RESTRICTED

G/TBT/M/63



19 September 2014

(14-5262)

Page: 1/57

Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 18-19 JUNE 2014

CHAIRPERSON: MR. FILIPE RAMALHEIRA

Note by the Secretariat¹

Contents

1	ADO	OPTION OF THE AGENDA	2
2	ELE	CTION OF THE CHAIRPERSON	2
3	IMF	PLEMENTATION AND ADMINISTRATION OF THE AGREEMENT	2
3.1	St	tatements from Members under Article 15.2	2
3.2	2 Sp	pecific Trade Concerns	2
3.2	2.1	Withdrawn concerns	2
3.2		New Concerns	
3.2	2.3	Previously Raised Concerns1	4
3.3	3 E>	xchange of Experiences4	9
3.3	8.1	Transparency (Thematic session of 17 June 2014)4	9
3.3	3.2	The Coherent Use of Notification Formats (G/TBT/35)5	0
3.3	3.3	Good Regulatory Practice	0
3.3	3.4	Other Matters	4
4	TEC	CHNICAL COOPERATION ACTIVITIES	6
5	UP	DATING BY OBSERVERS	6
6	ОΤН	HER BUSINESS	6
6.1	Ca	anada's new regulatory framework5	6
7	DA	TE OF NEXT MEETING	7

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.

1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in WTO/AIR/4305.

2 ELECTION OF THE CHAIRPERSON

2.1. The <u>Committee</u> elected Mr. Filipe Ramalheira (Portugal) as the Chairman of the Committee.

3 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

3.1 Statements from Members under Article 15.2

3.1. The <u>Chairman</u> said that the list of statements submitted under Article 15.2 of the TBT Agreement was contained in document G/TBT/GEN/1/Rev.13, dated 25 February 2014. He recalled that this information was available, and regularly updated, on the TBT Information Management System (the "TBT IMS"). He stressed that while 128 Members had submitted at least one Statement on Implementation under Article 15.2, 31 Members had not yet fulfilled this obligation and he urged them to do so in a timely manner.

3.2. The representative of the <u>United States</u> thanked the Chairman for emphasizing the importance of 15.2 statements and commended Mali on their recently submitted statement.

3.2 Specific Trade Concerns

3.2.1 Withdrawn concerns

3.3. The <u>Chairman</u> reported that the following Specific Trade Concerns were withdrawn from the Agenda at the request of the concerned Member:

- a. Argentina Non-acceptance of 200 Grade Stainless Steel withdrawn by India.
- Ecuador Emergency Technical Regulation of the Ecuadorian Standardization Institute (RTE INEN) No. 088: "Surface tension agents" (G/TBT/N/ECU/117) – withdrawn by <u>Mexico</u>.
- c. European Union Directive 2009/28/CE, Renewable Energy Directive (EU-RED) withdrawn by the <u>United States</u>.
- d. Mexico Draft Mexican Official Standard PROY-NOM-032-ENER-2013: Maximum electrical power limits for equipment and appliances requiring standby power. Test methods and labelling (G/TBT/N/MEX/263/Add.1) withdrawn by the <u>Republic of Korea</u>.
- e. Ecuador Cosmetic products (G/TBT/N/ECU/111 G/TBT/N/ECU/116) withdrawn by <u>Mexico</u>.
- f. New Zealand Proposal to introduce plain packaging of tobacco products in New Zealand (G/TBT/N/NZL/62, G/TBT/N/NZL/62/Add.1) withdrawn by Indonesia.
- g. Chile Bovine meat (G/TBT/N/CHL/254, G/TBT/N/CHL/254/Add.1) withdrawn by Paraguay.²

² This concern was not included in the Annotated draft Agenda.

3.2.2 New Concerns

3.2.2.1 China - Safety Requirement for Lithium Ion Cells and Batteries used in Portable Electronic Equipment

3.4. The representative of Japan expressed his delegation's view that, while under Article 2.4 of the TBT Agreement the IEC62133 had to be used as a basis for the Chinese draft regulation, these two instruments still differed in the following points: (i) approximately 70% of the test items proposed in the Chinese draft regulation did not conform to the relevant international standard; (ii) approximately 50% of the test items were not specified in the IEC62133; (iii) while the remaining 20% test items were identical to those specified in the IEC standard, the test procedures did not conform to IEC62133; (iv) the Chinese draft regulation contained test items that were not included in the notified document; and (v) given that the Chinese draft regulation should only cover single cells and assembled batteries, the inclusion of requirements for the circuitry of electronic devices was not appropriate. Furthermore, Japan believed that the objective of securing safety of electronic devices should be achieved through safety regulations for electronic devices and not through those for lithium ion cells and batteries.

3.5. The representative of the <u>Republic of Korea</u> highlighted that Korea had a similar regulation for lithium ion cells and batteries used in electronic equipment, which was fully aligned with relevant international standards. He pointed out that the Chinese requirements for markings and test methods regarding overcharge tests (Article 6.3), temperature cycling (Article 7.2), and thermal abuse (Article 7.8) differed from the corresponding international standards and had to be harmonized. Additionally, given that the Chinese draft regulation included requirements that were not specified in international standards, he asked China to explain the scientific rationale and background to introduce those requirements. Korea thanked China for the bilateral discussion in which the representative of Korea was informed that IEC62133 was being revised. However, given that the revised international standard would be published in June 2016, he requested China to harmonize the draft regulation with IEC62133 or, alternatively, recommended implementing the Chinese regulation after the revised international standard was published. Finally, Korea requested China to clarify ambiguous provisions of the draft regulation, such as the safety requirement for system protection circuit (Article 11) and the requirement of testing to verify consistency (Article 12).

3.6. The representative of <u>China</u> explained that the Chinese standard was drafted in order to protect the safety and health of consumers. In 2008, an ad hoc working group was established to develop the standard. Members of this working group included more than 40 domestic and foreign lithium producers and scientific research institutes. Within three years, a final version of the draft standard was formulated. Addressing the concern that the Chinese standard was not in accordance with IEC62133, she noted that China had adopted a standard (GB/T28164 2011) identical to IEC62133; and that the standard under discussion supplemented and improved the GB/T28164-2011. She referred to similar cases found with other Members, such as the relationship between the IEC62133:2002 and the Japanese standards JIS C8712:2006 and JIS C8714:2007. Due to the different scope of application, the Chinese standard did not fully correspond to IEC62133. Instead, the Chinese standard adopted the relevant criteria of IEC62133, when appropriate, and improved this international standard according to the characteristics of lithium batteries. In order to illustrate the effectiveness of the Chinese standard, she said that a number of proposals based on the national standard had been adopted by the IEC.

3.2.2.2 Russian Federation – Measure affecting import of Ukrainian dairy products.

3.7. The representative of <u>Ukraine</u> recalled that on 7 April 2014, the Russian Federation imposed an import ban of dairy products on six Ukrainian producers, based on alleged incompliance with the requirements prescribed by the Russian technical regulation on milk and dairy products, adopted on 16 June 2012. He said that the measure was introduced suddenly and in a non-transparent manner, as it was not notified to the Ukrainian authorities, except for a short notice published on the website of the Russian Federal Service for Supervision of Consumer Rights Protection and Human Well-Being. Moreover, the Ukrainian producers had not received any documents regarding the results of the tests conducted by the Russian authorities and were unaware of the details of alleged non-compliance with the Russian regulation. He also noted that the six Ukrainian producers had certificates of conformity with the requirements of the Russian technical regulation, and that the import ban also affected producers of the occupied territory of inconsistent with the non-discrimination principle contained in Article 2.1 of the TBT Agreement, and was unnecessarily trade restrictive, in violation of Article 2.2 of the TBT Agreement.

3.8. The representative of the <u>Russian Federation</u> said that the import suspension of dairy products applied to five Ukrainian companies and did not constitute a general import ban on Ukrainian dairy products. More than twenty Ukrainian companies continued to export dairy products to the Russian Federation. The suspension was introduced due to inconsistencies of these products with the relevant Russian technical regulation, in particular regarding requirements on fat, proteins and moisture content. This was a TBT-compliant measure that was introduced in order to protect consumers and prevent deceptive practices. He explained that the measure was not notified to the TBT Committee because it was an implementing measure taken under an existing technical regulation.

3.2.2.3 Thailand – Draft Notification of the Alcoholic Beverages Control, Re: Rules, Procedure and condition for Labels of Alcoholic Beverages, issued under B.E.

3.9. The representative of Canada said that while her delegation recognised and supported Thailand's right to implement regulations aimed at protecting consumers' health and safety, and at providing them with adequate information, Canada was concerned that this proposed measure would be more trade restrictive than necessary to meet such objectives. Canada noted that Articles 2(2) and 3(1-6) of the proposed rules prohibited the use of wine labels that contained images of athletes, artists, singers or cartoons as well as messages affiliated with sport or music among other activities. She explained that some Canadian wine labels portrayed depictions of athletes, artists and singers, and other artistic depictions which may be considered cartoons. She also clarified that Canadian wine labels were not intended to appeal to children or promote irresponsible alcohol consumption, and that 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. She enquired about the meaning of "cartoon" under the proposed rules, asked what studies suggested that such labelling constraints would help achieve Thailand's policy objective, and questioned whether Thailand had considered less trade restrictive alternatives. Finally, Canada reminded Thailand of the spirit of the "APEC Wine Regulatory Forum", which was to eliminate unnecessary technical requirements and impediments to the trade of wine.

3.10. The representative of the <u>European Union</u> noted that the definitions of "label" and "container" set out in Article 1 were not in line with the CODEX STAN 1 1985 and asked Thailand to clarify the reasons for such deviation. He also noted that Articles 2(1) and 3(4), related to warning messages, were ambiguous and invited Thailand to adapt the wording of the draft regulation to that used under the existing advertising notification. The EU also raised concerns regarding the administrative complexity of the label approval process, which was intended to be dealt with by two separate government agencies. The EU asked for clarification regarding the division of tasks and responsibilities between the agencies, and enquired about unnecessary delays in the approval of goods for free circulation. Finally, the EU expressed concerns about the time frame provided for compliance and asked Thailand to allow the sale of all products existing on the market until exhaustion of stocks.

3.11. The representative of <u>Mexico</u> echoed the views expressed by Canada and the EU and expressed her delegation's concern with the possibility that the proposed measure' had inconsistencies with the fundamental TBT principles of transparency and proportionality as well as certain provisions of the TRIPS Agreement. With respect to these IP-related concerns, she informed that they would be also raised before the TRIPS Council in due course. She requested Thailand to fulfil its WTO obligations and seek less trade restrictive alternatives to fulfil the measure's objectives. In this respect, she expressed the view that certain new labelling requirements contained in the draft regulation may not help Thai citizens obtain adequate information regarding the impact of the consumption of alcoholic beverages.

3.12. The representative of <u>New Zealand</u> recognised that the current draft regulation was less trade restrictive than the one submitted in 2010. However, New Zealand was concerned that Articles 2 and 3 of the draft were open to interpretation, which may lead to uncertainties as to whether certain labels were consistent with the regulation. New Zealand enquired whether the use of a trademark, and of a message certifying that an alcoholic beverage was of a particular quality, standard or grade, would be permitted. New Zealand also asked for clarity regarding the

interpretation of the provisions on pictures of athletes, artists and singers, and the definition of "recreation". She positively noted that the draft regulation allowed labels used before the entry into force of the regulation to be used for a period of 180 days after the regulation came into force. However, she was concerned that the period may not be appropriate for alcoholic beverages with a longer shelf life and asked Thailand to consider extending it.

3.13. The representative of <u>Thailand</u> thanked Canada, the EU, Mexico and New Zealand for their comments, and assured them that their comments were going to be forwarded to the Department of Disease Control of the Ministry of Public Health.

3.2.2.4 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)

3.14. The representative of Canada expressed his delegation's concerns with the far reaching effects of the measure on the medical device industry in China as well as foreign suppliers of these products. He noted that a number of draft administrative measures, notified in April and May 2014 and designed to facilitate the implementation of Order No. 650, failed to illuminate exactly how interested parties would be affected. Canada asked China whether, under the draft measures, imported medical devices must undergo product testing and clinical trials in China. In this respect, Canada reminded China that, in order to facilitate trade, it was important to avoid unnecessary and duplicative testing and clinical trials as they could result in additional time and expenses being incurred by medical device exporters wishing to enter the Chinese marketplace. Canada also asked China to confirm whether testing done by accredited foreign entities could be also recognized. He said that Canada was also concerned with the fact that China's regulations apparently required foreign manufacturers to have marketing approval in the country in which they were headquartered prior to receiving marketing approval in China. This requirement, he said, was problematic for Canadian exporters who may not necessarily choose to seek approval domestically. In addition, Canada requested China to clarify which standards companies were required to meet with respect to Good Manufacturing Practice (GMP) requirements for medical devices. For example, would China accept internationally recognized quality management standards (ISO 13485) or US Food and Drug Administration (FDA) GMP requirements? Finally, Canada expressed surprise at the fact that China notified such important regulatory changes with a limited comment period of only 30 days. Canada urged China to notify any amendments to the regulations or draft administrative measures for the recommended 60 day comment period.

3.15. The representative of the European Union welcomed the efforts of the Chinese authorities to amend the regulations on medical devices and the constructive dialogue between Chinese and EU authorities in this matter. He said that the EU nevertheless still had some concerns with the measure. He noted that all medical devices marketed in China (whether already registered in the country of origin or not) needed to comply with comprehensive Chinese authorization requirements. He also noted the requirement for the registration of medical devices in their country of origin. The EU did not understand the rationale for these requirements and considered them unnecessary and prone to create additional delays for placing products in the Chinese market without any added patient benefit. As regards the Electromagnetic Compatibility (EMC) testing, he recalled that in previous meetings China had informed the Committee that the Chinese standard on EMC was identical to the IEC one. In this context, the EU reiterated the request that the CFDA accept test reports from foreign laboratories accredited by accreditation bodies who were members of ILAC, as an alternative to in country testing in China. This would avoid unnecessary duplication of testing, as medical devices imported into China were already tested in accordance with the IEC standard. It would also ensure that there was no disruption in the importation of medical devices into China due to a lack of necessary infrastructure to perform the EMC testing. In addition, and concerning the format of the registration certificate, the EU considered that the certificate should exclude the documentation on "Product Technical Requirements", which might be confidential. Finally, the EU asked the Chinese authorities to provide for a transitional period from six to twenty four months, due to the major changes introduced by the new provisions. Moreover, the new measures should not be applied retroactively.

3.16. The representative of the <u>United States</u> associated herself with the concerns expressed by Canada and the EU. The US was particularly concerned with the fact that the measure did not provide sufficient transition periods for US industries to fully adjust to the many new requirements it introduced, especially for Class I medical product conformity assessment procedures. She said

that for such devices the US industry was requesting that a transition period of two to three years be provided so they could make the changes needed to comply with the measure. She also said that the US was interested in understanding how China, after taking into consideration industry comments, determined the length of the transition period. Further, the US was concerned that Order No. 650 could create significant obstacles to trade through its seemingly unnecessary indigenous clinical trial requirements. In this respect, she asked how the comments submitted by US industry to CFDA were being considered so as to ensure the clinical trials requirements would not bring undue costs to these industries and delay Chinese patients' access to life saving medical technologies.

3.17. The representative of <u>China</u> informed that the CFDA was still receiving and considering the comments from Members on these notifications.

