuador already counted with the services of various accreditation bodies, such as SAE ("Servicio de Acreditación Ecuatoriano"), AENOR ECUADOR ("Asociación Española de Normalización y Certificación en Ecuador), and Intertek. She said that the Ecuadorian authorities were currently working with national and foreign producers to review the technical regulation, and that a new amendment was expected to be finalized in the next semester.

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

3.220. The representative of China reiterated previous concerns about the refusal of Common Criteria (CC) evaluation and the validation bodies of EU member states to accept and process applications of Chinese producers for CC certification, and the lack of opportunities for Chinese companies to join CC-related standardization organizations, such as JIL Hardware Attack Subgroup. China had repeatedly asked the EU to provide additional CC-related information, and to take a constructive approach to address the concerns of the Chinese Industry. Her delegation was disappointed that so far no meaningful information had been provided by the EU. Rather, the EU delegation had responded by simply claiming that CC certification did not fall within the scope of the TBT Agreement. With regard of the coverage of the TBT Agreement, China believed that depending on the nature of CC validation bodies of the EU member states, either Article 5 of the Agreement (on assessment of conformity by central government bodies), or Article 8 (on assessment of conformity by non-governmental bodies), was applicable. In the case of central governmental bodies, she said those articles apply. The obligations imposed on Members under the TBT Agreement in this regard include, amongst others, national treatment, avoidance of unnecessary obstacles to international trade, prompt acceptance of applications, expeditious undertaking and completion of conformity assessment procedures, publication of the standard

processing period of each conformity assessment procedure, or communication of the anticipated processing period.

3.221. The representative of the European Union recalled his delegation's previous statement that neither the EU, nor its member states, had put in place mandatory cryptographic standards or conformity assessment procedures on commercial encryption products as a condition for their access to the EU market. He therefore failed to see the relevance of China's concerns under the TBT Agreement. The EU reiterated its willingness to further discuss these issues bilaterally, where there should be reciprocal willingness by the Chinese side to discuss EU concerns about a different matter in China. He stated that in China there was a regulatory framework that mandated certification as a condition to access the market, which formally discriminated against foreign companies, and against foreign technology vis-à-vis domestic technology. The representative stressed the absence of a level playing field between the EU and China. He said that in the EU Chinese companies had already received certificates, one of them up to security level 4+, which demonstrated that there were opportunities for Chinese companies to receive certificates from European certification bodies approved under the CCRA.

3.222. With respect to China's argument regarding the scope of the provisions of the TBT Agreement in the field of conformity assessment, he replied that solely because a conformity assessment body may be owned by the state, this did not mean, *ipso facto*, that even the activities of this conformity assessment body that were *not* related to a technical regulation providing for mandatory third-party conformity assessment or the enforcement of a technical regulation were covered by the TBT Agreement. As mentioned by the EU at the last Committee meeting, Article 5 of the Agreement began with a chapeau stating that "Members shall ensure that, in cases where a positive assurance of conformity with technical regulations or standards is required, their central government bodies apply the following provisions to products originating in the territories of other Members" the obligations provided therein. As regards non-governmental bodies, similar reasoning would apply. In this latter respect, he noted that the definition of a "non-governmental body" in Annex 1.8 to the TBT Agreement referred to a "[b]ody other than a central government body or a local government body, including a non-governmental body which has legal power to enforce a technical regulation." He said that none of these situations could therefore be qualified to exist at the moment in the EU so as to bring the matter raised by China under the ambit of the TBT Agreement. Finally, regarding information about testing organisations recognised under the CCRA, he drew China's attention to the information already available on the CCRA website.

3.223. The representative of China clarified that Chinese enterprises had achieved a high level of CC certificates in Norway, but Norway was not an EU member state. Therefore, China maintained its concerns about the fact that no Chinese enterprises had achieved a high level CC certificate in any EU member state.

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

3.224. The representative of China expressed continued concern 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. Regarding the existing limit values, China still questioned the scientific evidence on which the EU based the limit values for chromium VI in three types of toy materials, which he noted were more stringent than those for drinking water, as specified in the *WHO Guidelines for Drinking-Water Quality*[30], or those for foodstuffs as prescribed in Members' national standards. With regard to the proposed limit values, China thanked the EU for the update provided in a bilateral meeting.

