



Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 9-10 MARCH 2016

CHAIRPERSON: MS ALANA LANZA

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1 ADOPTION OF THE AGENDA

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

2 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

2.1 Statements from Members under Article 15.2

2.1. The Chairperson reminded the Committee of Members' notification obligation under Article 15.2 of the TBT Agreement and further informed the Committee that the latest list of statements on implementation submitted under this provision were contained in document G/TBT/GEN/1/Rev.15, issued 29 February 2016. She informed the Committee that since the last meeting in November 2015, Kazakhstan had submitted its statement. She further informed the Committee that since 1995, 132 Members had submitted at least one statement of implementation. Information on the list of statements is available at <http://tbtime.wto.org>.

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

2.2. The representative of South Africa informed the Committee that his delegation would soon submit a revision to its Statement on Implementation and Administration of the TBT Agreement.²

2.2 Specific Trade Concerns (STCs)

2.2.1 Withdrawn concerns

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 The Chairperson reported that the following STCs had been withdrawn from the agenda at the request of the concerned Member:

- a. European Union - Directive 2014/40/EU of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the member States concerning the manufacture, presentation and sale of tobacco and related products
- b. Finland – Draft Government proposal to Parliament for a Tobacco Act and Acts amending certain related acts
- c. Colombia – Ministry of Health and Social Protection Resolution 3117 of 2015
- d. Kingdom of Bahrain, State of Kuwait, Kingdom of Saudi Arabia, Qatar - Motor Vehicles: General Requirements "No. GSO 42:2003"
- e. Brazil - Toys

2.2.2 New Concerns

2.2.2.1 China - Formula Registration Regulation for Infant and Follow-up Formula, G/TBT/N/CHN/1165

2.4. The representative of the Republic of Korea expressed concern about the above-mentioned measure, notified on 7 January 2016, whereby infant formula products manufactured in, distributed in, or imported to China must be registered at the China Food and Drug Administration (CFDA). Article 10 of the regulation stipulated that an applicant should submit data, including formula composition, whilst Article 19 made on-site inspection, sample testing and expert review compulsory. Further, according to Article 12, one company should not register more than 3 series of products and 9 product formula. Whilst fully understanding the need for strict controls of infant formula products, the Republic of Korea remained concerned about the requirement to register at CFDA, as well as the limitation on the number of infant products allowed to be registered. He pointed out that all Korean exporting companies had been audited by the Certification and Accreditation Administration of China (CNCA) during the 2014 on-site inspection and that information including formula compositions had been submitted to obtain registration of export facilities, product types and individual products. It was therefore considered that the new regulatory requirement of registration at the CFDA, including repeated submission of data and on-site inspection, constituted a duplicate regulation. Concerning the quantitative limitation on product registration, various kinds of products with different formulas could be manufactured depending on nutrients, percentage of active ingredients (milk or grain), animal species (cow or goat), product types (liquid or solid), fortified substances, use of organic substances, and others. International standard-setting bodies, such as Codex, also provided requirements for substances, but without limiting the number of brands and formulas. Korea considered that new measures introduced in the regulation might restrict Chinese customers' rights as well as their freedom to select and purchase safe and healthy products. Furthermore, the additional cost and time constraint of duplicate registration would be a considerable burden to exporting companies, constituting a barrier to the WTO principle of free trade.

2.5. Accordingly, the Korean Government requested that China accept the following: (i) to recognize Korean formula products and compositions previously assessed by and registered at the CNCA in 2014, once the CFDA's new regulation came into effect; (ii) to simplify the registration process for new infant and follow-up formula product compositions, to ensure that on-site

² This document was circulated on 6 April 2016 with the symbol G/TBT/2/Add.60/Rev.2.

inspection and expert review were not duplicated in the course of new facility registration at CNCA and formula composition registration at CFDA; and (iii) to allow registration of new formula products through scientific demonstration of ingredients and compositions without limitation on the number of brands or formula compositions, if obvious differences in ingredients were scientifically demonstrated.

2.6. The representative of the European Union associated himself with Korea's concerns, particularly on the limitation which would apply to each company setting a maximum of 9 recipes within 3 product lines, stressing the potentially serious negative impact on EU exports to China. The impact of such a limitation would be aggravated by the fact that the limitation would affect producers who would be deprived of the possibility of serving major brands of infant formula who currently rely on them as production partners for their products. Without modification of this article, the number of brands on the Chinese market would be reduced by an estimated 80%. The EU could see no justification to this limitation, neither on the basis of food safety nor on the basis of any other legitimate objective. The EU requested reconsideration of this limitation and flagged that written comments had been sent to China covering other serious concerns.

2.7. The representative of Japan shared the concerns of Korea and the EU. Japan understood that Article 12 of the measure limited the maximum number of products for which manufacturers, including foreign companies, could obtain registration to 3 brands per manufacturer and 3 products per brand, in other words, 9 products per manufacturer. It was Japan's understanding that the measure would be unnecessarily trade restrictive, as it would reduce manufacturers' sales opportunities. Japan accordingly asked China to eliminate the quantitative limitation on registration of products.

2.8. The representative of China committed to conveying all comments and concerns back to its capital, since the substantive issues raised by Members were brought to her delegation's attention at very short notice.

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

2.9. The representative of the European Union stated that in January 2016 the EU had provided detailed comments on India's draft alcoholic beverages regulation (notified in December 2015) establishing the requirements and definitions applicable to different types of alcoholic beverages (such as spirits, wines and beers), as well as labelling requirements. He outlined several concerns on the notified draft. It was considered that, if adopted in its current form, the draft regulation would create a number of unnecessary barriers to trade, particularly in consideration of its inconsistencies with current international practices, notably the oenological practices and definitions set by the International Organisation of Vine and Wine (OIV), as well as inconsistencies with Codex.

2.10. Regarding wines, Chapter 3 of the notified draft limited alcohol content in wine at not more than 15.5% by volume; as the OIV did not provide for maximum alcohol strength, India was therefore encouraged to remove such a limit. Further, the draft did not foresee the blending of red and white wine in the production of red wine, whereas the OIV allowed such practice. Sugar content set in the notified draft for "dry", "medium" and "sweet" wine was also not in line with the OIV standard. Concern was raised about the requirement that sparkling wines be subject to a second fermentation, and other types of requirements for speciality wines, as explained in its written comments. Regarding beers, he noted that a number of requirements in the notified draft would render exports of some EU beers to India impossible. The notified draft set a maximum level of 8% alcohol by volume whereas the maximum alcohol by volume level obtained with traditional brewing (i.e. without fortification) was in the range of 15-18%. The notified draft also limited the type of flavours that could be used in the production of beers. His delegation recommended that both natural and artificial flavours be allowed. The notified draft included "clarity" as a requirement for beers whereas for many others cloudiness was desirable. Regarding spirits, there was concern for the maximum alcohol content of 50% by volume for some distillates and for a number of definitions/requirements for products such as brandy, cognac, vodka, whisky and others, which were not in line with OIV standards and would render exports of these products to India impossible. He went on to note that a number of labelling provisions were not in line with the Codex standard for the labelling of pre-packaged foods (CODEX STAN 1-1985) such as India's requirement for the indication of an expiry date. Moreover, concern was raised on the "allergen

and health warnings" suggested in the draft and India was requested to amend and clarify such provisions. Further, he suggested that in the current notified draft India explicitly refer to an extensive list of additives allowed in the production of alcoholic beverages, including all those set by Codex and the OIV.

2.11. He concluded by asking the Indian authorities to take on board his delegation's comments before publishing the draft text, and recommended that a reasonable transition period be provided to implement any changes necessary to comply with the new provisions, whilst allowing the sale of products already present on the Indian market until exhaustion of stocks.

2.12. The representative of the United States, whilst supporting India's efforts to develop safe and effective standards for regulating alcoholic beverages, considered that there were a number of areas where India's proposed standards fell outside of widely accepted international standards, and may be more trade restrictive than necessary. Following up on the comments recently submitted by the US, the regulation set a number of compositional limits for which standards did not exist in Codex, for example, levels for many chemical contaminants in alcoholic beverages. Limits regarding pH, carbon dioxide, and sugar levels pertained to the quality of alcoholic beverages rather than safety. She asked whether India had considered her delegation's request to include a number of additives frequently used in winemaking in the list of permitted additives and whether it could provide a scientific justification for such limits. If India had relied on specific scientific studies in setting these limits, it was urged to share them with the US.

2.13. Her delegation was also concerned with the labelling requirements associated with the measure and asked India to clarify whether stickers would be allowed to be placed on alcoholic beverages at port before the items went through customs. She requested a response to other important concerns, including irregular serving size measurements, limits for alcohol by volume (abv) that would prohibit many ciders, wines, and distilled spirits from being exported to India, and several compositional requirements that were either unclear or a cause for concern. In conclusion, she asked when India planned on finalizing and implementing the measure and stressed the importance of the provision of an adequate transition period to allow industry to come into compliance with the measure.

2.14. The representative of Japan echoed the concerns raised by the EU and the US. Japan had submitted technical comments to India, considering that part of the proposed regulations was not in accordance with the international standards and international practice. Japan encouraged India to take its comments into consideration by revising the regulations, but suggested that if they were implemented as currently proposed, that a reasonable transitional period be provided.

2.15. The representative of Australia welcomed India's consideration of its comments and looked forward to its response, recalling the obligation to ensure consistency with the TBT Agreement.

2.16. The representative of Chile echoed concerns raised the EU and the US, specifically the need for classification of these alcoholic beverages as not all such beverages were being considered and thus were not in line with OIV definitions with regard to additives. He expressed interest in the further development of this regulation and pinpointed the transitional period as a key issue. Chile sought India's indulgence in extending the deadline for comments beyond the standard 60 days.

2.17. The representative of New Zealand expressed support particularly for the interventions made by the US and the EU, underlining her delegation's concern that the new requirements proposed by the draft regulations were unnecessarily trade restrictive as well as unclear. Specifically, her delegation believed that wine should be seen as a single ingredient product and noted that numerically based labelling requirements such as the numerical definitions of wine and categories failed to take into account seasonal and regional variances in wine production, thereby constituting an unnecessary burden on wine producers. She looked forward to working with India and to hearing how India would respond to the concerns of wine producers and importers.

2.18. The representative of Guatemala expressed her delegation's concern and interest in closely following discussions.

2.19. The representative of Canada echoed the comments made by the EU and the US as his delegation was following with interest the development of the proposed regulation. In doing so, he

encouraged India to ensure that the regulation was not more trade restrictive than necessary to meet its legitimate objectives and that it did not discriminate among like products. He asked India to confirm whether its intention was for the proposed regulations to supersede existing standards for alcoholic beverages manufactured or sold in India. Further, with respect to the proposed limitation in the range of alcohol content of whiskies from 36% to 50%, he questioned India's rationale for this, since some variations of whisky did exceed 50%.

2.20. The representative of India recalled that the Food Safety and Standards Authority of India (FSSAI) had published the "Draft Food Safety and Standards (Alcoholic Beverages Standards) Regulation, 2015" on its website on 29 October 2015, seeking comments from all stakeholders, followed by its notification as document G/TBT/N/IND/51, with a 60-day comment period. The draft measure was still under consideration by the Indian authorities pending finalization. A more detailed list of permitted food additives was expected to be finalized in due course, and comments of WTO Members and other stakeholders were being considered appropriately in finalizing the measure.

2.2.2.3 South Africa - Amendment to Regulations Relating to Health Messages on Container Labels of Alcoholic Beverages, G/TBT/N/ZAF/48/Rev.1

2.21. The representative of the European Union recalled the proposed amendments to the regulation that were of concern to his delegation. The requirement for seven different health warnings to be rotated during a twelve-month cycle constituted an excessive burden and a potential technical barrier to trade, especially for small and medium enterprises. Some beverages had a lifespan-after-labelling of many years and predicting which label had to be used imposed an unnecessary burden on industry. Also of concern were different requirements on the size of the health warnings, which would be increased to at least one eighth of the total size of the container instead of the current one eighth of the total size of the label. Recalling Article 2.2 of the TBT Agreement, the EU asked the South African authorities to share scientific evidence on the relationship between these new requirements and the fulfilment of a legitimate objective (e.g. protection of human health) by reducing the harmful consumption of alcoholic beverages. The EU requested an update from South Africa on the status of the proposed amendment as well as a written reply to its comments.

2.22. The representative of Canada, whilst expressing support for South Africa's policy objective of promoting healthy choices related to alcohol, including the use of warning labels, voiced concern regarding the costs for exporters - notably smaller shipments - which would result from the change to the regulation requiring labels to be exhibited with equal regularity to each other within a twelve-month cycle. If a Canadian exporter were to send 4 shipments a year to South Africa, would the new regulation require each of the 7 labels to be distributed equally among those 4 shipments? If an exporter sent 700 bottles of wine a year would they require 100 bottles each with the 7 different labels? Would it be possible to consider adding an amendment for smaller producers to reduce the cost burden?

2.23. The representative of Guatemala flagged her delegation's systemic interest in the topic and the desire to follow discussions closely.

2.24. The representative of South Africa recognized the interest in health messages on alcoholic beverage containers, an issue raised frequently as a specific trade concern in the context of the clarification of labelling requirements, and underlined the need for government intervention via warnings about the public health and safety concern of alcoholic beverage misuse and of alcoholism. He informed the Committee that the regulation had not yet been adopted by its Department of Health. He went on to recall the previous day's thematic session on Good Regulatory Practice, which had highlighted the importance of regulatory impact assessment, public consultation and legal overview. In this light, after a thorough public consultation process taking into consideration all comments received, the Department of Health had now referred the draft regulation to the South African State Law Advisors for legal overview. He summed up by stressing his delegation's commitment to the Fifth Triennial Review's "follow-up" recommendation in 2009, whereby the Committee had agreed to stress the importance of making addenda when a proposed regulation is either adopted, published or enters into force and especially in cases where the

relevant dates have not been provided in the original notification or have been changed³ and in this light would notify the Committee when the draft regulation had been adopted.

2.2.2.4 United Arab Emirates - Control scheme to restrict the use of hazardous materials in electronic and electrical devices

2.25. The representative of the European Union stated that his delegation shared the objective of the notified draft of restricting, to the extent possible, the use of hazardous substances in electrical and electronic equipment, with a view to protecting human health and the environment. He nonetheless wished to raise some issues of concern to his delegation. The lists of exemptions in Annexes 3 and 4 of the notified draft did not include many relevant exemptions included in similar regulations on the restriction of the use of certain hazardous substances in electrical and electronic equipment, as was the case in the EU's own legislation on the matter. In particular, exemptions for the use of mercury and other substances currently used for the production of light sources, such as bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP), would be forbidden without appropriate transition, which would certainly disrupt trade in this area. Regarding the enforcement of the restrictions laid down by the notified draft, it was noted that Article 4.1 was unclear and did not specify whether the restrictions listed in Annex 2 only applied when the electrical and electronic devices were placed on the market for the first time or also to the following marketing stages. The EU therefore kindly invited the UAE authorities to clarify whether or not, and how, the restrictions listed in Annex 2 applied to electrical and electronic equipment already on the market. The re-use, refurbishment and extension of lifetime of products already on the market was beneficial for the protection of the environment, for which spare parts would need to be available. He asked the UAE authorities whether exceptions could be considered for the repair of products placed on the market before the application of the notified draft. Additionally, he highlighted that in Article 9.4 of the notified draft, the list of exemptions in Annexes 3 and 4 was related to "products", instead of "applications in a product", whereas the headings of both annexes referred to "applications"; an explanation was requested with regard to the exact scope of application of the exemptions at hand. As for the procedure for conformity assessment, the notified draft referred in Article 5 to "Model A" and to a submission to the Emirates Authority for Standardization & Metrology (ESMA), in Article 6 to registration, and in Article 8 to an application. Clarification was sought on the exact procedure for the placing on the market of products following the assessment by the manufacturer and the drawing up of a Declaration of Conformity, and in particular on whether a prior authorization by the UAE authorities was required.

2.26. The Chairperson asked that the EU's concerns be conveyed to the delegation of the United Arab Emirates.

2.2.2.5 Russian Federation - Rules of cement certification

2.27. The representative of the European Union raised concerns about the new mandatory certification requirements for cement in Russia, following the approval in September 2015 of a law on cement certification making it subject to mandatory certification. According to this law, applicable from 7 March 2016, all cement made available in Russia would have to be certified according to the new GOST standard P 56836-2016 ("Validation of conformity. Rules of cement certification"), valid from 1 February 2016. This GOST standard had been approved on 11 January 2016 by a ruling of the Ministry of Trade and Production, Federal Agency for technical requirements. According to the new certification procedure, cement would have to be certified every six months by an authorized laboratory, a frequency deemed by the EU to be disproportionate and unjustified. It also seemed that only a few certification bodies had been designated to undertake the certification with considerable costs for the producers. Furthermore, even more burdensome procedures applied to cement imports from third countries. Imported cement, although already certified, was to be subject to additional border controls, samples to be taken from each shipment for testing. Imported cement might be stopped at the border for 28 days until the results of the tested samples became available.

2.28. In this light, the EU asked Russia for the reasons for such requirements for imported cement; whether such requirements applied only to imported cement; if so, what the differences in treatment with locally produced cement were, and their justification; and which countries were

³ G/TBT/26, para 43(b)

considered as third countries. In addition, the EU requested further information from Russia on the meaning of shipment (whether it would mean each wagon, a whole train or the yearly production), by whom and how these samples would be taken from imported cement, how the tests would be performed, their length, and whether, after sampling and testing, the imported cement would be allowed to proceed further to the unloading point and/or to the end consumer or each time they were to be stopped at the border for 28 days. Russia was invited to provide further information on the health risks invoked in relation to certain imported cement products and on the reasons why each shipment of imported cement had to undergo testing. Finally, the EU asked Russia to suspend application of the measures in question pending their notification under the TBT Agreement, providing Members with the opportunity to comment on them.

2.29. The representative of Mexico shared the concerns raised by the EU on this regulation. Mexico would seek further clarification from Russia on some elements of the measure and asked that this measure be notified to the Committee.

2.30. The representative of the Russian Federation stated that Federal Law No. 184-FZ of 27 December 2002 "On Technical Regulation" and the Treaty on the Eurasian Economic Union of 29 May 2014 were the basis of the technical regulation. The Eurasian Economic Union currently lacked a technical regulation containing cement requirements. Federal Law requirements would apply until the Eurasian Economic Union technical regulations were adopted. Pursuant to the requirements of the Federal Law, Government Resolution No. 982 of 1 December 2009 "On Approval of the Single List of Goods Subject to Mandatory Certification and Single List of Goods Subject to Conformity Confirmation Procedures by means of Conformity Declaration" would apply. Government Resolution No. 930 of 9 September 2015 "On amendments of the Single List of Goods Subject to Mandatory Certification" added cement to the list, in response to a sharp decrease in cement quality in circulation in the Russian Federation and due to urgent problems of safety, health and environmental protection. His delegation was of the opinion that the measure would not have a significant effect on trade of other Members. He explained that the Russian Federation was a major exporter of cement and that domestic production covered more than 94% of total consumption, more than 50% of imports coming from countries (members of the Eurasian Economic Union) already having implemented the mandatory certification of cement. The draft government decree had been published on the official website of the Russian Federation Government on 13 March 2015.⁴ Government Resolution No. 930 had been notified to the WTO in document G/TBT/N/RUS/48 in accordance with Article 5.7.1 of the TBT Agreement. He would bring other questions of the EU and Mexico to the capital and would provide answers shortly.

2.2.2.6 Hungary – Proposal for Government Decree on the amendment of Government Decree 39/2013 (of 14 February 2013) on the Manufacture, Placement on the Market and Control of Tobacco Products, Combined Warnings and the Detailed Rules for the Application of the Health-Protection Fine, G/TBT/N/HUN/31

2.31. The representative of Indonesia said that while Indonesia respected Hungary's intention to pursue a public health policy so as protect consumers from the negative effects of tobacco products, his delegation had concerns that this measure was more restrictive than necessary. The full statement is contained in the document G/TBT/W/440.

2.32. The representative of the Dominican Republic thanked Indonesia for raising this issue. Her delegation fully supported the concerns raised. The Dominican Republic along with Cuba, Honduras and Indonesia were currently examining the measures on plain packaging implemented in Australia through the WTO Dispute Settlement System. She said these measures were inconsistent with WTO Members' commitments under the TBT and TRIPS Agreements. Experts had put forward extensive evidence and arguments to the panel including evidence related to how these measures actually worked in the three years since their adoption. The Dominican Republic believed that based on the arguments and evidence put forward, the panel would conclude that plain packaging measures were an ineffective way of addressing tobacco control. Alternative, less trade restrictive, measures, such as increasing the minimum age for buying tobacco products or increasing tax on those products, would achieve the objective of reducing tobacco consumption. These were particularly effective disincentives for youth consumption. The Dominican Republic encouraged

⁴ <http://www.regulation.gov.ru>

Hungary not to implement any plain packaging measures until the findings of the panel on the Australian measures were known.

2.33. The representative of Guatemala said her delegation was following this issue closely and aligned itself with the concerns expressed by other Members.

2.34. The representative of Cuba also thanked Indonesia for raising this issue and aligned her delegation with the statements made by Indonesia and the Dominican Republic. Plain packaging was an unnecessary barrier to trade that lacked any scientific evidence proving that it led to improved health. Less trade restrictive alternatives existed. Like the Dominican Republic, she urged Hungary not to publish the legislation until the DSB panel findings were made available.

2.35. The representative of Australia reiterated his delegation's strong support for other WTO Members' decisions to legislate for the mandatory plain packaging of tobacco products and congratulated Hungary on its recent notification of such measures. He said the important steps taken by Members in tobacco control demonstrated that efforts to delay the adoption of tobacco plain packaging measures had not been successful. Australia was of the firm view that Members had the right to implement measures necessary to protect public health, while complying with international treaty obligations including the TBT Agreement. Tobacco plain packaging was a legitimate measure, endorsed by leading public health experts as well as by the WHO and supported by extensive peer reviewed research, reports and studies. Given that Australia's measure was currently the subject of dispute proceedings, it was not appropriate to comment further. Australia felt it was also inappropriate for complainants in WTO disputes to invoke those proceedings in an attempt to delay or discourage other Members from developing or implementing their own legitimate tobacco control measures.

2.36. The representative of Canada supported Australia's comments. As a trailblazer with regard to measures in this area, Canada believed that plain packaging was an essential element in regulating in favour of public health. He was interested to hear other Members' views with regard to the fair balance between regulation, international trade and public health. Canada was committed to introducing the plain packaging requirements and would follow with great interest developments in this issue. These measures were being examined to see how they might be applied in Canada where there could also be restrictions on the use of colours of trademarks, logos and graphics on tobacco packaging. Any proposal would be notified to the WTO.

2.37. The representative of New Zealand supported comments made by others in backing Hungary's tobacco plain packaging measure. There was extensive and growing research that plain packaging and/or health warnings, as part of a comprehensive tobacco control programme, would contribute to improving public health. Additionally, those Members who had implemented plain packaging measures showed that post-implementation, these measures were working as intended. The TBT Agreement recognized the fundamental right of Members to implement non-discriminatory measures necessary to protect public health. New Zealand believed it was possible to implement plain packaging regimes that were consistent with all WTO obligations including those under the TBT Agreement

2.38. The representative of Norway supported the important steps taken by Hungary and other Members in tobacco control measures. As tobacco smoking was the leading single cause of early death and illness in Norway, there was strong support for tobacco control measures so as to achieve a tobacco free society in the long term. Norway had launched a public consultation on standardizing tobacco packaging in March 2015 and the preparation of the bill was now in the final stages. This bill would soon be sent to the parliament and most likely be adopted towards the end of 2016.

2.39. The representative of Uruguay said that given Uruguay's well-known position in support of tobacco plain packaging measures, the statements made by his delegation in previous meetings should be also be taken into account on this measure.

2.40. The representative of Nigeria supported the concerns raised by other Members. While recognizing Hungary's right to take appropriate measures to protection public health, it was important for Members to question whether such measures were consistent with the provisions of WTO Agreements. She requested that Hungary take into account the comments of concerned

Members and reverse the decision to introduce this measure. Her delegation would provide a full statement at the next meeting of the TBT Committee.

2.41. The representative of the European Union reiterated that tobacco products had recognized harmful effects on human health and Article 2.2 of the TBT Agreement included the legitimate objective of the protection of human health. It was recognized that any measure pursuant to this legitimate objective must not be more trade restrictive than necessary and create unnecessary obstacles to international trade. Article XX(b) of the GATT 1994 also emphasised the importance of public health by justifying measures "necessary to protect human ...health". The Hungarian draft decree aimed at protecting public health by introducing additional measures for tobacco control, targeted in particular at reducing smoking initiation among young people. In addition to the provisions implementing the EU Tobacco Products Directive, the draft included examples of plain packaging of tobacco products. This measure was the latest strand in a comprehensive range of tobacco control legislation already in place in Hungary aimed at decreasing tobacco consumption. Under existing legislation, there was already a ban on advertising of tobacco products, as well as sponsorship linked to tobacco products; a prohibition on smoking in enclosed public places and public institutions; the majority of tobacco products featured packaging bearing health warnings combining images and illustrations; tobacco products could only be sold in dedicated retail units and only to adults over the age of 18; and several tax increases on tobacco products, most recently in April 2015. In addition to the notified draft, Hungary had also made an impact assessment available which detailed the rationale of the measure and its expected economic and health impacts. Hungary had also notified the measure to the European Commission in accordance with internal EU requirements. Comments and opinions had been made by the European Commission and some EU member States, which had been replied to by Hungarian authorities. No comments had yet been received from WTO Members under the WTO TBT notification procedure where the deadline for comments was 22 March 2016.

2.2.2.7 France – Amendment 367 on Biodiversity Law

2.42. The representative of Indonesia expressed its concern with the consistency of Amendment 367 with the WTO principles of national treatment and non-discrimination. Its full statement is contained in document G/TBT/W/441.

2.43. The representative of Brazil shared Indonesia's concern and requested clarification on the nature of the amendment, as it appeared to refer to a tax measure concerning third-country environmental damage.

2.44. The representative of the European Union noted that the general objective of the French draft Biodiversity Law was the better protection of natural resources and ecosystems and agreed with Brazil that amendment 367 proposed by a group of French senate members did indeed provide for an additional tax on palm oil used in food. However, the draft measure did not fall under the scope of the TBT Agreement and as such the present Committee was not an appropriate forum in which to discuss it. In terms of the state of play of the adoption procedure, the draft law had been approved in the first reading by the National Assembly and the Senate, and submitted to the National Assembly for a second reading on 27 January 2016.

2.2.2.8 Russian Federation – Implementation plan related to excise tax on palm oil and soda products

2.45. The representative of Indonesia expressed its concern that the Russian Federation's implementation plan potentially violated GATT Article III:2 on National Treatment as well as being inconsistent with the TBT provisions of non-discrimination and avoidance of unnecessary trade barriers. The full statement is contained in document G/TBT/W/442.

2.46. The representative of the Russian Federation welcomed the opportunity to bring clarity to the list of products on which excise taxes are levied in order to avoid any future misunderstanding. His delegation considered that the matter was not covered by the TBT Agreement by virtue of the fact that the inclusion of certain products in a list of excisable goods did not relate to technical regulations, standards or conformity assessment procedures. He indicated that the legal basis for excise taxation was set out in Chapter 22 of the Tax Code of the Russian Federation in which the corresponding list of products was also to be found. Any product listed, whether imported or

domestically produced, was subject to identical excise tax rates – and no changes had been made to the list in the previous five years. It was noted that discussions were currently underway in Russia concerning hypothetical changes to the list of excisable goods and underlined that these were broad public discussions, rather than a governmental plan. Different approaches were being discussed, including, inter alia, the inclusion of palm oil, tyres, soft drinks, and other products. It was expected that the discussions would result in the drafting of amendments to the Tax Code and that these would fully address the interests of stakeholders, consumers, whilst being in full compliance with WTO law. Proposals would be available for public comment on the website of the Government of the Russian Federation. Finally, attention was drawn to the requirements for palm oil and other oils established in Customs Union technical regulations "On oil and fat products"; these were in full compliance with the international standard CODEX STAN 210-1999 and with provisions of Article 2.4 of the TBT Agreement.

2.2.2.9 Bolivia - Food Labelling and Advertising Law

2.47. The representative of the United States expressed support for Bolivia's public health objectives of reducing obesity and related non-communicable diseases. Given the potential trade impact of Law No. 775 "Promoting Healthy Eating" which was promulgated on 8 January 2016, the US asked Bolivia to notify the implementing regulations of the law to the TBT Committee. Could it elaborate on the next steps in implementing the Healthy Eating Act, including the process for drafting its corresponding technical regulations? How would Bolivia be able to take into account further scientific information and research now that PAHO nutrient levels had been codified? She expressed her delegation's commitment to working with Bolivia on this important matter.

2.48. The representative of Guatemala expressed her delegation's concern over the lack of transparency and compliance with notification requirements, which would normally allow for public consultations among Members prior to implementation of the measure. Guatemala acknowledged the legitimacy of the measure's public health objective of preventing diet-related diseases. However these requirements appeared to place the blame solely on processed food. There were also concerns with the application and implementation period of the measure. Guatemala was closely following the development of discussions on this measure and urged Bolivia to notify its measure and to establish a period for public consultation. Moreover, Guatemala was concerned that the labelling regulations had not considered the Codex Alimentarius discussion.