3.2.2.5 Brazil - Higher Risk Medical Devices Good Manufacturing Practice (GMP) Certification (G/TBT/N/BRA/564)

3.18. The representative of <u>India</u> expressed concerns with the procedures laid down in Resolution No. 11, published in March 2009, which, as from 1 May 2010, requires health products considered as having a "higher risk" to present a certificate at the time of their registration proving compliance with Brazil's Good Manufacturing Practices (GMP certificate). He noted that ANVISA would be responsible for issuing these GMP certificates on the basis of inspections conducted by ANVISA at the production facilities. He said that India's traders found this certification process time consuming and expensive, reportedly costing more than USD 20,000, with an approval timeframe of as long as four years. India asked Brazil to explain why such as process should not be considered more trade restrictive than necessary under the TBT Agreement's applicable disciplines. Additionally, he noted that certificates of conformity with International Standard ISO 13485 were no longer accepted in Brazil for the purpose of this new GMP certification scheme. In this respect, he asked Brazil to indicate the scientific justification for deviating from ISO 13485, an internationally accepted standard dealing with Quality Management System for all types of medical devices, whether with lower or higher risk. India also asked Brazil to again accept ISO 13485.

3.19. The representative of Brazil said that the new ANVISA Resolution 15/2014, on good manufacturing practices certification for higher risk devices, replaced the previous measure on this matter, Resolution 25/2009. This draft measure was notified to the Committee during the public consultation period (notification G/TBT/N/BRA/564), so that Members could be acquainted with it and make comments. He explained that the new Resolution addressed a number of concerns previously raised by Members in past sessions of this Committee, including by improving the procedures for obtaining the certification of Good Manufacturing Practices (GMP), thus reducing processing times. He also highlighted the fact that the new regulation exempted lower risks products (classified as "class I" and "class II") from the manufacturing certification formalities, while maintaining the requirements of efficiency and safety that were necessary for registration. Due to the simplification in the procedures, he said that it was expected that a significant number of companies would benefit from lower processing times. As regards requests for registration, revalidation and modification of higher risks products (classified as "class III" and "class IV"), he explained that under the new measure manufacturers would no longer need to wait for the issuance of GMP certification in order to have the analysis process started. In other words, product analysis could be initiated once the certification request was made, provided relevant documentation was presented. Brazil also highlighted that, along with its counterparts from other WTO Members, ANVISA - the Brazilian health surveillance agency - was part of the "Medical Device Single Audit Program" (MDSAP), a working group within the "International Medical Device Regulators Forum" (IMDRF). This initiative aimed at harmonizing models of inspection reports. In this sense, the new Regulation allowed for the use of third party inspection reports, within the scope of specific programs recognized by ANVISA. Interested companies would then have the option to use the services of MDSAP accredited certifying bodies in order to prepare inspection reports to be submitted to ANVISA. Brazil concluded by emphasizing the importance it attached to confidentiality agreements between the health authorities of Members, an essential tool that enabled them to exchange inspection reports.

- 7 -

3.2.2.6 United States - Formaldehyde; Emissions Standards for Composite Wood Products; Third-Party Certification Framework for the Formaldehyde Standards for Composite Wood Products (G/TBT/N/USA/827-828)

3.20. The representative of Indonesia said that while his delegation recognized the US' right to protect human health and the environment, it was nonetheless concerned with certain aspects of the US Environment Protection Agency (EPA)'s proposed rules to implement the Formaldehyde Standards for Composite Wood Products Act, entitled Formaldehyde Emissions Standards for Composite Wood Products and Third-Party Certification Framework for the Formaldehyde Standards for Composite Wood Products (notified in G/TBT/N/USA/827-828). One concern related to the EPA proposal that the formaldehyde emission standard would be applied respectively to: (i) hardwood plywood (maximum 0.05 ppm); (ii) medium density fibreboard (maximum 0.11 ppm); (iii) thin medium density fibreboard (maximum 0,13 ppm); and (iv) particleboard (maximum 0,09 ppm). In this respect, Indonesia asked the US whether the standards would also apply to the softwood plywood and, if it did not, whether Indonesian authorities were afraid that this technical requirement may lead to any discriminatory treatment. Further, given that the proposed technical requirement's objectives were human health as well as environmental protection, Indonesia also asked the US to explain the basis for the EPA allowing the use of different standards for different products. With respect to Conformity Assessment Procedures, Indonesia asked the US to explain the relation between the proposed standard and the requirements set up by the California Air Resources Board (CARB) Airborne Toxic Control Measures (ATCM). Given the similarities on testing parameters between these two standards, would the latter replace the former? If this was the case, would there be a transitional period? Indonesia was also concerned with the EPA's proposal product testing should be carried out once every three months. He expressed Indonesia's concern about the possibility that this requirement would create unnecessary burdens for producers, and asked US's views on the cost and transparency implications of such certification and testing process. Finally, he expressed his delegation's concern that the requirement that certifications must be conducted by third parties/agents located in US, as mandated in paragraph 770.7 of the EPA regulations (G/TBT/N/USA/828), would not only become a burden to related industries, but may also cause inefficiency as double certification may occur.

3.21. The representative of the United States explained that since it had proposed these rules on 10 June 2013, which included an initial comment period of 60 days, the EPA had twice granted extensions to public comment periods for both proposals, as requested by numerous commenters, by noticed in the Federal Register. The Formaldehyde Emissions Standards for Composite Wood Products proposed rule was extended on 23 July 2013 and 21 August 2013 and closed on 9 October 2013. In addition, she said that the EPA, on 8 April 2014 reopened, until 8 May 2014, the comment period for the implementation rule to try to obtained additional public input regarding potential modifications to the Agency's proposed treatment of laminated products. Further, she explained that the EPA also announced a public meeting, held on 28 April 2014, which provided the opportunity for further public comment on this set of issues. Then, based on input from public meeting participants, the EPA, on 9 May 2014, extended the comment period related to the treatment of laminated products under the regulation until 26 May 2014. Comments submitted to date on this proposal could be found at docket identification number EPA HQ OPPT 2012 0018, entitled Formaldehyde; Formaldehyde Emissions Standards for Composite Wood Products. She also informed that the Third Party Certification Framework for the Formaldehyde Standards for Composite Wood Products proposed rule was extended on 23 July 2013 (78 FR 44090) and 21 August 2013 (78 FR 51696), and closed on 25 September 2013. Comments submitted to date on this proposal could be found at docket identification number EPA HQ OPPT 2011 0380, entitled Formaldehyde; Third-Party Certification Framework for the Formaldehyde Standards for Composite Wood Products. In this regard, she remarked that, despite these many opportunities to provide comment in the development of these rules, the US Inquiry Point and EPA confirmed that they had not received any written submissions from Indonesia. The EPA was carefully considering all comments as they worked to develop final rules. Therefore, the Agency would be still considering the issues, including those raised in comments. She said that these issues, and many others, would be addressed when the final rules were published; including a comprehensive response to comment document that would be placed in the dockets for the final rules. Finally, she said that additional information on these rules were still available in the US Government website both for proposed rule on the Economics Assessment for the Formaldehyde Emissions Standards for Composite Wood Product as well as for the proposed rule on The Economics Assessment for the Third-Party Certification Framework for the Formaldehyde Standards for Composite Wood - 8 -

Products. She concluded by informing that that The Economics Assessment for the final rule would be available in the above referenced docket when the final rules were issued.

3.2.2.7 European Union - Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers establishes the general principles, requirements and responsibilities governing food information, and in particular food labelling

3.22. The representative of <u>Indonesia</u> said that this EU food labelling measure should balance its environmental and health objectives with the obligation of not being unnecessarily trade restrictive. In this respect, Indonesia asked the EU to provide the risk assessment or impact analysis it had made on the implementation of this regulation. He also urged EU authorities to consistently monitor the implementation of this regulation so as to prevent unfavourable excessive practices by the EU companies that could result in discrimination against particular products, such as Indonesian palm oil.

3.23. The representative of <u>Malaysia</u> expressed the interest of the Malaysian Government on this matter.

3.24. The representative of the European Union recalled that this EU Regulation was notified to WTO in April 2008 under G/TBT/EEC/191, and that, after the legislative procedure, was published in the EU Official Journal on 25 October 2011. He explained that the new requirements under this Regulation, which changed existing legislation on food and nutrition labelling, would apply from 13 December 2014, except for the obligation to provide nutrition information, which would only apply from 13 December 2016. He informed that the European Commission had produced, and updated regularly, a question-and-answer document to help food business operators to comply with the Regulation requirements and that the EU is ready to address any question Indonesia might have at bilateral level.

3.2.2.8 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)

3.25. The representative of <u>Mexico</u> understood the updating and amendments introduced by the draft Decree were meant to make clearer the Colombian framework for conformity assessment, technical regulations, accreditation, metrology, designation and market surveillance. She noted that Title III of the draft Decree specified three levels of risk for the preparation and issuance of technical regulations: (i) "moderate"; (ii) "medium"; and (iii) "high". Mexico was particularly concerned with the clarity of the criteria for the distinction between the "moderate risk" category and the other two risk types, which may lead to confusion. In the same sense, she said that while the "medium" and "high risk" levels referred to specific conformity assessment schemes, labelling was a type of requirement for which conformity was assessed via inspection. However, there were technical regulations that established labelling requirements which did not necessarily concern "moderate" risks, for example health warnings or sanitary requirements, which were implemented by means of labelling. In addition, Mexico's authorities noted that it was also necessary to clarify the risk associated with technical regulations that established different types of requirements, including those concerning safety and labelling, as it was not obvious which level were applicable. Mexico thus considered that the way the draft measure dealt with the criteria for "high risk" level may not be in accordance with the basic principles of the TBT Agreement relating to conformity assessment procedures. This was so, said Mexico, because the establishment of this "high risk" category would result in the need of having a system of "double certification", that is, one certificate from a foreign body recognized under multilateral recognition arrangements, and another certificate issued by a third party. In this respect, she requested Colombia first, to explain the purpose of the draft Decree as well as the reasons why it was necessary to define, a priori, the risk level of technical regulations in light of the legitimate objective that Colombia sought to achieve by issuing such legislation. Second, she requested Colombia to explain the reason why it had chosen that particular parameter for determining the type of risk in the preparation and issuance of the technical regulation. Third, she requested Colombia to remove the possibility regulatory entities currently had in the draft Decree of not automatically accepting the results of conformity assessment procedures issued by conformity assessment bodies that were accredited in other countries and were party to multilateral recognition arrangements. Mexico also asked for the inclusion of a transitional period of six months for the entry into force of the draft Decree,

following its publication in the Official Journal of Colombia. Finally, she requested an official reply to the comments already submitted by Mexico.

3.26. The representative of Japan asked Colombia to confirm whether, after the amendment to the Decree, its National Quality Subsystem (NQS) would cover safety related automobile parts and components with respect to the conformance certification requirement. If this were the case, Japan then requested Colombia to ensure that the conformance certification requirement for such products to be equivalent to those currently imposed under other existing laws and regulations. Specifically, [the registration and sale][the registration for marketing approval] of automobiles should be permitted, as they were under the current certification system, by way of: (i) submission of a certificate of conformance to the current Colombian laws and regulations; or (ii) submission of a certificate of conformance to relevant international standards. In this respect, he recalled that Colombia had already imposed conformance certification requirement for safety related automobile parts and components under the current certification system. Japan understood that the objective pursued by the amended NQS was the same as that of the current certification system. In this respect, as noted by Mexico, Japan was concern with the fact that the draft decree would result in the duplication of certification of conformance requirements. Furthermore, if the NQS were to be amended to introduce a unique and exclusive certification system compared with the international standards, there would be concern from the viewpoint of the international harmonization of the vehicle regulations.

3.27. The representative of <u>Colombia</u> thanked Mexico and Japan for their comments and clarified that the draft was not seeking to do anything other than incorporate the best practices with respect to technical regulations, conformity assessment and metrology. He said that Colombia would discuss these issues bilaterally with the countries concerned in the margins of the meeting.

3.2.2.9 Ecuador - Draft Technical Regulation of the Ecuadorian Standardization Institute (PRTE INEN) No. 189: "Labelling of alcoholic beverages" (G/TBT/N/ECU/243)

3.28. The representative of the <u>United States</u> firstly thanked the delegation of Ecuador for the very constructive bilateral meetings that had taken place during the week. She continued by saying that the US concerns on the conformity assessment aspects of this measure would be addressed later in the agenda under "Ecuador - Resolution establishing the "General conformity assessment framework for Ecuador" and the "Handbook of procedures to be observed prior to all stages of the customs clearance, marketing and market surveillance of manufactured, imported and marketed goods subject to Ecuadorian technical regulations". The US was concerned with the requirement that the name of the importer of alcoholic beverages be placed in the country of origin, with no flexibility for placement in customs bonded warehouses via the use of supplementary labels (stickers). She asked if Ecuador had considered other less trade restrictive measures.

3.29. The representative of Ecuador said that the measure responded to a customs regulation implemented by SENAE in order to prevent the illegal entry of liquor into the country. Liquors were among the products with the highest rate of smuggling in Ecuador, particularly due to the low cost of the product in neighbouring countries. He explained that this measure was complemented by other policies implemented by the Ecuadorian health authorities, such as a recently launched campaign to reduce the consumption of liquors, in general, and raise awareness with respect to the particular health risks associated with the consumption of adulterated liquors. He said that one of the mechanisms considered by regulators was the ability to provide accurate information to consumers about the origin of beverages as well as details of those engaged in the manufacture and importation, through the labelling of the products. Accordingly, he noted that the Ecuadorian Standards Institute had developed a draft Regulation RTE No. 189 which was notified to the WTO in April 2014, in which the labelling parameters of products were set. This draft Regulation required that labels should be printed or put directly on the package by the manufacturer in the country of origin. For imported alcoholic beverages, he also noted that labelling or re-labelling was not allowed in primary zone. The draft regulation was open to comments and reviews of trading partners in order to assess their impact and for further revision if necessary.

3.2.2.10 European Union – Proposal for a Directive of the European Parliament and of the Council amending Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic (COM(2013) 195 final)

3.30. The representative of the <u>United States</u> recalled that this proposed EU measure would amend an existing Council Directive that regulated the maximum dimensions and weights authorized in national and international traffic for certain vehicles. More specifically on the proposed changes, the US noted that Article 8 of the Directive would be revised to allow for exceeding the maximum lengths in cases where attachments were made to the rear of the vehicle so as to increase their aerodynamic characteristics. Additionally, Article 9 would be changed so as to make it possible to exceed the maximum length to allow the construction of tractor cabs improving the aerodynamic characteristics of vehicles and improving road safety. The US noted that while revised Article 9 appeared to provide some leeway for the introduction of aero nosed trucks, at the same time, paragraph 2 of this same revised provision included constraints for the enjoyment of this option, including the requirement that such tractors would only be acceptable if the "blind spot" under the windscreen was reduced (compared to current tractor designs).

3.31. She recalled that from previous bilateral discussions between the US and the EU on this matter, the US had understood that the Commission would be developing test methods and technical specifications for type approval through an amendment Directive 2007/46/EC, or through a delegated act. The US remarked that, while the proposal allowed for derogations from the fixed dimensions, it still lacked details for how to evaluate an aerodynamic design of the cabin. The US was also concerned that the technical requirements developed by the Commission to support the proposal's requirements could unnecessarily restrict export to Europe of US trucks that were at the same time somewhat longer but more aerodynamic and fuel-efficient. She also said that the US was interested in any technical specifications developed for type approval that included the ability to use an aerodynamic cabin to qualify for such derogation (Art. 9 of the Commission proposal). She then expressed various additional questions her delegation still had with respect to various aspects pf the proposed measure.