3.225. The representative of the European Union reported that there were no new developments on this matter. With regard to the current limits for chromium VI, he stated that they were based on science and that there was evidence that these limits were technologically feasible, achievable by industry, and detectable according to available testing methodologies. As reported at the last Committee meeting, the European Commission had requested an opinion from the EU's *Scientific Committee on Health and Environmental Risks* (SCHER)[31], and the final opinion on toxicologically

[30] http://www.who.int/water_sanitation_health/dwq/guidelines/en/.
[31] http://ec.europa.eu/health/scientific_committees/environmental_risks/index_en.htm.

safe limits for chromium VI was issued on 10 February 2015. As part of its risk management tasks, the European Commission would consider whether the current migration limits for chromium VI would need to be revised, taking into account the final opinion of SCHER. He reiterated that this evaluation would certainly take account of available technology in the industry and available testing methodology for detection of chromium VI in toys. If the European Commission did decide to make a proposal for a revision of the current limits, any such proposal would be subject to an extensive stakeholder consultation, impact assessment and would be duly notified in accordance with TBT Agreement. However, he said that at this time there were no plans to proceed with such a proposal.

3.2.3.33 China - Administrative Measures on Cosmetic Labelling (AMCL), G/TBT/N/CHN/1064 (IMS ID 456)

3.226. The representative of Canada expressed appreciation for China's assurances that they would consider public comments when drafting the final version of the Administrative Measures on Cosmetic Labelling. Canada welcomed any opportunity for foreign governments and industries to comment on proposed legislation. In the spirit of public consultation, Canada reiterated concerns related to China's draft labelling requirements for cosmetic products, and the registration and approval framework for cosmetics and their ingredients. Canada believed that, in its current form, the proposed new requirements for China-specific primary and secondary original packaging would significantly disrupt production lines and schedules, increase costs for foreign manufacturers and create confusion among consumers who were accustomed to global branding. Denying the use of over-labelling would be a departure from global norms and Canada expected this regulation to cause significant delays in time-to-market (TTM) for new products. He also asked China to confirm whether it was planning to allow "over-labelling stickers" for imported products if they contained all languages included on the original packaging. Canada was also concerned with the new "information and claim verification requirements" that would compel companies to use third-party facilities in China in order to verify the efficacy of claims, which would undermine the efforts of the China Food and Drug Administration (CFDA) to have manufacturers take additional responsibility for themselves and self-regulate their products in China. Canada hoped that China would either permit efficacy testing by third-party labs outside of China, or would allow in-house company testing, as long as those labs were able to conform to CFDA criteria and guidance.

3.227. Canada also requested that China allow a longer implementation period. Canadian manufacturers had expressed their inability to comply with these new requirements within a six month period, since significant adjustments to package design and production lines would be required. Canada supported Korea's request, as expressed in the last TBT Committee meeting[32], of having a two-year transition period in order to allow foreign companies to acquaint themselves with the new regulations. He highlighted the importance of ensuring that products already approved for sale be able to remain on the market until their expiration date in order to minimize any further disruption or lost sales. Canada was also concerned about the stated requirement of including on the label the name of all sub-contractors used in the manufacturing process. He requested that China elaborate on how this information would enhance consumer safety. He stressed his delegation's hope that, as China continued to review its draft regulation, that it would make the proper adjustments to ensure that there was a level-playing field for foreign and Chinese cosmetic manufacturers consistent with China's MFN obligations, including in particular its obligations under the TBT Agreement, taking into account widely accepted international practices in this sector.

3.228. The Canadian representative expressed appreciation for China's introduction of the "Adjustment of cosmetic ingredient registration management" on 1 April 2014, in order to expedite the approval process of new cosmetic material. However, Canada continued to be concerned with CFDA's burdensome approval and registration process for cosmetics and their ingredients. Canada understood that the "positive list" being developed by China was more of a guideline of ingredients currently used in China, acting as a benchmark for future ingredient approvals. Canada hoped that China would continue to improve upon their new ingredient approval process so that Chinese consumers would be able to access the safest and most innovative products on the market. By way of example, he mentioned that of the 20,000 cosmetic ingredients listed in INCI, only 8,783 were included China's approved ingredient list. Canada hoped that with the introduction of a

[32] G/TBT/M/65, para. 2.10.

streamlined approval process, the number of approved ingredients would approach the 20,000 benchmark.