2.49. The representative of the European Union echoed concerns raised by the US, in particular regarding the absence of notification of the measure. Whilst fully supporting the final objective of this measure - the protection of human health - his delegation recalled the obligations established by the TBT Agreement on the notification of technical regulations in order to give other Members the opportunity to provide comments, and regretted Bolivia's lack of compliance with this obligation. As the EU was in the process of analysing the content of the measure, it requested Bolivia to suspend the application of the measure, notify it to the WTO and provide enough time for Members to provide comments.

2.50. The representative of Canada, echoing the comments made by the US, Guatemala and the EU, expressed support for the objective of the protection of human health but urged Bolivia to notify the measure to the TBT Committee, at which time Canada would provide substantive comments through the enquiry point process and in the meantime requested Bolivia to suspend the measure.

2.51. The representative of the Plurinational State of Bolivia assured Members that concerns raised in an informal meeting between its focal point and the delegation of the US, as well as in the present meeting, would be dealt with by the appropriate bodies in capital. In the meantime, he informed Members that the Government of Bolivia had adopted Law No. 775 promoting healthy eating and that it was currently in the process of being developed as appropriate in consideration of the provisions of the TBT Agreement. He assured Members that the regulation would be made available to Members as established in the TBT agreement when ready.

2.2.2.10 Indonesia – Halal Product Assurance Law No. 33 of 2014

2.52. The representative of the United States, recognizing the importance for Indonesian consumers of knowing whether products are halal, expressed its commitment to work with

Indonesia to ensure that this objective was achieved without creating any unnecessary barriers to trade. She reiterated her delegation's hope that previously noted concerns would be addressed through implementing regulations. It was their understanding that the Ministry of Religious Affairs, in conjunction with a number of other government ministries, was currently drafting the new implementing regulations and requested an update on their content and status, as well as on preparations to set up the new institution provided for in Presidential Decree 93/2015. During the development of the implementing regulations, Indonesia was urged to ensure that the drafts were submitted to the TBT Committee prior to being finalized in order to allow for sufficient notice and comment from all stakeholders and to allow time for those comments to be taken into account.

2.53. The representative of the European Union shared the concerns raised by the US. According to the information available, the scope of the law was very broad and extensive, affecting, among other sector, food and beverages, pharmaceutical and cosmetics. The law would be implemented gradually and enforced as from 2019. However, certain Halal requirements had already been set out in separate regulations (e.g., for imports of carcasses and meat). His delegation considered that the lack of transparency on implementing rules and this fragmented approach created uncertainty as to the requirements applicable at any point in time. The EU requested that Indonesia notify the law via the TBT notification system, as well as any subsequent implementing rules, and that reasonable time be allowed for Members to comment, in accordance with Article 2.9 of the TBT Agreement. In particular, on Halal certification and labelling, the EU requested clarification as to whether the provisions on mandatory labelling would also apply to non-Halal products. It also welcomed information on any other potential trade restrictions that the law might bring to non-Halal products.

2.54. The representative of Brazil expressed his delegation's interest in following the matter closely, especially with regard to the obligation for non-discrimination between domestic and imported products under the WTO TBT Agreement.

2.55. The representative of Indonesia provided responses to the intervening delegations, contained in document G/TBT/W/443.

2.2.2.11 Thailand – Milk Code – Draft Act on Controlling to the Marketing Promotion on Food for Infant and Young Children and Other Related Products BE, G/TBT/N/THA/471

2.56. The representative of the United States stated that while her delegation strongly supported efforts to ensure that marketing of infant formula did not negatively impact breastfeeding, it was nevertheless concerned with the clarity of the draft measure, and in this light urged Thailand to allow for sufficient time after publication of the final rule and before implementation and enforcement, for further bilateral technical discussions, allowing US industry to come into compliance with the measure.

2.57. She expressed concern that the regulatory approach outlined in the draft may be more trade restrictive than necessary. Following up on the comments previously submitted through the Enquiry Point, the US asked Thailand to provide a scientific explanation for its complete ban on marketing and advertising on follow-up formula intended for children up to 36 months of age. In particular, scientific explanation was requested for how a ban on health claims and trademark information on labels would help accomplish the desired goal of increasing and sustaining breastfeeding. Further, explanation was sought as to the lack of distinction in regulating the marketing of infant formula and follow-up formula.

2.58. She went on to note that the draft proposed treating violations of the advertising and marketing requirements as criminal offenses as well as imposing prison time for certain offenses. The US sought clarity on the reasons for the necessity of criminal penalties, as well as additional detail with respect to the procedures for prosecution. She also recalled the voluntary nature of the WHO's International Code of Marketing of Breast-Milk Substitutes in the US, complemented by similar codes developed by leading US medical professional societies on the marketing of these products. Finally, she enquired if Thailand had an estimated timeframe for the ratification of the measure and flagged her delegation's intention to deepen technical engagement with Thailand on how to achieve its health objectives without negatively impacting trade.

2.59. The representative of Thailand thanked the United States for its comments, which would be passed on to the Department of Health, under the Ministry of Public Health, for consideration. She informed the US that the draft act was in the process of being published in the Government Gazette and that it would only come into force 180 days following the date of publication.

2.2.3 Previously Raised Concerns

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

2.60. The representative of Japan expressed concern regarding this long-standing issue, dating back to 2011. He stressed four points in particular: (i) the ISI marking fee requirement on every tyre on which ISI mark was attached, regardless of the destination country; (ii) the high cost of the marking fee; (iii) the length of time needed for certification; and, (iv) the bank guarantee fee which was required only for tyre factories outside India. On the cost of the fee, Japan had repeatedly showed India the evidence that the ISI marking fee was expensive compared to other countries and requested India to reduce the fee.

2.61. Japan also requested that India review the increase in the Conformity of Production (COP) testing frequency, which had been announced at the end of November 2015. India had announced that the test frequency would become "once in three months" from current "once in two years", and furthermore, the frequency of some tests was "earlier one of every 10th control unit (50,000 numbers) of a family or once in a year" and the frequency of the other tests was "every control unit (5,000 numbers) of a family". Although an annual frequency was feasible, adding the condition of per manufacturing number would make the frequency excessive. For example, if a tyre was manufactured by 300 thousands per year, the frequency of the former test would be 6 times a year and the latter test would be 60 times a year. Management by manufacturing number was a complex requirement for the tyre industry that had never been seen in other countries before. Japan considered that it would be possible to ensure safety with the previous test frequency. Japan requested that the test frequency not be per number of manufacturer, but per period, or once a year.

2.62. The representative of the European Union reiterated his delegation's concerns about the Indian Quality Order on Pneumatic Tyres and Tubes for Automotive Vehicles, which introduced a certification procedure with a mandatory marking for tyres. The EU referred back to its statements concerning the ISI marking fee and the USD 10,000 bank guarantee. In particular, the EU requested India to align its procedures with international practices and remove the obligation to pay a marking fee per marked tyre as well as to eliminate the discriminatory bank guarantee requirement. During the last meeting of the TBT Committee, the EU had asked India to provide information about the frequency of the new COP testing on tyre varieties exported to India. Since that meeting, the EU had received information that further changes in the testing requirements had taken place. These were set up by the Scheme of Testing Inspections (STI) 15633/5 of November 2015. The new measure introduced the concept of a "control unit" (a control unit meaning 5,000 tyres of the same family). It required testing of every tenth control unit for load and speed performance, endurance test, bead unseating resistance test and tyre strength test. The EU considered these testing requirements extremely burdensome and costly and asked what specific safety-related objectives India was pursuing by requiring such frequency in testing. Finally, as this requirement seemed to stem from a new measure, which had not been notified under the TBT Agreement, the EU asked India to notify the measure.

2.63. The representative of India noted that most of the issues raised were not new and had been sufficiently explained in previous meetings. He requested interested delegations to refer to previous minutes, particularly of the meeting held in March 2015.⁵ Regarding the frequency of testing STI (Scheme for Testing and Inspection), the STI for Pneumatic Tyres for passenger car vehicles as per IS 15633 had been revised as STI/15633/5 in November 2015. One sample had to be tested for every 50,000 tyres compared to once in three months specified earlier in STI/15633/4. In case quantity of some varieties was less than 50,000 in a year, it was specified that they needed to be tested once a year. However, based on the feedback received, some more inputs had been sought from the manufacturers and BIS would review the STI frequency further on receipt of the information.

⁵ G/TBT/M/65, paragraphs 2.41, 2.42 and 2.43.

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

2.64. The representative of Japan asked China to clarify how the "Guidance for Application and Evaluation of New Cosmetic Ingredients" would be updated (in particular with respect to the contents and schedule) in accordance with the revision of the "Regulations concerning Hygiene Supervision over Cosmetics". Regarding the current version of the "Guidance", he said that Japan remained concerned with the following three issues: the speed of examination, the safety evaluation requirement, and the information disclosure.

2.65. The representative of the European Union reiterated his delegation's concerns in relation to the pace of progress on the procedure for the authorization of new ingredients. The EU also welcomed plans to set up a differentiated approach between priority ingredients, which were of higher risk, requiring a pre-market registration, and ordinary ingredients, which would only need to be notified to the competent Chinese authorities. In this respect, the EU asked China to indicate the state of play and the planned timeframe for the adoption of this change. The EU also asked China to explain the current state-of-play of the new Chinese draft on Cosmetics Supervision and Administration Regulation.

2.66. The representative of China explained that the provisions for the Administration of Cosmetics Application Acceptance had been notified on 8 July 2011. Since then, China's Food and Drug Administration (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 kept bilateral channel open and had formed several working groups on this issue with several Members. She also said that the CFDA had paid great attention to the approval of new cosmetic ingredients. The term "new ingredients", she explained, referred to natural or synthetic materials that were used to make cosmetics for the first time in China. Before a new ingredient was used, a registration had to be made to the relevant authority for approval. Previously, the determination of a new ingredient had been done solely by experts on the basis of their personal experience, in the absence of an objective criterion.

2.67. The representative of China noted that her delegation attached importance to this issue and was in communication with both domestic and foreign businesses and industry organizations to carry out research on this matter in order to find effective ways to solve the problem. After three rounds of public consultations, a catalogue of 8,783 cosmetic ingredients already used in China had been published on 30 June 2014. She said that another deficiency hindering the registration process was the absence of a classification system for new ingredients. According to the draft revision of Regulations Concerning the Hygiene Supervision over Cosmetics, a new classification system would be set up for cosmetics. In the new system, she said, only higher risk substances such as aseptic, sun-screening agents, colouring agents, hair colorants, and skin lighteners require registration with the relevant authority, while lower-risk substances just needed to be filed. Moreover, different documentation requirements would apply to different substances to accelerate the authorization process in an efficient and predictable manner. China would keep the bilateral channel open and welcomed interested parties to continue to cooperate with China and put forward valuable inputs.

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

2.68. The representative of Canada reiterated concerns with India's testing requirements for telecommunications products, and supported the points made by the EU in the last meeting.⁶ He believed that India's in-country security testing regulations for telecommunications products would hinder, or possibly shut, Canadian exports out of the Indian market. Canada disagreed with the universal approach applied by India to testing in the telecommunications sector and did not understand why Common Criteria Recognition Arrangements (CCRA) testing was not appropriate

⁶ G/TBT/M/67, para 2.75.

for India's telecommunications framework, given that it was already internationally accepted. Authorizing 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 the explanation of India's approach provided at the previous meeting, but was still not convinced that deviation from CCRA testing would improve the security of these products. He requested that India provide a detailed explanation of the possible security improvements of its alternative approach.

2.69. The representative of the European Union asked India whether the date of entry into force of the security testing requirements would be further postponed; the EU understood that the current date of entry into force was 1 April 2016. The EU also understood that the relevant testing infrastructure was not ready hitherto and that the Indian Ministry of Communications and Information Technology was therefore considering further postponement. He sought confirmation that pending entry into force of the new requirements, the status quo would continue to be applied and therefore foreign test results would continue to be accepted and suppliers would be allowed to self-certify their products. The EU reiterated its query regarding the value added of the new requirements for mandatory in-country testing and questioned whether such requirements would contribute to enhanced security. He appreciated India's previous explanations regarding the reliance on and leveraging of test results and certificates based on the common criteria standards and issued under the CCRA as well as based on the Third Generation Partnership Project (3GPP) standards on telecom network equipment. The EU sustained the view that any Indian specific requirements would increase costs without enhancing security and urged India to rely on international standards and global practices. EU industry continued to request more clarity on the new security testing requirements; in particular, that testing should be based on product type testing instead of batch testing, as the latter would arguably create a bottleneck on importation creating supply change disruption. The EU urged India to provide flexibility under the new requirements for companies with a proven track record, and deemed that when they have demonstrated the ability to self-certify products through adequately accredited and competent in-house laboratories, they should be allowed to do so under the new requirements.

2.70. The representative of the United States expressed gratitude for the postponement of the 1 April 2016 entry into force date, and requested that India formally notify this postponement through an addendum. The US also continued to request that India accept internationally accepted standards, such as 3GPP, and recognition of conformity assessment through the CCRA. She also requested that India notify to the TBT Committee the proposed revised telecommunications security regulations of 30 May 2011, and provide Members and interested stakeholders adequate opportunity to comment. She continued to urge India to remove the in-country testing requirement from the proposed regulation because it was unnecessary, costly, more trade-restrictive than necessary, and contradicted the national treatment principle of conformity assessment bodies. The US asked India to provide the US TBT Enquiry Point with its risk analysis upon which the in-country testing requirement is based. Finally, she said security testing that would potentially compromise companies' proprietary information, such as source code or other intellectual property, would potentially discourage companies from selling high-quality telecommunications equipment on the Indian market. In turn, this would limit Indian service provider access to critical network products and components.

2.71. The representative of Japan supported the statements of other Members and confirmed Japan's continued interest and concern. She recalled India's statement at the June 2015 Committee meeting that "IT product testing carried out against the CC process would be leveraged without necessarily repeat testing. However, some additional test could be conducted if required in the interest of nation".⁷ Japan again requested that India clarify the concrete meaning of "interest of nation". Japan asked India to ensure its telecom regulations do not impede market access for foreign industries. She also requested that India confirm the date of entry into force of the in-country security testing requirements.

2.72. The representative of India reported no change in the status of this policy since the November 2015 Committee meeting and therefore invited interested delegations to refer to India's intervention at that meeting.⁸ He also informed the Committee that the date of entry into force of the in-country security testing through authorized and certified labs was likely to be extended. He

⁷ G/TBT/M/67, para. 2.80.

⁸ G/TBT/M/66, para. 3.79.

stated that India had mandated security certification of network elements before their induction because telecom networks are critical infrastructure upon which other important infrastructure (e.g. power, transportation and defence) depend. India disagreed with the arguments made by some Members that security testing would potentially compromise companies' proprietary information such as source code and would potentially discourage them from selling high quality telecom equipment in India. That argument, he pointed out, seemed to suggest that in-country security testing would tend to compromise companies' proprietary information, whereas security testing in a foreign lab would not. Regarding the feasibility of using 3GPP standards, India noted that 3GPP by its own admission was in the process of developing security standards and had taken up the MME as the first element, for which standards had not yet come out. India took note of the additional questions raised at this meeting, and said these would be forwarded to capital for response.

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

2.73. The representative of Canada was concerned that China's regime for regulating the information technology sector was overly burdensome and restrictive to international trade. While Canada recognized that China was seeking to address security concerns, avoiding duplication of conformity testing by recognizing foreign accreditation would significantly reduce the burden on industry, representing a net benefit for all parties. China's approach to regulating the IT security sector appeared to lack coordination and ran counter to well-established international best practices in the sector.

2.74. The representative of the European Union continued to be concerned about China's overall regulatory approach in the IT security sector; he reiterated the EU's request for an update on the status of the revision of the regulation on commercial encryption products by OSCCA. This had been on the agenda of the State Council for several years. Was there a more precise timeline for finalizing the process? And could a TBT notification be made of the final draft?

2.75. He said that the Multi-Level protection scheme (MLPS) raised the more general question of what constituted "critical infrastructure"; the EU had already noted its concern about the overly extensive scope that had been given in the MLPS. Besides the MLPS, subsequently, a national security law had been passed according to which all key cyber infrastructure within China had to be secure and controllable. No definition of "secure and controllable" was available and it had been on this basis that the draft implementation guidelines concerning banking and insurance sectors (subject to discussion below) had been prepared. Overall this created uncertainty about what critical infrastructure was, and what requirements applied to companies operating such critical infrastructure and supplying equipment to networks that were defined or considered as critical infrastructure. In addition, in 2015, the National People's Congress had issued a first draft of a cyber security law that also elaborated on the notion of critical information infrastructure, operator of critical infrastructure, critical equipment for network related products for cyber security and again contained the notion of "secure and controllable". The European Union requested that this draft be notified under the TBT Agreement. Moreover, was a revised draft under preparation? If so, what was the timeline for progress on this file?

2.76. Regarding relevant standards, on a more positive note, the European Union had observed a recent opening by Technical Committee 260 (TC260) under the Standardization Administration of China. This technical committee dealt with information security standards and had recently allowed participation of foreign companies in China, including wholly foreign-owned companies. Nevertheless, this opening had been managed in a way that did not allow all potentially interested foreign companies to apply for being included so the EU requested that TC260 reopen the call for interest in order for European companies to also manifest their interest and be included among the participants in TC260; equal treatment needed to be granted to all companies in China regarding participation in Chinese standardization organizations.

2.77. The European Union stressed the importance of enhanced international cooperation in this field; he said that cyber security is a global issue. It needed a general commitment to develop compatible regimes that enhanced security without hindering trade in commercial encryption products – this was in the mutual interest of all Members.

2.78. The representative of Japan supported the positions set out above. Japan was closely following Chinese regulation in this area. During the meeting in March 2015, China had made a statement that "the revision of OSCCA is listed in the legislation plan and opportunity for public comment is also going to be arranged." However, China had not said anything on the current status of the revision for which Japan requested more information.

2.79. The representative of the United States supported the above interventions.

2.80. The representative of China said that there were no further updates to be made and referred Members to the minutes of previous Committee meetings.⁹

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

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

2.82. The representative of Guatemala indicated her delegation's interest in following discussions on this issue.

2.83. The representative of the Russian Federation indicated that since the previous Committee meeting, there had been no changes to the draft, which was being developed with the purpose of establishing unified requirements for commercialization of alcoholic products, both imported and produced domestically. Although public hearings on the draft technical regulation had been completed before Russia's accession to the WTO in December 2011, all engaged stakeholders had been invited to provide comments during a 60-day period, in full conformity with the provisions of the TBT Agreement. In May 2015, the Eurasian Economic Commission had sent an amended text of the technical regulation to member states of the Eurasian Economic Union (EAEU), including the more recently-acceded members Armenia and Kyrgyz Republic, taking into account comments and suggestions of stakeholders and WTO Members. He said that concerns of WTO Members were being taken into account during the on-going consultation process among the member states, which had some differences of opinion about the draft.

2.2.3.6 Korea – Regulation on Registration and Evaluation of Chemical Material (IMS ID 305)

2.84. The representative of the United States thanked the Republic of Korea for its receptiveness to stakeholder input. The US intended to maintain an ongoing, constructive dialogue that was open and transparent. In particular, the US had appreciated the Ministry of the Environment (MOE) opening the Ministerial Decree for amendments and public comments. The US industry had submitted very extensive comments. However, the US was very concerned about the 16 November 2015 MOE announcement. The announcement had moved the implementation date up to 1 January 2016, despite promises to consider delaying implementation. The United States was especially concerned about the new requirement that submitted information be published on the Internet. The US reiterated its support for a strong definition of Confidential Business Information (CBI) that recognized the possibility of protecting specific chemical identity, composition, and uses.

⁹ G/TBT/M/67, para 2.85; G/TBT/M/66, para.3.83; and, G/TBT/M/65/Rev.1, para. 2.68.

2.85. There seemed to be a general lack of guidance. Even though progress had been made, the US was constantly faced with new challenges when the regulation changed. Because of this, US industry continued to request detailed guidance documents to assist manufacturers, importers, suppliers, and stakeholders in ensuring accurate and consistent compliance with Korea REACH (K-REACH). For example, the US reiterated its concern that it needed much more specific guidance on all products that would be classified under the biocides group. The guidance documents available had not been clearly communicated to all stakeholders, and they had also changed frequently. This had caused uncertainty among chemical manufacturers, as well as manufacturers of products that used trace amounts of chemicals as inputs of production. It was important for Korea to consult stakeholders closely, openly, and transparently, if it was to minimize the trade restrictiveness of K-REACH.

2.86. The United States was also concerned that the guidance documents had only been published in Korean. As a result, many stakeholders had to have these documents translated. This decreased the time available to come into compliance. To address this challenge, the US suggested that these significant documents be allowed more time for public comment. In this respect, there was also a lot of confusion about the respective requirements of K-REACH and the Chemical Controls Act (CCA) – especially since there was no English translation of the CCA.

2.87. The representative of the United States noted that registrants, especially foreign manufacturers, needed time to determine the substances covered by the regulation, identify Only Representatives, establish agreements for joint registration, conduct studies, and submit the necessary information to be in compliance. Due to the constantly changing requirements and lack of guidance already mentioned, registrants needed additional time to implement such compliance activities. For example, while companies only had 2 years to conduct the necessary studies for registration, the US needed guidance on how to submit data, types of data accepted, etc. Chemicals also continued to be added or removed from the toxic substances list without proper notice, opportunity for comment, or reasoning for the changes.

2.88. With respect to CBI, the US respected the legitimate government interest in allowing the reporting of generic chemical names, and providing adequate hazard information to downstream users. Industry stakeholders were willing to disclose this information as long as there was reasonable assurance that their trade secrets would not end up leaked to their market competitors – especially since their products required a substantial amount of investment in highly competitive markets. The US repeated its request that the MOE allow registrants to declare specific-uses CBI for hazardous and non-hazardous substances. Similarly to the type of substance or chemical group, should the specific use of a substance be leaked, it would communicate information to competitors that may know its true value.

2.89. With respect to Data Acceptance and Article 13 of the Final Presidential Decree, the United States asked that the MOE confirm that it would accept qualitative or quantitative structure activity relationship models (QSAR) and read-across techniques in order to reduce duplicative testing. When such data was submitted, the US suggested that the MOE accept the scientific expert's statement and not require additional evidence for the waiving or omission. The United States had also received reports that the implementation was not running smoothly, such as that: the Help Desk and Authorities were difficult to reach and provided poor responsiveness to stakeholder inquiries; notifications and registrations were taking much longer than the legal targets; and some Lead Registrants were operating on their own without consulting with other co-registrants.

2.90. The representative of Japan also expressed concern about the "Act on Registration and Evaluation of Chemical Substances"– on the threshold for reporting on new chemical substances. Japan asked Korea to adopt an exemption scheme for new chemical substances of small volume, as Japan had suggested at the meeting in October 2013 and November 2015. At the last meeting of the Committee, Korea had said that it had simplified report procedures, by revising the ministerial decree so that foreign manufactures could submit the report directly to MOE, lightening the burden to industries. However, a report obligation without a minimum threshold for new chemical substances remained a heavy burden for industries. In the case of existing chemical substances, reporting was required only on chemical substances that were manufactured, imported or sold at 1 tonne or more per year. In the case of new chemical substances, no minimum threshold had yet been set for quantity, so even at 1 gram, new chemical substances would need to be reported. Moreover, although there would be less risk for chemical substances of small volume, the annual reporting requirement imposed too great a burden on businesses. Japan

requested Korea to establish a minimum threshold for reporting on new chemical substances (such as more than 0.1tonne per year) as other countries had.

2.91. The representative of Australia supported the US and Japanese statements. While Australia supported the objective of reporting products which contained hazardous substances so as to protect consumers and the environment, it was also important to ensure regulatory quality in terms of predictability, transparency and clarity of regulatory guidelines – as well as adequate stakeholder consultation and a need to implement adequate checks and balances to protect commercial-in-confidence information from registration and evaluation processes.

2.92. The representative of the Republic of Korea said that before implementation of the regulation, Korea had interacted with stakeholders of domestic and foreign companies, and planned to keep gathering the opinions from stakeholders closely, openly and transparently. From the early stage of the enforcement of the regulation, Korea had provided detailed guidance and intended to provide additional material if needed. Korea also intended to strengthen promotion and training activities to facilitate the use of the document by foreign companies. With respect to the protection of CBI, Korea was protecting it at the international level, as mentioned during last Committee. It was noted that QSARs and read-across techniques could be submitted as registered data under K-REACH and if these were scientifically reliable, no additional data would be required.

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

2.93. The representative of the European Union requested an update on the Ministry of Industry's on-going review of Toy Safety Decree No. 24, announced at the November 2015 meeting, which had been followed up by the establishment of a working group composed of representatives of domestic and foreign toy manufacturers, tasked with working alongside the Ministry on the review. A timeline for its completion as well as any information on likely amendments to the decree were welcomed. He recalled the EU's two main issues of concern. Firstly, the current discriminatory conformity assessment procedures differentiated, without justification, between imported toys and domestic products: while the former are subject to batch testing, the latter are subject to testing based on samples taken from the production line every six months. Secondly, concerning the ability for foreign manufacturers to use foreign test results in the certification process, his delegation considered that Indonesia should allow test results issued by adequately accredited foreign labs, namely accredited by ILAC MRA signatories, as the basis for any certification issued by certification bodies approved by the Indonesian Ministry of Industry. It was hoped that these two aspects would be carefully considered and addressed in the context of the on-going review and that a TBT notification of the revised draft decree would be made at the appropriate time.

2.94. Concerning the current situation, Indonesia was urged to prolong the two-year grace period for the acceptance of foreign test results beyond its 30 April 2016 expiry date pending the review of Decree No. 24, and in any event to consider as a permanent solution the EU proposal to use foreign test results as a basis for any certification issued by certification bodies approved by the Indonesian Ministry of Industry. The EU was aware that consideration was being given to ensuring alignment between the Indonesian national standard for toys and the corresponding ISO standard. The review would also provide for a certain automatic alignment between the national and the international standards, in order to avoid any discrepancy between the two. His delegation invited Indonesia to urgently consider amending the current testing methods for formaldehyde, which it deemed erroneously based on limits that applied to infant clothing rather than toys, the former being much stricter due to the prolonged skin contact with clothing. He welcomed the opportunity for a future bilateral with Indonesia in order to advance discussions.

2.95. The representative of Canada recognized the importance of enhancing toy safety to ensure appropriate protection of consumers. However, his delegation considered certain aspects of Indonesia's toy regulatory regime considerably more restrictive than necessary and at odds with internationally recognized practices in the sector. The provisions relating to laboratory accreditation, testing frequency, sampling, documentation, and substance restrictions were of particular concern and had not been adequately addressed despite repeated interventions from other Committee Members. Canada urged Indonesia to adhere to international best practices by allowing ILAC signatories and properly accredited ISO 17025 laboratories to test without requiring additional approval by the Ministry of Industry. The differences in sampling criteria for domestic

products (every 6 months) and imported products (every shipment) adopted by Indonesia were deemed discriminatory towards imported products. Whilst his delegation recognized the difference in the volume of products to be tested, it was considered to be at odds with Indonesia's national treatment and MFN obligations. He invited Indonesia to provide additional information on the anticipated implementation date for the new formaldehyde test method. Currently, manufacturers had to conduct separate tests that were unique to the Indonesian market. Canada was also concerned that the 20ppm requirement was very close to existing feasible detection limits, making it difficult to conduct accurate tests, and in this light suggested that existing international standards and limits be used.

2.96. The representative of the United States expressed concern at the lack of information available from the Indonesian government on the matter. Of particular concern were the acceptance of test results from accredited laboratories, testing frequency, sampling, documentation, and substance restrictions, and the constraint of having a bilateral MRA in addition to the ILAC MRA requirements in place by the fast-approaching deadline of April 2016. In this regard, it invited Indonesia to ensure that the current transition period for acceptance of foreign lab tests would be extended until issuance of the new regulation. She recalled her delegation's support of Indonesia's intentions to revise the regulation as part of President Jokowi's effort to reduce wait times at Indonesian ports, requesting an update on the status and content of the revisions. The US was keen to work with Indonesia in what it hoped to be a transparent revision, allowing for meaningful foreign stakeholder participation. The Ministry of Industry's creation of a Toy Industry Working Group was also welcomed. She urged Indonesia to notify the draft at an early enough stage to allow all stakeholders to provide comments and to allow them to be taken into account with adequate time for necessary changes to be made to the final measure. Summing up, she recalled her delegation's previous interventions on the issue, hoping that the concerns raised would be addressed by the revisions.

2.97. The representative of Japan expressed her delegation's continued support for the positions of Canada, the United States and the European Union. She reported that serious delays in exports had been caused by a sequence of events such as sampling, testing, SNI certification and pre-shipment inspection and in this light invited Indonesia to revise the requirements that her delegation considered to be more trade-restrictive than necessary. Regarding one particular issue of concern relating to the laboratory accreditation requirement, Japan understood that most toys imported to Indonesia had been tested by foreign laboratories. Regarding these toys, Japan considered that only using foreign laboratories located in countries with which Indonesia had an MRA and domestic laboratories would not ensure smooth and accurate testing. Japan strongly urged Indonesia to continue to accredit foreign laboratories located in countries not having an MRA with Indonesia. Could Indonesia confirm whether or not there were any countries with which Indonesia had an MRA at this stage? Japan requested an update on Indonesia's commitment in the November 2015 meeting to review its toy safety regulation and to provide an opportunity for Members to comment on the regulation.