3.32. First, she recalled that the new Article 9.1 of the Commission's proposed revision to 96/53/EC stated that "[t]he main purpose of these exceedances was to allow the construction of tractor cabs to improve the aerodynamic characteristics of vehicles or combinations of vehicles, and improving road safety." While the US believed that this revision had the potential to improve environmental performance of trucks while also facilitating expanded trade opportunities, it however remained concerned that conditions laid down in Article 9.2 - in particular Article 9.2(i) would result in the imposition of design based criteria on tractor cabs that would exclude products that otherwise would meet the Commission's environmental and safety objectives. She thus asked: (a) would manufacturers be able to meet the visibility objectives expressed in Article 9.2(i) through technological means other than specific designs? How would the criteria be balanced against possibly competing objectives, such as increased aerodynamic properties?; (b) how would the conformity with Article 9.2(ii) be assessed and balanced, both with the aerodynamic performance of a tractor as well as among the various aspects of damage reduction (i.e. balancing the need to reduce damage to the tractor cab (and driver) itself with the competing need to avoid damaging other vehicles involved in a collision); What were the types of safety data that the measure would be relied on?

3.33. Second, she asked whether the Commission would publish the text of any draft delegated acts referred to in Article 9.2.5, so that interested stakeholders could comment or offer alternative ways to meet the policy objectives.

3.34. Third, with respect to Annex I, Article 1.5 of the current Directive, she asked the Commission to consider a more market based approach that would not unduly limit the designs of tractor cabs (specifically aero nosed traffic cabs). This was important because different types of trucks were used for different freight and distribution needs – operators would logically only use longer trucks on roads that could handle them. Alternatively, the US asked if a road signage could be used to indicate roads (e.g. signs containing small traffic circles) that were inappropriate or off limits to vehicles over a certain length.

3.35. Finally, the US asked the EU to provide more information on DG Move's "informal group of 70 companies" that discussed the details of the delegated and implementing acts under the proposed revision of 96/53/EC. In this respect, she asked whether there were any arrangements for companies that did not have a presence in Brussels to monitor and provide input into these discussions.

3.36. The representative of the European Union informed that this European Commission proposal was adopted on 15 April 2013 and only recently, on 15 April 2014, the Parliament adopted its general position, which was followed by the Council position on 5 June 2014. The legislative process, which would entail discussions between the European Parliament, the Council and the Commission, would continue after the 2014 summer break. The Commission was well aware of the US concerns and said that they had to be fed in this process. He also explained that, regarding the questions on the implementation of Article 9.2, as drafted in the Commission proposal, the Commission should receive the mandate to adopt delegated acts to complement the requirements which the new tractor cabs must meet; these shall take the form of technical characteristics, minimum levels of performance and design constraints. These delegated acts would also establish the procedures to issue the certificates regarding aerodynamic performance. The EU explained that it was, however, premature to engage in discussions on the content of the implementing measures in this Committee when the main text of the Directive had still not been decided upon. The EU remained open to discuss these issues as they would be further developed. The EU also emphasised the fact that technical content of the delegated acts foreseen under Articles 8 and 9 would be defined by an expert group which had already been created. This group, which was open to any company willing to apply, already had 70 participants, including one US Company providing rear aerodynamic devices (Article 8). Companies which were not based in the EU would need to subscribe to the group and received the documentation by mail in order to provide written comments; alternatively, such non-EU based companies could also choose to be represented by any business association taking part in the group. However, participation to the group remained subject to the agreement of the European Commission. Moreover, regarding the possible modification of Article 1.5 of Annex I of the current Directive, the EU noted that no modification was foreseen in the near future. This criterion had been defined taking into account the size of the road infrastructure in EU member states. In this sense, the EU pointed out that some member states already had difficulties coping with vehicles complying with the requirements of this Article, as their infrastructure was not always large enough. Finally, the EU also remarked that specific length limitations already existed (Article 7 of Directive 96/53/EC) for certain geographical areas, such as villages, national parks or mountains.

3.2.2.11 Kingdom of Saudi Arabia - Certificate of Conformity (not notified) and GSO marking requirements for toys

3.37. The representative of the United States expressed her delegation's appreciation for GSO's willingness to meet with the US bilaterally in Geneva, and for engaging in a frank discussion on the significant challenges involved in implementing systems of regional integration and coordinating seven member state national regulatory regimes in accordance with WTO Agreements. She noted, however, that the US had some concerns with respect to the lack of uniformity in transparency in the development of regional technical regulations and with the duplication of conformity assessment procedures – both regional and national being applied by some GCC members. The US also noted that the first technical regulation adopted by the GCC was the Gulf Technical Regulation on Toys, notified in 2013 by Kuwait, Qatar, Saudi Arabia and Bahrain, but not by Oman and UAE. She mentioned, however, that the second GCC technical regulation, the Gulf Technical Regulation on the "G" Mark, had never been notified to the WTO. The UAE notified the Guidance Document on the Registration of Products Bearing the "G" Mark on 1 June 2014 and the comment period was open until 4 August 2014. Both documents appeared had been approved by the GSO Board of Directors in 2009, and the measures published on the GSO website on 15 December 2013. In this respect, the US recalled the TBT Agreement's transparency obligations, and noted that while some GCC states had notified one or two of the measures, not all had. Five of these seven states had notified the Gulf Technical Regulation on Toys, and one of seven notified the Guidance Document for the Technical Regulation on the "G" Mark, while none had notified the Technical Regulation on the "G" Mark itself. Further, the US industry reported that some GCC Members may be implementing their own additional conformity assessment requirements, in addition to the "G" mark requirements, such as Saudi Arabia's Certificate of Conformity. She sought clarification on the status of this issue and stressed that the precise requirements themselves must also be clear,

definitive, and drafted in a way that would avoid conflicting information. The US asked Saudi Arabia when the "G" Mark requirement would enter into effect.

3.38. The US also expressed hope that any work at the GCC level would result in requirements that would be implemented in a consistent manner at the national level and that products would be mandated to test conformity with only one set of requirements. Additionally, on the toy safety regulation, she noted that the GCC measure contained a requirement for a separate registration number for each toy model that was not found in any other country. In this respect, she called Saudi Arabia's attention to the fact that registration numbers were typically assigned to a manufacturer. Since the average toy company turned over about 75% of its inventory each year, the US believed that the burdens resulting from requiring a unique registration number per model could such that they would preclude many products from continuing to be offered in the GCC market. Based on their productive bilateral discussion, the US requested follow-up discussions on whether the GCC was establishing procedures for eliminating potentially duplicative national conformity assessment requirements, such as the Saudi Certificate of Conformity or a voluntary Abu Dhabi Trustmark. Finally, the US urged the GCC to consider the benefits and efficiencies to be found in relying on international systems of accreditation wherever possible.

3.39. The representative of the <u>European Union</u> supported the US comments and stressed the EU's appreciation for the technical harmonization efforts within the Gulf region. However, the EU also noted some inconsistency in the implementation practices of individual GCC states, an issue that the EU was also bilaterally discussing with them.

3.40. The representative of the <u>Kingdom of Saudi Arabia</u> thanked the US and the EU for the comments and asked that they be sent in written form so Saudi authorities could address them in due course.

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

3.41. The representative of the <u>United States</u> said that, as highlighted in the US interventions regarding previous versions of these requirements, her delegation recognized and supported the objective of labelling products in official national languages in order to facilitate trade and protect consumers. However, the US remained concerned that these amendments appeared to deny the option of applying these labels while products were still in Indonesian Customs. Producers throughout the world had found that such "stickering" in Customs allowed greater flexibility and significantly reduced the costs for shipments destined for multiple markets with different national languages. The US believed that this approach would meet the fundamental Indonesian language labelling requirements while preventing any unnecessary burdens on US and other Members' exporters. Finally, the US requested that Indonesia delay implementation of the new requirements so as to fully take into account the concerns of its key trading partners.

3.42. The representative of the Republic of Korea said that while his delegation supported Indonesia's efforts of protecting consumers, it was nonetheless concerned with certain aspects of the regulation's requirement that labelling be provided in Indonesian language. He noted that, under the measure, those labels containing product information should be understandable, and had to be embossed, printed or glued permanently on the goods and packaging. He explained, however, that, in practice, in order to attain the purpose of providing consumers with product information, labels could be affixed on products in various manners depending on products' features. For example, in case of a product which should provide much information, the size of its label would unlikely be small enough to be affixed on products and packaging permanently. Therefore, Korea was of the view that the Indonesian regulation of affixed mandatory labelling would be an excessive measure without considering the amount of information which would be differ from case by case. Additionally, Korea raised concerns that this labelling scheme would lead to increased manufacturing cost thus resulting in higher product price for consumers. He noted that for electronics and information technology goods, which were developed by rapid innovation in technology, affixing stickers were the preferred and widely used labelling method. Hence, Korea requested Indonesia to allow for the possibility of fulfilling the labelling requirement by affixing stickers, and to provide Members with specific criteria of permanent sticker labelling. As the regulation was only notified to the WTO on 11 April 2014, and because this measure was expected

to be adopted and implemented by 25 June 2014, Kore requested Indonesia to provide a grace period greater than 6 months from the date of adoption in order to give a sufficient time for manufacturers to adapt.

3.43. The representative of the <u>European Union</u> echoed the US concerns on this draft and recalled that it has recently submitted written comments to Indonesia on what it considered as a complicated and unnecessary barrier to trade.

3.44. The representative of <u>Japan</u> supported the comments made by previous delegations and invited Indonesia to ensure that the regulation was not more trade-restrictive than necessary.

3.45. The representative of Indonesia explained that the labelling regulation was intended to provide consumers with correct, clear and truthful information on the products they buy. The Ministry of Trade issued Regulation No. 67 in 2013 in order to replace similar regulations issued, respectively, in 2009 and in 2010. He also informed that, based on comments received by some Members, Indonesia issued in June 2014 a revised version of the regulation under No. 10/2014. In this regard, he noted that the current regulations contained several improvements, such as: (i) an increase in the number of the products covered from 103 to 127; (ii) adjustments of HS codes; and (iii) a requirement for permanent labelling through embossed printing or firmly attached labels on the packages. He explained that importers or producers of products not listed in the attachment of the regulation may put labels in the Indonesian language, which was adjusted to the characteristics of the products. Those listed in the attachment of the regulations, and who had their products already distributed on the Indonesian market, were granted a transitional period until 24 December 2014 so as to adjust to the required label. However, he said, for new products, the regulation would apply from 24 June 2014. Finally, he observed that some types of products were exempt from this regulation, such as basic materials for production processes, products in bulk, temporary imported products and several other categories. Exemption was also given to producers, trademark holders, general importers and suppliers of automotive products who submitted a "letter of exemption" to the Directorate of Consumer Empowerment of the Ministry of Trade.

3.2.2.13 Ecuador – Draft Technical Regulation of the Ecuadorian Standardization Institute (PRTE INEN) No. 103: "Sugar confectionery (G/TBT/N/ECU/123)

3.46. The representative of <u>Panama</u> raised concerns with conformity assessment procedures for these products, which had already been given accreditation in line with international standards. She thanked Ecuador for the bilateral meeting that had taken place and informed the Committee that her delegation would continue to work bilaterally with Ecuador on this issue.

3.47. The representative of <u>Ecuador</u> did not take the floor.

3.2.2.14 Republic of Moldova – Tobacco (G/TBT/N/MDA/22)

3.48. The representative of Ukraine noted that the text of the proposed amendments to the "Tobacco Control Law" that were submitted to the Parliament differed from the English translation provided in the TBT notification G/TBT/N/MDA/22. She reminded Moldova of the Committee's recommendation of allowing at least 60 days for comment and asked, given the nature of the amendments proposed, and their significant effect on trade, that this be extended to 90 days. This extension, she said, should not delay the legislative process as the adoption of the amendments to Law No. 278-XVI was foreseen for the end of November 2014. She voiced several concerns with the proposed amendments. Firstly, they modified the Tobacco Control Law so as to require large graphic health warnings ("up to 75%") on the packaging of tobacco products thus creating consistency concerns both under the TBT and TRIPS Agreements. Such larger graphic health warnings were highly trade-restrictive as they left very little space for including trademarks. She thus asked Moldova to provide evidence that such large warnings were necessary and effective in protecting health. Secondly, the proposed amendments included a number of product requirements and labelling restrictions aimed at preventing misleading terms and labels, including banning colours, such as red and golden, and words such as "extra" and "slim". Products with a diameter of less than 7.5 mm would also be banned. She asked that Moldova explain what evidence it relied upon to determine that these were of a "misleading" nature. Thirdly, concerning the ban of ingredients and additives commonly used in the manufacture of tobacco products, such G/TBT/M/63

as menthol and vanilla, as well as "addictive ingredients or additives which have a potential of dependency", she asked Moldova to justify how this ban would protect human health. Finally, she asked if any alternative, less restrictive, trade measures had been considered and if so, why Moldova had chosen more trade restrictive measures. WTO Agreements, she said, did not restrict government efforts to ensure the health of their citizens, so long as positive, scientific evidence supported the proposed measures and such measures were not more trade-restrictive than necessary to achieve the stated health objective. She noted that, as Ukraine was the largest exporter of tobacco product to Moldova, it had substantial interest in ensuring that the proposed amendments were TBT-compliant.

3.49. The representative of the <u>Republic of Moldova</u> informed the Committee that this draft measure had been notified to the TBT Committee in accordance with transparency requirements. The relevant parliamentary committees were in the process of examining the amendments to the Law on Tobacco and Tobacco Products and this was still at a very preliminary stage. Any draft laws or amendments had to be passed in two readings by the Moldovan Parliament. The very preliminary nature of the submission of the notification, he said, should be taken into consideration. He noted that the comment period had not yet closed and no comments or requests for bilateral consultations had yet been received. He requested Ukraine to submit their comments in writing.

3.2.3 Previously Raised Concerns

3.2.3.1 European Union – Registration, Evaluation, Authorization, and Restriction of Chemicals - REACH (G/TBT/N/EU/73) (IMS ID 88)

3.50. The representative of China expressed concern with Commission Regulation (EU) No. 1272/2013, published on 6 December 2013, which amended, with effect as from 27 December 2015, the limit of concentration of Polycyclic Aromatic Hydrocarbon (PAH) to 0.5 mg/kg for toys, including activity toys and child care articles. Regarding the scientific justification for such limit change, China noted that, according to the draft regulation notified by the EU in G/TBT/N/EU/73 on 31 October 2012, 6 categories of consumer articles, including toys whose rubber or plastic components contained more than 1 mg/kg of any of the PAHs shall be prohibited from being placed on the EU market. China recalled that the EU had previously explained that the setting of this maximum PAH content had a strong scientific foundation, and that the protection of children, as the most vulnerable segment of the population, had been considered when this value was set. However, without prior notice, the final Commission Regulation (EU) No 1272/2013, which was published in the EU Official Journal on 7 December 2013, stipulated that 0.5 mg/kg, rather than 1 mg/kg, shall be the maximum PAH content in the rubber or plastic components of toys. While the Chinese delegation recognized the sensitivity of toy products, China was not convinced of the need for such a substantial change in the final regulation. China requested the EU to provide scientific evidence and regulatory impact assessments (RIA) justifying this change. Finally, turning to transparency, China understood that Commission Regulation (EU) No 1272/2013 constituted a substantial re drafting of the previously notified text. In line with the current discussion in the TBT Committee on "Coherent Use of Notification Formats" and, as the EU itself has proposed, Members should use the notification format "revision" to indicate that the notified proposed measure has been substantially re drafted prior to adoption or entry into force, and should normally open a new comment period. Therefore, China requested the EU to use the format "revision" to notify WTO Members again and provide Members no less than 60 days for comments.