3.229. Canada was further concerned that domestic cosmetic manufacturers were able to register "new ingredients" without an additional application process. If so, China would be providing preferential treatment to domestic producers, thereby contravening their obligations under Article 2.1 of the TBT Agreement. He asked China to confirm that all cosmetic manufacturers were treated equally with respect to product registration and approval. He said that streamlining the approval process 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.

3.230. Finally, Canada expressed concern with, and hoped that changes would be made concerning, China's requirement for animal testing for the safety of cosmetic products, even when alternative testing was available and acceptable by most other regulators. Examples of tests where suitable alternatives to animal testing existed and have been proven efficacious include tests on "skin irritation", "photo-toxicity", and "skin corrosion".

3.231. The representative of Japan said that, if the proposed new draft "Administrative Measures on Cosmetics Labelling" were implemented, the global cosmetics industry in the Chinese market, including Japanese firms, could suffer an immense economic blow, and China's domestic consumers could also suffer visible disadvantages. She outlined the four main reasons why Japan believed these negative effects would occur. First, she noted that Article 7 of the draft measures stipulated that "cosmetic labels shall ensure complete and clear contents and shall be free of missing characters or unstable adhesion, and shall not be modified or supplemented by sticking, cutting, altering, etc." It was not clear to Japan however if this provision would nonetheless permit the continued use of sticker labels in the Chinese market, as currently permitted. She explained that the use of stickers as labels for cosmetics in accordance with the laws of each country was generally accepted. China explained that a purpose of the prohibition on the use of all sticker labels was to prevent illicit companies from re-labelling products with stickers. However, Japan considered that allowing the use of certain kinds of sticker labels would fulfil China's objective, i.e. those stickers that were difficult to remove and rarely peel off. If sticker labels were totally prohibited and only printed labels were permitted, this, in her view, could make these draft measures more trade-restrictive than necessary for the attainment of its objective. For the forgoing reasons, Japan was of the view that the continued acceptance of the use of sticker labels should be clearly stipulated.

3.232. Second, regarding manufacturer labelling, she noted that Articles 14 and 15 of the draft measures required labelling of not only the name and address of the company legally responsible for the concerned cosmetics' quality and safety, but also the names and addresses of manufacturing subcontractors. However, given that the purpose of labelling the name and address of the manufacturer was to explicitly show consumers and regulatory authorities the locus of the final legal responsibility for product quality and safety, Japan was concerned that labelling the names of all manufacturing subcontractors might conversely lead to consumer misunderstanding and market confusion. Japan was therefore of the view that the manufacturer labelling should only present the name and address of the responsible company and for imported goods, a company inside China with final legal responsibility for the quality and safety of the concerned cosmetics.

3.233. Third, regarding promotional advertising of cosmetics efficacy claims, the Japanese representative noted that according to Article 19 and 20 of the draft measures, and considering the importance of cosmetics efficacy claims as a business practice, cosmetics efficacy claims must be tested by an "efficacy assessment testing organization" with the testing results disclosed on a designated website. However, "cosmetics efficacy" and its assessment methods included know-how gained through many years by companies, which led to concerns that disclosing results without limitation would reduce corporate motivation for research and development and would ultimately obstruct fair competition. For these reasons, Japan was of the view that test results should not be disclosed. In addition, she stated that all institutions - not only the ones in China but also those located outside its territory -, that would meet the requirements of an "efficacy assessment testing organizations" should be recognized as such.

3.234. Finally, she said that in order to enhance understanding and ensure the appropriate application of the draft measures, clear guidance in addition to the draft measures was

indispensable. Furthermore, given that the new labelling under this proposed scheme would require significant changes to existing labelling processes, the implementation date of 1 July 2015 stipulated in Article 34 of the draft measures was completely unfeasible. Without a sufficient grace period, she said, the supply of products to the Chinese market would become very difficult. It could also cause harmful environmental effects from the disposal of a large volume of stock. Given these considerations, she stressed that a sufficient implementation plan with, for example, a two-year transition period, would be essential for the smooth implementation of the new labelling regulation.