2.98. The representative of Indonesia indicated that thus far there had been no further developments regarding the mandatory application of SNI Toys and recalled its responses in the June 2015 meeting.¹⁰ He flagged Indonesia's intention of conducting a review on the implementation of regulations on mandatory application of SNI Toys to ensure that it was running effectively and efficiently. His delegation welcomed any requests for further clarification that Members may have on the policy.

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

2.99. The representative of the European Union invited India to update the Committee on the latest developments regarding this measure. He first raised concerns with draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulation 2015 (notified to the WTO SPS Committee under G/SPS/N/IND/108), which covered a very wide range of products and could disrupt imports into India. His delegation believed the regulation set too restrictive "recommended maximum levels of additives" for use in all kinds of products.

¹⁰ G/TBT/M/66, paragraph 3.95.

2.100. He noted that the regulation did not acknowledge that "the lack of reference to a particular additive or its usage in food does not imply the unsafeness or unsuitability of an additive or its usage in food", in line with the Codex General Standard for Food Additives (GSFA, Codex Stan 192-1995). Furthermore, he said that the regulation did not take into consideration the adoption of standards by other international standard bodies such as the World Vine and Wine Organization (OIV) or by other countries, which were set on the basis of science, of longstanding good practices, of technology needs and safety. The EU asked India to take into consideration in the final version of the Regulation all comments sent by the EU and asked that India introduce a flexible and expeditious procedure to authorize new additives within a reasonable period of time.

2.101. Finally, he requested India to update the Committee on the process of amending specific parts of the Indian food standards in line with Codex standards. The EU said this process was important to facilitate the imports of products such as olives, whole-wheat pasta, vinegar and mineral water, among others.

2.102. The representative of the United States shared concerns raised by the EU delegation and recalled her delegation's intervention from the previous meeting.¹¹ She sought an update on the status of India's efforts to align domestic requirements with international standards and understood that India had expected to complete those efforts by the end of 2014. The US greatly appreciated the information provided by India regarding the issuance of two new SPS and TBT product-specific notifications on food additives and vegetable oils, respectively. She requested India to provide a timeline for the publication of the amended FSSAI Rules. The US was of the view that wholesale bags of agricultural commodities should not need be labelled with consumer-focused information upon arrival at Indian ports. This should not be deemed as a rectifiable labelling defect in the first place given that the end use of the product is not direct consumption. The US respectfully requested India to consider the end use of the product as the determinant factor when assessing compliance with labelling requirements.

2.103. The representative of Australia reiterated her delegation's concern on India's delays in harmonizing with Codex standards and associated labelling requirements as this work was due to be finalized in 2014. She asked India to advise Members on when the process of harmonization with Codex standards would be finalized and expressed Australia's willingness to continue working with India towards completion of the Codex harmonization process. She recalled that India had agreed at the June 2015 TBT Committee meeting¹² to forward queries from WTO Members to New Delhi and to send a response to interested delegations in due course. As no response had been received, her delegation asked if India could advise on when a response would be provided.

2.104. The representative of Guatemala said that her delegation shared the legitimate objective of informing the Indian population about the food that they were eating, including information on ingredients therein, but Guatemala also shared the concerns which had been expressed by other Members and would follow the development of this discussion very closely.

2.105. The representative of India expressed gratitude to the other delegations for their continued interest in the matter and informed the Committee that the FSSAI had harmonized its standards on food additives with Codex, with effect from 23 December 2015. He said that his delegation took note of the new concerns and suggestions such as that concerning labelling of wholesale food items, which would be forwarded to the capital for consideration.

2.2.3.9 European Union – Draft Implementing Regulations amending Regulation (EC) No. 607/2009 laying down detailed rules for the application of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products, G/TBT/N/EU/246, G/TBT/N/EU/246/Add.1 (IMS ID 345)

2.106. The representative of the United States recalled previous concerns expressed at the last meeting: "...that this measure would severely restrict the ability of non-EC wine to use common or descriptive and commercially valuable terms, on the grounds that those terms are traditional to European wines."¹³ This was a particular concern because some of these terms did not have a

¹¹ G/TBT/M/67, para 2.100.

¹² G/TBT/M/66, para 3.102.

¹³ G/TBT/M/67, para. 2.107.

common definition across EU member States. Furthermore, she recalled her delegation's concerns about the enforcement of the regulation and how the Commission would ensure consistency of interpretation across EU member States,¹⁴ and requested an update from the EU on the status of the application that was submitted by the US wine industry four years ago.

2.107. She held that the continued lack of transparency and fulsome response to repeated requests and interventions on behalf of the US was unacceptable and considered this issue as a serious trade concern that negatively impacted bilateral trade without resolution for years. Indeed, many US suppliers were still unable to ship their products to the EU. The US failed to see why several other countries had already been granted permission to use various traditional terms, while other countries including the US continued to wait on their applications. The ongoing delay by the Commission continued to erode market access for US wines in EU member States, and the US asked what was the basis for the extended delay in approving US applications.

2.108. On the question of approving the applications, the US had been hearing for months that the EU would imminently make more information available about the status of the traditional terms of applications, as well as changes within the EU to the application review process. The US expressed disappointment that there was still no news on how this process was moving forward, as communicated by the EU at their most recent bilateral meeting. The US delegation said the consistent delay and lack of information about the process was completely unacceptable. While the US valued its close trading relationship with the EU, the sustained lack of responsiveness, transparency, and timely review of these pending applications put a strain on the ability of the US to work productively with the EU.

2.109. The representative of Argentina shared the concern expressed by the United States regarding the modification of the EU wine regime. Since the current amendment process was not transparent, there was no information whatsoever on the regime that is to replace the current one and on how it will affect pending applications for registration such as those relating to the traditional terms "Reserva" and "Gran Reserva". In this regard, Argentina asked whether the EU planned to consult interested third countries, whether it would conduct a public assessment of the impact of the proposal, and whether a tentative date had been set for circulation of the legislative reform proposal.

2.110. The representative of the European Union thanked the other Members for the interest in the EU's requirements on wine products. As noted at the last TBT Committee meeting, an internal assessment on traditional terms had been carried out within the EU involving stakeholders and experts from EU member States (in accordance with Article 114(3) of Regulation n° 1308/2013 establishing a common organization of the markets in agricultural products).¹⁵ The alignment and simplification of wine labelling provisions and traditional terms rules, as well as the pending applications for traditional terms, were still under consideration in the context of the general reflection on the marketing rules for all agricultural products. Therefore, no proposals on traditional terms were expected shortly. The EU would continue to make the possible and necessary efforts to simplify its current policy on protection of traditional terms and their indication on the labels of wines, taking into account trade partners' concerns. The concerns raised by the other Members were noted and he said these would be considered when carrying out the complex simplification exercise. Finally, he informed that the handling of the pending applications (whether from EU member States or third countries) would be part of this process, and also expressed the EU's openness to hold bilateral discussion with trade partners at expert level.

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

2.111. The representative of Canada reiterated his delegation's concerns with this measure. He appreciated Chile's responses (from August 2015) to the concerns raised by several Members in the previous Committee meetings, and expressed Canada's support for the objective of promoting healthy dietary choices and reducing obesity and related non-communicable diseases. Nevertheless, Canada encouraged Chile to consider less trade-restrictive measures. His delegation was concerned that the regulations published on 26 June 2015 deviated from international

¹⁴ G/TBT/M/46, paras. 310-311.

¹⁵ G/TBT/M/67, para. 2.110.

standards, may not be based on scientific evidence, and may be more trade restrictive than necessary. He suggested that nutrient content limits based on actual serving sizes normally consumed at one sitting could provide an effective way of meeting the policy objective.

2.112. The representative of Mexico recalled concerns on Chile's Food Health Regulations, Supreme Decree No. 977/96, notified to WTO Members as a draft technical regulation on 22 August 2014, in document G/TBT/N/CHL/282, and on its amendment, Decree No. 13 dated 16 April 2015, which was circulated to WTO Members on 9 July 2015, as document G/TBT/N/CHL/282/Add.1. On 27 August 2015, Chile notified the replies to the comments submitted during the public consultation on this technical regulation. She noted that this concern had first been raised at the TBT Committee meeting of 6-7 March 2013 and had been reiterated on several occasions, and also noted that Mexico's previous statements had been circulated to Members.¹⁶

2.113. Mexico elaborated several specific concerns. First, although the measure had characteristics of a technical regulation as provided for in Annex 1 to the TBT Agreement, Mexico considered that Chile had failed to comply with the transparency obligation set forth in Article 2.9 of the TBT Agreement, preventing Committee Members from submitting comments. Second, Mexico considered that Chile may be contravening principles of the TBT Agreement, specifically the need to base technical regulations on international standards, as stipulated in Article 2 of the TBT Agreement, since these provisions were not consistent with the General Guidelines on Claims of the Codex Alimentarius (CAC/GL 1 1979, point 3.5).

2.114. Third, Mexico considered that every food possessed inherent nutritional characteristics, and no food could therefore be characterized as "good" or "bad" in relation to its nutritional content. The provisions of the amendment to the Regulations, specifically the provision relating to the label "HIGH IN" (fats, sodium, sugar or calories), could arouse fear in consumers by leading them to assume that non-communicable diseases such as obesity are caused by the consumption of specific foods. Fourth, as already pointed out by Mexico on previous occasions, the Codex Guidelines on Nutrition Labelling stated that labelling "should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product", given that a "more exact quantitative delineation for individuals is not valid because there is no meaningful way in which knowledge about individual requirements can be used in labelling". Fifth, in light of the principle of proportionality established in Article 2.2 of the TBT Agreement, Mexico was of the view that the most recently notified measure required sound scientific and technical substantiation to ensure that the proposed label did not become more trade restrictive than necessary for pursuing the legitimate objective of Chile.

2.115. Sixth, the Food Health Regulations also stipulated that "foods or food products whose nutritional composition comprises energy, sodium, sugars or saturated fats in amounts higher than those specified in Table No. 1 of Article 120 bis, may not be advertised in the media or channels of communication, irrespective of location, that targets minors aged under 14 [...]". Mexico noted that this prohibition on advertising did not apply to foods containing energy, sugars, sodium, or saturated fats in a natural form. Seventh, Mexico requested Chile to provide the scientific or technical evidence justifying the prohibition on advertising to minors aged 14 and under, as well as the exception established for products whose energy, sugar, sodium or saturated fat content is in a natural form. There were products on the market with a higher sugar, sodium or saturated fat content than natural foods; therefore, if the aim was for children below the age of 14 to refrain from eating foods high in sugars, sodium or saturated fats, this requirement did not meet the legitimate objective of the Regulations.

2.116. Mexico requested that Chile submit the provisions that had given rise to the amendments to the Food Health Regulations to public consultation. In addition, Mexico asked Chile to harmonize the requirements set forth in the Regulations with the General Guidelines on Claims of the Codex Alimentarius (CAC/GL 1 1979, point 3.5). Mexico further requested Chile to provide an explanation of the scientific or technical evidence supporting the use of labels bearing the term "HIGH IN", considering the legitimate objective pursued by the amendment to the Food Health Regulations. Finally, Mexico asked that Chile modify the classification of foods on the basis of a distinction

¹⁶ G/TBT/W/406 (18-19 March 2015 TBT Committee meeting), G/TBT/W/428 (4-6 November 2015 TBT Committee meeting).

between liquid and solid foods and, in accordance with international parameters, to classify foods according to the category to which they belong.

2.117. The representative of the United States strongly supported Chile's public health objectives of reducing obesity and related non-communicable diseases, and appreciated the extensive bilateral engagement on Chile's nutrition labelling regulation and its associated WTO notifications. The US appreciated the inclusion of an implementation review mechanism in the final measure, but asked Chile to delay implementation in order to fully review and consider comments received from foreign stakeholders in the context of this mechanism. As raised in past meetings, the US encouraged Chile to evaluate the impact of the "warning" element of the icons, and the use of 100 gram and 100 ml portion sizes. She reiterated the US request for a two-year implementation window from the date that the final regulation was published in order to allow industry reformulation and compliance with the labelling requirements based on nutrient thresholds.

2.118. In addition, the US emphasized five outstanding issues: first, whether concentrated fruit juice would be considered "sugar" and unflavoured syrups used in baking such as corn syrup would be considered "syrup". Second, she asked how Chile would verify the addition of sodium, saturated fats, sugar, and honey, amongst others. Chile indicated that, in addition to the ingredient list, it would consider technical specifications of the product or its ingredients, audits of production methods, chemical laboratory analysis, and possible other means. Third, she asked whether foods such as whole grain breakfast cereals, whole milk, yogurt, cooking oils, and cheese would be exempt from the measure. Fourth, the US requested Chile to develop guidance or otherwise provide transparency on these issues and to consult with all stakeholders in doing so. Fifth, she asked Chile to confirm whether voluntary claims would be allowed when the claim was not related to a nutrient that exceeds the relevant threshold.

2.119. The representative of Guatemala reiterated concerns regarding the measure expressed in past Committee meetings. Her delegation shared Chile's concerns about childhood obesity and expressed deference to Chile's right to adopt appropriate measures to address these issues. Nevertheless, it was not clear to Guatemala how the establishment of nutrient content thresholds and labelling requirements could potentially reduce obesity since the level of a nutrient ingested by an individual depended on the habits of consumers. She said that any foodstuff had inherent nutritional characteristics and that it was not possible to decide what was good or bad solely on the basis of nutritional content. While her delegation appreciated that Chile took into account some concerns that had been raised by other Members, she noted that the Chilean delegation did not answer Guatemala's question on how the measure would reduce obesity and why the measure as designed did not constitute an unnecessary obstacle to trade. Guatemala said the measure should be based on Codex standards, and be based on science.

2.120. Guatemala requested consultations with the Chilean Ministry of Health of Chile regarding the conditions for labelling and asked whether the measure would enter into force on 26 July 2017. Guatemala also asked if there is a timeframe for products which were already on the market and if additional time would be given to these products to align with the labelling requirements. Finally, Guatemala expressed concern about the convergence problem in labelling requirements in the region. Her delegation did not believe that Codex standards were being taken into consideration, and that each Member was adopting different national measures to protect the health of their respective population, with the consequence of obstructing trade in foodstuffs.

2.121. The representative of Costa Rica supported the concerns voiced by Canada and Mexico. Costa Rica continued to question the compatibility of the measure with the provisions of the TBT Agreement, especially regarding the lack of scientific evidence to substantiate these measures as stated in the Codex Alimentarius. Costa Rica urged the Chilean government to adopt necessary measures to safeguard the legitimate objectives of protecting health, while taking these concerns into consideration.

2.122. The representative of Chile thanked Members for their interest in the modification of Decree 977 of 1996 by the Chilean Ministry of Health, Health Regulations Food, to fulfil the mandate set out in the Act 20,606 on Nutritional Composition of Food and Advertising. He first recalled Chile's statement at the November 2015 TBT Committee meeting.¹⁷ He stated that Chile had complied with the obligations of the TBT Agreement in terms of transparency by notifying to

¹⁷ G/TBT/M/67, para. 2.116

the WTO, as well as complying with recommendations of the Committee by responding to comments received from trading partners, and informing the general public via the website of the Ministry of Health. With respect to advertising, Chile doubted that such measures were covered by the TBT Agreement as stated on previous occasions. Statistics showed that the prevalence of childhood obesity and related non-communicable diseases had increased in Chile, which is the reason why it had enacted this measure together with other related measures over time. Finally, he expressed Chile's willingness to hold consultations with concerned Members who needed further information regarding implementation of the measure, bilaterally, in the Committee or elsewhere.

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

2.123. The representative of the Republic of Korea thanked India for the numerous bilateral meetings and their efforts to improve the Compulsory Registration Order on secondary cell batteries. While many of Korea's issues had been resolved, Korean companies continued to have difficulties in complying with the regulation. First, as a member of the IECEE CB Scheme, India's certification bodies already had MRAs with other Members and should therefore accept test reports approved under the Scheme. Second, the Bureau of Indian Standards (BIS) certification was only valid for two years whereas others, such as Chinese Taipei's BSMI and Korea's KC certification were valid for five years. In addition, it took approximately six months to receive BIS certification. Therefore Korea requested for a one- or two-year extension of BIS certification.

2.124. The representative of Canada said exporters continued to face challenges in gaining access to the Indian market due to delays in registration and testing. Recognition of foreign conformity assessment bodies accredited by signatories to the ILAC and IAF MLAs to test and certify to India's regulatory requirements would minimize the negative impact on companies wishing to export to India. This would also provide assurance to India that the recognized conformity assessment bodies were competent, and by allowing accredited foreign conformity assessment bodies to test and certify to India's regulatory requirements, they would reduce testing costs and allow exporters to bring their products to the Indian market more quickly. Canada also queried the rationale of the BIS requirement for an MRA in order to accept test results from non-BIS labs, even if they were ILAC, IAF accredited and produced test reports following the IECEE-CB scheme. Given the substantive amendments to the Order, Canada asked that the measure be notified to the TBT Committee and looked forward to continuing to work with India to address the outstanding issues.

2.125. The representative of the European Union associated his delegation with the comments made by Korea and Canada. He thanked India for providing some clarification regarding the various categories of products covered and for the recently notified addenda concerning changes in the date of entry into force. However, the EU continued to have concerns with the registration procedure and reiterated its request to consider a single registration for multiple factories where identical products were manufactured under the control of the same manufacturer, as had been reflected in the minutes of the previous two TBT Committee meetings. India had indicated that this matter was under active consideration by the Department of Electronics and Information Technology of the Ministry of Communication and IT. An update on this active consideration, and a shortening of the processing time for incoming applications, would be appreciated. On the issue of testing reports, the status quo was that India accepted test reports issued under the IEC CB scheme or by laboratories accredited to international standard ISO/IEC 17025 by an ILAC MRA signatory, but only for safety critical components. He reiterated the request for India to consider improving reliance on the IEC CB scheme as well as ILAC MRA so as to increase acceptability of test reports issued under the CB scheme by CABs accredited by an ILAC MRA signatory beyond the safety critical components. The EU also requested more flexibility concerning the validity of test reports which was currently limited to 90 days which was considered by industry to be overly restrictive.

2.126. The representative of the United States reiterated her delegation's appreciation for India's continued engagement with industry and the expansion of the list of products under the Highly Specialized Equipment (HSE) exemption. She urged India to further broaden the list so as to include all products that were not destined for the commercial market such as servers, storage systems, and large-scale printing machines which were installed, operated, and maintained by trained professionals and therefore did not pose any risk to the average consumer. The US encouraged India to modify FAQ No.18 to indicate that HSE shall stand exempted from the

Compulsory Registration Order (CRO) provided that it is intended for sale to medium to large enterprises and requires the medium to large enterprise to order directly from the product vendor or through Business Partners representing the vendor, and was not available through consumer retail channels.

2.127. She asked that India explain why it was necessary for foreign products to be retested against a BIS standard when they had already been tested against an identical international safety standard (IEC 60950-1). On the MRA requirement, she asked why an additional MRA was necessary when, as a member of the IECEE CB Scheme, India should provide reciprocal approval of tests performed at IECEE CB accredited labs outside of India. On the acceptance of lab test results, she reiterated the request that appointed labs should only require a product sample to conduct verification testing if the labs could not resolve a suspected non-compliance issue from information exchanges between the Certification Body issuing the CB Test report and/or the manufacturer. This would be of great assistance to manufacturers and allow India's labs to improve testing. The US also had concerns with the expiration of test reports after 90 days as this was not in line with international norms. As no other national certification agency had expiration dates on their test reports, she asked why India required this deviation from international practice. She questioned what risk factors this addressed and requested that India remove this constraint. Concerning brand-based certification, the US appreciated the shift to this type of certification. However the change was still insufficient in addressing concerns as the CRO process required registration of each factory rather than brand owner registration. The US asked that the BIS recognize global supply chain best practices whereby the brand owners were responsible for the safety and compliance of their products rather than individual factories, as laid out in IECEE Definitions, Edition 2.0 2014-06-04. The brand owners had greater authority to act in a situation of an alleged or suspected safety issue and determine whether there was a risk to the consumer, whereas a factory could only understand the product design to the extent allowed under contract. They rarely had the engineering resources to conduct a safety analysis on their own. Making the brand owners responsible would therefore enable India to align the CRO with global supply chain models and reduce redundant testing and timelines. Concerning the CRO product registration and renewal process, the US requested that the product registration process at BIS be automated and a clear timeline from application submission to final approval be established. This would allow industry to comply with BIS standards and ensure that consumers had access to the most recent ICT products. Finally, the US encouraged India to continue its collaborative consultations with stakeholders so as to bring its safety testing regime into line with international best practices.

2.128. The representative of India thanked delegations for their continued interest in the measure and invited Members to consult the minutes of the previous TBT Committee meeting as many of the issues raised (e.g. reliance of CB Scheme, recognition of foreign labs and accredited conformity assessment bodies, expiry period of test results and validity period of registration) had already been responded to in that meeting. On more recent developments, he informed the Committee that on 30 November 2015, the Government of India had further extended the implementation period of the Compulsory Registration Scheme for some products, such as for sealed secondary cells and batteries to 1 June 2016. India was making progress in harmonizing national standards with international standards and while it had done so in the case of IEC 60950-1, there were requirements to deviate in some areas like the use of Indian plugs and issues such as environmental conditions. On the suggestion to automate the registration process, he said that this system had always been automated and the process time for registration was also clearly defined. Finally he assured Members that all the comments and suggestions would be conveyed to capital for consideration.

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

2.129. The representative of the United States expressed support for Peru's objectives of reducing obesity and other NCDs, however the US was concerned that certain aspects of this measure lacked clarity on implementation and could unnecessarily disrupt trade. She appreciated the extensive bilateral engagement on the proposed regulation to implement the Healthy Eating Act and urged Peru to notify the Supreme Decree 007-201-SA as a revised notification of G/TBT/N/PERU/59, given that this Decree significantly differed from the originally notified text. She informed the Committee that the US had submitted a request through the Peru TBT Enquiry Point for notification of this measure on 24 April 2015. She asked whether Peru was still considering a re-notification and whether there was a timeframe for its submission.

2.130. The US also reiterated substantive concerns about the technical parameters for labelling enacted in the Supreme Decree 007-2015-SA. First, the US was concerned that nutrition labelling was only mandatory when either a voluntary claim was made or the consumption warning was required. Nutrition panels could be regarded by consumers in a negative way if only the least healthy foods were required to display nutrition information. In this regard, the US asked whether Peru considered other less trade-restrictive alternatives. Second, the consumption warning expressed in this measure would apply to significantly more foods and non-alcoholic beverages than those specified in WTO notification G/TBT/N/PER/59. The US requested Peru to explain why it decided to expand the scope of the foods subject to advisory nutrient labelling. Third, the proposed threshold for the amount of sodium and saturated fats that would require a consumption warning and nutrients facts panel was significantly lower than the Codex guidance. The US asked Peru to clarify the process for the establishment of these proposed limits, and the reasons for preferring them over the Codex nutrient reference values (NRV). Fourth, she asked Peru to provide clarification of the basis by which it established the per portion nutrient content limit for sugar, and how Peru determined that an across-the-board nutrient threshold based on 100 gram or 100 millilitre amounts of large categories of foods was appropriate for the Peruvian population.

2.131. The representative of Mexico expressed concerns with regard to Law No. 30021, "Law to Promote Healthy Eating Among Children and Adolescents", published on 17 May 2013 in the Official Journal El Peruano. This concern was first presented to the Committee in June 2014, and had been reiterated on subsequent occasions. This matter had also been the subject of bilateral dialogue with Peru, which Mexico appreciated. Peru had indicated that the regulatory provisions that would implement the Law had not yet been issued. However, Supreme Decree No. 007/15/SA, "Regulations establishing the technical parameters for sugar, sodium and saturated fat content in processed foods and non-alcoholic beverages", had been published on 18 April 2015, approving technical parameters in respect of the content of certain substances (sugar, salt and saturated fats) in processed foods. Specifically, the "Final Additional Provision" stipulated that these new provisions "shall enter into force within the time frame determined by the Regulations implementing Law No. 30021", and Mexico therefore asked for an update on the progress on their preparation.

2.132. Mexico reiterated a number of previously expressed concerns. First, Mexico acknowledged the right of Peru to safeguard its legitimate interests, in this case, protecting its population from non-communicable diseases. It must be pointed out, however, that all public policies must have a scientific basis or be in accordance with international parameters in order to fulfil international commitments. Second, Law No. 30021 had characteristics of a technical regulation as provided for in Annex 1 to the TBT Agreement. Mexico considered that Peru had failed to comply with the transparency obligation set forth in Article 2.9 of the TBT Agreement, preventing Mexico and other Members from submitting comments for consideration in the course of its preparation.

2.133. Third, Mexico considered that Peru may be contravening principles of the TBT Agreement, specifically the need to base technical regulations on international standards, as stipulated in Article 2.4 of the TBT Agreement, since the provisions of the Law were not based on the General Guidelines on Claims of the Codex Alimentarius (CAC/GL 1 1979, point 3.5). Fourth, Mexico considered that every food has inherent nutritional characteristics, as each person has different nutritional needs, and no food can therefore be characterized as "good" or "bad" in relation to its nutritional content. Therefore, use of the term "HIGH" on food labels could arouse fear in consumers by leading them to assume that non-communicable diseases such as obesity were caused by the consumption of specific foods. Fifth, Mexico noted that the Codex Guidelines on Nutrition Labelling state that the label "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", given that a "more exact quantitative delineation for individuals is not valid because there is no meaningful way in which knowledge about individual requirements can be used in labelling".

2.134. Mexico therefore urged Peru to provide an update on the current status of preparation of the measures that will implement the provisions on labelling contained in Law No. 30021, as well as the time frame for entry into force of the technical parameters for processed foods and non-alcoholic beverages, as set forth in Supreme Decree No. 007 2015 SA. Finally, in preparing these measures, she requested that Peru provide a time frame in which to receive and consider comments from other Members.

2.135. The representative of Guatemala reiterated concerns expressed in previous interventions and said that her delegation was looking forward to Peru's response to its comments. She said that Guatemala had submitted comments within the appropriate time-frame of the public consultation and had raised questions in the Committee. She argued that the impact of eating certain foods did not depend on the pre-established values of food but rather depended on the consumer. As a result, she expressed Guatemala's belief that the measure at issue was not supported by scientific or technical basis and expressed concern regarding the technical parameters of Supreme Decree 007-2015-SA, which differed from the previously notified measure. She emphasised Article 3 of the measure which referred to recommendations of the WHO and the Pan American Health Organization, in particular in terms of the application of the Profile Modelling Tool (PMT) of the act which contains parameters for measuring foodstuffs and beverages and their content in terms of sodium, saturated fat and sugar. Guatemala asked for further information on the measure and clarification on how Peru used the PMT. Finally, Guatemala remained concerned about the new changes in the labelling requirements at the regional level, and expressed Guatemala's willingness to discuss the measure bilaterally.

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

2.137. The representative of Costa Rica reiterated his delegation's concerns on this measure, and asked for an update on its implementation.

2.138. The representative of Peru stressed the importance of reducing levels of obesity and other non-communicable diseases amongst the vulnerable population, particularly children and adolescents, objectives this measure sought to address. He stated that the legislative amendments adopted had the legitimate objective of protecting public health as had been recognized by the other Members in their interventions. He reported that Peru was working on a complementary measure which would allow implementation of the Law 3-21 with a multi-sectoral commission which aimed to establish and implement provisions on nutrition, overweight and obesity issues. He said that it was difficult to say when this law would come into force in the short term; however, Peru recognized that businesses needed a reasonable length of time to allow them to adapt their production to new requirements. Finally, Peru reiterated its commitment to avoid creating unnecessary barriers to trade.

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

2.139. The representative of Argentina reiterated his delegation's concern with the revision process being undertaken by the European Union to define its criteria for identifying substances with endocrine disrupting properties. Argentina supported the need to provide stronger protection for human health and the environment so long as this was done in way that was consistent with WTO Agreements, in particular the SPS and TBT Agreements. Argentina referred to the European Commission's statement with respect to the judgment of the EU General Court (Sweden vs the Commission) and underscored the Commission's reference on the fact that impact assessment was an essential tool to guide a future decision on identifying endocrine disruptors. He said that taking a rapid decision to achieve early finalization of the impact assessment could adversely affect the resulting legislative proposal, undermining its quality and scope. Argentina was concerned that in accelerating the roadmap deadlines, comments submitted by the international scientific community, industry and third countries would not be taken into account in the final proposal.

2.140. Therefore, in order to avoid unnecessary barriers to trade, the future regulation to be adopted by the EU should rely on an effective risk assessment taking into the account the actual

exposure to risk, including the possibility of establishing maximum residue limits under the import tolerance approach, instead of classifications based on hazard identification, which will ultimately determine a default MRL detection level of 0.01 ppm for substances covered under that approach. He argued that a measure based solely on an approach that considers only the hazard and not the risk of its likelihood and severity, may lead to disproportionate and unnecessarily trade-restrictive measures that were inconsistent with WTO obligations. Moreover, he reiterated that the European Food Safety Agency (EFSA) had already stated that substances with endocrine disrupting properties could be dealt with on the basis of a risk assessment approach and not just a hazard identification approach.