3.51. The representative of the <u>United States</u> said that, while sharing the goal of protection of human health and the environment, her delegation was still concerned with the transparency, implementation burdens, and adverse impacts on SMEs as outlined in previous interventions on this measure.

3.52. The representative of <u>Australia</u> said that his delegation was still concerned with the volume of chemicals imported, irrespective of the hazard they posed, was taken as a proxy for exposure. This policy subjected large imports of relatively benign substances to significant barriers to access the European market, which operated as a disincentive for exporters. Australia was further concerned that the implementation of REACH obligations was inconsistent and burdensome. Several EU member states had imposed costly inspection rules which fell for the most part on importers. In light of findings of the European Commission's recent review of REACH, Australia was interested in the practical steps the EU was taking to try to mitigate the impact of REACH on SMEs.

He suggested there may be other measures available to manage the risks of industrial chemicals, which could achieve the EU's objective. For instance, screening on the basis of a chemical's potential risk to health and the environment would encourage continued access for chemicals of little regulatory concern and focus efforts on those chemicals with the greatest risk.

3.53. The representative of the European Union said that when G/TBT/N/EU/73 was notified on 31 October 2012, the draft measure contained the limit of 1 mg/kg for each of the 8 PHAs listed. The EU member states later made the decision to decrease the limit to 0.5 mg/kg for PAHs in toys and children's articles at the REACH Committee meeting of June 2013. He said the decision was taken according to the usual procedures provided in the REACH regulation, and that the large majority of member states voted for the lower limit based on concerns about greater sensitivity of children and therefore a need for special protection. It was noted that the full transparency of the process was ensured, since the vote by member states only occurred more than 60 days after the expiry of the TBT notification comment period, and comments from Chinese authorities were discussed and considered. With respect to the Chinese request for scientific evidence and regulatory impact assessment justifying the change to 0.5 mg/kg, the EU recalled that its 13 July 2013 written reply to China contained extensive information in this respect. Nevertheless, he reiterated that the basis for the limit values derived from analysis by the European Commission and member states based on information provided in the report of the German competent authority for REACH in June 2010. The German report provided an assessment that limits as low as 0.2 mg/kg for each individual PAHs should be established to ensure adequate protection, especially for children. Further assessment and discussions of the European Commission and member states, in which scientific uncertainties and analytical and practical considerations were taken into account, led to the adoption of the 0.5 mg/kg limit for articles intended for children, such as toys and child care articles. He said that these values were adopted based on the generally accepted consideration that children displayed greater sensitivity to chemicals. Regarding the comments of Australia and the US on SMEs, the EU referred to previous responses detailed in the minutes of past meetings.

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

3.54. The representative of Japan expressed concern with Article 10.2 of the revised "Agreement for the Granting of BIS licence", under which only foreign tyre manufacturers were required to provide a bank guarantee of USD 10,000. In this regard, Japan recalled that India had previously explained that the reason why the bank guarantee fee was not required for tyre manufacturers in India was because they were under the supervision of the BIS. Similar to the deleted clause 6.3 of the previous agreement, this provision clearly had an impact on the competitiveness of tyre manufacturers depending on whether their plant was located inside of India or not, and he reiterated that this clause should be corrected. According to the information obtained from BIS, the bank guarantee was supposed to disburse expenses such as visiting costs of BIS persons for audit of overseas plants when any quality problems occurred with tyres manufactured in the overseas plants, or to compensate for the expense of legal procedures conducted or following a breach of contract, such as non-payment of the marking fee. India had asserted at the last Committee meeting that bank guarantees for breach of contract were common international practice, and Japan requested that materials or documents be provided by India to this effect. Furthermore, he said that under this compulsory standard the payment of the ISI Marking fee was required for all ISI marked tyres, including those which were exported outside the Indian market. Japan stressed that tyres exported outside of the Indian market should be exempted. He recalled that during the last Committee meeting India had mentioned that the total payment structure of ISI Marking fee was equal to, or less expensive than, similar fees charged by other Members. However, said Japan, as of February 2014, when a certified factory applied for certification for a new tyre size, an additional certification fee per size of USD 90 was levied. In addition, since April 2014, the renewal application fee of Rs500 had been raised to Rs1,000. In light of this, Japan requested India to present evidence that the total payment structure of ISI Marking fee was equal to or less than similar fees levied in other Members.

3.55. The representative of the <u>Republic of Korea</u> reiterated previous concerns that ISI Marking fees appeared to be significantly unjustifiable and unreasonable, given that they were levied on all tyres with the ISI mark regardless of their destination market, rather than only on tyres imported to India. Compared to similar marks issued by other countries, these fees were considerably higher for the ISI system, and were a significant barrier to trade. Korea urged the Indian

authorities to revoke or amend the requirement such that marking fees would be determined on the basis of importing country, not on ISI mark. Lastly, Korea asked why India required the USD 10,000 performance bank guarantee for foreign manufacturers only when breach of the license and civil liability problems could also arise with respect to domestic tyre manufacturers. Korea believed that this requirement clearly discriminated against foreign tyre manufacturers located outside India, and requested India to achieve the measure's stated objectives in a nondiscriminatory and less trade restrictive manner.

3.56. The representative of the <u>European Union</u> once again asked that India reconsider its marking fee system, which currently applied to each ISI-marked tyre, and not only on those tyres which were actually imported into India. The EU requested that India remove the royalty fees, which were extremely burdensome and more restrictive than necessary; or at least to modify their calculation so as to limit them to tyres which were *de facto* exported to India. Furthermore, the EU considered the USD 10,000 bank guarantee to be unjustifiably discriminatory because it only applied to foreign manufacturers. Pursuant to Article 3.4 of the BIS Agreement, it appeared that liability for the breach of the Agreement could already be exerted on the authorized representative of the foreign manufacturer in India. India was therefore invited to explain the rationale for introducing a new bank guarantee when other legal means already existed to ensure compliance with the BIS Agreement, and therefore was asked to remove this provision. Finally, the EU asked India to confirm that it was now possible to renew licences for two or three years, without the need for additional plant inspection.

3.57. The representative of India said that "Pneumatic Tyres and Tubes for Automotive Vehicles (Quality Control) Order, 2009" was issued by India on 19 November 2009, and came into force on 13 May 2011. The Order applied to both domestic and foreign manufacturers, and prescribed quality standards for pneumatic tyres with the objective of ensuring safety of human life and vehicles. He explained that by virtue of this Order, pneumatic tyres could be imported in India only if they conformed to the specified standards and bore the Standard Mark of BIS. Foreign manufacturers desiring to export their goods to India were thus required to enter into an agreement with BIS for granting of the BIS license, so that those foreign manufacturers could use the BIS Standard Mark on goods to be exported to India while ensuring conformance to relevant Indian Standards. In addition, foreign manufacturers were required to furnish a bank guarantee of USD 10,000 in favour of BIS for due compliance with the provisions of the BIS Act, rules and regulations, and terms and conditions of the license. The bank guarantee was also intended to protect the BIS from any breach of terms and conditions of the license, and covered any civil liability that may arise during the period of the license or thereafter. He noted that bank guarantees were prevalent in international trade, specifically with regard to performance of contracts. India did not see any problem in maintaining such bank guarantee requirement given that in case of breaches committed by domestic manufacturers the BIS could seek compensation through a court of law in India, while this would not be possible in case of breaches committed by foreign companies. A foreign manufacturer desiring to export pneumatic tyres to India had to ensure that the goods conformed to the specified Indian standards and were marked with the ISI Mark. For this purpose, the representative said the BIS charged a fee calculated on all the goods produced and marked with ISI. While some Members have requested that the fee be calculated only on those ISI marked goods which were exported to India, India did not understand the concerns expressed with the present calculation method, since as the owner of the ISI mark, the BIS was entitled to royalty fees on all the goods marked with ISI. Moreover, there was the possibility that ISI marked goods initially sold in other markets could be later sent to India.

3.58. Finally, with respect to the pace of the certification process, he explained that India believed that BIS labs were managing their workload adequately. He noted various steps taken to expedite the granting of licences, and said that the time taken for processing applications had been reduced considerably. On the validity period of licenses, he informed delegations that under the BIS Certification Regulation 1988, a license once granted was extended from time to time, keeping in view inter alia the performance of the license holder. Therefore, there was no problem with extension of licenses, provided the licensee's performance remained satisfactory and there was no breach of terms and conditions.

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

3.59. The representative of <u>Canada</u> disagreed with India's blanket approach to testing in the telecoms sector as India's in-country security testing regulations for telecoms products would hinder or possibly even shut Canadian exporters out of the Indian market. While Canada appreciated India's security concerns, there were well-established international standards for evaluating the competencies of conformity assessment bodies, particularly ISO/IEC 17025 and ISO/IEC 17065. Furthermore, the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF) mutual recognition arrangements (MLAs) provided for peer review systems to ensure the competence of signatory accreditation bodies. She said recognition by India of foreign conformity assessment bodies accredited by signatories to the ILAC and IAF MLAs to test and certify to India's regulatory requirements would minimize the negative impact on companies wishing to export to India while at the same time providing assurance to India that the recognized conformity assessment bodies were competent. Finally, allowing accredited foreign conformity assessment bodies were competent. Finally, allowing accredited foreign conformity assessment bodies were competent. Finally, allowing accredited foreign conformity assessment bodies were competent. Finally, allowing accredited foreign conformity assessment bodies to test and certify to India's regulatory requirements would reduce testing costs and allow exporters to bring their products to the Indian market more quickly.

3.60. The representative of the <u>European Union</u> recalled past concerns expressed with this measure, including on the detailed product scope and testing requirements, and the lack of testing capacity. He observed that the system did not appear to be ready for the implementation of the security clearance requirements as of 1 July 2014. In light of this situation, he suggested that another postponement be considered, and that another year would be an adequate additional period of time to allow for full entry into force. The EU appreciated the efforts of Indian authorities to align the applicable Indian standards with the Common Criteria international standard, ISO/IEC 15408. He also appreciated that specific aspects related to mobile telecom network elements which were not covered by the Common Criteria international standard, namely those developed by the 3rd Generation Partnership Project (3GPP), and the 3rd Generation Partnership Project 2 (3GPP2) would be taken into account when formulating relevant Indian standards. This was important for ensuring that India standards were aligned with relevant international standards, and the EU invited India to consider joining the ongoing standardization work in the 3GPP, which stemmed directly from the ITU, and in which the most important standardization organizations were already participating.

3.61. In relation to the testing procedures and the acceptance of foreign test results, the EU welcomed the earlier statement of India that test results of laboratories appointed by members of the Common Criteria Recognition Arrangement (CCRA) would be accepted for the purposes of the required security clearance assurance, in line with the recent admission of India as a full certifying member under the CCRA. He sought confirmation of this point from India, and also enquired about testing for other security aspects not covered by the CCRA, such mobile telecom network elements covered by 3GPP standards. He requested that foreign laboratories holding accreditation from ILAC MRA signatories should be allowed to perform the required testing. He suggested that a certain margin should be allowed for telecom service provides to determine which of their vendors' products required formal testing and certification, and how to most effectively procure certified products. The EU also asked for clarification about testing modalities. It appeared that Indian authorities would favour batch testing of samples, which his delegation considered a burdensome testing modality. Instead, he suggested that initial testing of a representative sample suffice, and that new testing only be required if there was a major hardware or software change affecting the information security of the product. He welcomed further engagement with Indian authorities with a view to developing workable testing methods and procedures reflecting international practice, which he believed was in the mutual interest of India and the EU and European industry.

3.62. The representative of the <u>United States</u> fully affiliated her delegation with the EU comments and expressed disappointment that India had not yet articulated a plausible explanation of how in country testing in India was able to advance the objective of telecom security. The US further echoed the point made the EU concerning collaboration and engagement, in light of mutual interests of trade and meeting needs with respect to importing equipment and exporting equipment.

3.63. The representative of <u>Japan</u> supported the points made by the previous delegations and said that Japan was interested in a new Unified Access Service License Agreement. Finally, Japan requested that India ensure that its telecom regulations did not impede market access for foreign companies.

3.64. The representative of India reiterated that, due to the fact that telecommunication equipment was vulnerable to spyware and malware attacks, the in country security testing of telecom equipment had been mandated for national security reasons. For the purpose of security testing of telecom equipment, India believed that the Common Criteria testing did not suffice, since it was limited to IT and IT related products. Moreover, as to process based testing, he said that Common Criteria largely addressed commercial security considerations, and not national security issues. When an IT product was used in a telecom network, it became a telecom network element where functional or operational requirements were governed by 3GPP or 3GPP2 standards. In this regard, he noted that the 3GPP has already constituted a sub-group to prepare security standards and specifications of Telecom Equipment for Security Certification, since Common Criteria testing had no such test standards and testing mechanisms for telecom equipment. He stated that India also intended to use the 3GPP and 3GPP2 standards for testing and certification of telecom equipment. India emphasized that becoming an authorized nation from a consuming nation for testing under the CCRA did not change India's position with regard to the requirement of security testing and certification of telecom equipment from labs located in India, due to national security considerations. At the same time, he informed delegations that in respect of testing of IT products to be used in telecom networks which have already been tested under CCRA, leverage will be given to the Common Criteria testing, and additional tests, if required, would be carried out as per the prescribed systems and standards.

3.65. With respect to concerns about testing bottlenecks and delays due to non-availability of test facilities in India, he explained that it had already been clarified that testing and certification done under third party arrangements, such as Common Criteria, would continue to be accepted in the interim period, as would testing and certification done by independent vendor labs in case such a third party arrangement did not exist. He clarified that, if necessary, the Indian Government would extend the date for entry into force of requirement for security certification from labs located in India. He recalled that India's position had been discussed and explained to the representatives of the EU, Japan and the US, including their industry and the United States-India Business Council (USIBC), at several occasions. In these discussions, it appeared that the reason for India's regulation was appreciated, and that there was a desire to cooperate on the issue.

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

3.66. The representative of the European Union expressed a desire to continue the ongoing useful dialogue with China on this matter, both in Geneva and in Beijing. The EU first asked for an update on the regulation on commercial encryption by the Office of State Commercial Cryptography Administration (OSCCA), which had been under revision for several years. He recalled China's assurance that the revision would aim to introduce a level playing field for all producers of commercial encryption products and would therefore eliminate the current prohibition on foreign producers and products containing foreign technology obtaining the necessary certification from OSCCA. He sought confirmation that this was still the direction being followed in the ongoing revision, and also asked about the timeline for the public consultation, and when a public call for comments could be expected domestically. The EU also requested that a TBT notification be made in parallel or afterwards to ensure full transparency of the process. He also reiterated his delegation's interest in learning more about the implementation of the multi-level protection scheme mentioned in past meetings, including whether consideration had been given to clarify the concept of critical infrastructure. He asked whether the current prohibition on use of encryption products with foreign technology and incorporating foreign technology was still appropriate to meet China's security concerns and ensure the necessary resilience of critical infrastructure to possible attacks.