3.235. The representative of the European Union reiterated concerns from the March 2015 TBT Committee meeting, and also those sent to the Chinese authorities on 12 January 2015. The EU noted in its written reply of 18 March 2015, China indicated that it would consider the comments received. However, it did not provide any reply on the specific issues raised by the EU. In general, the EU again highlighted that the notified draft introduced significant changes to the current requirements on the labelling of cosmetic products in China, which would essentially oblige economic operators to produce specific packaging for the Chinese market. Additionally, 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 Chinese authorities to consider granting a transition period of at least 24 months. The EU also invited the Chinese authorities, and especially the CFDA, to publish practical guidance early during the transition period in order to ensure harmonised understanding and smooth application of the new measures.

3.236. He said that since the March 2015 meeting, the EU had received information that the labelling of cosmetic products by means of stickers would be accepted in China. He requested that China confirm this information, and provide further information on requirements relating to the stickers, such as their language or their required place on the product or packaging. He also explained that the notified draft required products to display the name and address of the manufacturer and of subcontractors, when part of the production was completed 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, the EU considered that additional labelling of the name and address of manufacturing subcontractors was not necessary and might be confusing for the consumer. The EU therefore invited the Chinese authorities 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.

3.237. Furthermore, the EU requested confirmation that the 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. The EU believed that 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. He stated that 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. The EU was of the view that the detailed efficacy information should be accessible only to official control authorities, who have appropriate training and expertise to assess scientific study reports and the compliance of cosmetic claims with legal requirements. The EU therefore invited the Chinese authorities to clarify that efficacy assessment reports issued by foreign verifying organisations would be accepted by the Chinese authorities, and to remove the obligation to publish the detailed efficacy reports on a publicly accessible website.

3.238. The representative of the Republic of Korea noted that his delegation was aware that China was considering the elimination of the ban on "over-labelling" in the regulations. Korea expressed appreciation for China's continuing efforts to accommodate Members' concerns. He stressed that "over-labelling" was a key practice in the export and import procedure of cosmetic products. Korea remained nonetheless concerned with the efficacy assessment and cosmetic claim verification as outlined in the regulation. Under Article 19 and 20 of the administrative measures for cosmetic labelling, notified to the TBT Committee on December 2014, all efficacy claims on labelling were required to be verified by a testing organization designated by Chinese authorities. Korea was of the view that this requirement would only increase unnecessary burdens and expenses to

exporting companies without any added value. Korea also acknowledged that information on labels must be valid. However, for basic efficacies, such as moisturizing and cosmetic astringent, which had been broadly tested and widely admitted, Korea did not see the need to require individual test to prove efficacy. Therefore, Korea requested that China reduce and clarify the scope of cosmetic efficacy claims that were required to be proven. Korea also requested that China allow manufacturers to self-verify the efficacy of the products, instead of requiring third-party verification. Finally, Korea requested China to provide at least a 24-month transitional period, so that companies would be able to adapt themselves to this regulation.

3.239. The representative of China explained that 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" (notified in G/TBT/N/CHN/937) to solicit public opinion. However, this regulation had never gone into effect and was now replaced by the "Administrative Measures on Cosmetic Label" ("AMCL"). In November 2014, AMCL was made available online so as to solicit public comments and the CFDA had subsequently received feedback from domestic as well as foreign cosmetic enterprises and industry associations. China pledged to accept constructive opinions and to comply with international practice. She also clarified that, once finalized, this measure would allow "over-labelling" on imported cosmetic products.

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

3.240. The representative of Japan reiterated his delegations previous concerns and noted that on 13 April 2015 China notified banks in China of its intention to review the "Guideline for promoting the Application of Secure and controllable Information Technology in Banking Sector 2014-2015". He requested China to: (i) provide for sufficient exchange of views with stakeholders; (ii) revise the Guideline in accordance with international common standards; (iii) ensure transparency; and (iv) provide a review schedule with reference to the aforementioned points. He asked whether China had notified foreign financial institutions, and if not, what would be the concrete manner of notification.

3.241. The representative of the United States referred to the Chinese notification dated 13 April 2015 that suspended the banking rules on which the US had issued a statement in the previous TBT Committee. She requested that China notify any subsequent revisions of the banking rules to the Committee, and conduct a transparent process allowing meaningful opportunity for comments and inquiries by all interested stakeholders.

3.242. The representative of Australia said that his country was monitoring the progress of this issue as its industry and businesses were interested in any potential regulations that may impact their ability to operate in the Chinese market. He thanked China for suspending the regulations during a period of continued public, business and industry stakeholder consultation. He requested to be kept abreast of developments and the status of the regulation, including on a bilateral level.