2.141. Argentina requested that any measure adopted be applied in a transparent and non-discriminatory manner, and not constitute an unnecessary restriction on international trade. He stated that the measure at issue would clearly have extensive commercial and socio-economic impact, affecting countries that produce raw materials, particularly developing countries. Finally, Argentina requested the EU to provide the scheduled timetable for publication of the impact assessment, as well as any changes to the calendar included in the regulatory proposal presentation and whether the possibility of further public consultation was envisaged.

2.142. The representative of Canada reiterated concerns with the EU's proposed approach for the categorization of compounds as Endocrine Disruptors. Canada continued to be concerned with the implementation of a hazard-based approach for the regulation of plant protection products, as this could unnecessarily restrict trade. By focusing on the mere possibility of a hazard instead of the actual risk, a chemical found to pose an acceptable risk under the EU's own risk assessment process may not be authorized under the hazard-based approach. He noted that hazard characterization was an important step in the scientific risk assessment framework. However, it was also imperative that these adverse effects be put into context of the level of potential human and environmental exposure, based on conditions of use. Canada was interested in learning more about the EU's current approach and any evidence that would demonstrate how the EU's deviation from internationally accepted practices was safer for human health. Furthermore, he argued that using hazard-based screening criteria for the categorization of compounds as endocrine disruptors could deprive EU and Canadian producers and farmers from taking advantage of valuable and safe crop protection products. Canada was concerned that the options presented in the EU's Roadmap did not include a risk-based approach.

2.143. Canada said that the EU's hazard-based approach could unnecessarily disrupt trade in food and feed without appreciably increasing the safety of consumers in their markets. Canada strongly believed the EU's regulatory shift only served to undermine international trade in agriculture and contravened the fundamental principle of the WTO SPS agreement, which was to base measures on scientific risk assessments and to not maintain them without scientific justification. As the EU was a global leader in agricultural trade, Canada urged the EU to play a leadership role in demonstrating to other trading nations that it was both possible, and important, to use sound, science-based and trade-consistent measures to protect the safety of consumers. Canada was actively monitoring these measures, and sought further clarifications on the interplay between Regulation 1107/2009 (Placing of plant protection products on the market and repealing council directives 79/117/EEC and 91/414/EEC) and Regulation 396/200 (Maximum Residue Limits of Pesticides in or on Food and Feed of Plant and Animal Origin). Canada asked the EU to reconsider the hazard-based approach which would not make consumers safer, but would have a negative, unnecessary and unjustified impact on trade. Finally, Canada requested that the EU provide information on the upcoming impact assessments to be released in the summer.

2.144. The representation of the United States strongly supported strengthening public health and environmental protection by properly identifying, understanding, and regulating the use of plant protection and biocidal products that may have endocrine-disrupting properties. She emphasized that for several years the United States had been raising concerns with the EU process for identifying endocrine disruptors. For example in January 2015, the US had submitted extensive comments regarding the possible impact of this draft proposal on billions of dollars of trade worldwide. The US remained concerned that a large number of substances, and the products that contain them, could be affected by the new categories and could be withdrawn from the EU market as a result. Given the high level of uncertainty that this issue was causing for global trade, the US urged the EU to adopt an evidence-based approach that considered risk from exposure. The US also asked the EU to provide timely updates on the status of this issue and to follow a process

which would allow for broad public participation. The US looked forward to working with the EU to ensure that the approach followed was risk-based and the least trade restrictive possible.

2.145. The representative of Colombia shared the concerns expressed by other Members with the proposal by the EU to introduce categorization of compounds of Endocrine Disruptors under the EC 07/2009. Colombia also shared the legitimate concerns of the EU with regard to the possible effects on public health of these substances which can affect the endocrine system. However, Colombia stated that any measure adopted by the EU needed to respect WTO agreements. He noted that the EU proposal to regulate products (commonly called agrochemicals) should be based on risk assessment and techniques established by competent international authorities to consider the level of danger involved. Instead, the EU approach meant that any agricultural product containing minimum risk levels or that had been treated by any of the endocrine disruptors falling into these categories would not be allowed into the EU market.

2.146. According to the calculations undertaken by various authorities, it was estimated that the impact on Latin American products to the EU market could be significant. Considering only one of seven categories of products which would be included in this risk assessment according to the 2009 regulation, potentially up to 1.3 billion Euros in trade per year could be affected. Colombia believed that it was important for the EU to undertake a regulatory impact assessment to look at the possible consequences of this regulation. He expressed his delegation's concern that it would be very difficult to limit the number of components falling into each category for defining endocrine disruptors and that many substances, synthetic or natural, can interact with the endocrine system, including phytochemicals, alkaloids such as caffeine, foods, medicines, cosmetic products and plastic products. For this reason, Colombia was of the view that the regulation should be accompanied by a regulatory impact assessment taking into consideration scientific evidence, processes and production methods, relevant inspection methods, testing, and ecological and environmental standards, in order to avoid barriers to trade.

2.147. The representative of Chile supported the interventions of other Members. He shared the view that a full analysis should be carried out with regard to the risk based on scientific evidence, and that any measure adopted by the EU should be based on such evidence, and accompanied by a full impact assessment on the implications of the measure.

2.148. The representative of the European Union informed the Committee – as explained in previous meetings – that the European Commission would be carrying out a comprehensive impact assessment analysing different options on defining criteria for the identification of endocrine disruptors and their corresponding health, socio-economic and environmental effects in the EU legislation. Detailed information about the impact assessment, including the analytical report of the responses to the public consultation of 24 July 2015, was published on the website of DG Health and Food Safety. With regard to the impact assessment, he stated that the Commission had organized several roundtables and a public conference on 1 June 2015 informing EU member States, MEPs, third countries and stakeholders about the on-going impact assessment. He also said that a technical meeting on the Joint Research Centre Methodology held on 6 November 2015 supported the impact assessment and estimated which chemicals would fall under the different criteria to identify endocrine disruptors as outlined in the roadmap. He said that the impact assessment was now entering its final stage and the Commission would present proposals for the new criteria to identify endocrine disruptors in the EU's plant protection products regulation and biocidal products regulation before summer 2016. He informed the Committee that the EU would notify the new proposal to the WTO, in full transparency, to allow interested parties' comments to be taken into account.

2.2.3.14 Indonesia – Ministry of Health Regulation 30/2013 on the inclusion of sugar, salt and fat content information, as well as health messages on the label of processed foods, G/TBT/N/IDN/84, G/TBT/N/IDN/84/Add.1 (IMS ID 389)

2.149. The representative of the European Union reiterated concerns with Regulation 30/2013, which introduced a mandatory health warning message on sugar, salt and fat content on the label of all processed food products. The EU noted that Regulation 30/2013 had been amended by Regulation 63/2015, which postponed the date of application until 2019. However, Regulation 63/2015 did not alter the substance of Regulation 30/2013. He asked for information about the results of any study undertaken by the Indonesian Ministry of Health to determine types of food included in the high risk and low risk classifications. The EU looked forward to the issuing of

implementing provisions for this Regulation addressing product coverage in detail, as well as of guidelines including further details. He 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.

2.150. The EU reiterated its previous request for clarification and detailed information on three issues: (i) how nutrition information and related health warnings would be placed on the label, the testing methods for nutrition levels and the conduct of risk assessment related to non-communicable diseases (NCDs); (ii) the possibility for Indonesia to accept test results issued by laboratories other than the ones accredited by the Indonesian National Accreditation Body (KAN) or by other competent institutions having a Mutual Recognition Arrangement (MRA) with KAN; and (iii) the possibility to place stickers after importation, and before the placement of the products on the market in Indonesia, for instance, in customs warehouses, as an alternative to labelling in the country of origin.

2.151. The representative of Canada expressed support for Indonesia's objective of reducing the risk of non-communicable diseases and appreciated Indonesia's transparency on this issue. Nevertheless, Canada was concerned about the potential trade impact of Indonesia's regulatory proposals requiring labels of all processed and fast foods to bear a health warning regarding content of sugar, salt and fat. She appreciated that the entry into force of the measures was delayed until 2019, and hoped this delay would give Indonesia further opportunity to take into account Members' concerns. She recalled some of these concerns, for example, whether Indonesia's requirement to include a message identifying certain risks in relation to the quantity of sugar, fat and salt ingested per day would be necessary to achieve Indonesia's policy objective. Canada requested Indonesia to provide scientific evidence supporting the use of these measures and to provide reference to the international standards on which the measure was based. In addition, Canada requested that Indonesia provide, in due course, an update on the acceptance of test results from accredited laboratories that use internationally recognized and appropriate methodologies. Finally, Canada encouraged Indonesia to notify further amendments to this regulation.

2.152. The representative of Guatemala expressed support for the legitimate objective of informing the population about foods and their ingredients. Nevertheless, she said that Guatemala shared concerns expressed by other Members and would follow the development of the discussions on this measure carefully.

2.153. The representative of Australia recognized Indonesia's right to implement measures which would provide consumers with information to make appropriate dietary choices and reduce the risk of diet-related non-communicable diseases. However, she stressed that such measures should be no more trade restrictive than necessary to achieve legitimate objectives. Australia sought further clarification on why Indonesia considered a mandatory health message on processed foods was necessary to achieve Indonesia's public health and consumer information objectives. Finally, Australia reminded Indonesia of the obligation to notify the WTO of any proposed regulatory changes and to take into account comments received from Members.

2.154. The representative of Indonesia responded to concerns raised by other Members. Indonesia's full statement is contained in document G/TBT/W/445.

2.2.3.15 Ecuador – Resolution No. 116 of the Foreign Trade Committee of Ecuador of 19 November 2013 and Technical Regulation of the Ecuadorian Standardization Institute RTE INEN 022 on the labelling of processed and packaged food products, G/TBT/N/ECU/19, G/TBT/N/ECU/19/Add.1–Add.10 (IMS ID 411)

2.155. The representative of Canada expressed concern with regard to the burdensome nature of the conformity assessment procedures for this regulation. Canada had received industry complaints on the requirement to provide a verification checklist to demonstrate compliance on a per shipment basis. Adequate data management, coupled with periodic audits, was a less burdensome method of achieving the same objective. Canada was of the view that the measure was already having an impact on trade and was more trade restrictive than necessary. The process of providing samples to an Ecuadorian Accreditation Organization, in addition to self-certification, suggested this conformity assessment was duplicative, redundant and trade restrictive. Finally,

Canada asked Ecuador to explain this measure, and what efforts were undertaken to improve the product certification process.

2.156. The representative of the European Union shared Canada's concerns with RTE INEN 022 on the labelling of processed and packaged food products. He recalled the EU's previous interventions¹⁸, in particular regarding the lack of proportionality of the measure, its departure from Codex guidelines and the use of "high in" warnings.

2.157. The representative of Mexico limited her remarks to Ecuadorian Standardization Institute Technical Regulation (RTE INEN) No. 022 on the labelling of processed and packaged food products. She noted that this concern had first been raised at the 5-6 November 2014 TBT Committee meeting, and reiterated at the March and June 2015 Committee meetings. At the 4-6 November 2015 TBT Committee meeting, Mexico once again expressed concern regarding this measure.¹⁹ Mexico remained concerned about notification G/TBT/N/ECU/19/Add.11, circulated on 18 December 2015, which related to Corrigendum 1 to the second revision of RTE INEN No. 022. Mexico still had concerns in this respect, as the amendments only provided that labelling was mandatory not only on the front but also on the back of the packaging.

2.158. Mexico appreciated the bilateral dialogue held with Ecuador to address this issue. She noted communications at Vice-ministerial level, which enabled Mexico to reiterate its concerns with regard to the labelling scheme set out in RTE INEN No. 022, and to request evidence justifying how the measures meets its legitimate objective. In this respect, Ecuador had informed Mexico that it based the Regulation on the results of the National Health and Nutrition Survey (ENSANUT), taking into account consumer health, state disease reduction policies and the PAHO Plan of Action for the Prevention of Obesity in Children and Adolescents, which advocated the establishment by countries of requirements "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". Mexico was also informed about the reference to non-caloric sweetener content, based on United States Food and Drug Administration (FDA) provisions, without any explanation, however, as to the technical or scientific basis justifying a reference to the transgenic content of foods.

2.159. Mexico reiterated a number of specific concerns. First, although the regulatory provision forming the basis of the draft revision of PRTE INEN No. 022 (Sanitary Regulations for the Labelling of Processed Foods for Human Consumption) had characteristics of a technical regulation as provided for in Annex 1 to the TBT Agreement, Mexico considered that Peru had failed to comply with the transparency obligation set forth in Article 2.9 of the TBT Agreement, preventing Mexico and other interested Members from submitting comments. Second, Mexico considered that the system of colour-coded charts may contravene the provisions of Article 2.4 of the TBT Agreement, as it was not based on international standards such as the General Standard for the Labelling of Pre Packaged Foods of the Codex Alimentarius (CODEX STAN 1 1985, point 2).

2.160. Third, it should be emphasized that the General Standard for the Labelling of Pre Packaged Foods of the Codex Alimentarius did not stipulate a system of colour-coded charts (showing "high", "medium" and "low" concentration of total fats, sugars and salts); scientific evidence was therefore requested to demonstrate that the system complied with Article 2.2 of the TBT Agreement, by not constituting the least-restrictive alternative necessary to fulfil the desired legitimate objective. She reiterated Mexico's concern that this system could arouse fear in the consumer. Fourth, scientific or technical evidence is also requested to justify the requirement of transgenic content specification on the label. Fifth, Mexico considered that the measures on advertising, which prohibited the use of images of real or fictitious persons and animals in labelling, may be contrary to the provisions of Article 20 of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights, as they may unjustifiably encumber the use of a brand name in the course of trading.

2.161. Finally, she reiterated Mexico's previous requests to Ecuador with respect to this measure. First, Ecuador was requested to notify the Sanitary Regulations for the Labelling of Processed Foods for Human Consumption, in accordance with the provisions of the TBT Agreement, so that comments and observations on the regulations could be submitted. Second, Mexico requested that

¹⁸ G/TBT/M/67, para. 1.148.

¹⁹ G/TBT/W/430.

PRTE INEN No. 022 be amended so that concepts such as "food" and "nutritional claim" would coincide with the provisions of the Codex Alimentarius, and that the difference between "food" and "processed food" be eliminated. Third, Mexico asked for an explanation of the justification and scientific evidence for using the system of colour-coded charts specifying the "high", "medium" or "low" concentration of three components: total fats, sugars and salts. Mexico also asked Ecuador to provide information on the results achieved by this system. Fourth, Mexico requested that justification be provided or, if appropriate, consideration be given to eliminating the requirement of including the term "transgenic" on the label, in case of transgenic content. Fifth, Mexico asked that the restrictions on advertising in labelling be reconsidered.

2.162. The representative of Guatemala reiterated concerns regarding the lack of transparency in terms of complying with TBT Agreement notification obligations and the lack of public consultation. Guatemala said the measure had a negative impact on trade, and was more restrictive than necessary. Although Guatemala did share the legitimate objective of combatting obesity, she was not convinced that the regulation would achieve this objective, and said it would rather create an unnecessary obstacle to trade. She recalled that Ecuador had stated at the last meeting that the labelling requirements were in line with the PAHO provisions and the Codex guidelines. Guatemala asked Ecuador to share scientific information on which the measure was based. She expressed concern about the changes in labelling requirements in the region, and stressed that Codex guidelines were not being taken into consideration. As a result, a range of different measures were being taken by Members to safeguard the legitimate objective of protecting public health, which was creating obstacles to trade.

2.163. The representative of Costa Rica echoed concerns expressed by other delegations, in particular with regard to the lack of scientific evidence and the departure from relevant international standards. She asked Ecuador to consider less trade-restrictive measures which were aligned with the principles of the TBT Agreement.

2.164. The representative of Ecuador noted that Resolution No. 116 was related to certification requirements corresponding to an administrative measure. She said that RTE INEN No. 022, in force since 23 December 2014, was based on the 2012 Ministry of Health's study on health and nutrition, which concluded that Ecuador's epidemiological profile reflected an upward trend in the number of non-communicable diseases across the population, regardless of age or socio-economic status. She noted that Ecuador also encouraged other strategies with regard to nutrition such as promoting maximum levels of fat and sugar and encouraging exercise. She said that the requirements of foodstuff labelling was in line with Article 12 of the TBT Agreement to guarantee the right of consumers to relevant, clear and precise information about the content and characteristics of the foodstuffs in order to make informed choices. In addition, Ecuador was complying with paragraph 3.3.1 of the PAHO "Action Plan for the Prevention Obesity in Children and Adolescents", which established rules that take into consideration Codex 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. She confirmed that the comments made by Members with respect to the procedures for assessing compliance with RTE INEN No. 022 and for obtaining sanitary registration had been reassessed by both INEN (the Ecuadorian Standardization Service) and ARCSA (Sanitary Regulation and Control Agency) and that the processing time had been substantially reduced. With regard to sweeteners, although some had been considered as safe by the FDA, Ecuador decided to inform consumers given that some suffer from metabolic difficulties, unable to metabolize sweeteners. Ecuador informed the Committee that RTE INEN No. 022 was being properly implemented, and that both industry and importers were complying with the regulation. Finally, she noted that the reference standards for RTE INEN No. 022 were adapted to Codex standards.

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

2.165. The representative of the European Union requested further information on whether the amendments notified under G/TBT/N/RUS/29 had been adopted and, if so, when they would enter into force. In addition, the EU wished to receive the final adopted text once available.

2.166. The representative of the Russian Federation thanked the EU for comments on draft amendments to the Customs Union's Technical Regulation on "Safety of products for children and

adolescents." Recalling Russia's statement from the previous meeting²⁰, he said that the "Regulation on the development, adoption, amendment and cancellation of technical regulations of the Eurasian Economic Union" did not impose time limits for internal EAEU member state discussions and that the exact adoption date of the amendments could not be predicted. Russia would continue to share information with Members on the ongoing process.

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

2.167. The representative of Canada reiterated concerns relating to the Food Safety and Standards Authority of India's (FSSAI) advisory re-affirming the position that the product in question must be labelled and marketed as "Imported Rapeseed - Low Erucic Acid Oil (Canola Oil)", which directly affected exports, marketing and sales of canola oil in India. Canada was concerned that the regulation was more trade restrictive than necessary to achieve India's legitimate objective and strongly encouraged India to accept "canola oil" as a synonym for "rapeseed - low erucic acid oil," consistent with India's past practice, the existing Codex standard for naming of vegetable oils, as well as with India's application of the Codex standard to other vegetable oils (i.e. maize and arachis). Noting that the Supreme Court of India had ruled against the FSSAI's interpretation of the regulation and that the decision had been sent to the Bombay High Court for final ruling, he asked when a ruling on the issue was expected. Canada encouraged India to consider an alternative measure regarding labelling requirements for canola oil that did not unnecessarily create a barrier to trade.

2.168. The representative of Australia said that her delegation remained concerned that India's Food Products and Food Additives Regulation only allowed canola oil to be used as a secondary term, which was not consistent with the Codex Standard for named vegetable oils, which permitted the use of synonym descriptors for "rapeseed oil", including canola oil. This was an unnecessary labelling burden for Australian exporters of refined canola oil to India while it was their understanding that the term canola oil was often used to describe domestic products that were available for local sale in India.

2.169. The representative of India replied that there had been no change in the regulatory status since the previous meeting held in June 2015 and referred interested delegations to India's intervention from that meeting.²¹

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

2.170. The representative of the European Union reiterated his delegation's concerns regarding the Regulation on Criteria, Procedures and Conditions for Labels of Alcoholic Beverages (B.E. 2558/2015), which had entered into force on 22 April 2015 and was applicable as from 19 October 2015. As expressed in previous Committee meetings²², the EU welcomed the technical guidelines on the implementation of the Regulation issued by Thailand on 30 September 2015 and also acknowledged Thailand's reply to the EU letter of 13 October 2015 expressing concerns on the strict labelling requirements. In December 2015, the EU had submitted further comments on the Regulation, focusing in particular on the following points: the need for definitions to comply with international standards (i.e. "label" and "container"); the lack of clarity of the provisions relating to the messages permitted on the label, which might lead to inconsistent interpretation by economic operators; the potential risks that the Regulation might bring to specific terms commonly used in the EU linked to the ageing or maturation process, to the conditions, quality or characteristics of the product; the need to allow the sale of all products covered by the Regulation already placed on the market until exhaustion of stocks; and the need to clarify the scope of the exemption related to alcoholic beverages manufactured or imported for export and not for commercial purposes in Thailand. The EU sought confirmation of information received that the Thai Regulation and the technical guidelines would be amended in the near future in order to clarify their provisions and that enforcement would be delayed. The EU also requested an update on the outcome of considerations on graphic health warnings and invited Thailand to notify any draft proposal to the TBT Committee so that Members had the opportunity to comment on it.

²⁰ G/TBT/M/67, paras. 2.153-2.154.

²¹ G/TBT/M/66, para 3.167.

²² G/TBT/M/67, paras. 2.158-2.159; G/TBT/M/66, paras. 3.171-3.172.

2.171. The representative of the United States said that her delegation supported Thailand's efforts to address its valid public safety and health concerns related to excessive alcohol consumption but requested the opportunity for further consultations to address these concerns without unnecessarily restricting trade. The US was disappointed with Thailand's continual lack of responsiveness to questions on this measure as it was still unclear what was, and was not allowed on labels and how this measure was being enforced. The US had not received a response to questions submitted to Thailand via the WTO comment process, during the previous three TBT Committee meetings²³ and also bilaterally. As stated previously, the lack of enforcement procedures, the lack of clarity on how labels would be determined to "directly or indirectly persuade consumption or make claims on the benefit or quality of an alcoholic beverage", and the lack of definition for terms such as "immoral" and "exaggerated statements" were all very troubling, as also indicated by other Members. The long-promised technical guidelines had been expected to answer these questions, but the guidelines recently published failed to provide further clarity on the requirements, without which it was impossible for companies to comply with the regulation. The US and its alcoholic beverage industry were very concerned that a significant amount of trade would be disrupted as a result of the pending implementation. Furthermore, basic questions as to the scientific basis and rationale for the measure had still not been answered. The Thai government had previously alluded to scientific studies that had informed this policy, but had not yet responded to requests to provide that study. She asked that Thailand provide the scientific evidence it referenced as well as clarifications to questions posed as soon as possible. The US was planning to monitor the impact of Thailand's requirements on US alcoholic beverage exports and was wondering whether Thailand was considering an evaluation of the regulation after 18 months. If so, Thailand was invited to explain the evaluation process and whether evaluation results would be shared with trading partners. The US continued to have serious concerns that this measure unnecessarily restricted trade and looked forward to deeper engagement with Thailand on this issue.

2.172. The representative of Canada thanked Thailand for the meeting held that day with several delegations to go through some of the joint issues raised. Canada also welcomed new developments regarding Thailand's regulations on alcohol, as his delegation had serious concerns with the existing version as explained during previous TBT Committee meetings²⁴ and through a letter sent to Thailand's Enquiry Point in May 2014. He understood that the new regulations would be developed in consultation with relevant stakeholders including importers. Canada looked forward to reviewing and commenting on this process and hoped that the results would be in line with the TBT Agreement and would take into account the fact that Canadian wine labels were not intended to appeal to children or promote irresponsible alcohol consumption. Similarly, Canada had not witnessed any correlation between the sale of products labelled with sport figures or cartoon-like images with an uptake in youth or irresponsible drinking. Canada hoped that new regulations would be clear and reduce uncertainty for wine and spirits exporters. Canada was also interested in knowing more about the use of graphic warning labels, which Thailand was considering.

2.173. The representative of Mexico indicated that this concern had first been raised at the June 2014 TBT Committee meeting and then reiterated during several subsequent meetings. Mexico's statements from the March and November 2015 TBT Committee meetings had been circulated on 11 May 2015 and 19 January 2016 in documents G/TBT/W/408 and G/TBT/W/431, respectively. Mexico's concerns related to Thailand's notification of the date of adoption and entry into force of the "Notification of the Alcoholic Beverages Control, Re: Rules, Procedures and Condition for Labels of Alcoholic Beverages" in document G/SPS/N/THA/221/Add.1 of 15 April 2015 and also to notifications in documents G/TBT/N/THA/437 and G/TBT/N/THA/437/Add.1, the latter of which was notified on 27 April 2015, regarding the adoption and entry into force (on 22 April 2015) of the draft notification of the Alcohol Control Committee, Department of Disease Control, under the title "Notification of the Alcoholic Beverages Control, Regarding Rules, Procedure and Condition for Labels of Alcoholic Beverages". A few days earlier, Mexico had received an update on ongoing discussions within the Thai Government concerning the content of the measure and its consistency with international commitments at the World Trade Organization and had been told informally that efforts were under way to promote the consistency of the measure with the WTO principles, specifically as regards technical barriers to trade. Mexico

²³ G/TBT/M/67, paras. 2.163-2.164; G/TBT/M/66, paras. 3.173.

²⁴ G/TBT/M/67, paras. 2.161-2.162; G/TBT/M/66, paras. 3.168-3.169.

welcomed an update from Thailand in this respect and asked whether they could confirm the informal update received.

2.174. The representative of Guatemala said that her delegation supported efforts to protect consumer health and acknowledged the legitimate objective that Thailand was pursuing to reduce the level of consumption of alcohol among its population. However, Guatemala was not convinced that the measure establishing certain criteria with regard to labelling requirements for alcoholic beverages would be effective in reducing consumption. Guatemala thanked Thailand for the detailed explanation, including scientific information, which had led Thailand to conclude that the measure in question would indeed reduce the consumption of alcoholic beverages without being more trade restrictive than necessary to achieve its legitimate objective. However, the prohibitions referred to not only endangered the acknowledgement of the quality of certain products but could also undermine registered intellectual property rights. Guatemala looked forward to receiving further information from Thailand and was available for bilateral discussions if necessary.

2.175. The representative of New Zealand thanked Thailand for the meeting held that day and acknowledged and supported Thailand's right to introduce new regulations to address this specific public health concern. However, as previously raised, New Zealand was concerned that the new labelling requirements were unnecessarily trade restrictive and unclear. She joined the delegations of the US and Canada in seeking confirmation on indications by the Thai Ministry of Public Health that the regulation would be amended to address these concerns. New Zealand thanked Thailand for the guidelines that had been published in September but remained concerned that the regulation was still subject to and open to interpretation, which might lead to uncertainty for manufacturers and importers and have a disproportionate impact on trade. In particular, she sought further clarification around terms such as cartoon and on what constituted overstating of the properties, benefits or quality of a product. Furthermore, she sought information on whether there was an appeal process. New Zealand encouraged the Thai Ministry of Public Health to settle outstanding questions on this regulation and given that the guidelines on implementation were only published at the end of September, requested that the transitional grace period be extended in order to provide industry with sufficient time to ensure that their products could meet this regulation. She also sought an update on whether Thailand was intending to introduce mandatory graphic health warnings on alcohol labels and if so, when the draft regulation would be notified to the WTO.

2.176. The representative of South Africa supported the statements and trade concerns raised by other delegations and recalled its statement from the previous meeting.²⁵ South Africa had also sent comments to Thailand, asking for certain clarifications on the regulation but unfortunately had not received any response thus far. Therefore, South Africa requested that Thailand provide responses to their questions as well as any updates or revisions to the regulation.

2.177. The representative of Japan said that his delegation continued to have concerns, similar to those already raised by other delegations, regarding the regulation and its guidelines notified on 28 March 2014 (G/TBT/N/THA/437) and 30 September 2015 (G/TBT/N/THA/437/Add.1), respectively. Japan understood the intention of Thailand to restrict false, exaggerated or overstating messages on alcoholic beverages; however, prohibiting accurate information would be more trade restrictive than necessary to fulfill a legitimate objective. Therefore, Japan hoped that Thailand would take comments from Japan and other Members into consideration and reconsider the examples listed in the guideline.

2.178. The representative of Chile echoed the concerns expressed by other delegations and also thanked Thailand for the meeting held that day. He hoped that they would be able to continue working together to support Thailand in pursuing their public policy objectives and adopting measures which were proportionate and which did not impose unnecessary barriers to trade. He welcomed the fact that there might be some amendments to the current measure, even though it was not quite clear what form these would take. He also indicated Chile's interest in the status of proposed graphic health warning on alcohol labels.

2.179. The representative of Australia said that they understood from talking to industry in Bangkok that the Ministry of Public Health (MoPH) intended to draft amendments to clarify the current alcohol labelling and implementing guidance document and sought confirmation that this

²⁵ G/TBT/M/67, paras. 2.167-2.168.

was the case. Clarification of the guidance documents would be greatly appreciated. Australian exporters were keen to work with the Thai Government and their importers to comply with the new requirements. She requested that the Thai government submit an official translation of the technical guidance to the TBT Committee in one of the official WTO languages.

2.180. The representative of Thailand thanked delegations for their comments and continued interest on this measure and indicated that all comments would be forwarded to the Department of Disease Control, Ministry of Public Health, for consideration.

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

2.181. The representative of the European Union recalled his delegation's concerns about Technical Regulation 189 on the labelling of alcoholic beverages, already expressed in previous Committee meetings²⁶, in particular on (i) the obligation to state the name of the importer in the front label, (ii) the requirement that the labelling of alcoholic products be done in the country of origin, not allowing labelling or relabeling in a primary customs area, and (iii) the need to undergo certification by a conformity assessment body in order to verify compliance with labelling requirements. In November 2015, Ecuador had informed the Committee that they were still in the process of analyzing the comments received from Members and the EU wished to know the status of this process. The EU was looking forward to receiving a reply to the comments they had submitted on 1 July 2014. The EU also sought clarification on the relation between the proposed technical regulation and resolution SENAE DGN 2013 0300 RE.