3.67. On standards, the EU restated its general call for predictability, transparency and openness in China's standardization process in the field of ICT and ICT security. He noted that ICT standardization around the world followed an open process with peer review, which was greatly

- 19 -

beneficial to the quality of the final outcome of standardization. He stated this was not always the case in China. For instance, the main standardization forum in China for the development of information security standards, the National Information Security Technology Standardization Committee (Technical Committee 260), did not allow participation of foreign owned or foreign invested enterprises. From the EU perspective, all companies legally registered in China regardless of the nationality of their ownership, should be allowed to participate and provide inputs in this process. Failing this, he argued the Chinese standardization process would be deprived of the usual peer review in the global consortia or international standard setting bodies, and this could be detrimental to the reliability of the chosen algorithms to ensure the required level of protection. He noted that numerous home-grown standards had been developed in the Chinese ICT sector over recent years, often featuring unique Chinese technology. Foreign technology was not taken into account, and information necessary to develop products in compliance with these standards, such as the algorithms mentioned therein, was not made available to foreign companies. This prevented innovative products featuring the best available security technologies from being placed on the Chinese market, thereby resulting in a less secure information security environment. Regarding the draft standards produced by Technical Committee 260, while foreign entities were unable to participate, he noted a positive trend of publishing draft standards for comment. However the comment period was often too short to allow for meaningful input - often 30 days or less whereas the Code of Good Practice recommended a comment period of at least 60 days. The EU urged Technical Committee 260 to consider providing longer comment periods on draft standards.

3.68. Finally he stated that Chinese information security standardization would greatly benefit from being based on international standards and practices. He recalled that industry in this field was global, and that all stakeholders had to work together to ensure interoperability of solutions. He stressed that it was not in anyone's interest to fragment and compartmentalize the digital world at a national level. Increased openness and alignment to international practice was beneficial for all, as it increases the interoperability of information security products and equipment. He commended a positive recent example, wherein an algorithm developed by a Chinese company (algorithm ZUC TD-LTE) was submitted for peer review to the 3GPP, and was subsequently accepted as a voluntary international standard in September 2011. In the view of the EU, this was a practice that should be consistently followed and would be of great benefit to China. He continued to recommend engagement by the Chinese authorities on these issues, and in this regard mentioned an upcoming event to be organized in the margins of the Government and Authorities Meeting on Semiconductors (GAMS). This meeting was taking place in Japan in mid-October, and would bring together industry and regulators from the countries participating in GAMS (China, Chinese Taipei, Japan, Korea, US and EU), which would offer a good opportunity to foster exchange of experience and dialogue on this issue.

3.69. The representative of <u>Japan</u> associated himself with the EU positions and said that Japan was closely following the negative impacts on IT trade of the various schemes and regulations within China. He additionally reported that several Japanese industries had last month submitted comments for "Security Criterion of Supplying Conduct for Information Technology Products" and "State Encryption Management Bureau's Administrative Approval Directories of State Council Departments", and Japan requested that China consider these comments.

3.70. The <u>United States</u> reiterated previously expressed concerns on this issue.

3.71. The representative of <u>China</u> said that, since there was no update on this issue, he would simply refer Members to the minutes of previous Committee meetings.

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

3.72. The representative of <u>Japan</u> restated two concerns regarding the "Guidance for Application and Evaluation of New Cosmetic Ingredients" (hereinafter "the Guidance"). First, since the implementation of the Guidance in May 2011, only four new ingredients have been registered to date, and there had been significant difficulties in exporting cosmetic products with new ingredients to China. Japan thus requested that China accelerate examination of new ingredients. Second, Japan considered as excessive and trade-restrictive the Guidance's requirement for safety data for each single molecule isolated from plant extracts and fermented solvents. Japan requested China to revise the Guidance in this respect, taking into account the practices of safety evaluation of cosmetic ingredients in many other Members, such as Japan, the US and the EU, so that cosmetic manufacturers were able to register new ingredients without additional processes of isolation. Japan sought clarification from China on two additional points: (i) what were the scientific grounds for evaluating a single molecule isolated from a complex ingredient instead of a complex ingredient itself?; and (ii) what was the assumed risk in terms of the product safety evaluation of a complex ingredient, given that they were without isolation?

3.73. The representative of the Republic of Korea echoed Japan's concerns and said that, while Korea respected China's efforts to protect consumer safety, it was nevertheless concerned that the China Food and Drug Administration (CFDA) was carrying out excessive evaluation of new ingredients, and had approved only a small number of new ingredients since 2011. He considered the CFDA's burdensome approval process for cosmetics to be a serious barrier to trade. He also said that the "Adjustment of Cosmetic New Ingredient Registration Management", which was notified to the TBT Committee in February 2014, permitted the temporary usage of new ingredients by companies which satisfied certain requirements. He noted that an additional management system needed to be in place in order to comply with the requirements of the regulation, and only companies which had done so could register for temporary usage. Korea did not believe that there were any improvements in this measure and, in fact, it seemed to be more burdensome than before. He said that under the revised regulation, China was treating cosmetic ingredients which had been proven to be safe in other Members as new ingredients. Therefore, he urged China to exempt ingredients with a proven safety record outside China from registration, or to consider a negative list approach rather than a positive list approach. Regarding the labelling requirements notified under G/TBT/N/CHN/937, he reiterated concerns about overlap and contradictions between the regulations of the CFDA and AQSIQ. Korea thus requested that China harmonize the CFDA regulation with the existing regulation of AQSIQ, which was based on ISO standards, so as to avoid unnecessary burden and confusion for manufacturers.

3.74. The representative of <u>Canada</u> echoed the comments of Japan and Korea, and said that the CFDA's burdensome approval and registration process for cosmetics and the lack of progress in approving new cosmetics ingredients was a serious barrier to trade. The creation of a positive list of ingredients prevented manufacturers from exporting cosmetics products into China, and reduced Chinese consumers' access to safer and more innovative cosmetics products. Moreover, China's related new ingredient registration process decreased the competitiveness of the cosmetic industry. Once a company dedicated time, money and resources to test and apply for registration of a new ingredient, that ingredient would no longer be considered as new and would be available for use by competitors at no additional cost. Canada noted that Chinese cosmetic manufacturers benefitted from a different domestic registration process for new ingredients that was much less burdensome than the one applied to foreign cosmetic manufacturers. He requested an update from China in this regard. In addition, he asked that China explain the reasons for the differences in the approval process for domestic and foreign cosmetic manufacturers. Finally, he requested China explain why it was not accepting cosmetic ingredients already approved and considered safe in other leading foreign jurisdictions.

3.75. The representative of the European Union asked China to update the Committee on the measures taken since the last meeting on the list of ingredients that were authorized to be used in cosmetic products in China, and the procedure for the authorization of new ingredients. He recalled that at the last Committee meeting China had informed delegations that CFDA had issued a "Notice on Matters Relating to Adjustment of Cosmetic New Ingredient Registration Management", so as to improve the approval process for new ingredients. The EU was of the opinion that the new registration procedure would likely not deliver with the speed, efficiency and predictability that was essential in this sector, where several new ingredients were developed every year. Taking into account that under the previous registration system only four ingredients had been approved in four years, he said the situation needed to be closely monitored to make sure that the new system provided for an efficient approval of ingredients. From a systemic point of view, the EU reiterated that cosmetics were not pharmaceuticals, and therefore a system whereby an authorization procedure would be restricted to only certain ingredients, such as UV filters, colorants and hair dyes, would be more adequate. For the remaining majority of cosmetic ingredients, he suggested the safety characterization and assessment should be done under the responsibility of the manufacturer. Regarding the list of existing ingredients, the EU had learned that the list had been completed and corrected, and that there were additional ingredients that could be added to the list provided there was proof that the ingredients had been used in China. The EU had also recently learned that the list would only be used as a reference in order to take stock of ingredients existing in China, but would not be an exhaustive "positive list". The EU sought a written confirmation to this effect. Lastly, he noted that significant further efforts were necessary to ensure that the registration of ingredients, and of products with new ingredients, increased back to levels comparable to those prior to the introduction of these requirements. The EU concluded by expressing its appreciation for the constructive regulatory dialogue between the European Commission's Directorate General for Health and Consumers, and China's Food and Drug Administration (CFDA).

3.76. The representative of <u>China</u> explained that an inventory of cosmetics ingredients used in China was still being drafted. This was not a "positive list" of cosmetic materials, but only developed to distinguish if one material was firstly used in cosmetics produced or sold in China. This document was being prepared in order to design a sole standard on approving new cosmetic materials. In the two rounds of public opinion soliciting that CFDA had carried out, industry had submitted over 10,000 existing material to CFDA. Except the materials banned for safety hazards, all cosmetic materials that had been used in the Chinese market would be included in this document. She said that every material would be marked by both the Chinese and INCI name. At the present stage, CFDA was still finalizing this document. She explained that "Adjustment of Cosmetic New Ingredient Registration Management" (G/TBT/N/CHN/1019) was issued to accelerate the approval procedure of new cosmetic materials through an adjustment at the administrative level. As for the "Cosmetics Label Instructions Regulations and Guidance", she noted there would be a new regulation on cosmetics labelling before the end of 2014 due to the adjustment of CFDA's legislation plan, and it would be notified to the TBT Committee.

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

3.77. The representative of the <u>European Union</u> recalled that at the March 2014 Committee meeting, Russia informed the Committee that a revised version of the technical regulation on alcoholic drinks was being prepared. Russia noted that the widely accepted oenological practices of the International Organisation of Vine and Wine (OIV) and the Codex were being considered. As mentioned in previous meetings, the EU had a number of concerns regarding wines, beers, and protection of geographical indications (GI). The EU asked for confirmation that the new draft text being prepared addressed the concerns of WTO members and invited Russia to update the Committee on the status and timeline for adoption of the new draft technical regulation.

3.78. The representative of <u>Mexico</u> asked Russia to provide information on the current implementation of this technical regulation and that Mexico's comments be taken into account in the final version of the measure.

3.79. The representative of Australia expressed continued concerns with the measure and reiterated its shared commitment to adopt internationally accepted standards for alcoholic products, as recommended by the OIV as well as to avoid creating unnecessary obstacles to trade in wine. He recalled that Australia submitted comments on this notification on 6 February 2013, and his delegation's concerns focused on a number of commonly used additives and processing aids that did not affect the safety of the alcoholic product. Australia noted that it had been joined in its concerns by a number of other Members, who considered the new measures to be both overly burdensome and repetitive. Australia welcomed, and asked for an update about, Russia's decision to consider adopting the OIV list of approved additives and processing aids, as set out in the "International Oenological Codex" and the "International Code of Oenological Practices". Australia remained concerned, however, about the legal status of wines which conformed to the health warning statement under the previous legislation, and were in circulation at the time the draft regulation entered into force. He reiterated his delegation's request that Russia introduce a suitable transition period for these products so as to enable industry sufficient time to implement the stated labelling requirements. In addition, he again raised the issue of wines which used an Australian GI in their description and presentation. In this respect, he enquired if Russia had considered Australia's request that wines labelled with an Australian GI be considered as a "protected geographical indication" under the new technical regulations, and asked that the relevant exemptions from the regulations relating to wines with a "protected geographical indication" apply. Australia also reminded Russia of it concerns over the requirements relating to the bottling location of wines which included a GI in their description and presentation. He asked whether the Customs Union regulations required such wines to be bottled within the boundary of the GI stated in the description and presentation of the wine.

3.80. The representative of the <u>Russian Federation</u> said the draft technical regulation was still under development, and that the last public version of which was published on the website of the Eurasian Economic Commission and had been notified to the WTO. Under the normal process of adoption and implementation of technical regulation in the Custom Union, the next stage was internal coordination between countries of the Custom Union (Belarus, Kazakhstan and the Russian Federation). He hoped that the draft technical regulation would be finalized during this summer, after which it would be published on the Eurasian Economic Commission website. Following publication, the Russian Federation would await comment from trading partners. Thereafter, the Council of the Customs Union would adopt the text and a six month transition period would be provided before entry into force.

3.81. As to substance, he explained that the definitions of alcoholic products provided in the current text of the draft technical regulation were developed on the basis of international practices, including OIV definitions and the definitions provided by the Codex Alimentarius and other international standards, taking into account the specificity of alcoholic consumption practices in the territory of the Custom Union. These definitions of alcoholic products were composed in such a way so as to allow consumers and regulatory authorities to properly identify type and category of each alcoholic products produced and consumed. Additives and processing aids, such as grape, must and concentrated must, and which did not affect safety of alcoholic products mentioned by the OIV, were fully reflected in the current version of the draft technical regulation, taking into account oenological practices authorized for use under the regulatory mechanisms of the member states of the Customs Union. Concerning food additives, such as food colouring, food stabilizers and flours, he clarified that the current version of the draft technical regulation did not set specific requirements on the use of additives in relation of production of alcoholic products. He said such requirements were established in the Customs Union Technical Regulation on Food Safety, and in the Customs Union Technical Regulation on Safety Requirements of Food Additives, Flourings and Processing Aids. On the issue of GIs, he said that the regulation did not contain a list of alcoholic products with protected GIs. He states that this issue related to intellectual property rights, and not to the safety of alcoholic products. He concluded by stating that all comments of Members would be taken into account in the revision of the draft technical regulation.

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

3.82. The representative of the United States asked Korea for an update on the status of the measure as well as to provide further information about how Korea planned to take into account the comments received to date to ensure a level playing field for domestic and foreign registrants. The US applauded Korea's decision not to subject small quantities of new chemicals to the full registration process, which was in line with the need to ensure that conformity assessment procedures were commensurate with actual risks. She however indicated that her delegation still had three key outstanding concerns. First, she recalled that Korea had stated in this Committee that confidential business information would be protected and that only safety-related data would be shared. Moreover, composition and processing information would not be required and would be kept confidential. The US again urged that the K-REACH framework prevent any disclosure of confidential business information to the public or other manufacturers and importers throughout the supply chain. Likewise, her delegation believed that applying confidential business information protections to chemical identity, composition, uses, processes, manufacturer/importer, and customer lists would significantly boost US and international business confidence and support further technological innovation in the chemical sector. Second, the US recommended that product exemptions under K-REACH should not require certification from the Ministry of Environment. Specifically, she recommended that the polymer exemption be similar to that of US Toxic Substances Control Act, which did not have any data requirements for reproductive/development screening, melting point, boiling point, and vapour pressure endpoints. Third, the US suggested that by products and impurities be exempted from hazard examinations.

3.83. The representative of Japan echoed the comments of the US. He then noted that for around 500 hazardous substances covered by the measure (consisting of around 400 toxic substances and around 100 restricted/prohibited substances) it would become necessary, as of 1 January 2015, to notify the Korean authority of the production, sale and import of articles containing such hazardous substances in quantities not less than 0.1% by weight and not less than 1 ton/year in total. He further noted that, under the measure, the assessment of such substances thresholds would have to be undertaken against the backdrop of complicated supply chains, including

substance producers, article processors/assemblers and sellers of the articles. Japan considered that if the assessment of so many hazardous substances were to start at the same time, this would be burdensome, in particular for businesses focused on importation. Japan was also concerned whether, once the law came into force on 1 January 2015, there would be sufficient lead time for distribution and/or trade of chemicals in Korea. He further noted that the number of around 500 substances was much larger than the 151 Substances of Very High Concern (SVHC) under the EU REACH. While Japan agreed that the introduction of legislation to protect human health and the environment was the legitimate right of Korea, he nonetheless requested the Korean authority to take into account not only the seriousness of the hazards corresponding to the criteria for designation of hazardous substances, but also the actual conditions of use and exposure, and to introduce the regulation in a stepwise manner.