3.243. The representative of the European Union welcomed the suspension of the regulation and invited China to conduct the review process in a transparent and inclusive manner. He said that, under the TBT Agreement, any further revisions had to be notified in order to provide WTO Members, and their affected stakeholders, with an opportunity to comment. The EU remained available for bilateral engagements with China on this issue.

3.244. The representative of China updated the Committee on three aspects saying that: (i) the regulation was suspended and was under revision; (ii) China did not require a full reveal of source code, but only to keep a file of it. China would improve the rules and ensure that the legitimate interests of domestic and foreign enterprises be protected; and (iii) given that China attached great importance to the protection of intellectual property rights, China only required enterprises to prove a legitimate source of software intellectual property.

3.2.3.35 Indonesia - Regulation of the Minister of Agriculture No. 139/Permentan/PD.4, 10 December 2014, concerning Importation of Carcass, Meat and/or Processed Meat Products into the Territory of the Republic of Indonesia, and Regulation of the Minister of Agriculture No. 02/Permentan/PD.4, 10 January 2015, concerning the Amendment of the Regulation of the Minister for Agriculture No. 139/Permentan/PD.4, 10 December 2014, G/TBT/N/IDN/98 (IMS ID 461)

3.245. The representative of Canada thanked Indonesia for its written response regarding the proposed measures for the importation of meat products. Canada remained concerned with the broad product coverage of the regulations and the lack of clarity surrounding its intended objectives. He 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. The proposed measures could further be unduly trade restrictive and inconsistent with the national treatment obligations of the TBT Agreement and the GATT. He urged Indonesia to provide clarity regarding its proposed measure, specifically with regards to how those measures fell within the scope of the TBT Agreement and, if they do, how those measures were consistent with Indonesia's national treatment obligations. He also urged Indonesia to continue to provide sufficient scope for comment before bringing those proposed regulations into force.

3.246. The representative of Australia said that his delegation was still concerned that the regulations allowed only State Owned Enterprises (SOEs) to import secondary beef cuts and that those imports could only be undertaken in limited circumstances. He asked how Indonesia considered this restriction to be consistent with Indonesia's WTO obligations. He expressed his ongoing concern that additional packing, labelling and purpose of use requirements were being imposed on imported meat products and not on domestic products. He asked Indonesia to confirm this understanding and to clarify the purpose of the regulations in relation to these measures. He also noted that Indonesia had raised concerns about the safety of offal imports. Australian offal was produced for human consumption and was regulated under the same food health standards and legislation as meat for human consumption. Australian beef and offal had a reputation for quality, safety and reliability around the world. He added that food safety was, however, an SPS issue.

3.247. The representative of Indonesia stated that the Indonesian Ministry of Agriculture Regulation 139/2014 was not aimed at limiting imports or disturbing trade relations but rather to protect Indonesian consumers' health from risks that arose from diseases carried by offal that contained residual hormones. Both Regulations also contained halal provisions under which only establishments that produced Halal-products alone, and operated under the halal system, were eligible to export meet to Indonesia. The butcher that had done the actual slaughtering was required to be a Muslim and was only eligible if he fulfilled all the requirements stipulated by the Government. Further, Indonesia's requirements for manual slaughtering in poultry were consistent with the Codex Alimentarius Commission's CAC-GL 24-1997. Additionally, the requirement regarding transportation in the same container, contained in Article 21, was not excessive and had to be respected. This measure was aimed at separating halal products from non-halal products to preserve its pureness in observance of the Islamic Sharia on handling of halal products. Container was defined as "a place that had specific technical requirements for storing and distributing carcasses, meat and/or processed meat products." Indonesia said that the aforementioned requirements applied non-discriminatorily to locally produced carcasses, meat and processed products. They were also highly essential to implement the "Halal Assurance System" within Indonesia's territory. Indonesia was also of the view that directing STEs to import secondary cuts was not inconsistent with Indonesia's WTO obligations and that the regulation would not lead to price increases as it was intended to address price fluctuations.