2.182. The representative of the United States supported other Members' interventions and raised concerns, particularly with Ecuador's requirement that the name of the importer of alcoholic beverages be placed on the exported product in the country of origin, with no flexibility for placement in customs bonded warehouses via the use of supplementary labels (stickers). During the previous TBT Committee meeting, Ecuador had noted that it was suspending this regulation, which would be deeply appreciated. The United States requested that Ecuador confirm the suspension through a notification to the WTO and also asked for an update on Ecuador's efforts to align the suspension with customs regulations.

2.183. The representative of Mexico reiterated her delegation's concerns with respect to Ecuadorian Draft Technical Regulation No. 189, "Labelling of Alcoholic Beverages", notified to WTO Members in document G/TBT/N/ECU/243, on which concerns had been first raised at the November 2014 TBT Committee meeting and thereafter at the March, June and November 2015 meetings.²⁷ One of Mexico's main requests was that the requirement for labelling in the country of origin with the name of the importer in Ecuador be eliminated or made more flexible so that elements that were necessary solely for marketing purposes in Ecuador did not have to appear on the label at the point of origin of the product. It was important to have scientific and technical justification for the labelling requirement in light of the legitimate objective of the measure. Mexico had also requested that the definition of Tequila, as contained in Ecuadorian Technical Standard NTE INEN No. 338, be adjusted so that it did not run counter to the definition in Mexican Official Standard NOM-006-SCFI-2012. Alternatively, Mexico had asked for the procedure to follow in order to request Ecuador to make this amendment and was willing to work with Ecuador on this point. Mexico requested an update regarding the issuance of the final version of Technical Regulation RTE INEN No. 189 since they had been informed that the formal adoption process had been suspended pending the review of Ecuadorian technical regulations relating to alcoholic beverages. Mexico also requested further details on the other requirements on Mexican industry for importing into Ecuador, as regards the labelling at origin provisions laid down in Resolution SANAE-DGN-2013-0300-RE on labelling of alcoholic beverages.

2.184. The representative of Canada said that his delegation remained concerned that Ecuador's customs regulation (SENAE-DGN-2013-0300-RE), first published in their official registry No. 86 on 23 September 2013, along with the related technical regulation notified on 8 April 2014, were more trade restrictive than necessary when it came to labelling requirements. Ecuador's requirement that the labelling of products be done in the country of origin was a concern for

²⁶ G/TBT/M/67 para. 2.174.

²⁷ Mexico's statement from the November 2015 meeting is available in document G/TBT/W/432.

Canada. Standard practice in the internationally traded spirits industry was to apply, in the country of production, generic front labels providing mandatory information. All country-specific information was then affixed on the back or secondary label in customs bonded warehouses located in the importing country. Ecuador had indicated at previous TBT Committee meetings that the competent authorities were looking at revising the measure in view of the comments received. He invited Ecuador to provide an update on whether the comments had been taken into account and on whether Ecuador would be notifying any amendments to the regulation.

2.185. The representative of Chile echoed the concerns expressed by the US and the EU on the regulation on the labelling of alcoholic beverages and indicated that Chile was also awaiting responses to its comments.

2.186. The representative of Guatemala said that her delegation recognized the importance of reducing alcohol consumption levels but questioned whether the regulation in question was based on evidence demonstrating that it would in fact reduce consumption without being more trade restrictive than necessary in order to achieve this legitimate objective. Guatemala would follow closely the discussions on this measure.

2.187. The representative of Ecuador said that draft regulation INEN 189 on labelling of alcoholic beverages had been notified in 2014 and that its entry into force remained suspended until the completion of the revisions of Ecuadorian Technical Regulation 33 on labelling of alcoholic beverages, INEN 338 on alcoholic beverage definitions and other standards and requirements for alcoholic beverages. These standards would be open for public consultation shortly and would then be considered for approval.

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

2.188. The representative of Canada understood that China had made a number of commitments on certain aspects of the above-mentioned regulation. Canada welcomed these new developments but remained concerned about other important aspects of the regulation and on the general lack of clarity and transparency regarding the measure. Canada continued to be concerned at China's Medical Device Registration Fee Schedule that had been published on 27 May 2015. This new fee schedule had been put into force without any notification to the WTO, failing to give Members a "reasonable interval between the publication of requirements concerning conformity assessment procedures and their entry into force", as per Members' obligation under the TBT Agreement. As had been already mentioned at the November 2015 TBT Committee meeting, Canada was concerned with China's approach of combining registration fees with on-site inspection fees for foreign manufacturers. Further, Canada continued to be concerned about the lack of transparency regarding the registration fees for domestic products which were to be levied by China's provinces. In order to enhance transparency, Canada would be grateful if China could publish the on-site inspection fees separately from the registration fees for foreign manufacturers. In addition, could China publish the registration fees to be levied by China's provinces on domestic manufacturers? Canada strongly suggested that China separate the registration fees with on-site inspection fees for foreign manufacturers so that it was clear what manufacturers were being charged, and for which services. This was important to ensure that a) the registration fees conformed with China's WTO national treatment obligations, and b) the on-site inspection fees corresponded to international averages.

2.189. With regards to the accelerated service being offered by the CFDA to fast-track applications for drugs and medical devices, Canada understood that foreign drugs and medical devices considered "innovative" could be eligible for fast-track evaluation and that China had also made efforts to accept more submissions. Canada welcomed China's initiative to expand the scope of the fast-track program and for providing guidelines on what constitutes an "innovative product." Nevertheless, Canada would like China to confirm this commitment and whether domestic and foreign firms would be charged the same fast-track fee, in line with National Treatment provisions.

2.190. Finally, Canada had recently taken note of China's WTO notification (G/TBT/N/CHN/1169), issued on 26 February 2016, regarding new registration categories of chemical drugs and would

appreciate receiving additional information concerning the changes. In particular, Canada would be interested to receive an explanation from China as to the rationale for the changes to the drug registration categories. Regarding registration categories 1-5 for chemical drugs, was it China's intention to charge different registration fees for these categories and would this result in drug registration fees that differ from those China announced on 27 May 2016? With respect to the description of the categories, how did China define "innovative drugs" and "new improved drugs"? Did "imitation of drugs" mean generic drugs? What was the difference between Category 3 (Imitation of drugs that are marketed overseas but unavailable domestically) and Category 5 (Application for the domestic marketing authorization of drugs marketed overseas)?

2.191. The representative of the European Union reiterated his delegation's concerns regarding the Chinese regulations for medical devices, notified under G/TBT/N/CHN/1022 to 1026 and 1029, as sent to the Chinese authorities on 23 June 2014 and subsequently raised in the last TBT Committees. In particular, the EU referred to its concerns raised during the last meeting of the Committee in relation to the issue of the clinical trials required for the registration in China for Class II or Class III medical devices, the delays in this registration procedure, and the requirement to register the medical devices in the country of origin. The EU had repeatedly raised concerns with regard to the unnecessary duplicative clinical trials to be conducted in China. During the last meeting of the TBT Committee, China had confirmed that according to the CFDA (China Food and Drug Administration) Technical Guideline for Clinical Evaluation of 19 May 2015, manufacturers may present during the marketing approval of medical devices data obtained in clinical trials carried out abroad. However, in the meantime, the EU had received information according to which clinical trials would have to be performed for Class II and III in-vitro diagnostic medical devices on Chinese populations living in a Chinese mainland environment, and results of testing on Chinese populations living abroad or on non-Chinese populations would not be accepted. The EU asked China to clarify this issue. The EU also asked China to accept test reports from foreign laboratories accredited by accreditation bodies that were members of ILAC as an alternative to in-country electromagnetic compatibility testing in China and to exclude from the registration certificate the documentation on product technical requirements, which might be confidential. China was also, once again, requested to grant a transitional period of three years. Further guidelines detailing the relevant processes would be also welcome.

2.192. The representative of Korea shared the concerns expressed by previous speakers. In particular, Korea emphasized the importance of accepting test reports issued by the internationally accredited laboratories.

2.193. The representative of China said that the Regulations for the Supervision and Administration of Medical Devices divided medical devices into three categories according to the level of risk: Class I, II, III – from low to high risk. These were regulated differently: Class I medical devices only needed to be filed while Class II and III had to go through registration. On manufacture, Class I medical devices only need to be filed, while Class II and III needed to be examined and approved by CFDA. Regarding business operation, there were no special limits set by CFDA on Class I medical devices while Class II medical devices need to be filed, and Class III medical devices had to be licensed. The medical devices not listed in the catalogue could also apply for exception if relevant materials could be provided when registered to prove the security and effectiveness of the medical devices. CFDA had received many comments on market approval from the country of origin. It was stressed that the requirement was important to ensure the security and effectiveness of medical devices and to protect the health of Chinese consumers. CFDA would continue to communicate with relevant enterprises and associations – both foreign and domestic – on these measures and would fully considered comments received from Members.

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

2.194. The representative of Mexico thanked Peru for the on-going bilateral dialogue on Law No. 29811. While Mexico recognized the right of each Member to regulate so as to protect the environment, there were concerns with some provisions of the Peruvian measure. On the access for conventional seed to Peru, the requirement for absolute zero presence of GM events in seeds was considered neither possible nor commercially practical and could therefore infringe on Article 5.1.2 and 5.2 of the TBT Agreement. Absolute zero did not exist in the setting of thresholds for GM vegetable material as the biological product passed through various stages in production where all existing detection technologies had a margin for error which could product false positives and false

negatives. The most widely recognized quality standards for varietal identity and purity established by OECD and AOSCA²⁸ recognized that there was some degree of variability inherent in any biological reproduction system and achieving 100% varietal purity was practically impossible and economically unviable. Mexico believed that Peru could be in breach of Article 2.4 of the TBT Agreement as this provision did not appear to be based on an international standard. Therefore, Mexico requested that Peru: (i) recognize the OECD and AOSCA purity standards and certification; (ii) consider recognizing non-GMO certification issued by third party laboratories that were certified by a recognized authority and accepted by the standards of the Peruvian authorities, at the port of loading, rather than subjecting shipments to border inspections; (iii) promote bilateral dialogue with regulatory bodies studying low GMO levels in batches of conventional seed, as well as the determination of thresholds and detection technologies; and (iv) take into consideration the position of seed industries in other countries when analyzing national regulatory measures. Finally, she said that Mexico was aware that the Ministry of Agriculture and Irrigation of Peru had instructed the National Agricultural Research Institute of Peru to draft a proposed amendment to the regulations implementing Law No. 29811, allowing GMO tolerance limits in imports of conventional seed. She asked for an update on how this was progressing.

2.195. The representative of Peru said that the law establishing the moratorium on the planting of GMO crops in Peru was contained in an environmental regulation – it was not a specific technical regulation. Hence, Peru was not required to notify the measure to the WTO because it was not a technical regulation under the TBT Agreement.

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

2.196. The representative of Mexico recalled that formal comments had been submitted to Ecuador on 12 November 2013 and concerns had been reiterated bilaterally, including at the vice-ministerial level. Nevertheless, some concerns remained regarding Ecuadorian Standardization Institute Technical Regulation RTE INEN No. 034 on motor vehicle safety parts.²⁹ The concern had first been raised at the Committee meeting of 5 and 6 November in 2014 and reiterated in March 2015. Likewise, on 8 May 2015 Mexico had circulated the "Statement by Mexico to the 18-19 March 2015 meeting of the Committee on Technical Barriers to Trade", circulated on 11 May as document G/TBT/W/410. Mexico's concerns relate to the following points. First, regarding the transition period for the entry into force of the Regulation, a period of 180 days (six months) had initially been established. Mexico requested that the deadline be extended in order to provide suppliers with sufficient time in which to comply with the measures imposed. Although the latest amendment provided for implementation by October 2016, thereby granting a transition period of one and a half years, Mexico believed that the deadline needed to be extended until April 2017, which would provide a period of two years in which to offset the business losses of the Mexican automotive export industry. Second, Mexico had been informed that the provisions of Technical Regulation RTE INEN No. 034 (1R) might be changed in order to recognize foreign standards that could be considered equivalent to those of the United Nations Economic Commission for Europe (UNECE). While Mexico appreciated this, Mexico reiterated that it would like Suppliers Declaration of Conformity (SDoC) not to be excluded as one of the options for complying with this technical regulation.

2.197. Mexico thus requested Ecuador to extend to two years the transition period for implementation of the changes envisaged in the technical regulation, as from the date of its publication, and to provide information regarding the current state-of-play concerning acceptance of the results of the assessment of conformity as regards compliance with foreign standards, and whether this would include acceptance of self-certification (SDoC) as a demonstration of producers' compliance with the technical regulation.

2.198. The representative of the United States supported the comments from Mexico.

2.199. The representative of Ecuador said that, as had been indicated on previous occasions, the requirements established in Regulation No. 034 were consistent with international standards (UN standards) developed through a system supported by the World Forum for Harmonization of

²⁸ Association of Official Seed Certifying Agencies.

²⁹ Notified in document G/TBT/N/ECU/32 and its most recent amendment, circulated in G/TBT/N/ECU/32/Add.9 on 27 November 2015.

Vehicle Regulations (WP.29) which provided the guarantees needed to regulate the safety of vehicles and to protect its citizens. The system ensured that vehicles were produced in such a way as to provide safety throughout the production life cycle of each model. With regard to the transition periods established for the implementation of RTE INEN No. 34, the Ecuadorian authorities had once more extended the time frame for the entry into force of the Regulation, this time until October 2016. The declaration issued by the manufacturer would be accepted during this period. Under NTE INEN No. 1155, daytime running lights (front and rear fog lights) were optional; however, where present, they had to comply with the provisions of this Ecuadorian Technical Standard. The conformity assessment procedure established in RTE INEN No. 034 (3R), which was based on standards equivalent to those of the United Nations Economic Commission for Europe (UNECE) referred to in this Regulation, was being examined by the competent national authority and the other Ecuadorian regulating entities concerned.

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

2.200. The representative of Switzerland noted that his delegation had already voiced concern about the above-mentioned Decree (N°176) of 4 March 2014, notified in G/TBT/N/SAU/669. Comments had also been issued regarding the draft GSO standard on handling of energy drinks, notified under G/TBT/N/ARE/262, and recently under N° 910 and 912, on behalf of Saudi Arabia and of the Gulf Cooperation Council (GCC) members. These technical regulations required mandatory statements on the product for "energy drinks", as well as restrictions on marketing. The mandatory statement for "energy drinks" had hardly been modified since the last draft. The latest version, notified on 28 January 2016 required a mandatory statement aimed at people with high blood pressure, youth under 16 years of age, or athletes during sport, to the effect that these groups should not drink the beverages. The latest notification included a specific Saudi annex with stronger statements to be put on the products: "warning"; "this product has no health benefits"; "drinking more than 2 cans per day may harm your health". These measures differed from Codex standards on claims and on nutrition, including the principle whereby declarations on products should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather convey an understanding of the quantity of nutrients contained in the product. According to the most recent scientific studies reviewed by Switzerland, there were grounds to mention caffeine content, and to raise awareness to pregnant or breastfeeding women, and children. No rationale to warn other groups could be found. The representative of Switzerland also noted restrictions to sales to people under the age of 16 and the prohibition of mixing these drinks with non-alcoholic beverages such as juices as examples of trade restrictive practices. It was unclear what health impact Saudi Arabia and GCC countries expected from these unique measures, how the public reacted to such warnings, and if alternatives had been considered. Switzerland shared the legislators' intents regarding public health and consumer information. However, the measures appeared to be more trade restrictive than necessary. While Switzerland appreciated the notification from GCC countries, and their openness to dialogue, answers were still needed to questions on the draft standard. Switzerland hoped that these would be clarified before entry into force and that the draft standard would be less costly to implement and more in line with international standards.

2.201. The representative of the United States noted that although the present concern was directed towards Saudi Arabia, it was a GCC-wide technical regulation so the US comments were directed towards all of the Members of the GCC. While the United States supported efforts to promote public health through increased consumer information, the US remain concerned about the scientific and other technical evidence used to support this regulation. As had been stated in US comments submitted in August, the US requested further information regarding the rationale for, as well as any research or data supporting the regulation, including size and total acidity limits, and the need for multiple health warnings. It was noted that at the Committee's last meeting, it had been said that there were consultations underway – however, the United States still had not received a response to its concerns. Could the GCC members provide an update on the status of these consultations? In addition, the United States would also like to again formally request a response to the comments submitted earlier.

2.202. The United States was concerned that the GCC's approach, particularly with regard to the ban on advertising and sponsoring events, which went beyond the approach that many other

countries had adopted, might unnecessarily restrict trade without improving public health outcomes. Could the GCC provide a timeframe in which it planned to respond to concerns raised, and could they explain when they expected the rulemaking process to progress?

2.203. The representative of the European Union supported the points made by Switzerland and the US. In particular, the EU shared concerns regarding the large discretionary restrictions which, on the basis of the notified draft, could be imposed on the marketing of these products by regional or local authorities. Such an approach made it possible for lower level authorities to create barriers to trade and as such was a source of regulatory uncertainty. The EU was also concerned about the lack of clear scientific substantiation of the statement to be included on energy drinks. The EU reiterated its proposal to Saudi Arabia to engage bilaterally in a dialogue.

2.204. The representative of the Kingdom of Saudi Arabia thanked delegations for their comments. As had been explained at the previous meeting, held in June 2015, Saudi Arabia had already explained the reason for the implementation of this measure.³⁰ Regarding the draft regulation which had been notified on 28 January, the GSO TBT Committee was still receiving comments from Members and questions would be replied to in due time; about 20 days still remained to complete the comment period.

2.2.3.24 Brazil – Draft Technical Resolution n° 69, 9 September 2014, Regarding the Requirement of Describing the Chemical Composition, in Portuguese, in the Label of Personal Hygiene Products, Cosmetics and Perfumes, G/TBT/N/BRA/608 (IMS ID 443)

2.205. The representative of Mexico said that by failing to consider the existence of a widely accepted international nomenclature for the ingredients of cosmetic products (INCI nomenclature), the proposed measure might not be in line with Article 2.4 of the TBT Agreement. Mexico was also concerned with the distinction that the draft made between products from the European Union and imports from Brazil's other trading partners (specifically those of the Latin American region), in violation of the non-discrimination principle in Article 2.1 of the TBT Agreement. It was also noted that, in view of the foregoing, on 19 January 2015 Mexico had submitted formal comments to Brazil about the non-reliance on the INCI nomenclature system. Mexico had also requested an explanation of – or justification for – the benefits of translating the names of product ingredients into Portuguese, since these use a large number of raw materials with highly complex technical names. In response, Brazil had said that the matter was subject to domestic judicial proceedings. Mexico therefore requested Brazil to inform Members of the state of progress of the aforementioned judicial proceedings and, if appropriate, whether the comments made in regard to compliance with Article 2.1 and 2.4 of the TBT Agreement could be taken into consideration.

2.206. The representative of Brazil explained that the measure at issue was not yet in force and was still under a process of public consultation. The draft resolution was developed by Brazil's competent agency in this field - ANVISA - in order to comply with a judicial decision. This decision established the obligation for producers of cosmetics to display on the label the chemical composition in Portuguese. This judicial decision, which was based on Brazil's consumer rights law, had been appealed and its effects suspended until further decision of a higher court. He also explained that ANVISA had held consultations on the draft measure and that all comments received were still under technical analysis. Therefore, the final draft may still be changed. He also said that the draft measure did not prevent the use of the INCI (the International Nomenclature of Cosmetic Ingredients). INCI would create an additional obligation to translate into Portuguese the chemical composition of cosmetics. Brazil believed that the draft measure should only be applied after the resolution of this judicial process and that it would be consistent, both with Brazil's internal laws and regulations, as well as with the TBT Agreement.

2.2.3.25 Ecuador - (PRTE INEN) No. 111: Energy efficiency. Clothes dryers. Labelling, G/TBT/N/ECU/152, G/TBT/N/ECU/152/Add.1, G/TBT/N/ECU/87, G/TBT/N/ECU/87/Add.1-4 (IMS ID 455)

2.207. The representative of Mexico said that the Mexican industry continued to be concerned about the marketing of products of energy efficiency classes "A" and "B". The industry maintained that while in principle, the technical regulation recognized both classes, in practice only energy efficiency class "A" washer-dryers were permitted. Moreover, it had emerged from bilateral

³⁰ G/TBT/M/67, para 2.196.

communications with Ecuador that Technical Regulation RTE INEN No. 111 was currently being revised and studied in order to consider the equivalence of UL standards and IEC or European standards. She said that if the products were to be assessed as being in conformity with IEC, EN, or UL standards, the results of the analysis under way would be accepted.

2.208. Given the foregoing, Mexico requested Ecuador, with respect to Technical Regulation RTE INEN No. 111: (i) to provide an update on the revision of this measure, in terms of the recognition of foreign standards; (ii) to provide technical or scientific justification for the requirements of this measure concerning authorization for energy efficiency class "A" washer-dryers. On this particular point, Mexico expressed its view that Ecuador may be contravening the proportionality principle established in Article 2.2 of the TBT Agreement by defining excessively high ranges of energy efficiency in relation to the legitimate objective pursued, which would unnecessarily limit the access of products to the Ecuadorian market; and (iii) to provide information regarding the risk that might arise from not achieving the measure's legitimate objective, by adopting the restriction laid down in Article 10.4 of the measure.

2.209. With regard to Ecuadorian Technical Regulation RTE INEN No. 072, "Energy efficiency of ductless air conditioners", she recalled that Mexico had asked Ecuador whether it based this measure on International Standard ISO 5151:2010 ("Non-ducted air conditioners and heat pumps - Testing and rating for performance"). Regulation No. 072 stipulated that tests must be carried out in conformity with Ecuadorian Technical Standard NTE INEN No. 2495, section 7 (Test Method). This Technical Standard provided for the application of the "test method established in Standard ISO 5151", which established the conditions specified under this standard that were most representative for the country.

2.210. Further, as to the specific concern related to the application of International Standard ISO 5151 to types of air conditioner known as "inverter" air conditioners, she said that, according to conformity assessment experts in Mexico, these types of air conditioners were units equipped with a variable speed compressor, with a variable flow rate. She also said that testing has demonstrated that the method was not designed for this type of technology. Additionally, follow-up testing has shown that it may not comply because of the actual functioning of the unit. In this regard, Mexico asked whether this type of product may be exempted from compliance with ISO 5151.

2.211. Finally, she expressed the Mexican industry's view that one of the ongoing problems concerning Ecuadorian technical regulations on household electrical goods was that amendments were applied almost immediately without allowing a reasonable period of time for their implementation. She thus asked Ecuador to take this comment into account when adopting or amending measures in the future.

2.212. The representative of Ecuador explained that since 2013, Ecuador had been developing a number of policies seeking to improve the quality of products marketed in the country. In this context, INEN (*Servicio Ecuatoriano de Normalización*), together with the regulatory body, the Ministry of Electricity and Renewable Energy (MEER), had prepared Ecuadorian technical regulations on the marketing of energy-efficient products, whereby ranges had been established in accordance with product characteristics. Keeping in mind the legitimate objective of promoting energy efficiency, Ecuador had carried out an analysis and considered it appropriate for the country to adopt the criteria established in IEC international standards and European standards. The inclusion of UL standards was currently being reviewed, as reported to Mexico at the bilateral level.

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

2.213. The representative of China reiterated her delegation's concerns with the refusal of the CC certification bodies of EU member States to accept and process the applications of Chinese producers for CC certification and the lack of opportunity for Chinese companies to join CC-related standard organisations, such as JIL Hardware Attack Subgroup. She also repeated China's request for the EU to provide additional CC-related information to China and take a constructive approach to address the concerns of the Chinese industry. To date, the EU's sole response to these questions and concerns had been to claim that CC certification did not fall within the scope of the

TBT Agreement. In this respect, China believed that depending on the nature of CC certification bodies of EU member States, either Article 5 ("Assessment of Conformity by Central Governmental Bodies" or Article 8 ("Assessment of Conformity by Non-governmental Bodies) of the TBT Agreement would apply. Further, in the case of a central governmental body, then both articles would apply. She noted that TBT obligations imposed on Members in this regard included: national treatment, avoidance of unnecessary obstacles to international trade, prompt acceptance of applications, expeditious undertaking and completion of conformity assessment procedures, publication of the standard processing period of each conformity assessment procedures or communication of the anticipated processing period. Moreover, the EU had mentioned that EU companies received discriminatory treatment under China's regulatory framework. However, according to Chinese statistics, dozens of foreign companies had received production permits in China. For example, Giesecke & Devrient, from Germany, received not only a production permit, but also sales permission for a cryptogram product.

2.214. The representative of the European Union said that, so far, China had failed to identify concrete specific measures (technical regulations or conformity assessment procedures) in this area which would fall within the scope of the TBT Agreement. Instead, China's claims had been made in a rather generic manner. He also explained that in the EU there were no general mandatory requirements for certification of commercial encryption products and that this was quite different from the situation observed in China. He also expressed his delegation's belief that this was a very specialized field where there was a genuine need for exchanges at expert level. In the field of information and cyber security all interested parties faced similar challenges, where all systems were exposed to the same type of cyberattacks. There was therefore a need for these systems to be able to use the best technology available on the market in order to harness their protection and the protection of the data of information exchanged. The EU therefore invited China to engage more in cooperation and discussions with its main trading partners in this field and avoid developing home-grown solutions which could prevent operators in China from procuring the best technology available on the market.

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

2.215. The representative of Japan welcomed the clarification made by China in previous meetings that this measure would not entail "over-labelling" on imported cosmetic products. She said that, nonetheless, Japan was still concerned with Articles 14 and 15 of the draft measures, which required, inter alia, labelling of the names and addresses of manufacturing subcontractors. Japan considered that this requirement could cause consumer misunderstandings and market confusion. Instead, the manufacturer labelling should only present the name and address of the company with final legal responsibility for the quality and safety of the products concerned. Japan was also concerned with the promotional advertising of cosmetics efficacy claims. According to Articles 19 and 20 of the draft measures, results from tests by an "efficacy assessment testing organization" had to be disclosed. However, she said, since testing results could include companies' know-how, they should not be disclosed. In addition, the "efficacy assessment testing organization" should not be limited to institutions inside China.

2.216. She also said that the measure needed to be accompanied by clear guidance. Japan asked China to provide an implementation plan, including a two-year transition period, for the smooth implementation of the new labelling regulation. Since the old implementation date (1 July 2015) had already passed, she asked China to explain what the new implementation date would be. She also asked China to clarify whether or not a public comment period would be established. It was recalled that at the last Committee meeting in November 2015, China had mentioned that this draft AMCL would be revised according to the contents of "Regulations concerning Hygiene Supervision over Cosmetics", which was a superior regulation to the draft measures. In this regard, Japan asked China whether it would revise requirements for manufacturer labelling and efficacy assessment testing.

2.217. The representative of Canada noted the significant time needed for industry to adapt and comply with the measures. He asked China to provide for longer timelines to manufacturers before the measures entered into force. Canada also asked whether manufacturers would be required to change their non-Chinese product names and sublines to comply with the Administrative Measures and be required to re-register their products in China. If this were the case, Canada further asked how much time companies would have to sell through products that were already placed on the

market in China. Canada was particularly concerned that such measures could negatively impact the cosmetics industry by forcing existing products off the market and delaying exports of new products into China. Canada also asked China to confirm that product names that were registered as trademarks in English, or other foreign languages, would be subject to the Administrative Measures. Canada was concerned that if manufacturers were required to create a different English name, or remove the English name from products sold in China, it would create significant confusion among Chinese consumers and opportunities for the production of counterfeit goods, causing severe disruptions on the market.

2.218. With respect to over-labelling, the representative of Canada said that, while China's willingness to allow over-labelling to apply Chinese language on product packaging was commendable, Canada would nonetheless need more clarification regarding the widely accepted practice of "global packaging variant". Global packaging variant allowed manufacturers to create one package featuring several regulatory warnings and claims complying with multiple markets. It also allowed manufacturers to only over-label a smaller portion of the packaging. Canada was therefore concerned that if over-labelling could not be utilized in this manner, it could affect a manufacturer's ability to sell in the Chinese market given the significant extra costs for supporting a China-only packaging variant for all products.

2.219. With respect to the December 2014 draft of the Administrative Measures, Canada was concerned that Chinese language was required on the primary and secondary packaging as well as on the leaflet. Canada was of the view that, given that consumers would be only able to view the outermost packaging at the point of sale, it should be acceptable to include the mandatory information (such as warnings and usage instructions) on the secondary leaflet in Chinese and not on the primary packaging. Otherwise, these requirements would place China at odds with international practices, and it would also create additional burden for industry to over-label the primary packaging. Canada was further concerned about the Administrative Measures' requirements according to which a formula must be sold in the country of origin before it could be sold in China. This requirement would make China the only major market in the world with such a requirement. Canada believed that this would fundamentally interfere with the launch of innovative new products in the Chinese market. Finally, Canada asked China to confirm whether, and when, a new draft of the Cosmetics Supervision and Administration Regulation would be released.