3.84. The representative of the <u>Republic of Korea</u> informed that at the 10th consultative group meeting, held on 25 April, additional comments from industry and stakeholders were appropriately reviewed. Such comments would be reflected in subordinate legal works within the intent of the draft regulation. A regulatory impact audit was conducted from 15 May to June, and several provisions, including the extension of reporting period, were eased to the extent possible. The Presidential and Ministerial Decrees to the Act would be published in September 2014 and the Act was scheduled to enter into force on 1 January 2015. He emphasized that under the draft regulation, small quantities of new chemicals were not subject to a full registration process and submission of dossiers was minimized and the registration period was significantly shortened. Regarding protection of confidential business information, he explained that Article 29 of the Act, the provision dealing with chemical information within the supply chain, clearly specified that the scope of information to be provided excluded this kind of confidential information (e.g. those on composition, contents), and that manufacturing volumes and the amount of used chemical substances were to be tentatively provided only for the safety reasons. Additionally, Korea informed that the official responses from the Ministry of Environment on the specific enquiries submitted in April would be forwarded to the US by the end of June, and that the other issued that had been raised would be sent to the competent authorities.

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

3.85. The representative of the European Union noted that, as planned, the measure entered into force on 30 April 2014. The EU still did not understand the rationale of, on one hand, requiring imported toys samples to be taken from each shipment for the purpose of testing and certification, whereas, on the other hand, domestic production samples only needed to be taken every six months from the production line. The EU informed that it had recently learned that certain measures were taken as part of the implementation of the new requirement to alleviate some of the burden on foreign suppliers and importers of toys. These new measures were enacted through regulation by the Director General of the Indonesian Ministry of Industry, as part of the Guidance on the implementation of the Toy Safety Decree. If the EU understanding was correct, under this regulation samples would no longer be taken by individual batches and per each different toy model, but rather within a single shipment (which could contain many batches) and samples would be taken from all toys falling under the same Harmonized System code and per each trademark. The EU asked Indonesia to explain how such measure would alleviate the burden on foreign toy suppliers. The EU further noted that acceptance of testing performed at foreign laboratories accredited by ILAC MRA signatories were currently granted for a period of two years. He asked Indonesia to confirm that continued acceptance of foreign testing would be possible beyond this two year period, and what would be the conditions for such continuance. He underlined the importance of enabling certification bodies approved by the Indonesian Ministry of Industry to issue certificates on the basis of foreign test reports. He clarified that this did not mean the EU was asking that the full certification be conducted abroad, but rather that foreign toy manufacturers be able to apply for certification in Indonesia on the basis of test reports issued in their home country by qualified laboratories.

3.86. The representative then highlighted a new element of concern, linked to the specific impact on toys of the new labelling requirements, which were discussed earlier on in this meeting under STC No. 12, which was covered by notification G/TBT/N/IDN/85. As mentioned earlier, the EU was concerned with the burdensome nature of such labelling requirements as the information to be provided appeared to go well beyond the essential elements of information which should appear on

G/TBT/M/63

labels. With respect to the application of this labelling regulation to toys, the EU pointed out that the requirement of permanently affixing labels on these particular products could, in itself, give rise to safety concerns. In the EU's view, permanent labels could be removed by children playing with the toys. This could damage the toy and expose its filling, ultimately exposing children to materials which were not supposed to be accessible to them. In this respect, the EU invited Indonesia to allow enough time for discussion with toy manufacturers on feasible labelling solutions capable of meeting Indonesia's policies objectives, while ensuring proportionality and the not compromising toy safety. He observed that the draft notified in G/TBT/N/IDN/85 had a planned date of adoption on 25 June 2014, with immediate entry into force. The EU asked Indonesia to postpone the adoption of this measure until discussion with WTO Members and affected stakeholders had taken place, and in any event, to allow a reasonable interval between adoption and implementation.

3.87. The representative of the <u>United States</u> said that while her delegation fully supported the objective of protecting children worldwide from unsafe toys, US industry continued to have questions about potentially duplicative in country testing requirements, onerous sampling requirements, documentation, and burdensome inventory requirements. The US considered that the new amendment did not appear to address these long standing concerns prior to the regulation coming into force at the end of April 2014.

3.88. The representative of <u>Japan</u> supported the comments of the US and the EU and expressed his delegation's disappointment that the measure went into effect on 30 April 2014, despite the outstanding concerns expressed by Japan and other Members, including the fact that the testing requirement for each-and-every import shipment was unnecessarily frequent. Additionally, Japan still considered as unprecedented and unreasonable that only laboratories located in countries which had concluded bilateral mutual recognition agreements with Indonesia with respect to accreditation of foreign laboratories would be allowed to be accredited as testing laboratories. Other laboratories, he noted, even if they had been accredited during temporary two-year grace period, would not. Finally, Japan continued to be of the view that phthalate, azo and formaldehyde restrictions were stricter than necessary.

3.89. The representative of <u>Indonesia</u> explained that the current regulation required sample taking to be based on the batches of shipments. A shipment could consist of several batches which were determined in terms of each trademark of toys which fell within the same HS code. He said that this improved requirement would significantly reduce the time for testing. Regarding acceptance of test results issued by foreign laboratories, Indonesia confirmed that it had granted a two year grace period for such results to be recognized. However, this special treatment during this grace period could only be further extended if the government of the country where the laboratories were based had entered into a mutual recognition agreement with the Indonesian Government.

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

3.90. The representative of Argentina reiterated its concerns regarding the EU's unjustified delay in resolving this longstanding specific trade concern. He recalled that Regulations (EC) Nos. 479/2008 and 607/2009, which granted EU member states the exclusive right to use certain traditional expressions in their own languages, restricted the right of third parties to use those expressions on their labels, which seriously affected wine exports from Argentina to the EU. Argentina believed this legal regime was inconsistent with the TBT Agreement. In order to help find a practical and constructive solution to avoid the barriers posed by this measure, and at the EU's invitation, in July 2009 Argentina submitted its dossier on the terms "Reserva" and "Gran Reserva". Argentina's dossier was approved in March 2012 by the European Commission (EC) Wine Management Committee. Although the substantive procedure was completed in March 2012, the final formal step – the adoption of the Argentine dossier by the College of Commissioners and its publication in the Official Journal of the EU – had not yet been taken. Argentina stressed that the substantive procedure took two years and seven months – i.e. from July 2009 until the approval of the dossier in March 2012 –, while the delay to comply a single administrative act of a formal nature had already reached two years and three months, i.e. from March 2012 to June

2014. It is striking that the delay to finalize a merely formal administrative act has almost equalled the time taken to end the substantive procedure that approved the dossier. It was not coherent that only one formal act required the same amount of time than the total amount of acts of this process, during which Argentina had also responded to objections by different entities and supplied additional information in response to requests from the EC for clarifications regarding its documentation. Moreover, he stressed that the delay was doubly unjustified, since neither had the process been concluded in a reasonable period of time, nor had a reasonable explanation for the delay been given. The delay to resolve the issue definitively, which was approaching five years, constituted in and of itself alone an unnecessary barrier to trade. He expressed Argentina's perception that no willingness had been shown to settle the matter, a situation that was clear from the fact that no date had ever been communicated for the inclusion of this item on the agenda of the College of Commissioners. Argentina once again requested the EU to lift the unjustified restrictions on its exports of quality wines by including this item on the agenda of the next meeting of the College of Commissioners and publishing the relevant regulatory act in its Official Journal.

3.91. The representative of the <u>United States</u> echoed the statement of Argentina, and recalled previous concerns and requests as to the status of the applications that were submitted by the US wine industry four years ago. The US had learned in bilateral meetings that the EU was reconsidering this scheme on Traditional Terms for wine, which was appreciated. She requested additional information on this review, such as its objectives and parameters, whether the review process was transparent, and the scope of the stakeholder participation in the review, in particular, whether foreign stakeholders may participate in the process. The US requested information about the Wine Advisory Group, chaired by DG Agriculture, regarding its plans for the approval of the use of Traditional Terms on wine by the US and other leading wine producing nations. She noted that no information had been shared with key trading partners since the last traditional term application was approved in 2012. She said that the lack of transparency in this process continued to have significant impact on US exports of wine to the European Union; companies that legally use those terms in the US as well as third markets were unable to sell their wine in the EU.

3.92. The representative of the <u>European Union</u> informed the Committee that the new Regulation establishing a common organisation of the markets in agricultural products had been adopted by the European Parliament and the Council (Regulation (EU) n° 1308/2013). Following its publication in December 2013, an internal assessment on traditional terms had been carried out in accordance with Article 114(3) of that Regulation. He explained that the consultation included the conditions and specificities under which these traditional terms could be used on the labels of products from third countries. Possible derogations, based particularly on minimum requirements for production methods and controls under product specifications of the wines concerned, had been also covered by this discussion. The EU was making efforts to bring new elements in its current policy on protection of traditional terms and their indication on the labels of wines in order to accommodate trade partners' concerns. The concerns expressed by the US and Argentina had been taken into account in the assessment process currently underway in the EU, which was of a complex nature. The procedures under consideration (whether from EU member states or third countries) would be taken once this evaluation was accomplished. The EU continued to be open to discussion with both trade partners bilaterally at expert level.

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

3.93. The representative of <u>Japan</u> noted that gradual progress had been made in registrations under this Order. However, a survey of Japanese industry showed that as of 3 April 2014 - i.e. 3 months after the date of full entry into force (3 January 2014) -, testing and registration procedures were still taking significant time. In the worst cases, said Japan, it took over 12 months for testing and over eight months for registration. The launch of the products in the Indian market had been delayed significantly due to the length of time taken for testing and registration procedures. Japan requested India improve aspects of testing and registration procedures to accelerate the process. Japan understood that BIS allowed only factories to be "applicants", and required registration on a per-factory basis. Even if one product model was manufactured at several factories, each of the factories was required to undergo testing and registration. Japan thus requested India to allow a manufacturer (a brand owner) and its representative in India (an

importer) to be "applicants", and to change the current registration system to a per manufacturer (or per brand owner) basis, under which testing and registration would be required only for each manufacturer or brand owner, instead of each factory. He also expressed Japan's concern with the length of time for testing and suggested accepting CB certificates and CB test reports issued by National Certificate Bodies (NCB) of the other countries as a way to shorten testing time. Finally, Japan noted that BIS also took a long time to confirm test reports submitted for registration, even though they were issued by the laboratories which BIS itself accredited. Japan requested India to ensure that BIS completed registration procedures in three weeks from the time of application for registration, which was a common practice in other countries.

3.94. The representative of the Republic of Korea echoed Japan's concerns on this Order and reiterated Korea's full support for efforts to protect consumer safety. Korea understood that the Order notified under G/TBT/N/IND/44 required manufacturers to mark information on their certified products. He noted that, until recently, the BIS allowed manufacturers to mark information by affixing stickers. However, BIS had recently amended the regulation to require that information be either embossed/engraved on products or screen printed on products and packaging material. He noted that this amendment was published on the BIS website on 11 April 2014, without any notification to the WTO. Since this amendment was subject to the TBT notification provisions, Korea recommended that India notify the amended regulation to the TBT Committee and provide WTO Members with an opportunity to submit comments. Korea believed that affixing stickers on products to mark the registration number specified by the current regulation would be sufficient to achieve the purpose of the regulation, which was to inform consumers about whether products were certified or not. In addition, he explained that markings by screen printing, embossing or engraving information on products would increase production time and cost due to added manufacturing processes. As a result, this would lead to price increases for these products. Furthermore, given that electronics and information technology goods had a relatively short lifecycle and were developed by rapid technological innovation, Korea considered that affixing stickers would be more reasonable and less trade restrictive. Therefore, Korea requested that India continue to allow the marking requirement to be met through affixing stickers.

3.95. The representative of the <u>European Union</u> supported previous Members' interventions, and shared the concern about the need for further streamlining of the registration procedure that had resulted in long delays. Given the often short lifecycle of the products concerned, he said these long delays could effectively prevent meaningful market access. The EU continued to view the overall scheme as excessively burdensome in view of the low risk associated with the products concerned. As mentioned by Japan, given the concrete risk of a testing bottleneck, he underscored the importance of ensuring the continued acceptance of test reports and certificates issued under the IECEE CB Scheme or by laboratories which were adequately accredited under the international standard ISO/IEC 17025 by an ILAC MRA signatory. In this respect, he recalled the assurances given by India in past meetings and requested further confirmation that this would continue to be the case in the future. He noted that, in principle, because India's standards were based on, and in many aspects fully aligned with, the corresponding IEC standards, the acceptability of IECEE CB Scheme test reports and certificates should not pose any problem.

3.96. He also stressed the need to extend the time validity of test reports, which was currently 90 days. From the EU perspective, test reports should have a longer validity and testing should only be repeated if a product had been substantially changed in such a way that its safety properties were affected. The EU fully supported the concerns of Korea surrounding the BIS labelling Order of 11 April 2014, which introduced very extensive labelling requirements and represented a significant change compared to the current situation. Implementation of this requirement would imply significant costs and the requirements appeared to be disproportionate compared to the consumer information objective pursued. He noted that the entry into force of the new labelling requirements was foreseen for 1 July 2014. Given the very short implementation period, the EU urged India to postpone the entry into force of this Order and engage with industry in order to find practical solutions that fit the nature of the products and the needs of the sector concerned.

3.97. The representative of the <u>United States</u> supported the statements made by previous concerned Members. She recalled that India had implemented the testing requirements for the measure from 3 January 2014, and had delayed implementation of the labelling requirements until April 2014. With respect to the requirement that testing be conducted solely in labs domiciled in India, the US recalled its previous interventions on this issue and encouraged the BIS to accept

G/TBT/M/63

test reports under the IECEE CB Scheme, and to only require testing in cases of suspected noncompliance. This would ease the burden on manufactures of the in country testing requirements, while improving the capacity of Indian labs. She reported concerns of US industry about the expiration of test reports and noted that no other national certification agency imposed expiration dates on test reports. She requested that India reconsider the annual re registration and re testing as there was no basis for this redundant testing. The US understood that at least 18 foreign labs had applied to be approved to perform testing as early as July 2013. She recalled that during the March 2014 Committee meeting, India indicated that BIS had recognized 11 labs, and asked for an update regarding the status of the other applications.

3.98. The US also continued to have concerns about India's practice of regulation by FAQs, rather than regulation through amendments which were notified to the TBT Committee for comment. The labelling requirements applying to the embossing/etching of products were the latest hurdle. She also noted the current confusion across Indian Government agencies with respect to the Highly Specialized Equipment (HSE) exemption under the compulsory Order, and she encouraged India to promote inter-ministerial consultation amongst the Customs Agency, Department of Electronics and Information Technology (DeitY) and the Department of Commerce to ensure that the exemptions provided were in fact enforced at the border. On the requests for exemption, she requested that DeitY put in place a process to enable a manufacturer to make such a request through a simple form, with a reasonable timeframe for the process to be completed, and a contact person for related enquires.

3.99. The representative of <u>India</u> said this Order was issued in October 2012, and mandated fifteen categories of electronics items under the Compulsory Registration Scheme, based on their compliance to specified safety standards. The Order envisaged that manufacturers, importers, sellers and distributors of the notified goods must conform to the specified standards and obtain registration numbers from BIS after testing from BIS recognized labs. He noted that the Order was initially foreshadowed to come into force from 03 April 2013 but subsequently its entry into force was extended. The Order was uniformly applicable to both domestic manufacturers and foreign suppliers. Industry needed to have goods tested by laboratories recognized by BIS. On meeting requisite standards, BIS granted a unique registration number. Industry then needed to mark a self-declaration of conformity on their products in a prescribed manner, followed by the registration number assigned by BIS. Each registration was valid for two years, a period which could be renewed merely upon request if no adverse issues came up during the period of registration.