3.2.3.36 Canada - Tobacco Reduction (Flavoured Tobacco Products) Amendment Act, 2013 – Bill 206 (IMS ID 463)

3.248. The representative of Indonesia reiterated concerns with regard to the amendment which would prohibit the use, distribution and sale of "flavoured tobacco products". In particular, he stressed his delegation's concern with respect to the exception for menthol cigarettes. Indonesia acknowledged Canada's right to pursue public health objectives. However, Indonesia was also of the view that this policy should be prepared in such a manner so as not to infringe Canada's WTO obligations. Indonesia noted that 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. Finally, Indonesia urged Canada to postpone the implementation of the regulation.

3.249. The representative of Canada thanked Indonesia for the bilateral discussions and said that his delegation would discuss these issues with their provincial counterparts. He then noted that Alberta had recently announced that the sale of menthol-flavoured tobacco products would also be prohibited on 30 September 2015. He stated that Canada was committed to deal with youth smoking issues and that this legislation would be notified following internal consultations.

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

3.250. The representative of Mexico reiterated his delegation's concerns as contained in document G/TBT/W/405. He then asked Ecuador whether the technical regulation had undergone changes to facilitate its compliance as Mexico's private sector remained concerned with fulfilment of this measure.

3.251. The representative of Ecuador explained that this 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. This technical regulation was notified under the TBT Agreement and entered into force on the 11 April 2015. 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.

3.2.3.38 Russian Federation – Technical regulations on safety of railway transport (TR CU No. 001/2011, No. 002/2011 and No. 003/2011) (IMS ID 460)

3.252. The representative of Ukraine reiterated concerns with regard to the technical regulations, in particular, the negative effects on trade for Ukrainian railway transport products. She then noted that Ukrainian producers effectively applied quality management systems according to the requirements of ISO 9001:2008. Ukrainian products met the requirements of the Russian standard, had valid certificates of compliance issued by Ukrainian Certification Body, conformed by the certificates of conformity with Technical Regulations of the Customs Union issued by the authorized Certification Bodies of Belarus and included in Russia's Register of Certification of the Federal Railway Transport. Regardless of the reasoned concerns, Russia refused to recognize the certificates issued by Ukrainian and Belarus authorities. She insisted on the position that the measure was inconsistent with Articles 2.1, 2.2 and 5.1 of the TBT Agreement and called upon Russia to immediately lift this trade ban. Finally, Ukraine requested Russia to take into account the above concerns in good faith and with a view of ensuring compliance of the Customs Unions technical regulations by addressing objectives of safety in a less trade-restrictive manner and in accordance with the provisions and principles of the TBT Agreement.

3.253. The representative of the Russian Federation thanked Ukraine for their interest in the technical regulation. He noted that these measures 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. He stressed that 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 of compliance with mandatory requirements was also allowed until 1 August 2016. In fact, Russia and the EAEU had provided a five-year period between the adoption and entry into force of the technical regulations so as 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. He noted

that the decision of the adoption of the technical regulations contained a list of the standards which ensured compliance with the technical regulation. Finally, he explained that 90% of standards in this list were GOSTs, interstate standards applied throughout the Commonwealth of Independent States, in particular in Ukraine and the Russia.

4 EXCHANGE OF EXPERIENCES

4.1 Seventh Triennial Review

4.1. The Chairperson reported on the 16 June 2015 Thematic Session held on the Seventh Triennial Review. Her full report, provided on her own responsibility as Chairperson, is contained in document JOB/TBT/134.

4.2. In response to some questions about clarification on dates, the Secretariat explained that the deadline for submissions on the Seventh Triennial Review had been 1 June 2015 – this was a date that Members had agreed in the preparatory process. The 10 July 2015 date mentioned by the Chairperson was an encouragement for Members to submit any further comments on other Members' proposals, or revisions to their own proposals, by that date. This would facilitate the preparation of the first draft of the triennial review report by the Secretariat.

4.2 Status of Work on GRP (JOB/TBT/119/Rev.1)

4.3. The former chairman of the TBT Committee, Mr. Filipe Ramalheira (Portugal), in his capacity as Friend of the Chair, updated the Committee on the status of work on GRP. His report is contained in document G/TBT/GEN/181.

4.4. The representative of Brazil reported that during the consultations, Brazil had understood that Members' concerns were not limited to the issue of disclaimers but also other issues under consideration in the SPS Committee. Therefore, during the Chairperson's consultations, Brazil had presented considerations on the potential systemic implications of the matter.