2.220. The representative of the European Union welcomed the possibility of labelling cosmetic products by means of stickers. His delegation was, however, still concerned with the following issues included in the notified draft, namely: (i) the requirement for the products to display the name and address of the manufacturer and of the subcontractors when part of the production was done by subcontractors; (ii) the need to confirm that the efficacy assessment and the cosmetic claim verification could be conducted by any verifying organization that was scientifically and technically competent to do so according to the criteria and guidance established by the China Food and Drug Administration (CFDA) – on the latter, the EU believed that any requirement for third party verification by a Chinese organization would be more trade restrictive than necessary; and (iii) the need to align the requirements regarding cosmetic claim substantiation with international best practices.

2.221. The EU understood that the process for the revision of the general legal framework for the placing on the market of cosmetics in China (i.e. the future Cosmetics Supervision and Administration Regulation) was still ongoing. He therefore asked China to confirm that the AMCL would be developed in parallel with this general framework and would not enter into force before the Regulation. He also asked China for information on the implementation of the guidelines on the verification of efficiency of claims related to cosmetic products presented by CFDA at the technical meeting with their EU counterparts in March 2015.

2.222. The representative of Australia asked China to clarify its current transparency practice to ensure Australian businesses had full information about the regulatory measures. In this respect, he asked China to confirm: (i) that animal testing for the safety of cosmetic products was not required when widely accepted alternatives were available; and (ii) whether all cosmetic manufacturers were treated equally with respect to product registration and approval.

2.223. The representative of China said that, in most markets, cosmetic labels in particular were essential for consumers to understand basic information on these products. Currently, AMCL was

still under drafting. She stated that CFDA would follow international rules and give full consideration to valuable inputs from interested parties before finalizing this measure.

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

2.224. The representative of Japan asked China to provide updated information about the revision of the "Guideline for Promoting the Application of Secure and Controllable Information Technology in Banking Sector (2014-2015)", issued in December 2014. He said that his delegation still had concerns that some points of the measure would be more trade restrictive than necessary, such as requiring source code submission without clarifying the range of data scope. Therefore, Japan requested China to revise the Guideline in accordance with international standards, ensuring transparency during the review process. In addition, he noted that Fact Sheet of 26th Session of the US-China Joint Commission on Commerce and Trade, held in November 2015, stated that China would revise these Guidelines, and Japan asked for further information in this respect.

2.225. The representative of Canada welcomed the opportunity to discuss China's proposed national security regime and the related banking security guidelines. While Canada understood China's desire to minimize threats to its ICT infrastructure, he was of the view that China's approach to "secure and controllable" ICT would decrease – instead of increase – cyber security for China's network and banking ICT infrastructure. Canada agreed with the concerns raised by other Members and emphasized that the drafting of the measure at issue was more trade restrictive than necessary to achieve China's national security objectives. In Canada's view, China's insistence on requirements to divulge and review source code, local content requirements for hardware, software and intellectual property, and mandatory adoption of Chinese encryption processes would not be consistent with China's national treatment obligations under Articles 2 and 5 of the TBT Agreement. Canada understood that China had suspended the implementation of its banking security guidelines as of June 2015, and asked China to elaborate on whether the suspension was definitive or whether there was a timeline for revision.

2.226. The representative of the European Union supported the statements of other Members, and asked for an update on the ongoing review of the banking guidelines. He requested China to address the concerns voiced by Members and industry, and to ensure that this process would be transparent and inclusive. He said that further revisions to the guidelines should be notified to the TBT Committee in order to provide Members and their interested parties with adequate opportunities to comment.

2.227. The representative of the United States supported the interventions made by the other delegations on this issue.

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

2.229. The representative of China said that the "Guideline for Promoting the Application of Secure and Controllable Information Technology in Banking Sector (2014-2015)" was currently under revision and that China would take comments from stakeholders into consideration. She informed the Committee that there was currently no timeline for the release of a finalized version.

2.2.3.29 Indonesia - Regulation of the Minister of Agriculture No. 139/Permentan/PD.4, 10 December 2014, concerning Importation of Carcass, Meat and/or Processed Meat Products into the Territory of the Republic of Indonesia, and Regulation of the Minister of Agriculture No. 02/Permentan/PD.4, 10 January 2015, concerning the Amendment of the Regulation of the Minister for Agriculture No. 139/Permentan/PD.4, 10 December 2014, G/TBT/N/IND/98, G/TBT/N/IND/98/Add.1 (IMS ID 461)

2.230. The representative of Canada said that his delegation remained concerned with Indonesia's measures notified under G/TBT/N/IDN/98, and was currently assessing the amendments notified on 11 January 2016 under the draft Regulation of the Minister of Agriculture No. 58/Permentan/PK.210/11/2015 concerning Importation of Carcass, Meat and/or Processed Meat

Products Into the Territory of the Republic of Indonesia. Canada remained concerned with the broad product coverage of the regulations and the lack of clarity about their intended objectives. Canada added that the proposed measures could be unduly trade restrictive and inconsistent with national treatment obligations of the TBT Agreement and the GATT. He urged Indonesia to provide more clarity regarding the proposed measures, specifically with regard to how these measures fell within the scope of the TBT Agreement and how they would be consistent with Indonesia's national treatment obligations.

2.231. The representative of Australia expressed continued concern with Indonesia's regulations on the importation of meat and meat products. She noted that Indonesia had replaced Minister of Agriculture Regulations Number 139/2014 and Number 2/2015 with Minister of Agriculture Regulation Number 58/2015, which entered into force on 7 December 2015. She said that Indonesia's notification of this amendment in Addendum G/TBT/N/IDN/98/Add.1 was not issued until 11 January 2016, after the new regulation entered into force. Furthermore, the new regulation did not address the concerns previously raised by Australia and other WTO members, and retained trade-restrictive provisions which were inconsistent with Indonesia's WTO obligations. She stressed that the new regulation imposed additional restrictions on imports of meat and meat products, including new restrictions on how long meat products can be stored before arrival to Indonesia. Australia was particularly concerned that the new regulation continued to only allow State Owned Enterprises (SOEs) and Regional State Enterprises to import secondary beef cuts and carcasses, and only then in limited defined circumstances at the direction of Government Ministers, in volumes determined by Ministers in a 'coordination meeting'. The new regulation maintained additional packing, labelling and purpose-of-use requirements on imported meat products that did not apply to domestic products and continued to prohibit the importation of a range of meat products and cuts, including certain types of offal. 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. Finally, Australia asked to Indonesia for further information on how its new regulation was consistent with its WTO obligations and offered further constructive bilateral discussions on this issue.

2.232. The representative of the European Union supported concerns of other Members with the Regulation of the Minister of Agriculture No. 139/Permentan/PD.4, of 10 December 2014 on Importation of Carcasses, Meat and/or Its Processed Products Into the Territory of the Republic of Indonesia, as amended. He reported that on 1 February 2016, the EU provided written comments to Indonesia on the latest amendment to this Regulation, which was notified after the measure entered into force. He asked for a written reply to these concerns, in particular on the requirements for production premises and transportation of Halal products, which should be aligned with relevant standards.

2.233. The representative of Brazil endorsed the Australian and Canadian concerns about the restrictive measures enacted by Indonesia on the importation of bovine meat and related products. His delegation noted three specific concerns with the Minister of Agriculture Regulations Number 139/2014, namely: (i) the measure established the purchase of a certain amount of domestic beef as a condition for the importation of bovine meat; (ii) the importation of beef would only be allowed in some specific and limited end-uses, such as for hotels, restaurants, catering and special needs, among others; and, (iii) one of the licensing requirements for importation was subject to short time periods and strict deadlines.

2.234. Although Minister of Agriculture Regulation Number 139/2014 was recently replaced by Minister of Agriculture Regulation Number 58/2015 as mentioned in previous interventions, Indonesia continued to impose prohibitions and restrictions on international trade in violation of its commitments under the WTO agreements. Brazil therefore invited Indonesia to bring its measures into conformity with its WTO obligations; however, if this situation persisted, Brazil would be ready to exercise its rights before the WTO Dispute Settlement system.

2.235. The representative of Indonesia replied to the concerns raised. Indonesia's full statement is contained in document G/TBT/W/444.

2.2.3.30 Ecuador - Emergency Technical Regulation (RTE) No. 088: "Surface tension agents" of the Ecuadorian Standardization Institute (INEN), G/TBT/N/ECU/117, G/TBT/N/ECU/117/Add.1-2, G/TBT/N/ECU/106, G/TBT/N/ECU/106/Add.1-3 (IMS ID 458)

2.236. The representative of Mexico reiterated her delegation's concern with respect to this measure, originally notified to WTO Members as an Emergency Technical Regulation on 22 November 2013, in document G/TBT/N/ECU/117 and its addenda. This concern had first been raised at the March 2015 Committee meeting and reiterated at the June 2015 meeting, and Mexico's statements at those meetings had been circulated to Members.³¹

2.237. She reported that the bilateral exchange between the two countries had clarified Mexico's doubts concerning the amendments made to this technical regulation. Mexico asked Ecuador to explain the mechanism under which the Ecuadorian Accreditation Service (SAE) would accredit first-party certificates as stipulated in Article 10.2.4, which provided: "the first-party conformity certificate shall be accepted until such time as there are product certification bodies and laboratories, accredited or designated in the country of destination, or accredited in the country of origin, whose accreditation is recognized by the SAE". Finally, she observed that this measure had been notified to Members in various document symbols on different dates. Mexico reiterated the importance of ensuring that notifications concerning the same measure preferably be submitted as addenda to the original notification, facilitating the notification follow-up process.

2.238. The representative of Ecuador said that the Amendments Nos. 1 and 2 to RTE INEN No. 088: "Surface tension agents" were published in Official Journal (Registro Oficial) No. 655 of 23 December 2015, and the Supplement to Official Journal No. 660 of 31 December 2015, respectively. These amendments modified certain provisions relevant to the application of this Regulation. The Regulation was based on the Andean Community (CAN) Decision No. 706 of 10 December 2008 on the harmonization of legislation on domestic hygiene products and absorbent personal hygiene products. Finally, she informed the Committee that the Ecuadorian Ministry of Foreign Trade had formally responded to the trade concerns submitted on various occasions by the Mexican delegation in Official Communication No. MCE-VNIDC-2016-0060-0 of 27 January 2016, and in bilateral meetings.

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

2.239. The representative of Canada reiterated his delegation's concerns on this proposal, including those expressed at the last two TBT and SPS meetings held in the latter part of 2015.³² Canada thanked the EU for the August 2015 reply to their comments on this notification. He restated Canada's questions about the consistency of this proposal with the WTO commitments and internal market rules of the EU. He referred to the recent opinion of the European Council's Legal Service which echoed Canada's view. His delegation was still concerned that EU member State measures taken under this proposal could cause serious trade disruptions and uncertainty for the EU's international trading partners with respect to food and feed imports to the EU. He asked for an update on the progress of this proposal and whether the EU intended to present an alternative proposal. He said that Canada would continue to closely monitor the proposal as well as its potential impacts on trade.

2.240. The representative of Argentina shared the concern expressed by Canada with the proposal enacted by the EU and reiterated his particular concerns on account of its inconsistencies with the EU's WTO commitments and the EU's own regulations. Argentina reiterated that EU member States already had the option of adopting emergency measures to prohibit or restrict the marketing and imports of biotechnological products based on scientific evidence of serious risk to human, animal health or the environment. Argentina found it difficult to comprehend the objective of the notified proposal by the EU and requested the withdrawal of the current proposal, and the implementation, in a timely and proper manner, of current EU legislation on the approval and authorization of GMOs throughout EU territory. He argued that the measure in its present form would create a high level of unpredictability in international commodity markets and would unjustifiably impact producers in the EU and third countries. Further, he asked the EU delegation

³¹ G/TBT/W/405 and G/TBT/W/439.

³² G/TBT/M/67, para. 2.220 and G/TBT/M/66, para. 3.10.

to advise about the next steps to be taken in respect of this dossier, in particular: whether the EC's legal services had finished preparing their opinion; whether amendments to the proposal were under discussion; or whether the Commission was considering putting forward a new proposal or withdrawing the proposal altogether, as had been requested by third countries and EU institutions. Finally, Argentina insisted that the EU should notify any proposal to the WTO SPS Committee, the appropriate forum for discussing measures of this nature.

2.241. The representative of the European Union provided an update on the proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for member States to restrict or prohibit the use of genetically modified food and feed on their territory. He stated that, on 28 October 2015, the Commission proposal had been rejected in the European Parliament through the adoption of a Legislative Resolution, which called on the Commission to withdraw the proposal and propose a new one. Nevertheless, the Commission had informed the European Parliament that it maintained the existing legislative proposal. Discussions at the Council of Ministers, which was co-legislator together with the European Parliament, were still on-going and the legislative process would continue. Finally, he noted that the Commission would continue enforcing the existing legislation on GMO food and feed, and informed the Committee that the EU had replied to comments received on notification G/TBT/N/EU/284.

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

2.242. The representative of Canada expressed concerns with respect to Indonesia's intention to introduce local content requirements for smartphones using 4G/LTE technology, which were in addition to other Indonesian local content requirements, whereby telecom service providers and telecommunication operators were forced to allocate 50% of capital expenditures to local companies. He sought clarification on whether these new local content requirements had been notified to the WTO and whether Indonesia planned to take Members' concerns into account when finalizing these draft regulations, as per their obligation under Article 2.9.2 of the TBT Agreement. By providing treatment that was less favourable to foreign firms than that accorded to like products of national origin, Indonesia's approach was at odds with the provisions of Article 2.1 of the TBT Agreement. He requested that Indonesia provide a justification for the approach and indicate the legitimate objective pursued. He also asked whether Indonesia had considered less trade-restrictive means given the objective of the regulation and what the consequences would be for a foreign company if it were to sell 4G-enabled equipment that did not meet the local content threshold in Indonesia. Finally, he asked when KOMINFO was planning to finalize the regulation. He also noted that there were many competent telecoms test labs worldwide and associated itself with previous comments of the EU and US in recommending that Indonesia accept test results from duly accredited labs regardless of their location.³³ He sought clarification as to whether local testing of software might count towards the local content requirements and welcomed any additional information from Indonesia that could provide clarification on the nature of the draft regulation.

2.243. The representative of the United States joined Canada in continuing to express concerns about the regulation that contained both technical requirements and conformity assessment procedures. First, these significant measures had not been notified to the TBT Committee prior to adoption, limiting the opportunity for other Members to provide meaningful and useful comments, nor had Indonesia explained what circumstances had prevented notification. While recognizing and appreciating Indonesia's notification of KOMINFO Regulation 27/2015 in February 2016 for public comment, she wondered how comments received would be taken into account given that the regulation had already been published and entered into force. Second, she was concerned that the requirements, including the testing and conformity assessment procedures had gone into effect without providing for a reasonable interval between adoption and entry into force to allow companies time to adjust to the new requirements. In sum, she noted her delegation's disappointment that Indonesia had proceeded with this regulation despite concerns received from several Members.

³³ G/TBT/M/67, paras. 2.230 and 2.232.

2.244. The representative of Australia said that his delegation was monitoring the status and implementation of the regulation, thanked Indonesia for notifying the WTO of previous regulations, such as No.5/2013 and No.18/2015, and invited Indonesia to notify all current regulations for LTE devices to ensure that Members' concerns could be considered during the proposal and implementation phases. He sought information on the expected impact that the requirement for local testing and certification was likely to have on the compliance of LTE equipment. Further, he sought clarification on Indonesia's previous statement: "in principle, Indonesia accepted the test results issued by foreign test institutions, which were accredited internationally" as it was unclear what "in principle" meant in practice.

2.245. The representative of Indonesia said that Indonesia had notified the Ministry of Communication and Information Technology Regulation No.27 of 2015 concerning Technical Requirements for Long Term Evolution Technology (4G LTE) based Telecommunication Devices under G/TBT/N/IDN/103. With respect to concerns regarding local content calculation, he suggested that the concerned Members submit their enquiries to the Indonesia TBT Enquiry Point as the two-month comment period was open until April 2016.

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

2.246. The representative of Canada said that while recognizing and supporting Chinese Taipei's right to implement regulations that provided consumers with adequate information to make informed choices in the marketplace, Canada believed that this objective could be best achieved through voluntary, industry-led market-driven initiatives, as these were less trade restrictive. Voluntary standards could also help ensure that labelling claims were truthful and not misleading. Mandatory labels should only be used to convey important information about the health and safety of a product, where there were health risks such as allergens, or significant nutritional changes that could be mitigated through labelling. Products of biotechnology that had been assessed as safe and had been authorized for sale did not pose any risk to human health and safety, and therefore should not require labelling. He reiterated Canada's concern that, in the absence of identified safety risks, mandatory GMO labelling could be misleading to consumers, as it implied that there might be "issues" with the product, where in fact there were none. Implementing disproportionately trade-restrictive measures could be counterproductive to Chinese Taipei's efforts to modernize its food regulations. Canada continued to be concerned with what seemed to be a developing trend, whereby TFDA pre-empted potential political or public reactions through trade-restrictive regulations.

2.247. The representative of the United States said that her delegation continued to question the science- and risk-based justification for Chinese Taipei to increase the stringency of its genetically engineered (GE) labelling requirements. Such labels implied an inherent difference for GE foods in relation to conventional food products where no such difference existed and were often taken by the consumer to imply a greater safety/health hazard. Although mandatory labelling might be proposed to ensure "consumer choice", economies with overly restrictive mandatory GE labelling requirements actually experienced reduced consumer choice as companies usually sourced non-biotech ingredients rather than using a label. She noted the US comments on the measure dated 16 April 2015 and 27 July 2015 as well as concerns expressed in letters to the Ministry of Health and Welfare from the Office of the United States Trade Representative in March 2015 and the US Department of Agriculture in May 2015. In particular, as the presence of authorized GE ingredients in food products did not pose a greater human health risk in comparison with conventional foods on a categorical basis, there was no scientific basis for these amendments and they might raise unjustified food safety concerns among the public. Overall, more restrictive mandatory labelling requirements would have a negative impact on Chinese Taipei's domestic food processing industries, increase administrative burden as well as potential for corruption, and limit consumer choice, while not improving food safety. In addition, these requirements could significantly disrupt US agricultural exports to Chinese Taipei, especially as enforcement and traceability requirements were unclear. Overall, there was likely to be an additional burden on food producers, exporters, and importers, increased costs to consumers and pressure for affected companies to exit the Chinese Taipei market.

2.248. Furthermore, she asked how the labelling requirements would be applied and enforced, including with respect to refined products that did not contain genetically engineered protein or DNA. Additionally, she asked what the intent was of the proposed traceability system for GE and

other agricultural products, as notified on 17 August 2015 under G/TBT/N/TPKM/207/Add.1, and how it would work. She also requested that Chinese Taipei notify details to the WTO so that Members could have an opportunity to review and provide comments. Given that the enforcement and traceability requirements were unclear, the new regulations could not be implemented on a fair and transparent basis. Therefore, the US requested that Chinese Taipei revise its decision to implement regulatory changes on biotech labelling and continue with previous GE labelling requirements of a 5.0% threshold for labelling of food, where introduced protein and DNA may be present, since they had sufficiently addressed consumer choice for many years.

2.249. The representative of Australia thanked Chinese Taipei for responding to their comments on the proposed draft labelling requirements for food containing Genetically Modified Organisms. While recognizing Chinese Taipei's right to implement measures to provide consumers with information to make informed food choices, Australia asked Chinese Taipei to reconsider the proposed requirement to label food products with no altered characteristics and no discernible GM material since there was no scientific methodology to test highly refined food products derived from GM ingredients and since complying with the proposed changes would be costly for producers. She also requested an update from Chinese Taipei on the timeframe for implementation.

2.250. The representative of New Zealand welcomed Chinese Taipei's engagement both bilaterally and in the Committee on the regulations on pre-packaged food, food additives and unpackaged food containing ingredients of GMOs. New Zealand considered that the labelling requirements promulgated through the regulations could be confusing to consumers, resulting in unjustified concerns. When applied to food that was highly refined, where processing removed all transgenic DNA and transgenic proteins, the labelling requirements could raise unnecessary consumer concern and potentially desensitize them to labelling regarding GMOs. Consumers might not readily appreciate the difference between food derived from GMOs that no longer contained transgenic DNA or transgenic protein and food that did not contain transgenic DNA or transgenic protein. Food or food ingredients containing GMOs that were highly refined or where the processing removed all transgenic DNA or transgenic proteins had the same composition and characteristics as non-GMO food. There was no food safety concern for the consumer. Therefore, New Zealand encouraged consideration of an exemption in the regulation for foods and/or ingredients produced using GMO, where the final product did not contain transgenic DNA and and/or transgenic proteins and for highly refined ingredients.

2.251. The full response of the representative of Chinese Taipei is contained in G/TBT/W/466.

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

2.252. The representative of Canada thanked China's initial response provided at the November 2015 TBT Committee meeting regarding registration fees for drugs and medical device products. Since then, Canada understood that China had made a number of commitments on certain aspects of the regulation. Canada welcomed these new developments but remained concerned about other important aspects of the regulation and on the general lack of clarity and transparency regarding the measure. In particular, Canada continued to have concerns regarding China's new Medical Device Registration Fee Schedule published on 27 May 2015, which had entered into force without any notification to the WTO, failing to give Members a "reasonable interval between the publication of requirements concerning conformity assessment procedures and their entry into force", as per Members' obligation under the TBT Agreement. As already mentioned at the previous Committee meeting, Canada was concerned with China's approach of combining registration fees with on-site inspection fees for foreign manufacturers and with respect to the lack of transparency regarding the registration fees for domestic products, which were to be levied by China's provinces. In order to enhance transparency, Canada asked that China publish the on-site inspection fees separately from the registration fees for foreign manufacturers as well as the registration fees to be levied by China's provinces on domestic manufacturers so that it was clear what manufacturers were being charged and for which services, with a view to ensuring that the registration fees were in conformity with China's WTO national treatment obligations and that the on-site inspection fees corresponded to international averages.

2.253. With regards to the accelerated service being offered by the CFDA to fast-track applications for drugs and medical devices, Canada understood that foreign drugs and medical devices considered "innovative" could be eligible for fast-track evaluation and that China had also

made efforts to accept more submissions. Canada welcomed China's initiative to expand the scope of the fast-track programme and for providing guidelines on what constitutes an "innovative product." Nevertheless, Canada asked China to confirm this commitment and clarify whether domestic and foreign firms would be charged the same fast-track fee, in line with national treatment provisions. Finally, Canada had recently taken note of China's WTO notification G/TBT/N/CHN/1169, issued on 26 February 2016, regarding new registration categories of chemical drugs and sought additional information concerning the changes, in particular regarding the rationale for the changes to the drug registration categories. Regarding registration categories 1 to 5 for chemical drugs, Canada asked whether China was going to charge different registration fees for these categories and whether this would result in drug registration fees that differed from those announced on 27 May 2016. With respect to the description of the categories, Canada also asked how China would define "innovative drugs" and "new improved drugs", whether "imitation of drugs" meant generic drugs and what the difference was between Category 3 (Imitation of drugs that are marketed overseas but unavailable domestically) and Category 5 (Application for the domestic marketing authorisation of drugs marketed overseas).

2.254. The representative of Australia said that businesses and industry organizations had raised concerns with the Australian Government regarding the introduction of the new fee schedule and resulting processes. Australia thanked China for its response to their query through the TBT Enquiry Point; however, it continued to have concerns with the measure. The fee structure and the registration process was a technical regulation, which might not be based on international best practice and as such Australia asked that China notify the measure to the TBT Committee in accordance with Article 2.9 of the TBT Agreement. Australia also wished to understand how China's notification G/TBT/N/CHN/1169, circulated on 26 February 2016, regarding changes to its Work Programme for the Reform of Chemical Drugs Registration Category, related to this specific trade concern and whether the notification changed any of the registration and fees for drugs and medical devices. Australia was concerned that the implemented fee structure and process requirements provided for different fees for domestic and imported drug and medical device products and asked China to outline how the fee structure and process requirements for imported products were proportionate to the testing process requirements, including for the costs of transportation, accommodation and allowances. He asked whether domestically produced drugs and medical devices were subject to the same testing process and registration requirements, though at different fees. Some of the domestic prices were based on what was termed a "provincial price". He asked China to confirm what the provincial price was, how it was determined and whether the same testing processes and requirements applied for the provincial price. Australia understood that the regulations allowed for small and micro business with an innovative medical device to have their registration fees waived for the first time registration and asked for additional information on how innovative products were defined, what the criteria were and whether domestic as well as imported products could be considered as innovative. Australia acknowledged that on-site inspections were necessary to promote public health and ensure that products were safe and effective and also that inspections at foreign facilities might be more expensive. However, fees associated with foreign inspections needed to be transparent and non-discriminatory and include industry consultation prior to implementation.

2.255. The representative of Korea drew attention to the unreasonably high level of fees for foreign companies, even if it took into account the on-site inspection costs. Therefore, Korea asked China for more transparency on how fees were determined and calculated with a view to securing fairness in the level of fees for foreign companies.

2.256. The representative of China said that China had issued a new measure on registration fees for drugs and medical device products in May 2015. Prior to this new measure, the rule of registration fees for drugs and medical device products, set in 1995, had not included charges for the registration of medical device products. A standard dating back 20 years was not suitable for today's market. Even with the new standard, the registration fee charged in China was still far lower than the international level. Many Members were concerned that domestic and foreign drug and medical device registration charges differed; however, the gap only reflected costs related to foreign on-site inspection, transportation, accommodation, meals and public charges. Article 5.2.5 of the TBT Agreement required Members to ensure that any fees imposed for assessing the conformity of products origination in the territories of other Members were 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 communication, transportation and other costs arising from differences between location of facilities of the applicant and the conformity assessment body.

Furthermore, differences in domestic and foreign fees were international common practice for partial product inspections. For example, in the United States, according to FDA prescription drug production facility inspection fees, foreign companies paid US\$15,000 more than domestic companies. Regarding transparency, according to Article 5.6 of the TBT Agreement, Members needed to notify to 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 and therefore China had no obligation to notify it. In fact, China had not found any notifications to the WTO by other Members of similar fee structures.

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

2.257. The representative of Canada said his delegation appreciated Colombia's initiative to ensure that Colombian consumers have access to safe products with high quality standards. Nevertheless, Canada sought clarifications from Colombia on the intention behind the restructuring of Decree No. 2269 of 1993. Canada was concerned that the regulation, as modified by Decree 1595, might create unnecessary barriers to trade and affect exports to Colombia. The requirement to obtain local conformity assessment for "medium- and high-risk" products, unless there was a mutual recognition of Colombia's certifications, could potentially discriminate against products exported to Colombia as well as constitute unnecessary barriers to trade. In particular, Canada was concerned that having to recertify products in Colombia could delay exports to the country - even if Colombia was not obliged to accept certificates from recognized accreditation organizations such as the ILAC or the IAF. With respect to the parameters for defining risk, not defining the risk level of products and allowing regulators themselves to determine risk levels could make requirements for exports unpredictable. He asked whether Colombia was planning to define what was considered medium and high risk.

2.258. Furthermore, Canada sought clarification on how the restructuring of the National Quality Subsystem and the new local certification requirement would affect products exported to Colombia. It was their understanding that technical regulations were updated every five years and that local certifications would be required for new technical regulations. In its formal response following the November 2015 TBT Committee, Colombia had stated that "Decree No. 1595 of 2015 does not modify technical regulations that were already in effect before its entry into force..." Therefore, he asked whether updates to technical regulations that were already in effect before the entry into force of Decree 1595 would incorporate local certifications. It had been brought to Canada's attention that some sectors might have favoured EU-based standards and certification bodies over others. Canada was concerned that most-favoured-nation and national treatment provisions might not be respected for all products imported into Colombia and sought clarification on the treatment of internationally-recognized standards and bodies. Finally, Canada was also concerned that amendments to Decree 1471 had not been notified to the WTO.

2.259. The representative of Colombia said that, in an effort to save time and be efficient, he would refer to some sections of Colombia's extensive statement circulated as G/TBT/W/438 in November 2015. Decree No. 1595 of 5 August 2015 had been drafted in an effort to update rules pertaining to the Colombian quality system and sought not only to organize and clearly define the functions of the various actors concerned, but to implement best practices for technical regulations. In this context, Colombia was in line with the recommendations heard during the thematic session held that week. Decree No. 1595 had been notified to the TBT Committee under Article 15.2 of the TBT Agreement as G/TBT/2/Add.18/Rev.1/Suppl.2 and was indeed an update of Decree 1471 notified as G/TBT/N/COL/201 on 7 Feb 2014, on which comments had been received through an exercise of voluntary transparency. It was fundamental for Colombia to undertake this update because it implemented best practices for regulations and standards, complied through various sources, including through the TBT Committee. Decree 1595 would have large-scale effects in guaranteeing free trade policies of Colombia. Colombia was interested in maintaining an open channel of communication and explaining in greater depth the implications of the Decree for both parties.

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

2.260. The representatives of the United States and Canada thanked Turkey for their information that that verifications of toy imports at the border would cease in 2016. However, they also expressed concern with the fact that toys with CE marking were still being tested at three border points.