3.100. The Indian representative also said that there were no issues relating to delays in testing or registration. With respect to testing, the recognized labs were well on track. He noted the list of recognized labs was available on websites of DeitY and BIS, and said that these labs were well equipped, and worked under an international safety certification programme. In fact, three of the recognized labs had parent companies of foreign origin. At present, Indian authorities had received no feedback of any delay in testing. With respect to allowing other labs for testing purposes, he explained that labs aspiring to test under the scheme would have to seek recognition from the BIS, and noted the existence of a foreign lab recognition scheme under the BIS provisions. Second, on the registration side, he informed delegations that as of 4 June 2014, 941 registrations had been granted covering over 5000 product models, and over 90% compliance had been achieved under the Compulsory Registration Order. Nevertheless, he said that suggestions made by concerned Members in this respect had been noted and would be communicated to Indian authorities.

3.101. He informed that, in order to address technical issues pertaining to the scheme, a Technical Advisory Committee (TAC) has been constituted under DeitY. Technical matters such as exemption on HSE fell under the purview of this Committee. In this regard, the quantity restriction of 5 per model under the exemption for R&D or demo samples had already been removed, and there was no limit on the number of units being imported for R&D or demo purposes. Likewise, he reported that BIS had formed a Policy Advisory Committee (PAC) to address policy issues of the registration scheme. The issues relating to new labelling requirements were presently under consideration.

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

3.102. The representative of the United States indicated that US exporters continued to face significant barriers to their access to the Ecuadorean market as a result of these conformity assessment requirements, which, while may be needed to ensure product safety and quality, were more stringent than necessary to accomplish such objective. The US was also concerned with Ecuador's inconsistent notification of measures. She further noted that Ecuador had issued new measures which were having a significant negative impact on trade given the absence of transition periods to adjust to new requirements and the failure of Ecuadorian officials to provide a way for exporters to be compliant with the new measures. The aim of these measures, she said, appeared to be to reduce imports in an effort to balance trade rather than addressing legitimate health, quality and safety concerns. For example, Ecuador had notified the Ecuadorian National Quality Council (CONCAL) Resolutions 009 2009 and 010 2010 (G/TBT/N/ECU/44) as final, without providing any comment period. Subsequent resolutions affecting conformity assessment procedures had also been notified in three addenda to this notification. Most recently, the Ecuadorian Foreign Trade Committee (COMEX, Ministry of Production, Employment and Competitiveness) had published Resolution 116 in December 2013, which vastly expanded the list of products requiring a Certificate of Recognition and Conformity for export to Ecuador, compared to the procedure originally set forth under the measure notified as G/TBT/N/ECU/44. She asked when Ecuador would notify Resolution 116 to the WTO and allow for interested parties to comment, in accordance with Article 5.6.2 of the TBT Agreement.

3.103. The main concern the US had with COMEX Resolution 116 related to the ability of exporters to obtain the Certificate of Conformity. US exporters had particularly reported that there was insufficient information about the requirements to obtain these certificates and that the number of Conformity Assessment Bodies approved by the Ecuadorian Accreditation Organization to issue Conformity Assessment Certificates required for obtaining Format INEN-1 (Certificate of Recognition) was insufficient to meet demand for certifications. To add to this uncertain environment, Ecuador had provided the US industry with a list of US located bodies from which to obtain certifications. However, these bodies had asserted that they could not issue the requisite certifications. The US noted that Ecuador already had in place stringent measures to control the quality of goods entering the market and it was not clear what benefits additional attestations of conformity were conferring. Therefore, the US requested that Ecuador explain the legitimate objectives of the additional certification requirements for each product and encouraged Ecuador to suspend the measures until they could be notified to the WTO and commented on by all interested parties. In the case of measures that were justified, the US further requested that Ecuador suspend implementation for one year to allow economic operators to comply with the new requirements without interrupting trade, consistent with the TBT Agreement's obligation to provide a reasonable interval between the publication of conformity assessment procedures and their entry into force. The US also noted that COMEX Resolution 116 had recently been the subject of Andean Community Secretariat-General Resolution No. 1695, dated 6 June 6 2014, which had found the measure to be a trade restriction and ordered its withdrawal. The US called on Ecuador to reflect on this decision and take the necessary actions in order to avoid further trade disruptions.

3.104. The representative of <u>Costa Rica</u> referred Members to the concerns they had raised at the previous meeting TBT Committee meeting and also supported the concerns raised by the US. Costa Rica was looking forward to receiving more information from Ecuador on this issue.

3.105. The representative of <u>Switzerland</u> pointed out that Ecuador had notified 145 legislative projects since the Committee's discussion in October 2013 of this trade concern, which was widely seen as more restrictive than necessary if applied across the board, as it required third party certification and registration of the product with the Ministry of Industry as a preferred procedure for most products. Despite concerns expressed regarding its notification practice, Ecuador continued to notify technical regulations after their entry into force by using the emergency procedure, thus effectively preventing Members to comment on them in due course. Switzerland encouraged Ecuador to ensure that legislative projects with effect on trade were notified in advance, allowing for at 60 days for comments and providing a reasonable timeframe for industry to adapt to new requirements and procedures. Emergency notification procedures were to be used

only in urgent and justified cases. Switzerland also asked Ecuador to clarify its stance on using international standards and whether the requirement to design regulations based on product performance rather than descriptive characteristics (TBT Agreement, Art. 2.8) was part of its general framework for technical regulation. Recalling that under Article 5 of the TBT Agreement conformity assessment procedures shall not be more restrictive than necessary, Switzerland drew attention to the work of the TBT Committee, in particular to the "indicative list of approaches to facilitate acceptance of the results of conformity assessment". Switzerland had made positive experiences in applying as widely as possible less burdensome methods of conformity assessment, which reduced the burden of compliance, reduced time to market and helped combating anticompetitive behaviours, eventually benefiting the consumer.

3.106. The representative of Ecuador said that Resolution N° 001 of 2 May 2013 (published in the Official Registry N° 04 of 30 May 2013), had been issued by the Inter-Ministerial Committee for Quality, an inter-agency body formed by several governmental and regulatory agencies of Ecuador. In accordance with the provisions of the Ecuadorian Quality System Law, it established the general framework for conformity assessment and the "Handbook of Procedures" to be observed prior to all stages of customs clearance, marketing and market surveillance of manufactured, imported and marketed goods subject to Ecuadorian technical regulations. The Handbook established that products subject to Ecuadorian technical regulations must demonstrate compliance with these through the certification of conformity assessments prior to importation or marketing. The certification had to be obtained from a certification body, whose accreditation had been issued or recognized by the Accreditation Body of Ecuador (OAE) or from one which had been appointed by the Ministry of Industry and Productivity. He said that, subsequently, Resolution N° 002 of 11 July 2013 (published in the Official Gazette in 22 August 2013), and Resolution N° 001 2014 (published in the Official Gazette N° 264 in June 10 2014), introduced several changes to the original Resolution N° 001-2013-CIMC in order to take into account cases where there were no bodies accredited by the OAE. In such cases, the importer or consignee could submit a suppliers' declaration of conformity to the Ecuadorian Standardization Institute according to standard NTE INEN ISO/IEC 17050 1, attaching the reports or tests results issued by a laboratory accredited and recognized by the Ecuadorian Accreditation Agency and demonstrating compliance with the relevant Ecuadorean or equivalent technical regulations or international standards for the product. He concluded by saying that these Resolutions only set out the procedures to be followed by business operators to comply with Ecuadorean technical regulations, both for products produced in Ecuador and those imported. They were not therefore intended to create unnecessary obstacles to trade.

3.2.3.12 Thailand - Draft Thai Industrial Standard for Ceramic Tiles (TIS 2508-2555) (G/TBT/N/THA/407) (IMS ID 401)

3.107. The representative of the <u>European Union</u> expressed concerns regarding the divergences between the mandatory Thai Industrial Standard and the relevant ISO standards for ceramic tiles. The EU considered that the requirement to fix the TISI marking on each and every tile, and not alternatively on the packaging, was burdensome, costly and not in line with ISO 13006:2012. In addition, water absorption thresholds were also not in line with this ISO standard. Furthermore, the mandatory Thai Industrial Standard required product testing and an onsite audit of a manufacturer's quality control system by the Thai Industrial Standards Institute (TISI), which appeared to be an overly burdensome conformity assessment procedure. The EU asked whether test results from EU laboratories and certificates from EU conformity assessment bodies would be accepted. Further to Thailand's statement at the March 2014 Committee meeting, the EU asked Thailand for an update on possible amendments to the Thai industrial standard for ceramic tiles.

3.108. The representative of <u>Thailand</u> said that the Thai Industrial Standard on Ceramic Tiles (TIS 2508:2555 (2012)) used as reference, and was to a large extent not different from, ISO 13006:1998, the content of which had not changed in the revised version in ISO 13006: 2012. Where it was not possible for the manufacturers or importers to display the TISI Mark on the product, the marking could be put on the product and/or packaging. Regarding the acceptance of test reports, according to Article 5 of the Industrial Product Standard Act B.E. 2511 (1968), TISI accepted test reports from laboratories designated to be inspection bodies. However, as an interim measure and to cope with a great number of applications for licences, TISI would accept test reports from the laboratories complying with ISO/IEC 17025 under ILAC/APLAC conditions during a period of one year commencing on 23 July 2013. After this period, only reports from laboratories designated to be inspection bodies according to Article 5 of the Industrial Product Standard Act

B.E. 2511 (1968) would be accepted. Otherwise, the laboratories to be accepted would have to enter into an agreement on MRA/MLA with TISI.

3.2.3.13 Russian Federation – Measure affecting the import of Ukrainian confectionary products (IMS ID 399)

3.109. The representative of Ukraine stated that Ukraine continued to have concerns regarding Russia's ban on import of Ukrainian confectionery, which had been enacted on 29 of July 2013 by the Resolution/Decision of the Federal Service on Customers' Rights Protection and Human Wellbeing Surveillance of the Russian Federation (Rospotrebnadzor) (No. 01/8612-13-23). Since the discussions in the March 2014 TBT Committee meeting, the ban had been expanded to the transit of Ukrainian confectionery products to the occupied territory of the Autonomous Republic of Crimea. Answers provided by Russia after eight months of consideration were vague, contradictory and triggered more questions. Russia still seemed undecided whether the ban was applied for consumer rights protection or to ensure compliance with the labelling requirements. In its answers, the Russia had stated that the import ban was related neither to violation of sanitary requirements nor to technical regulations of the Custom Union but due to violation of Art.10 of the Federal Law №2300-1 of 7 February 1992 on consumers' rights protection. At the same, Russia had indicated the possibility of reviewing Rospotrebnadzor's Decision after full compliance with the requirements of the Custom Union, referring in particular to the Technical Regulation on "Food products in sphere of its labelling". Ukraine believed that the measure was unjustifiably strict, discriminatory, and more trade-restrictive than necessary to fulfil a legitimate objective, taking into account of the risks non-fulfilment would create. Ukraine had not yet received any response to additional questions raised at the March 2014 meeting and requested a clear explanation as to why the ban had been introduced and continued to be maintained. Ukraine asked how the ban complied with the TBT Agreement and the official results of the inspection of Ukrainian factories conducted in October 2013, which still had not been provided to the Ukrainian producers and authorities. As of 1 January 2014, Ukraine had officially informed Rospotrebnadzor of the conformity of confectionary products produced by certain factories (in Kiev, Vinnitsa, Mariupol and Kremenchug) to Russian quality requirements for food products. However, Russia had disregarded the updated information and claimed that the measure could not be reviewed in accordance with Art.2.3 of the TBT Agreement. Ukrainian authorities and producers were open, fully cooperative and constructive in resolving this concern with the Russian authorities. In this respect, Ukraine recalled that that it had ensured enforcement of its part of the agreed roadmap for the elimination of trade barriers between Russia and Ukraine for 2013-2014. Ukraine expected unbiased cooperation from Russia because this was in the interest of both countries as mutually important trading partners, mindful of their obligations as WTO Members. Ukraine called upon Russia to immediately lift the trade ban and bring its measure in line with the TBT Agreement as well as commitments it signed at accession.

3.110. The representative of <u>Russia</u> indicated that the measure affecting confectionery products of the Ukrainian company Roshen was introduced due to inconsistencies of these products with Russian labelling requirements, as already explained during the previous TBT Committee meeting. During the previous year, some Ukrainian companies exporting food products to Russia had failed to comply with the technical regulations of Russia and the Customs Union. The import ban on the confectionary company Roshen had been introduced on the basis of numerous laboratory tests, the results of which were provided to Ukraine during bilateral consultations held in August, October and December of 2013. More than 90% of tested products had failed to meet the requirements of the applicable technical regulation. During the bilateral consultations held in December 2013, the State inspection service of Ukraine on the Protection of Consumers' Rights had recognized the inconsistencies of Ukrainian products with the Russian requirements. Moreover, during the course of consultations, an agreement had been reached to resume the export of confectionary products to the Russian market. Unfortunately, said Russia, Ukraine still had not taken the steps necessary to implement such an agreement. He emphasized that the ban only applied on the entire territory of Russia and was, consequently, not extended to the whole territory of the Custom Union.

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

3.111. The representative of <u>Costa Rica</u> said that the difficulties Costa Rican exporters have been facing in complying with the measures' conformity assessment procedures were affecting their capacity to access the Ecuadorian market. However, it was also their understanding that the Ecuadorian authorities were also allowing suppliers' declaration of conformity, which could facilitate the demonstration of conformity with technical requirements. Costa Rica asked Ecuador to supply more information about the status of implementation of the regulations and explain how Ecuador had taken into account the concerns expressed by Costa Rica and other Members at the March 2014 Committee.

3.112. The representative of the European Union thanked Ecuador for having eventually notified Technical Regulation 022 on Labelling of Processed and Packaged Food Products, which imposed nutrition food labelling obligations comprising "high in" warnings and a colour coded warning system. While fully sharing Ecuador's public health concerns regarding the provision of adequate nutritional information to consumers, the EU doubted whether the approach taken in the notified draft was the best way to achieve these objectives and whether it was proportional to the aim pursued, which was to empower consumers to make an informed choice in order to foster effective competition and consumer welfare. The EU asked whether Ecuador had considered alternative, less restrictive measures that would encourage the consumer to actually read the contents of sugar, fat and salt on the products in question and make the appropriate choice, in particular taking into account that the consumption of limited quantities of products high in sugar, fat or salt could reasonably be part of a healthy diet. The Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 CODEX) stated that the information contained in the nutrient declaration "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". No nutrient thresholds had been established by Codex for the nutrients targeted by the Ecuadorian legislation. The EU recognised that for certain nutrients there was evidence of a positive association between its excessive intake and the risk of developing a disease or disorder but there was no scientific evidence suggesting an identifiable threshold above which the risk existed. The risk increased rather continuously when the nutrient intake increased above the levels recommended by the nutritionists. Furthermore, "high in" warnings, such as those proposed by the Ecuadorian legislation, were not foreseen by the applicable Codex guidelines on nutrition labelling and risked demonizing some foods while their consumption in moderation could be part of a healthy diet. The EU recalled that according to Codex guidelines, the information to be provided in nutrition labelling was only factual, providing, among others, the energy value and the amounts of protein, carbohydrate fat, saturated fat, sodium and total sugars. In this regard, the EU noted that Ecuador's departure from these internationally recognised practices would have a significant impact on foreign manufacturers that would need to adapt their packaging for the Ecuadorian market only.