4.5. The representative of India thanked the Friend of the Chair for his tireless effort in bringing consensus in the matter. He said that India was ready to engage in the SPS Committee for exploring the possibility of resolving the issue horizontally, without prejudice to India's present position in the TBT Committee.

4.6. The representative of China welcomed the new ideas from Brazil to consider, in parallel, the pending issues in the SPS Committee. China was of the view that a horizontal approach – i.e. one undertaken across both Committees on comparable issues – including with respect to the text and the disclaimer, would provide not only consistency and balance, but also an opportunity for Members to demonstrate and restore confidence in the multilateral trading system.

4.3 TBT@20 Anniversary Event on 6 November 2015

4.7. The Secretariat updated the Committee on the state of play of the TBT@20 event. In marking the 20th anniversary of the WTO, the Secretariat had been organising a series of events since the beginning of the year. The last Committee meeting of the year (in early November 2015) presented an opportunity to organize such an event with the participation of capital-based TBT experts. The purpose, as had been previously reported, would be to take stock and reflect on the work of the Committee over the last twenty years. Like other Secretariat "@20 events", the intention was that the TBT@20 would be open to the general public and be organized as a side event to the November TBT Committee meeting. The programme of this event was being developed and would be shared with Members in due course. The Secretariat was open to ideas from delegations on the content of this programme. In this respect, one idea that had been considered was to hear views from the original negotiators of the TBT Agreement. The TBT@20 event will be held in the morning of 4 November 2015 at the WTO.

5 TECHNICAL COOPERATION ACTIVITIES

5.1. The representative of Malaysia referred to a national WTO Workshop on TBT Agreement that had been held from 27-28 May 2015 in Putrajaya, Malaysia, and expressed gratitude for the

assistance rendered to Malaysia. He reported that the workshop had received an overwhelming response from Malaysian authorities and that the Malaysian Government had found the workshop beneficial to its authorities as it had provided practical guidelines on the implementation of the TBT Agreement. In addition, the participants had been updated on current issues being discussed in the Committee.

5.2. The representative of Mexico thanked the Secretariat for a national workshop on the TBT and SPS Agreements that had been held in Mexico form the 28-30 April 2015.

5.3. The Chairperson invited Members to take note of the document containing information on TBT-related technical assistance activities undertaken or planned by the WTO Secretariat for the 2015/2016 biennial.[33] She drew delegations' attention to the unusually high demand for TBT-related technical assistance: the WTO Annual Report on Technical Assistance and Training[34] showed that more TBT-related technical assistance requests had been received and delivered in 2014 than in any other year since 1995. When combined, requests for TBT and SPS technical assistance activities corresponded to 25% of all requests made in all WTO areas in 2014.

5.4. A number of observers reported on their technical assistance related activities. The representative of ISO reported that ISO was currently working on a new programme to help developing country members to engage in ISO activities.[35] The representative of IEC reported that a conformity assessment regional seminar had been held in Singapore in June 2015 with the participation of seven IEC members. She reiterated IEC's willingness to provide WTO Members with assistance related to conformity assessment activities. Specifically on metrology, the representative of BIPM noted that BIPM had its own capacity building and knowledge transfer programme that was aimed at helping states with emerging metrology systems; a workshop had been organised in Mozambique earlier in 2015 involving a wide number of countries. The representative of OIML reported that his organization was trying to improve its work in supporting countries and economies with emerging meteorology systems. He said that in May 2015, in association with the General Administration of Quality Supervision, Inspection and Quarantine of China (AQSIQ), they had organised a seminar on legal metrology. 80 participants from 15 countries had attended this seminar, in which key problem areas were identified and action plans developed to address them. A follow-up event was planned to be held in October 2015.

6 UPDATING BY OBSERVERS

6.1. The representative of the OECD presented two recent submissions[36] to the TBT Committee She said that in March 2012, the Council of the OECD had adopted a new, updated international instrument to address regulatory policy management. This was a "whole-of-government" activity that needed to be addressed by sectoral ministries, regulatory and competition agencies: the recommendation on regulatory policy and governance. It addressed: consultation and citizen engagement; regulatory impact assessment (RIAs); export evaluation; multilevel coherence; risk and regulation; institutional responsibility for policy coherence; and oversight by, and the role in general of, regulatory agencies through the twelve principles. It was further reported that in October 2015, the OECD would launch the "regulatory policy outlook", the first evidence-based analysis of the progress made by OECD countries to improve the way they regulate using the 2012 recommendation as a benchmark.[37] This new policy outlook would assess the progress of countries in establishing the conditions for good regulation, reviewed stakeholder engagement and export evaluation and developed suggestions and recommendations to use in a more strategic manner to inform the development and delivery of regulations. The OECD Regulatory Policy Committee would work towards unbundling the components of the 2012 recommendation in order to develop more operational guidance on its implementation.