2.261. The representative of Turkey explained that, after a comprehensive domestic consultation process, all verifications of toy imports at the border had ceased as of 2016 (including with respect to all verifications that have started in 2015). Besides, according to Communiqué 2016/10 of the Ministry of Economy, toys to be imported to Turkey were subject to risk analysis under the Risk Based Trade Control System (TAREKS). According to the Communiqué, import controls for toys through TAREKS were carried out electronically and on a risk basis. In other words, only products presenting a risk would be subject to safety and conformity checks. In this regard, he said that inspections were conducted as physical checks and controls, including document/marketing checks. Products would be sent to accredited laboratories for testing only when there was doubt concerning product safety with respect to the framework given by the mentioned Communiqué. It was also noted that TAREKS took into consideration past performance and relevant data of the firms and products in the scope of risk assessment, as had been previously requested by the US. Turkey did not foresee any change to the risk-based implementation of the measure.

2.2.3.37 Brazil - Draft Ordinance Act N°. 374, 27 November 2014 (Portaria SDA/MAPA 374/2014), G/TBT/N/BRA/613 (IMS ID 478)

2.262. The representative of the European Union noted that the Brazilian authorities were currently preparing a revised draft of the measure at issue, establishing quality requirements for wine and derivatives of grape and wine. The EU invited the Brazilian authorities to take the EU comments from previous meetings into account during the revision process of the draft Ordinance, and in particular to consider aligning the draft Ordinance to international standards. In addition, the EU asked Brazil about the state-of-play of the revision and whether the revised draft Ordinance, which would presumably undergo substantial changes, would be notified under the TBT Agreement and what the timeline for this notification would be.

2.263. The representative of Brazil noted that the measure was related to quality and identity standards on wine and other bi-products of grape. The measure, however, did not change the labelling and quality criteria currently in force, which were in accordance with MERCOSUR rules. The Brazilian Ministry of Agriculture had held a public consultation about the measure at the end of 2014, during which it reviewed all comments received from governments, the private sector and other interested parties (including from the EU). The results, he said, would be the object of a public hearing. Brazil did not believe the measure would have, or was intended to have, any impact on trade flows in wine between Brazil and its trading partners. Brazil was reviewing the EU comments that the standards regarding sugar content in wine also had some degree of flexibility with regard to OIV standards. Brazil also considered that the measure was aligned with international standards given the flexibility that such standards allowed in this area. Finally, he said that if there would be a need for a new notification, Brazil would submit one.

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

2.264. The representative of the United States recalled that her delegation had raised concerns in the previous TBT Committee meeting, with what seemed to be a pattern on the part of the Chinese Government to impose "secure and controllable" requirements on ICT producers and service providers. These controls created disproportionate disadvantages for foreign ICT firms. Many relevant measures were not developed in a transparent manner nor gave sufficient opportunity for stakeholders to provide comments. Despite assurances to the contrary, China appeared to be working towards extending the "secure and controllable" policy to more and more sectors. She highlighted the importance of good communication and dialogue so as to ensure all measures in this area were adopted in an open and transparent manner. These measures should truly address the objective of the regulation, be aligned with international standards, and be no more trade restrictive than necessary. She requested China to limit its "secure and controllable" policies and related regulations to those areas where national security regulatory oversight was critical and

that those regulations be prepared in a transparent manner where stakeholders were given at least 60 days to comment, and any comments be taken into account by the relevant agencies. Should such measures deviate from internationally accepted cryptography algorithms or other standards, she asked that they be notified to the WTO. Concerning testing and certification requirements for encryption technology, she emphasized the importance of avoiding testing which could be unnecessarily burdensome, discriminatory, or include a review of source code, or other sensitive business confidential information. Finally, she asked when China was planning to notify the Insurance Regulatory Commission's draft regulation on "the Informatization of Insurance Institutions" to the TBT Committee.

2.265. The representative of Canada supported the concerns raised by the United States and reiterated the concerns raised by Canada in the previous TBT Committee meeting to which responses were still being awaited. It was Canada's view that China's approach to "secure and controllable" ICT would decrease, rather than increase, the cybersecurity of China's network and insurance ICT infrastructure. With respect to the Draft Supervision Rules on Insurance Institutions Adopting Digitalized Operations, he requested further information on: (i) the definition and scope of what constituted "core systems" and how "national security" was defined in that context, and clarification on how this article would function in relation to the MLPS; (ii) how the provisions related to testing by third party institutions would be operationalized in Article 22; and (iii) if China could clarify whether Article 25(2) which described the security management mechanism requirements, including the use of technologies and products that complied with national standards and encryption requirements, was referencing other existing legislation or if the terms would be uniquely defined for those rules.

2.266. Canada also had concerns that the requirements in Article 31 could be overly restrictive for the intended purposes. This article indicated that when data was from within the territory of China, the data centres handling the information should be located within China. It also required that the design of the computing facility comply with national standards as well as the requirements of the China Insurance Regulatory Commission (CIRC). He sought clarification as to why these measures were thought to be necessary for the insurance sector in China. On Article 53 which provided guidelines as to the type of equipment and software that insurance institutions should consider purchasing (i.e. secure and controllable hardware equipment and software products), he asked that China clarify whether foreign-made software and equipment would qualify under these draft regulations, and if not, could China explain why it was necessary to impose such limitations.

2.267. Article 54 highlighted the objective to work towards an "all-round application of domestic cryptography in the electronic insurance policy and insurance sector". Canada asked how this would work in practice and for any additional information about the objective. He requested clarification on the meaning of "indigenous IP protection" in Article 55, as well as information on CIRC's associated expectations regarding the implementation and interpretation of this Article. On Article 56, he asked that China provide additional information on what level of security might be required, as it appeared to reference MLPS security requirements but was non-specific, and could China indicate how this article would function in relation to Article 20, which also appeared to set out security requirements. Finally he requested China to provide additional information on the "security certification" process and asked whether China would be adhering to international standards of accepting third party test reports in this regard.

2.268. The representative of the European Union welcomed the statements made by the United States and Canada and in particular the request for an update on the ongoing review of stakeholders' comments. He requested that China carry out a substantive review of the draft guidelines in view of the comments received. On specific aspects of the draft, the EU fully concurred with the analysis made by the US and Canada in requesting an update on the timeline, the availability of the revised draft, and the notification of such drafts. The EU continued to be interested in further bilateral engagement with China on this matter.

2.269. The representative of Australia said that Australian industry and enterprises had a great interest in any potential regulations that might impact their ability to operate in the Chinese market. ICT and cybersecurity were global issues and to be most effective, required globally consistent solutions. Australia encouraged the use of internationally accepted approaches to encryption and ICT security, thereby minimizing conflicts across systems and ensuring best practices globally. He requested further information on the status of the regulations and specifically, on whether they would be notified to the TBT Committee. He also sought clarification

on the definition of "secure and controllable ICT" in Article 53 as it was unclear what was expected of ICT systems so as to fulfil this criterion.

2.270. The representative of Japan supported the positions of previous speakers on this issue. She requested that China clarify the unclear articles such as terms definitions, concrete requirements for examination and evaluation. She asked what was the scope of the regulation and that China ensure transparency so that market access for foreign companies would not be hampered. The requirement to use Chinese national standards should be consistent with the principles of non-discrimination and should not be more trade restrictive than necessary. Like others, Japan asked for an update on the current status of the regulation in view of the requests by Members that their concerns be addressed in the preparation of the regulation. Japan also asked when China would be notifying the measure to the TBT Committee.

2.271. The representative of China said that the rapid development of information technology had led to new challenges in information security. Since 2013, cybersecurity had been strengthened globally including in China. The measures in question were developed so as to protect and maintain stable development of Chinese cybersecurity. She assured Members that the drafting process would be carried out in a transparent manner and that comments would be taken into consideration.

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

2.272. The representative of Canada considered that the above-mentioned measures imposed unjustified costs and delays to the toy industry without resulting in any measureable increase in consumer safety when compared to internationally recognized and robust certification systems already in place for toys. He urged Brazil to consider reviewing the ordinance where currently-valid registration numbers would not be terminated and permit a suppliers' declaration of conformity or sampling by any International Laboratory Accreditation Cooperation accredited laboratories. In this respect, he asked Brazil to clarify the purpose of the recently amended Administrative Rule 321, which required laboratories to document on film the actual testing of toys and make this video a mandatory requirement of the registration process. He also asked how the information storage and retention requirements (for example, keeping records for a minimum of five years) would enhance consumer safety. It was Canada's position that these requirements were unnecessary, overly burdensome, and would increase costs to exporters and consumers with no tangible benefits.

2.273. The representative of the European Union noted that draft Ordinance 489 aimed to consolidate all existing rules on conformity assessment, while Ordinance 310 dealt with the technical regulation part and aimed in particular to define the testing requirement for toys. With respect to the timeline, it was the EU's understanding that INMETRO was currently reviewing the comments received, including the representations made at the public hearing held on 4 August 2015 and the timeline for final adoption of both ordinances was May/June 2016. The EU asked Brazil to confirm these understandings and also to indicate whether a final draft would be published with opportunities for stakeholders to provide feedback and comments before final adoption by INMETRO so that changes made to the original draft could be properly assessed. He said that this would be necessary if certain comments were not taken into account in the final draft.

2.274. Regarding specifically draft Ordinance 489, the EU was concerned with new requirements for registration of each toy model for traceability purposes. The EU wished to better understand the relationship between this new registration requirement and the actual conformity assessment process. In particular the following: who would be responsible for the registration? How long would it take for INMETRO to issue a decision or whatever other form of authorization that would be needed for the toy to be placed on the market? Why this type of registration was considered more adequate than a registration that would apply only for each producer and importer? This latter alternative, he said, could be coupled with a general requirement for toy manufacturers to have an internal traceability system capable of tracking relevant data supply information, such as date and place of production and batch number, while leaving it to the manufacturer to decide which traceability methods would be most adequate for its business and product. This was the approach that had been adopted in the EU under the EU Toy Safety Directive. The EU would be happy to provide further insight into the operation of the EU toy safety legislation in this area.

2.275. With respect to the draft amendment to Administrative Rule 321 of 2009, concerning the filming of toy testing, the EU asked Brazil to confirm if it was true that this requirement would be dropped. Finally, on the draft Ordinance 310, the EU requested Brazil to ensure coherence and no discrepancy between the testing criteria as defined in this Ordinance and that in the Mercosur MM300 series of standards for toy safety.

2.276. The representative of the United States asked Brazil to explain why, rather than continuing with the current system, it had instead opted for an overly burdensome requirement for companies to register toys in a "family of products". She also asked Brazil to clarify: (i) whether the testing for new products would only have to be done to get certification; (ii) whether market samples would only be taken as a follow-up once products were on the market; and (iii) when the operator would eventually need recertification. She further asked if such issues were reflected in the different requirements for original sample testing versus maintenance testing. She also noted that, according to the Toy Industry Association, subjecting toys to INMETRO'S Object Registration System may increase costs for toy manufacturers. It was nonetheless unclear how these new requirements would yield increased consumer safety beyond the current system. One result might be a reduction in consumer choice in the market as many small and medium-sized enterprises and developing country exporters may be forced to abandon the Brazilian toy market altogether.

2.277. She said that the US was also concerned that the Ordinance would require manufacturers to release confidential business information to INMETRO. In this respect, she asked Brazil to explain why the additional documents were necessary and what confidentiality protections would apply. The combination of new requirements under Ordinance 489 imposed disproportionately severe costs and burdens on the toy industry because of the sheer number of products. The US did not understand how the proposed changes would result in any improvement in safety over the robust certification system currently in place for toys.

2.278. The representative of Brazil said that his country took children's safety issues very seriously. The measures had been in place for seven years already. According to good regulatory practice, this was an appropriate time-frame for revision and update of measures. He recalled that INMETRO had held a public consultation on the Ordinances in 2014 and was currently considering the inputs it had received, including some related to the points raised on this meeting, in order to prepare a final rule. He explained that the purpose of the measure was, through the establishment of a registration procedure, to create a direct link between INMETRO and the producers as well as to facilitate access by consumers to certification information. This would, in turn, improve the Brazilian framework of conformity assessment in terms of transparency and traceability. In this context, although practices differ from one country to another (e.g. the EU in its intervention has presented its system, an approach that was also of concern to Brazil), Brazil believed that the requirements of the measure conformed to international best practices.

2.279. Regarding the US concerns with the confidentiality of information submitted to INMETRO, he stated that this agency maintained a strict policy which was consistent with international standards, in particular ISO/IEC 17065 item 4.5. On the other specific comment related to registration, he said that in Brazil it was a legal requirement. Thus, the regulatory process was just reacting to such legal requirements, i.e. law 12.545/2011 and Decision 05/2008 by CONMETRO (the inter-ministerial council in charge of deliberating such issues). The toy sector was the last sector to adopt this system of registration, which had already been applied, without any difficulties, to other sectors in Brazil for some time.

2.280. On the US issue of sampling that was used in the process of conformity assessment, he explained that, as a member of the International Accreditation Forum (IAF), Brazil strictly followed IAF model No. 5. With respect to the filming and recording requirements, he said that while Brazil considered that such requirements enhanced consumer safety, it was also giving serious consideration to the comments that were made both in this Committee and in the public consultation process. Although Brazil could not ascertain the outcome of the ongoing regulatory process, he confirmed that Brazil was in this process of redrafting the rule towards a final rule giving very careful consideration to the comments and concerns presented in this forum. He also confirmed the EU's understanding on how this new regime of regulations was structured, i.e. whether these two rules would address different issues. In other words, Ordinance 489 would consolidate conformity assessment rules, while Ordinance 310 would cover testing requirements and technical regulations.

2.281. As regards the timeline for a final rule, he said that, while Brazil could not give a definitive answer, it expected to have a final rule by the month of June 2016. In this regard, he also clarified that, in principle, his delegation did not believe it was necessary to issue a new draft before the final rule. This was because Brazil had already significantly advanced in the regulatory process. A public audience after consideration of the written submissions in the course of the consultation process had already been conducted.

2.282. Finally, regarding the registration process, at this stage Brazil could only share with Members the assessment from the experience of other products and other sectors that there had not been any problems and that the benefits of this new system would far outweigh any eventual costs. Further, there had been neither delays nor any complaints from the experience of other sectors. Brazil committed to verifying this information and to providing a more precise answer at a later stage. On the EU question regarding the system of certification by company or by kind of product, which was the approach that Brazil was adopting, he acknowledged the differences in approach from one country to another. Brazil believed that a system adopted by the EU worked for the EU. Brazil however also believed that it was right to follow in this case its own approach, which it considered would better serve its interests and needs in this area both in terms of transparency and traceability.

2.283. The representatives of the United States and Canada said that there had been significant problems with the registration system when it came to the medical device sector. Indeed, this had been discussed in the TBT Committee for quite some time. This was part of the reason the same issue was being raised with respect to toys.

2.284. The representative of Brazil said that with respect to certification procedures conducted by INMETRO there had been no complaints or difficulties in the registration mechanism.

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

2.285. The representative of Canada expressed his delegation's concerns with the provisions contained in Article 12 of Resolution 3388 of Colombia's Ministry of Health and Social Protection. Canada was of the view that local testing and certification requirements for toy imports were discriminatory and at odds with Colombia's MFN and National Treatment obligations. This was particularly so given that Colombia was not accepting test results from overseas laboratories accredited by ILAC. Canada also believed that the proposed 50 ppm total lead limit was unrealistic and was not aligned with currently accepted international standards. By way of comparison, requirements of other leading jurisdictions varied from 90 to 600 ppm. Canada believed that achieving 50 ppm would be difficult given that lead was a naturally-occurring element, which was also present due to erosion. Scientific evidence indicated that even the purest soil in wilderness areas contained approximately 40 ppm of lead and several hundred ppm was not uncommon in urban areas. Canada also believed that the labelling provision would lead to unnecessary consumer concerns and would add costly processing steps for companies selling products which did not pose a risk from lead. Canada thus recommended that Colombia adopt a lead limit aligned with international standards.

2.286. The representative of Mexico said that, while her delegation supported the right to protect consumers through regulatory instruments, it also believed that there were alternate ways to attain this objective through less costly processes. Under the proposed amendments, before the marketing and inward clearance of toys, as well as their components and accessories, domestic producers and importers of these items must obtain the corresponding certificate of conformity. Article 12 provided three alternatives for obtaining the certificate of conformity, all of which, in Mexico's opinion, contravened Article 5.1.2 of the TBT Agreement. This was because these alternatives imposed additional costs, arising, for example: (i) from having to take a certifier to the place where the tests were to be conducted; (ii) from having to translate the certificates into Spanish under certain circumstances; and (iii) from admitting that there may be a low level of certainty regarding certification using standards that would appear to be considered equivalent. Broadly speaking, she said, the foregoing entailed the submission of "third-party" certificates of conformity for toy industry products. This caused considerable delays in the import process. In light of the foregoing, she requested Colombia to provide the scientific and technical justification for the adoption of this certification requirement and to consider amending Decree No. 1471 of 2014 or exploring mechanisms for concretely determining conformity alternatives.

2.287. In addition to the above considerations, Mexico also had the following three points of concern: (i) with respect to Article 2.2.1.7.6.6 (*Risk Levels*), she noted that, previously, there were three different levels of risk. However, the fact that there were currently two risk levels increased the likelihood of a third-party conformity certificate being required; (ii) with respect to Article 2.2.1.7.9.2 (*Procedure for Assessing the Conformity of Products*), she stated that this provision still left scope for discretion entailing costs and giving rise to uncertainty for economic operators; and (iii) with respect to Article 2.2.1.7.9.5 (*Laboratory Testing*), she stated that, in her delegation's view, the conclusion to be drawn from this provision was that, sooner or later, all tests would have to be conducted in Colombia. Mexico therefore asked Colombia to provide some justification for this requirement.

2.288. The representative of the United States requested Colombia to notify the measure at issue to the TBT Committee, and allow interested parties an opportunity to comment, as had been previously indicated by Colombia. She called Colombia's attention to the fact that ILAC signatories committed to accept test results from ILAC accredited laboratories, regardless of location. Therefore, given that ONAC (*Organismo Nacional de Acreditación de Colombia*) was now an ILAC signatory, Colombia should consider the acceptance of test results from ISO/IEC 17025 accredited laboratories for toy safety testing. She recalled that during the US-Colombia bilateral meeting in December 2015, Colombia had noted that in-country testing requirements stemmed from a lack of confidence in foreign third-party certification bodies. She asked Colombia whether US' further explanation of how its accreditors participate in ILAC had alleviated those concerns that had been voiced bilaterally. She also noted that other WTO Members that had also been subjected to similar in-country testing requirements to toy imports had faced severe delays for imported products. As toys from compliant companies become more expensive, consumers may look for alternatives in the grey market, including illegal imports. This, she said, could result in safety risks.

2.289. The representative of Colombia thanked Mexico and the US for the opportunity of explaining bilaterally the measures that Colombia took in relation to Resolution 3117 of 2015, adopted by the Ministry of Health and Social Protection. He explained that Resolution 3117 modified Resolution 3388 of 2014, which had already been notified to the WTO and that another new technical regulation would be notified within the coming days. This new draft measure would derogate from Resolution 3117 by granting 90 days for comments. These comments would then be considered by the regulatory authority.

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

2.290. The representative of the United States said that there was growing concern among US wood product manufacturers and exporters that Korea's standards would effectively close US products out of the market unnecessarily. Would Korea accept product certification by an ISO 17025 accredited body? There was also growing concern that even if US companies could eventually comply with the new Korean standards, there was no mechanism to certify to the Korean standards outside of Korea. Could Korea explain how it would allow conformity assessment to be conducted in the territories of other WTO Members?

2.291. The US representative was also concerned that since the new standards were not performance-based, it would mean that higher-performing products would become too expensive for Korea's construction industry. For example, without a specific performance standard for Oriented Strand Board (OSB) that was meant for structures, construction firms would be incentivized to buy the lower priced OSB and create buildings that could unnecessarily endanger Korean consumers. In previous interventions, the United States had made general requests, such as on performance-based standards and consideration of less trade-restrictive measures. However, in order to help Korea understand what it entailed to prevent unnecessary trade barriers, and address Korea's consumer safety concerns, the United States now made the following specific requests: (i) that the Korea Forest Service recognize the U.S. Department of Commerce (DOC) PS 1 standard grade with the Korea Forest Research Institute structural plywood standard and did not require on-going testing on a per lot basis at the port of entry in Korea when the products had been marked in accordance with PS 1 by a recognized US certification body; (ii) that the Korea Forest Service recognize American National Standards Institute (ANSI) grade with the Korea Forest Research Institute structural glulam standard and did not require on-going testing on a per lot basis at the port of entry in Korea when the products had been marked in accordance with the ANSI glulam standard by a recognized US certification body; (iii) that the Korea Forest Service

recognize U.S. Department of Commerce (DOC) PS 2 standard within the Korea Forest Research Institute oriented strand board standard, recognize grades and span ratings for construction applications, and did not require on-going testing on a per lot basis at the port of entry in Korea when the products had been marked in accordance with PS 2 by a recognized US certification body; (iv) that the Korea Forest Service recognize the voluminous data already gathered related to negligible formaldehyde emissions for the above products and did not require on-going testing on a per lot basis at the port of entry in Korea when the products had been marked in accordance with PS 1, PS 2, or the ANSI glulam standard by a recognized US certification body; (v) that the Korean government pass the Foreign Quality Inspection Institute Law and grant US entities having appropriate credentials (such as ISO 17065) FQII status; and (vi) that Korea delay implementation of all mandatory standards until there was an effective method of recognizing conformity assessment conducted outside of Korea.

2.292. The representative of Canada noted Korea's ongoing efforts to work with Canadian trade and forestry officials to resolve issues related to a number of forest-product standards and said that Canada had similar concerns related to the standards mentioned by the US, the new standard for OSB in particular. Korea was basing its new OSB standard on an ISO standard that was explicitly indicated not to be used for structural design, and which was based upon property testing rather than performance testing. The representative of Canada asked Korea to take into account the fact that OSB in Korea was primarily used for structural applications. Canada asked Korea to reconsider its new standard to address the performance requirements of OSB used for structural purposes and recognize that the North American OSB, which encompassed the majority of the product in this market, should continue to be allowed in Korea based upon its well-known quality, safety and reliability. He also asked that Korea continue to accept OSB tested and graded in North America in accordance with Canada's rigorous and time-tested quality assurance systems. It was Canada's understanding that the new regulation's requirement to test and inspect this product in Korea would lead to lengthy and expensive delays given that similar quality-assessment systems were not currently in place in Korea.

2.293. The representative of the Republic of Korea stressed that Korea had attempted to collect opinions from stakeholders and experts during the development course of quality standard of wood product to secure transparency. Korea was currently preparing a procedure for the designation of Foreign Quality Inspection Institute (FQII) for the acceptance of test report issued by foreign testing bodies. Regarding the OSB test criteria issues, and the recognition of the US domestic standards issues, Korea would convey these concerns to the relevant ministry in capital for consideration.

2.2.3.42 European Union - Proposal for a Directive of the European Parliament and of the Council on the Cloning of Animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes (197) and Proposal for a Directive of the European Parliament and of the Council on the Cloning of Animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes (198), G/TBT/N/EU/197, G/TBT/N/EU/198 (IMS ID 492)

2.294. The representative of the United States expressed concern regarding the cloning measures currently under consideration by the European Union as they could be more trade restrictive than necessary and might not fulfil any legitimate objective the EU may have. She said that the amendments adopted by the European Parliament expanded the scope of the Commission's original proposals, as notified in G/TBT/N/EU/197 and G/TBT/N/EU/198, to include all farmed animals, including poultry and fish. It also sought to make the restrictions permanent rather than temporary. There were substantial trade implications for imposing bans or labelling requirements on animal clones, their genetics, their sexually-reproduced offspring and descendants, and the edible food products derived from such animals. Further, there did not appear to be any scientific or other legitimate rationale for the EU to impose restrictions on food from cloned animals, let alone on food or products from the descendants of cloned animals. Both the US Food and Drug Administration (FDA) and the European Food Safety Authority (EFSA) had concluded that meat and milk from cow, pig, and goat clones and the offspring of any livestock clones presented no food safety risk. Indeed, EFSA had also explicitly noted that there was also no scientific evidence that suggested a risk to genetic diversity, biodiversity, or the environment from farmed clones in comparison to conventionally farmed animals.

2.295. In addition, she noted that the International Embryo Transfer Society (IETS) had published guidelines for the health assessment and care for animals involved in the cloning process. This guidance detailed the recommended care for cattle, swine, goat, and sheep clones and surrogates to protect the welfare of the animals. These guidelines for the protection of animal welfare were met or exceeded by the cloning industry in the United States. The United States also stressed that this issue was not limited to the US, but a world-wide one. Descendants of clones were almost certainly in every country that imported genetics. US trusted the EU recognized that their own herds were not free of descendants of clones – and it was critical that EU measures did not unfairly disadvantage imports.

2.296. The US noted the potential burden that would be imposed if the European Parliament's amendments became law. It was not possible to test if an animal was descended from a clone as cloning left no genetic signature that allowed these animals to be distinguished from descendants of the original, thus creating the need for extensive traceability requirements that did not exist in many countries today. The United States hoped that the EU would be able to address US concerns by avoiding measures that failed to recognize the relevant science, that discriminated against imports, and that were unlikely to fulfil any legitimate objective.

2.297. The representative of Brazil said that it was currently reviewing the proposed EU Directive but at this point it associated itself with the concern just raised by the US.

2.298. The representative of the European Union noted that the draft proposals had been adopted by the Commission late in 2013 and had been notified to the TBT Committee in March 2014. The first Directive (Proposal for a Directive of the European Parliament and of the Council on the Cloning of Animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes (197)) would prohibit the use of the cloning technique in the EU for 5 species likely to be cloned for farming purposes and the import of live clones produced in third countries. The second Directive (Proposal for a Council Directive on the placing on the market of food from animal clones (198)) would prohibit the placing on the market of any food from clones. It was also mentioned that upon completion of the first reading on the first Directive in September 2015, the European Parliament proposed to merge both proposals and to extend the aggregate ban to reproductive material from clones, descendants of clones and products thereof. In addition, a traceability system that would extend to third-country trade partners was requested. The European Commission maintained its proposals. The next procedural step was the Council Common Position.

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

2.299. The representative of Canada said that while his delegation appreciated China's objective of decreasing air pollution, he remained deeply concerned about China's interim measures for quality management of commercial coal. It was important to ensure that China's coal testing procedures were consistent with its international trade obligations. In order to treat both domestic or foreign coal producers equally, Canada urged China to reconsider its position with respect to requiring testing to be performed in China as both Canada and China were members of the International Laboratory Accreditation Cooperation (ILAC) and trusted the expertise of ISO accredited inspection services and test labs, which were recognized worldwide. China did not currently recognize the results of ISO 17025 accredited testing labs and independent third party ISO 17020 accredited inspectorate services at the ports of loading in foreign coal producing countries. Canadian coal companies already used internationally recognized coal inspectorate services. If pre-inspection in Canadian ports of loading was accepted by China, it would not only avoid duplication of testing in Canada and in China, but would also alleviate the burden on Chinese inspectorate services and significantly reduce delays in clearing shipments in Chinese ports, which was a net benefit for all parties. Accepting pre-shipment results would permit China to more effectively implement and assess its air pollution reduction measures. In addition, Canadian stakeholders had questioned whether Chinese domestic coal was subject to the same inspection procedures as imported coal. Therefore, additional information with respect to China's testing procedures for domestic coal versus imported coal was requested to help manage Canadian stakeholders' concerns. The representative of Canada welcomed China's consideration to allow coal pre-inspection in some foreign ports of loading and encouraged China also to allow third-party testing in all coal exporting countries. In addition, Canada requested some clarification with respect to China's comments from the November 2015 TBT Committee meeting on its

methodology for assessing the effectiveness of the human health and environmental safety aspects of the commercial coal testing regime.

2.300. The representative of Australia noted that China was Australia's second largest coal export market and there continued to be great interest from the Australian industry and exporters regarding the implementation and application of this measure. Australia further expressed support for the environmental objective of improving air quality and promoting the efficient and clean use of coal, and Australia remained committed to being a reliable supplier of high quality thermal and metallurgical coal to China by supporting China's efforts to improve the quality of coal used in China's energy and industry sectors.

2.301. Nevertheless, Australia noted some concerns with the regulation in the following areas. First, regarding the time-frame – what was the reason for notifying the measure to the TBT Committee as "urgent" under Article 2.10 of the TBT Agreement, and was the measure still interim as had been stated in the notification? Second, on standards: China had based the standard in the interim measure on globalCOAL's Standard Coal Trading Agreement. However, Australia requested China to consider using existing international standards such as ISO 13909. Australia requested the reason for using the globalCOAL standard Coal Trading Agreement standard rather than the ISO standard. Further details of the globalCOAL's Standard Coal Trading Agreement and its application to domestic and imported coal were also requested.

2.302. Third, on conformity assessment procedures, Australia urged China to accept test results undertaken in other countries at internationally accredited testing facilities to reduce duplication and enable tests to be undertaken in a more expeditious manner. The information about interaction between national accredited testing authorities to discuss test results obtained in China where those test results differ from results obtained elsewhere was requested.

2.303. Fourth, Australia raised some concerns about the review or appeal process to question cases of Chinese test results differing from Australian or other countries' test results. Australia wanted to know whether China gave any consideration to an independent review or appeal process in the case of differences in results between tests conducted outside China and at Chinese ports, or different results between tests at different Chinese ports, on the same shipment of coal.