6.2. It was also reported that the OECD had undertaken work on the theme of international regulatory cooperation. The 2012 recommendation contained one principle that invited governments that developed regulatory measures to give consideration to all relevant international standards and frameworks for cooperation in the same field. International regulatory cooperation

[33] G/TBT/GEN/171/Rev.3.
[34] WT/COMTD/W/209, circulated on 27 May 2015.
[35] http://www.iso.org/iso/home/about/iso-and-developing-countries.htm.
[36] G/TBT/GEN/179 and G/TBT/GEN/180.
[37] http://www.oecd.org/gov/regulatory-policy/2012-recommendation.htm.

systems were not well understood and, consequently, the Regulatory Policy Committee of the OECD was collecting evidence on the practices of regulators and their oversight bodies to implement regulatory international cooperation. She said that the aim was to understand the benefits and costs of a selected number of international regulatory mechanisms and that part of this work was to look at mutual recognition agreements, the role of international organisations (including the WTO and ISO), as well as the role of good regulatory practices in various contexts. She said that the Trade and Agriculture Committee of the OECD was also undertaking work on international regulatory cooperation with particular emphasis to the trade aspect. The objective was to enhance the understanding of international regulatory cooperation as a mechanism to reduce or avoid unnecessary barriers to trade and increase trade opportunities. The final goal was to develop a practical tool with which policy makers could diagnose situations of policy regulatory divergence and identify the most appropriate international cooperation mechanisms.

6.3. The representative of BIPM recalled that as an intergovernmental organization, member states act together on matters related to measurement science and measurement standards. The main actors are the national metrology institutes and laboratories worldwide. This is an area where interest was growing. In this respect, he informed that the Republic of Azerbaijan had recently joined BIPM as an Associate State. On the other hand, BIPM membership had lost the Dominican Republic (as a Member State) and Sri Lanka (as an Associate State) due to repeated failures to pay their dues. In total, the number of countries participating as BIPM members and associates was around a hundred. He also welcomed the US paper on quality infrastructure that had been presented at the June 2015 thematic session and noted that the BIPM's role was to underpin the proposal with the scientific elements ensuring measurements worldwide were appropriate and comparable. He said that the BIPM operated the CIPM Mutual Recognition Arrangement that provided mutual recognition at national laboratory level and also underpinned the mutual recognition of the 49,000 accredited laboratories under the ILAC umbrella. The BIPM had together with the OIML and many national metrology laboratories worldwide recently celebrated the World Metrology Day, a major promotional event for quality infrastructure.

6.4. The representative of the OIML noted that "World Metrology Day" (20 May) was an event that promoted the importance of metrology as a fundamental element of a national quality infrastructure. TBT delegations were encouraged to participate in the activities of next year's event, which would be on the theme of measurement in a dynamic world. Noting the importance of national quality infrastructure in the context of the TBT Agreement's Seventh Triennial Review, the representative of the OIML reminded Members of the importance of legal metrology as a significant conformity assessment activity in the regulatory framework of most countries.

6.5. The representatives of UNECE and IEC also reported on their activities.[38]

6.6. The Chairperson took note that a new request for observer status had been received from Intergovernmental Authority on Development (IGAD). She informed Members that a document containing all pending requests for observer status, together with the original requests and available background documentation, had been circulated in RD/TBT/1/Rev 1. She suggested that delegations review this document. In addition, the complete list of observers and requests for observer status had been revised and was contained in document G/TBT/GEN/2/Rev 8.

7 DATE OF NEXT MEETING

7.1. The regular meeting is scheduled for 4-6 November 2015, preceded by a thematic session to be held on 3 November 2015.[39] A TBT@20 event will be held in the morning of 4 November as a side event to the regular Committee meeting. Tentative dates for the meetings in 2016 are contained in JOB/TBT/127.

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[38] G/TBT/GEN/183 and G/TBT/GEN/182.
[39] JOB/TBT/106/Rev.1