2.304. In addition, Australia expressed the following further concerns: (i) on the testing procedure of Chinese domestic coal and on consistency between testing conducted on imported coal and domestic Chinese coal; (ii) on the results of the tests conducted for domestic coal which had been undertaken so far; (iii) on what happens to domestic coal that did not meet the quality standard; and, (iv) on the consistency of testing across all of the import ports. Australia also requested an update on any improvements to timeframes and capacity for testing imported coal after arrival in China. Finally, Australia asked when it could expect a formal response to its comments on the measure to China's TBT enquiry point that had been set forth at the last meeting of the Committee.

2.305. The representative of China stressed that the interim measures for quality management of commercial coal had been adopted in response to the severe air pollution situation in China. It was noted that just last week China had suffered four days of serious haze in Beijing. The main cause of the haze was the excess of PM 2.5 which had a direct connection to the increase of coal consumption in China. As China did not have further information to respond to Members' concerns it invited Members to refer to the minutes of the November 2015 meeting.

2.2.3.44 China - Guidance for Notification and Registration for New Chemicals, G/TBT/N/CHN/1170 (IMS ID 490)

2.306. The representative of the United States thanked China for their bilateral meeting as well as the recent notification to the TBT Committee but also indicated that her delegation continued to have concerns regarding the Notification and Registration of New Chemicals in China. The US urged China to take all stakeholder comments into consideration and the Solid Waste and Chemical Management Technology Center (SCC-MEP) to continue seeking stakeholder input as it further developed China's chemical registration requirements. The chemical registration requirements, which came into effect in October 2010, were in many cases difficult to understand and imposed very significant administrative and compliance burdens. While the Guidance was a

welcome effort to address these issues, the Guidance itself raised a series of troubling concerns. In particular, the new language in Chapter I(1)2.4 on articles exempted from the New Chemical Notification (NCN) Guidance implied that any new chemical substance in an article, potentially having exposure to humans or the environment, would be subject to the full NCN obligations as per Decree Number 7. Specifically, this requirement would be applicable to all articles and their subcomponents, even if there was extremely low risk of hazard or exposure to humans or the environment and would not only impose significant administrative and compliance burdens on industry, but also impose a new administrative burden on the SCC-MEP itself, significantly increasing the number of applications it would have to review. US industry recommended that SCC-MEP maintain the previous version of the Article Exemption, under which articles and substances used in or released by articles, were exempt as they posed negligible risk to human health or the environment. Otherwise, the provision could potentially place an undue burden on manufacturers in China, as well as importers into China. Global suppliers to Chinese importers would be required to proactively inform their Chinese customers of substances new to China that may be contained in or released from their manufactured articles, placing a significant burden on manufacturers since they would have to ensure that substances were notified, resulting in amplified implications throughout the global supply chain, including on Chinese companies. Further, such requirements could impact global suppliers' future decisions to export substances and articles to China due to the increased administrative burden as well as the possibility of disclosing sensitive Confidential Business Information to customers.

2.307. The representative of China said that the revision of the Guidance for Notification and Registration for New Chemicals had begun in January 2014 and that the public consultation had taken place between 25 June and 31 July 2015. China had already introduced some changes to the Guidance, notified as G/TBT/N/CHN/1170, based on Members' comments and would continue to take Members' comments into consideration.

2.2.3.45 Saudi Arabia - Draft for update of the Technical Regulation No. SASO 2857:2014 "Vehicle Tyres Rolling Resistance and Wet Grip Requirements", G/TBT/N/SAU/835 (IMS ID 488)

2.308. The representative of Korea said that his delegation appreciated the active attempts by Saudi Arabia to improve the draft for update of the technical regulation on vehicle tyres rolling resistance and wet grip requirements; however, Korean companies continued to have difficulties in observing the regulation. First, the regulation specified that the validity period for the energy label was one year, putting financial and administrative burden on Korean companies to renew the label annually. Saudi Arabia was the only country requiring the renewal of the energy label when compared to other countries such as Europe, Brazil, Korea, etc., which enforced energy efficiency labelling requirements for tyres. Referring to Article 2.2 of the TBT Agreement, which specified that "...technical regulations are not prepared, adopted or applied with a view to or the effect of creating unnecessary obstacles to international trade", Korea requested Saudi Arabia to withdraw the validity period for energy labels.

2.309. Second, Korea requested Saudi Arabia to improve on the procedures, which required companies to go yet again through the registration procedure, obtain a new certificate and pay fees when they modified basic information, such as model name. Lastly, since the certification system was divided into two stages, namely application for registration and issuance of label, Korean companies had to pay fees at each stage and go through local branches in Saudi Arabia to pay these fees since it was not possible to pay through direct wire transfers from Korea. In this context, Korea requested Saudi Arabia to improve the process of certificate registration and support the overseas remittance procedure so that companies could remit total acquisition fees from foreign countries at one time.

2.310. The representative of the European Union said that his delegation had raised concerns about this draft, both when it was first notified as G/TBT/N/SAU/835 and also when notified in a revised version as G/TBT/N/SAU/907. The EU had submitted written comments to Saudi Arabia on both notified drafts and had also raised the issue during the previous meeting of the TBT Committee.³⁴ This time, the EU wished to raise both some new concerns arising from the version notified under G/TBT/N/SAU/907 as well as some which persisted since the earlier notification. Regarding the new version of the text, the EU noted that several of its provisions were not in line

³⁴ G/TBT/M/67, para. 2.49.

with relevant international standards and asked Saudi Arabia to fully align the notified draft with international standards, especially with UNECE Regulation 117. The EU also noted that the label specified in the latest version of the notified draft as "Tire Rolling Resistance and Wet Grip Label Dimensions and Color Scale" contained changes and sought confirmation that the new version of the label would be the applicable one. Regarding issues the EU had already raised in the past, the EU highlighted that the notified draft defined the timeline for compliance with phase I maximum limits for C1 and C2 tyres as November 2015. The EU asked whether this requirement was already in force and whether its time-frame could be aligned with the one set for C3 tyres, namely November 2016. Furthermore, as C3 tyres were normally used by professional users, the EU asked Saudi Arabia to consider exempting them from the requirement to be labelled in the form of stickers on tyres.

2.311. The EU had also been informed about a new Gulf Cooperation Council (GCC) measure concerning tyre labelling. In this respect, the EU sought clarification on the existence and application of such a scheme in Saudi Arabia, on whether both the labelling obligation of the notified draft and that of the GCC measure were applicable and mandatory in Saudi Arabia and on whether there were concrete plans for a transition towards a unique GCC tyre labelling system. Finally, the EU asked Saudi Arabia to notify all implementing measures, including the recent "Regulation for procedure of data registration and issuance of the energy efficiency labels in vehicles and tires". In relation to this measure, the EU also inquired about the reasons and justification as to why the licence to print and use the labels was only valid for one year even if the tyre model had not undergone any change in the meantime.

2.312. The representative of the Kingdom of Saudi Arabia thanked the EU and Korea for the bilateral meeting and asked for the comments to be provided in writing so that they could be forwarded to the capital for follow up.

2.2.3.46 European Union - Restriction on Polycyclic Aromatic Hydrocarbons (PAHs) in Tyres as specified in Annex XVII of REACH (IMS ID 480)

2.313. The representative of China said that his delegation was mainly concerned about the test method ISO 21461 (Rubber — Determination of aromaticity of oil in vulcanised rubber compounds), which was referenced in Entry 50 of Annex XVII of REACH (1907/2006/EC). ISO 21461 was testing aromaticity of oil and was not specific to BaP and the 8 listed PAHs. The conformity assessment method referred to in this Entry specified that bay protons should not exceed the limit of 0.35 % as tyres measured and calculated by ISO 21461. There was no specific scientific correlation between Bay protons not exceeding 0.35% of tyres on the one hand and BaP not more than 1 mg/kg, 8 listed PAHs not more than 10 mg/kg of extender oils, on the other. Therefore, it was not suitable for accurate quantitative testing of BaP and 8 listed PAHs in extender oils. According to research by relevant Chinese institutes, tyres were produced from various raw materials and consisted of diverse and complicated substances. The influencing factors on ISO 21461 testing results were far beyond extender oils and far beyond BaP and 8 listed PAHs. China's concern was neither the limits of PAHs nor the international standard ISO 21461 but rather that ISO 21461 was not suitable for use in conformity assessment of Entry 50 as it was an unusual and indirect quantitative method for the determination of PAHs. By comparison, GC-MS and HPLC, test methods specified in several technical regulations and international standards, were more accurate and mature methods to determine PAHs. For these reasons, the use of the test method ISO 21461 was unscientific, inappropriate and could cause misleading test results. In fact, there had been several cases of Chinese tyres found non-compliant with REACH, after being tested according to this standard. But they were compliant tyres if tested according to other more accurate, mature and commonly used test methods such as GC-MS and HPLC. Furthermore, China was very concerned about the huge costs of the test method to tyre manufacturers as it required testing laboratories to be equipped with very expensive and unusual instruments such as the 200 MHz NMR spectrometer. China requested the EU to provide the scientific rationale for the test method ISO 21461, conduct a timely review and make relevant revisions accordingly.

2.314. The representative of the European Union indicated that the measure in question had been notified under the TBT Agreement on 21 January 2004 as G/TBT/N/EEC/52 (so called REACH regulation) and that it had been extensively discussed with the WTO Members, economic operators and other interested stakeholders. Concerning the method for determination of aromaticity of oil in vulcanised rubber compounds (ISO 21461), he pointed out that the EU had been applying this method – an international ISO standard – since January 2010. Furthermore, the equipment needed

(nuclear magnetic resonance spectroscopy) was an instrument typically available in specialized laboratories.

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

2.315. The representative of the European Union informed the Committee that his delegation had submitted written comments on the draft Stainless Steel Products (Quality Control) Order on 23 October 2015. He reiterated the statement made at the previous meeting.³⁵

2.316. The representative of India thanked the EU for their continued interest in the draft Stainless Steel Products (Quality Control) Order. This draft order was published on the Ministry of Steel website and notified to the WTO on 25 August 2015, giving 60 days for comment. Several representations had been received from domestic and foreign producers, associations and other stakeholders, both in support of, and against the measure. The Ministry for Steel was currently examining all comments, on their merit, and would accordingly take those comments into consideration before making a final decision on the draft Order.

2.2.3.48 Russian Federation – Measure affecting import of Ukrainian wallpaper (IMS ID 476)

2.317. The representative of Ukraine reiterated his delegation's concerns with regard to the ban on import of Ukrainian wallpaper to the Russian Federation (Russia). He noted that Russia had stated that Ukrainian products were non-compliant with Russian sanitary and hygienic technical regulations for emission of formaldehyde and styrene. He argued that the measure was applied in a non-transparent and unpredictable manner because it did not provide any evidence for the alleged inconsistency with Russia's requirements. Ukraine emphasized that the ban affected 80% of Ukrainian wallpaper producers who exported more than 70% of their production to the Russian market. Moreover, Ukrainian producers had provided the Russian authority (Rospotrebnadzor) with all necessary documents and results of the tests carried out in Russian and Ukrainian laboratories qualified by the Russian Federation accreditation body, which confirmed the compliance with relevant technical regulations, including the requirements for emissions such as formaldehyde and styrene.

2.318. His delegation believed that the import ban was discriminatory as it treated Ukrainian wallpaper less favourably than like products of national origin as well as like products originating from other countries. Ukraine reiterated that the measure was inconsistent with provisions of Articles 2.1, 2.2 and 5.1 of the TBT Agreement, and in no way justified and created an unnecessary obstacle to trade. Consequently, Ukraine requested the Russian Federation to provide official detailed clarification and justification of the measure and its compliance with the provisions of the TBT Agreement. He stressed that no test reports – which would confirm the wallpaper safety discrepancy with requirements – had been provided to Ukraine by Russia, including in the letter received from Rospotrebnadzor. Moreover, no deficient test reports had been provided to the Ukrainian manufacturers, making it hard or impossible to undertake, if necessary, corrective action. Ukraine called upon Russia to immediately withdraw the ban and bring this measure in line with the TBT Agreement and the accession commitments made by Russia.

2.319. The representative of the Russian Federation regretted to report that no progress had been made in the resolution of this matter. He said that no actions had been taken by Ukrainian authorities since the previous TBT Committee meeting to resolve this issue in a constructive manner. He referred to Russia's previous statements which clarified the legal basis for introducing this measure, its legal nature, and further steps that were necessary for removing the measures at issue. First, he recalled that the import suspension of Ukrainian wallpaper had been introduced by the Russian Federation in April 2015, due to violation of the hygienic requirements on migration of formaldehyde and sterol into air. He underscored that measures were introduced with respect to products of a limited number of Ukrainian entities, and were temporary in nature. Accordingly, Russia informed the Sanitary and Epidemiological Service of Ukraine and the interested enterprises about the need to provide additional materials in the Russian language. Moreover, two bilateral meetings with Ukrainian producers concerning this matter were held in June and September 2015,

³⁵ G/TBT/M/67, para. 2.40.

but until now Ukraine had failed to provide the Russian authorities with the required documentation.

2.320. Second, with respect to provision of test results, he informed that in accordance with Law № 294-FZ of 26 December 2008, this information could not be delivered to any private person or legal entity with exception of those entities which were under inspection, in order to protect the commercial interests of such entities. Neither Russian, nor foreign, producers could receive this highly sensitive information. Taking into account that the inspections took place in respect of Ukrainian wallpaper traders, only they had the right to receive these results. Finally, he noted that his delegation responded to the Ukrainian request of July 2015 regarding this matter, received through the Ukrainian TBT enquiry point. Russia reaffirmed that these measures were in full compliance with the commitments of the Russian Federation and with Articles 2.1 and 2.2 of the TBT Agreement, and that the requirements on migration of chemicals into air were based on relevant scientific and technical information.

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

2.321. The representative of Indonesia appreciated the United Kingdom's (UK) notification on the proposal to introduce plain packaging of tobacco products and for their written response from the previous meeting, which was sent to the Indonesian TBT enquiry point. Indonesia agreed with what was mentioned in the written letter that in order to protect public health, WTO Member may introduce provisions on standards. However, Indonesia was of the view that the plain packaging policy requirements were inconsistent with the respective countries' obligation under the WTO TBT Agreement and TRIPS Agreement. The proposal for plain packaging policy for tobacco products as introduced by the UK should be undertaken in a manner that was not more trade-restrictive than necessary, as it could subsequently create unnecessary barriers to trade. As Members were aware, plain packaging measures to pursue the public health objective of a certain Member were now being challenged by Indonesia and several other Members in the DSB. Therefore, Indonesia urged the UK and other Members in the process of introducing similar measures to reconsider their intentions until the dispute was solved. Indonesia requested that other Members evaluate alternative measures which were more effective in achieving the health objective, and more importantly, consistent with WTO rules. Indonesia appreciated the opportunity to present its views on plain packaging regime and its consistency with the TBT Agreement.

2.322. The representative of the Dominican Republic shared the concerns of Indonesia. She requested that Members considering introducing plain packaging for tobacco products wait for the dispute to be resolved, as Dominican Republic and other developing Members had lodged this before the DSB against Australia on similar measures.

2.323. The representative of Guatemala shared the objectives related to the control and reduction of tobacco consumption. Nevertheless, Guatemala also shared the concerns of other Members with regard to how this measure could fulfil the legitimate objective of reducing tobacco consumption without being more trade-restrictive than necessary to achieve that objective. She said that Guatemala followed with great interest the discussion about this measure.

2.324. The representative of Cuba agreed with Indonesia and the Dominican Republic in asking other Members to wait for the results of the panel with regard to the case lodged by many developing countries.

2.325. The representative of Australia reiterated its strong support for the decision by other WTO Members to legislate for the mandatory plain packaging of tobacco products. In particular, he welcomed the passage of legislation to implement tobacco plain packaging in the UK which would come into force later this year. The important steps made by these WTO Members in tobacco control demonstrated that efforts to delay the adoption of tobacco plain packaging measures in these countries had not been successful. He stated that Australia was of the firm view that Members had the right to implement measures necessary to protect public health, while complying with relevant international treaty obligations, including the TBT Agreement. Tobacco plain packaging was a legitimate measure, designed to achieve a fundamental objective – the protection of human health. The tobacco plain packaging measure was endorsed by leading public health experts as well as the World Health Organization and was supported by extensive peer-reviewed

research, reports and studies. Australia further noted that Members were making reference to the case currently before the DSB. It was inappropriate in Australia's view for complainants in WTO disputes currently under way against Australia to invoke these proceedings as an attempt to delay or discourage other Members from developing or implementing their own legitimate tobacco control measures.

2.326. The representative of Canada reiterated his delegation's statement under new STC no. 6. He said Canada was a pioneer in package labelling requirements for tobacco products and he considered these requirements to be a core component of the right to regulate in the interest of the Canadian public. Tobacco use was a significant concern in Canada and worldwide, and in Canada alone 37,000 people died annually from tobacco use. It was a leading cause in Canada of preventable death and disease. Tobacco products were also the only good that was subject to a legally binding health treaty – the WHO FCTC. The Government of Canada had undertaken to introduce restrictions on the packaging of tobacco products very similar to those that the UK was proposing to adopt and Canada was considering measures implemented elsewhere in the world and their potential application in Canada.

2.327. The representative of Norway signalled Norway's continued strong support to the UK in their efforts to combat the tobacco epidemic. She also echoed the comments made by Australia and Canada and reiterated her delegation's statement under new STC no. 6. As tobacco smoking was the leading single cause of early death and illness in Norway, there was strong support for tobacco control measures so as to achieve a tobacco-free society in the long term. Norway had launched a public consultation on standardizing tobacco packaging in March 2015 and the preparation of the bill was now in the final stages. This bill would soon be sent to the parliament and most likely be adopted towards the end of 2016.

2.328. The representative of Uruguay said that given Uruguay's well-known position in support of tobacco plain packaging measures, the statements made by his delegation in previous meetings should be also be taken into account on this measure, including Uruguay's statement in the March 2016 Committee meeting.³⁶

2.329. The representative of the European Union thanked Members for their continuing interest in the United Kingdom Standardised Packaging of Tobacco Products Regulations 2015, notified in draft form under G/TBT/N/GBR/24. The EU informed that the Standardised Packaging of Tobacco Products Regulations 2015 would come into force on 19 May 2016, the same day as the EU Tobacco Products Directive, and would apply to the whole of the UK.

2.330. As already noted in previous meetings, the EU reiterated that tobacco products had recognized harmful effects on human health. In this sense, Article 2.2 of the TBT Agreement included the protection of human health as a legitimate objective. It was recognized that any measure pursuant to this legitimate objective must not be more trade restrictive than necessary nor create unnecessary obstacles to international trade. It should also be noted that Article XX(b) of the GATT 1994 emphasizes the importance of public health by justifying measures "necessary to protect human health".

2.331. The UK Standardised Packaging of Tobacco Products Regulations 2015 aimed at restricting the promotion of tobacco products to further reduce the prevalence of smoking in the UK by: (i) discouraging uptake of tobacco use by young people; (ii) encouraging and supporting tobacco users who wanted to quit; and (iii) reshaping social norms and attitudes around tobacco use to promote health and wellbeing.

2.332. The measure formed the latest strand of a comprehensive range of tobacco control legislation already in place in the UK aimed at decreasing tobacco consumption. Under existing legislation, there was already a ban on advertising tobacco products to the general public, a ban of tobacco sponsorship to sports and cultural events, and companies were forbidden to give out free samples of tobacco. Picture warnings on tobacco products were required in the UK. The sale of tobacco products from vending machines and tobacco displays in all shops was prohibited.

³⁶G/TBT/M/65, paras. 2.171 and 2.136.

2.333. In addition to the notified draft, the UK made available to the Members through the TBT notification an explanatory memorandum that detailed the rationale of the measure and its expected health impacts, an impact assessment and several scientific studies on the impact of plain packaging on smoking prevalence.

2.334. In parallel with the WTO notification, the UK had also notified the measure to the European Commission in accordance with internal EU requirements for notification of draft national technical regulations under Article 8 (1) of Directive 98/34/EC. The UK had received detailed opinions from some EU member States on the draft measure within the framework of the internal notification procedure. These had been analysed, considered and replied to by the UK authorities. As regards comments received from WTO Members under the WTO TBT notification procedures, these had been equally examined and written replies provided.

2.3 Exchange of information

2.3.1 Thematic Sessions

2.335. The Chairperson reported on the thematic sessions held on 8 March 2016. An advance copy of her report had been made available to Members in the room.³⁷ She thanked the 17 speakers who had shared their experiences in the areas of conformity assessment and good regulatory practice.

2.336. The representative of Australia said that his delegation would like to participate in the June thematic session on standards. Australia intended to provide further information with regard to Australia's regulatory reform agenda which encouraged Australian regulators to use international standards wherever possible. While Australia would submit a formal proposal in writing, its participation was likely to focus on the process Australia had gone through to develop the regulatory reform agenda, and processes undertaken by regulators to determine the use of international standards. Specific topics could include the Australian standard-setting body and how it encouraged the use of international standards; the experience of the Australian regulators and policy makers in implementing policy; experiences from the context of business industry or consumers; and the benefits to these groups from the use of international standards by regulators.

2.337. The representative of Brazil asked for more clarity on the structure and organization of the thematic sessions.

2.338. The Secretariat said that specific topics had been agreed in the context of the triennial review and these were set out in a work programme stretching to 2018.³⁸ In June, one topic would be standards and another regulatory cooperation between Members; the latter would focus on energy efficiency.³⁹

2.339. The representative of Canada said that there was a need to look at alternative formats for the thematic sessions that would engender a more meaningful engagement from Members. One possibility was panel discussions where technical experts could participate and answer questions from Members.

2.340. The US agreed with Canada. There had been too many presentations in too short a time, limiting the time for questions from the floor. It was important to give experts time to present and delegations time to discuss. For instance, on energy efficiency standards, it would be important to bring in the right expertise to have a useful dialogue.

2.341. The representative of China said that they had proposed clarification on the rules for thematic sessions. How, for instance, could international organizations such as the ISO and IEC participate in the thematic sessions, and how about the private sector?

³⁷ This report was subsequently circulated as two separate reports and are contained in G/TBT/GEN/190 (Thematic Session on Conformity Assessment) and G/TBT/GEN/191 (Thematic Session on Good Regulatory Practice).

³⁸ G/TBT/37, para. 8.3.

³⁹ More right background was provided in a fax from the Chairperson circulated subsequent to the meeting on 17 March 2016.

2.342. The representative of the United States said that the Committee had already clarified that observer organizations were welcome to participate in the thematic session; indeed, the representative of the OECD (an observer to the Committee) had made a presentation during the current week on the proposal from Mexico. And on the private sector, the US had proposed one particular speaker (for the thematic session on CAP) who had also spoken during the thematic session. What was needed was a better format for the discussions.

2.343. The representative of Chile agreed with the United States and Canada on the need for a better discussion on topics of interest. It would be important to include experts from capital, but this also had resource implications; perhaps the Committee could look at financing speakers from developing countries.

2.344. The representative of Mexico said that the thematic sessions had, in her delegation's view, been a very good experience. She supported the comments from the US, Canada and Chile.

2.345. The representative of the European Union stressed that the thematic sessions did not need to stick to a single model. The Committee had to be flexible, to adapt the format to the topic. There were topics like GRP where probably most presentations naturally came from Members because each delegation told a story about its own experience. For other topics there was actually a need to involve other types of actors from international organizations, maybe also from academia. What was needed – what all were looking for – was a good learning exercise. Perhaps, in view of the topics for the next thematic session, delegations could approach this with creativity; each delegation could make a proposal on the format and who, in their view, should be intervening. If more time was needed, the Committee could consider extending the meeting. On the participation in the thematic sessions it was important not to stick to whether an organization had formal observership status or not. Expertise was essential. For the private sector, the practice so far had been for Members to involve private sector as part of their delegation when this would bring added value.

2.346. The thematic sessions could also simply be an exchange of experiences where Members presented their own views on something – for instance on a document the Committee wanted to develop. This is what had happened in the area of GRP: discussion had started from an exchange of experiences and this had turned into something else. It needed to be an open discussion; there was no *one* model. He suggested that the Committee reflect on what model could best fit the topics for the June sessions.

2.347. The Chairperson thanked delegations for their useful suggestions and said that she would consult with the incoming chairperson prior to the June sessions, as there was clearly a need to examine this issue further.

2.348. The representative of China said that his delegation had benefited a lot from the presentations both by the government representatives as well as representatives from the relevant international organizations, as well as the private sector – China was open to the participation of interested stakeholders as long as their expertise was relevant to the topic of the thematic session.

2.3.2 GRP paper

2.349. The Chairperson read out her report on the informal discussions on Good Regulatory Practices held on Monday, 7 March 2016. Her full report is contained in G/TBT/GEN/192.

2.350. The representative of Brazil stressed that some Members were of the view that a disclaimer would not at all be necessary; it was not necessarily the case that all Members had accepted, in principle, to have a "simple" disclaimer. Brazil would continue to explore options on how to bring this work forward with the rest of the membership.

3 TWENTY-FIRST ANNUAL REVIEW

3.1. The Secretariat drew the Committee's attention to some proposed changes to the information contained in Annex A of the Review.⁴⁰ The Committee also took note of document

⁴⁰ A revision to the original report was subsequently circulated in G/TBT/38/Rev.1.

G/TBT/CS/2/Rev.22 containing a list of those standardizing bodies that have accepted the Code of Good Practice since 1 January 1995.

4 TECHNICAL COOPERATION ACTIVITIES

4.1. The representative of Paraguay thanked Mexico and ALADI for the workshop on the Impact of Standards, Technical Regulations and Procedures for Conformity Assessment in international trade that had taken place in October 2015. This important activity which brought together representatives of public and private sector was part of the project to build capacity of national technical committees within ALADI.

4.2. The representative of ISO emphasised the importance of developing country participation in international standardization so as to ensure global relevance of international standards. The ISO Action Plan for Developing Countries had been published in January 2016 where the focus was on strengthening national quality infrastructure.⁴¹

4.3. The representative of the IEC updated the Committee on recent activities relative to the TBT Committee. The full report is available on the IEC website.⁴²

4.4. The Secretariat referred delegates to the technical assistance section of the Annual Review document G/TBT/38 for an overview of activities undertaken by the Secretariat over the past year. She explained that the participants of the March 2015 advanced TBT course were back in Geneva for a follow-up course to share experiences regarding the implementation of action plans they had developed to address TBT-related challenges in their countries. She congratulated the participants for their commitment and very encouraging results.

4.5. The representative of the Kingdom of Bahrain, one of the course participants, said that the course was a large step forward in terms of how technical assistance activities were run. All participants, with the help of their coaches, had been engaged in applying their action plans throughout the year. Strengthening the capacity of the course participants had had a multiplier effect. She was highly motivated after the March 2015 course to spread awareness on TBT matters and had done so through intensive courses for colleagues, lectures at schools and universities, and outreach to customs officials. She would continue to share the knowledge and skills gained upon her return to Bahrain.

5 UPDATING BY OBSERVERS

5.1. The representative of ARSO made a comprehensive statement on TBT-related work.⁴³

5.2. The representative of the ACP said that the ACP Group had long recognized the enormous significance of non-tariff barriers, and TBT in particular. There was increased activity in TBT-related issues in regional economic communities as well as organizations dealing with quality infrastructure. The presence of ARSO in the Committee was a testimony to this. As part of this increased attention and effort, the ACP Group in Geneva had benefitted greatly from technical assistance, most notably through an expert operating under the ACP EU TBT Programme.⁴⁴ The ACP Group hoped to contribute further to the work of the TBT Committee as well as in ACP countries' TBT-related work. He thanked the ACP EU TBT Programme for its most valuable assistance to projects in capitals, at the regional level and in Geneva. He hoped the important work of this programme would continue beyond the current term and assured the Committee that the ACP secretariat for its part would continue to contribute to the work of the Committee as TBT was a matter of great importance to the ACP Group.

5.3. The representatives of the IEC⁴⁴, UNECE, WHO, OIML and Codex⁴⁵ updated the Committee on relevant work.

⁴¹ http://www.iso.org/iso/iso_strategy_2016-2020_en_-_lr.pdf

⁴² http://www.iec.ch/about/globalreach/partners/international/pdf_wto/iec_wto_2016_03_en_iec.pdf

⁴³ G/TBT/GEN/193.

⁴⁴ <http://www.acp-eu-tbt.org/>

⁴⁵ These statements were circulated in the documents G/TBT/GEN/194, G/TBT/GEN/195, G/TBT/GEN/196, G/TBT/GEN/197.

5.4. The representative of Uganda noted that many of the outstanding requests for observership status had been pending for a number of years. He asked that the Committee make a decision on those long-standing applications by accepting those organizations that met the criteria and rejecting those that did not. He welcomed the views of other Members on this matter.

5.5. The Secretariat explained that those organizations requesting observership needed to gather support among the Membership, as ARSO and IGAD had recently done, and then raise the issue in the Committee. Should any Member require historical information and background on the applications pending, he invited them to contact the Secretariat.

6 ELECTION OF CHAIRPERSON

6.1. The Chairperson informed the Committee that consultations were currently ongoing in the Committee on Trade in Goods. This agenda item was therefore suspended and would be reverted to at the next formal Committee meeting.

7 DATE OF NEXT MEETING

7.1. The next regular meeting of the Committee is scheduled for 15-16 June 2016. Two thematic sessions will be held on 14 June.