3.113. On the specific contents of the technical regulation, recalling Article 2.2 of the TBT Agreement, the EU inquired about the scientific basis to impose warning statements for products containing any level of caffeine or taurine. The EU also noted that EU legislation provided less burdensome nutrition labelling requirements for packages whose largest surface had an area of less than 80 cm2 and an exemption for packages whose largest surface had an area of less than 25 cm2. The EU invited Ecuador to consider a less stringent approach. In addition, the EU noted that according to the second transitional disposition of the regulation, it would come into force on 29 August 2014, barely four months after its publication, while the adaptation to the new requirements would require significant investment for manufacturers and a redesign of the packaging for some products. The EU asked Ecuador to temporarily suspend the application of the measure and provide sufficient time for its implementation. The EU informed that its own legislation on nutritional labelling had been adopted in 2011 and would come into force in 2014.

3.114. The representative of the <u>United States</u> welcomed Ecuador's notification in G/TBT/ECU/19/Add.8, which extended the date for compliance with the revisions to Ecuador's nutritional labelling until 15 August 2014 and increased flexibility for the placement of the "traffic-light" icons, allowing them to be placed on the back of the package alongside the nutrition panel,

- 32 -

in addition to the front of the package. Further, Ecuador had clarified that duty free goods were exempt from the traffic light labels. While these trade facilitating improvements and continuing bilateral discussions were appreciated, the US remained concerned that imported foods would not be able to come into compliance by the new enforcement date of 15 August 2014 and that the modifications had been introduced after the notification of the regulations to the WTO as final and without a comment period. The US recalled that Ecuador had clarified during an April 2014 bilateral discussion that all foods subject to the new labelling would need to be re-registered under Ecuador's Sanitary Food Registration Process. The US had previously raised the challenges of completing this onerous re registration process both bilaterally, during the November 2012 TBT Committee meeting, and in a letter to Ecuador's Ministry of Health, dated 4 October 2012. The US also considered as burdensome and duplicative the measure's per shipment requirement for a certificate of conformity to verify nutritional labelling, in particular because Ecuador already required a certificate of conformity for compliance with commodity standards and food products also needed to undergo a label review as part of the Sanitary Food Registration process. Consequently, argued the US, such additional certificate would provide no information that was not already gathered by the other two requirements. The US also recalled that at the March 2014 TBT Committee meeting, it had been joined by the EU and Brazil in questioning the need for a certificate of conformity in regards to nutritional information and the lack of practical guidance on how to obtain it. While Ecuador had provided a list of accredited labs and clarified (during an April 2014 bilateral discussion) that they would accept ISO/IEC 17050 Part 1 in fulfilment of the certificate of conformity requirement, US suppliers had nevertheless been unable to locate accredited labs willing to issue the ISO certificate. Alternatively, the US was pursuing the possibility of State authorities issuing the certificate, but this took time and might not offer a workable solution in time for foods to complete the re-registration process by August 2014. Furthermore, at the March 2014 TBT Committee meeting, Ecuador had indicated that a Supplier's Declaration to Demonstrate Conformity (SDOC) would be accepted. The US sought confirmation of their understanding that an SDOC would only be accepted if a supplier entered in a "supplier's agreement", or MoU, with the Government of Ecuador. The US also asked whether such agreements placed limits on the amount of product that could be imported.

3.115. The US also said that Ecuador's lack of transparency had resulted in multiple and costly label changes. The Ecuadorean National Association of Manufacturers of Food and Beverage estimated that some firms had invested up to two million dollars in new labels before the announcement of the recent changes. While the US understood the valid public health objectives that Ecuador sought to achieve through the changes to its Sanitary Regulations for the Labelling of Processed Foods for Human Consumption, it continued to emphasize the need for stakeholder input at an early and appropriate stage, and a reasonable time for compliance after the publication of final regulations in order to minimize the costs. While placement of the icons on the back of the label was helpful, the size remained unchanged at 20 percent of the total label. The large size of the icon could still interfere with supplier's ability to declare other important mandatory as well as brand information. The US continued to request that Ecuador suspend implementation of its new requirements on nutritional labelling, and the related conformity certification, for one year.

3.116. The US was also concerned with the mandatory requirements to label food and beverage products with the statement: "Contains Transgenics". The US recalled its long standing position that for foods derived from genetically modified organisms that had been found to be substantially equivalent to conventional counterparts, mandating "Contains Transgenics" labelling might create an erroneous impression that the product was less safe than conventional products. Genetically engineered products that had been evaluated through risk based safety assessments in accordance with international guidelines, such as through the Codex Alimentarius Commission, should not require different labelling, absent material differences from their conventional counterparts. In addition to confusing consumers, such labelling would likely also increase costs to industry, consumers, and government authorities. The US encouraged Ecuador to consider a voluntary approach to biotech labelling, which would allow for consumer choice without mandatory requirements that might create concerns in the eyes of the consumer about products that had the same quality and that were equally safe. Finally, the US noted that according to Articles 5.2 and 5.3 of the measure notified in G/TBT/N/ECU/19/Add.8, Ecuador was proposing to base its biotech labelling requirement on a 0.9 % threshold. The US sought clarification on how this threshold would be calculated. In addition, the US sought confirmation that the measure would exempt foods which did not contain transgenic protein or DNA, such as highly processed products, such as oil, sugar, and syrup, from genetically engineered crops; foods which may be produced using

genetically engineered processing aides, such as cheese, beer, and yogurt; and foodstuff derived from animals fed with genetically engineered feed.

3.117. The representative of <u>Switzerland</u> said that while sharing Ecuador's concerns on the necessity to combat non-communicable diseases, Switzerland was of the view that the colour-coded "traffic light" warning system foreseen under the project would unfairly discriminate against certain products without conveying sound information to consumers. No nutrient threshold was established under the relevant Codex standard, according to which information contained in the nutrient declaration should not lead consumers to believe that there was 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. Switzerland was concerned with the use of diverging warning messages by some Members, in this case, pictograms conveying negative messages on various types of foods containing certain nutrients.

3.118. The representative of <u>Brazil</u> said that Brazil shared the concerns raised by Members and would continue to follow the discussions with interest.

3.119. The representative of Ecuador said that the Foreign Trade Committee (COMEX) Resolution No. 116 established the certificate of recognition as a supporting document to the customs declaration for all goods shipped as from the entry into effect of the Resolution in December 2013. The Resolution was not in itself a technical regulation, but rather an internal administrative resolution addressing Customs matters and introducing controls on the marketing of products on the basis of regulations which, in several cases, were already in force in the country. Ecuador reiterated that the Resolution was therefore not subject to the notification procedures set forth in the TBT Agreement. Technical Regulation (RTE INEN) No. 022 of the Ecuadorian Standardization Institute had been amended on a number of occasions, precisely to take into consideration the concerns raised by trading partners. The most recent amendment had been issued by the Under Secretariat for Quality of the Ministry of Industry and Productivity and notified in document G/TBT/N/ECU/19/Add.8, repealing the draft notified in document G/TBT/N/ECU/19/Add.7. The Technical Regulation sought to lay down the labelling requirements for processed and packaged food products and it applied to all processed foods with health registration certificates that were marketed in Ecuador. It would enter into force on 29 August 2014 and provide for a labelling alternative that involved the affixing of additional permanent adhesive labels or indelible or printed stamps or seals either in the country of origin or at the marketing destination of the product. The aim of labelling was to guarantee the right of consumers to appropriate, clear, accurate and nonmisleading information on the content and characteristics of processed and packaged food, thereby enabling them to make the right choices as regards the purchase and consumption of such goods. The Regulation took into account the requirements previously developed by the Ministry of Public Health and set forth in Ministerial Decision No. 00004522 of this body ("Sanitary regulations for the labelling of processed foods for human consumption"), whereby information was provided by means of a "traffic light" rating system indicating high, medium or low levels of salt, sugar or fat. These labelling regulations sought to combat heart disease and diabetes, which were among the leading causes of mortality and morbidity in Ecuador, and thus to curb the high rates of excess weight and obesity caused by a lack of information on food consumption. Finally, with regard to the conformity assessment certificate, the Regulation provided for the alternative of a supplier's declaration of conformity (in accordance with Standard NTE INEN-ISO/IEC 17050 1), duly legalized by the relevant authority and submitted together with the valid health registration certificate, as issued or recognized by the relevant national authority of the country of destination.

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

3.120. The representative of the <u>European Union</u> reiterated their concerns regarding the implementation of the Indian food safety and standards regulation – food labelling requirements - dating from August 2011. In October 2011 and January 2014, India had issued *ad hoc* guidelines that spelled out that certain India specific information, such as the vegetarian/non-vegetarian logos and the name and address of the importer, were considered "rectifiable" information and could be affixed by the importer in customs warehouses. However, the same guidelines defined that several of the compulsory labelling elements, such as list of ingredients, were "not rectifiable", which meant that they could not be provided by means of stickers and had to be, instead, printed on the food packages. The EU noted that in most economies in the world, food products could be labelled by means of stickers provided they were accurate and not easily detachable. This was a

G/TBT/M/63

very important trade facilitating practice that, while duly protecting the consumer, allowed producers to serve different regions with different language requirements without having separate production lines. The Codex Standard for the labelling of pre-packaged foods (CODEX STAN 1-1985) stated that "[i]f the language on the original label is not acceptable to the consumer for whom it is intended, a supplementary label containing the mandatory information in the required language may be used instead of relabeling". This standard also stated that "in the case of either relabeling or a supplementary label, the mandatory information provided shall be fully and accurately reflect that in the original label." The EU was therefore of the opinion that the October 2011 Guidelines, were too burdensome and not in compliance with Articles 2.2 and 2.4 of the TBT Agreement. In this context, the EU recommended India to bring its implementing Guidelines in line with Codex and allow all types of labelling information - and not only the Indian-specific ones - to be provided by stickers (for example at customs bonded warehouses). This was a sound alternative to labelling in the country of origin that would allow India to fulfil its legitimate objectives in a non-trade restrictive way.

3.121. Regarding alcoholic drinks, the EU noted that the Indian legislation required that the labels of alcoholic drinks contained the full list of ingredients. This was a different practice than that used in other Members. For instance, according to the EU legislation, spirits and wine drinks entering and circulating in the EU were not obliged to have a full list of ingredients in their labels. As stickers were not allowed in India, and the labels had to be pre-registered in different Indian States by the state excise authorities, it was not clear to market operators what exactly was expected by the food safety authority (FSSAI) to be stated on the labels for each type of alcoholic drink. It was important to note that there could be different ways to label certain ingredients or additives. In addition, the formal process for State approval of labels took place only once a year at fixed periods according to the fiscal cycles of the given state. In this context, India was urged to provide some more detailed information to market operators regarding the formulation of ingredients and to allow sufficient time for implementation, which, depending on the excise cycle, should be up to 9-12 months. The EU considered fundamental to ensure that the approval of labels by Indian State authorities took place before the implementation date. Otherwise, the requirement to list ingredients in the label of alcoholic drinks could result in a major market access disruption. Besides the transition periods, it was also fundamental to ensure that all the products already exported to India could be marketed until stocks were exhausted. Finally, the EU wished to receive further information from India regarding the planned new technical regulation on alcoholic drinks and the envisaged timeframe for notifying it to WTO.

3.122. The representative of <u>Japan</u> said that the implementation of the Guidelines had significant negative effect on food products imported from Japan into India. Japan shared the concerns expressed by the EU, in particular the fact that certain ingredients or nutrition information were "not rectifiable" and not allowed to be labelled by means of stickers. Japan recalled that Article 2 of the Codex General Standard for the Labelling of Pre-packaged Foods defined "label" as "any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food" and that Article 8.2.1 specifically stated that "[i]f the language on the original label is not acceptable to the consumer for whom it is intended, a supplementary label containing the mandatory information in the required language may be used instead of relabeling." In addition, Article 8.1.1 stated that "Labels in pre-packaged foods shall be applied in such a manner that they will not become separated from the container." This well balanced standard reflected the real world practices where many countries, including Japan, allowed food products to be labelled by means of stickers, provided they were accurate and not easily detachable, achieving the goal of consumer protection while avoiding unnecessary trade disruption. Therefore, Japan urged India to review its Guidelines based on the Codex Standard in accordance with 2.4 the TBT Agreement. In addition, said Japan, the Guidelines were overly burdensome and costly especially for companies exporting various items in small quantities to India and were not, therefore, consistent with Article 2.2 the TBT Agreement.

3.123. The representative of <u>India</u> said that the Food Safety and Standards Authority of India (FSSAI) had issued the Foods Safety and Standards (Packaging and Labelling) Regulation 2011 in August 2011. It contained general labelling requirements that required, for instance, that: (i) every pre-packaged food shall carry a label containing the required information; and (ii) the label shall be applied in such a manner that it would remain attached to the container. In October 2011, FSSAI had published the "ad hoc guidelines related to clearance of imported food", according to which absences of the vegetarian/non-vegetarian logo and name and address of importer were considered "rectifiable labelling deficiencies", which could be dealt with via sticker labels in the

customs bonded warehouse at the port. However, absence of the full information, when required, would not be rectifiable with sticker labels: (i) name and address of the manufacturer; (ii) list of ingredients; (iii) production date; (iv) best before or expiry date; (v) batch or code or lot number; (VI) net weight or volume; or (VII) nutritional information. He explained that if a sticker got detached from the package, it lost its purpose of making consumers aware. Therefore, in the August 2011 regulations, there was a requirement that the label be such that it remained attached to the container. Stickers had been subsequently allowed for making minor corrections, such as indicating vegetarian or non-vegetarian, in customs warehouse but not for making the entire specified information available. Furthermore, if stickers with all mandatory information were allowed on packages, it could be misused by unscrupulous traders for manipulating or tampering with the labels of imported food. India did not have tracking and tracing facilities to identify the source of such food items if a manipulation of labelling was detected at a subsequent stage in the market. In this context, India did not see any problem in maintaining its existing labelling requirement.

3.2.3.16 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) (IMS ID 370)

3.124. The representative of <u>Canada</u> said that while supporting Chile's policy objective of promoting healthy dietary choices and reducing obesity and related non-communicable diseases, Canada urged Chile to, when reviewing the measure, consider a science-based and less trade restrictive alternative to achieve its policy goals, which was based on international standards. Canada asked if and when the 17 December 2013 regulations would enter in force and which elements of the regulations were under revision. In addition, Canada urged Chile to notify any amendments to the regulations, allowing for a full 60-day comment period.

3.125. The representative of Mexico expressed her delegation's concern that the measure was not complying with the TBT Agreement's requirement that it should not be more restrictive than necessary to fulfil their legitimate objectives. She asked that Chile change the measure to comply with this obligation by promoting public policies that helped the population to obtain accurate information on food nutrients, so that they could make food choices based on their particular needs. Mexico noted that Law 20.606 (published on 6 July 2012) required "manufacturers, producers, distributors and importers of food products to display on the packaging and labels the ingredients they contain, including all additives, in descending order of proportion, and nutrition facts, as a percentage of composition, a unit of weight, or under the nomenclature specified by the technical regulations in force". In addition, the proposed amendments to Law 20.606 laid down criteria for classifying foods as "high in" certain constituents, with a view to reducing their consumption among the Chilean population and thus addressing the health problem of obesity. She noted that the Chilean Ministry of Health was responsible for determining which foods contained high amounts of calories, fats, sugars, salt or other ingredients, and which must be labelled "high in calories", "high in salt", or the like, without scientific justification regarding the way in which this contributed to achieving the legitimate objective pursued. She recalled that the Codex Alimentarius discouraged the use of any label or labelling - such as "high in calories" or "high in salt" which employed words, pictures or other devices that may lead the consumer to fear consuming a food product. Mexico questioned the scientific foundation for the measures promoted by Chile. Similar to Canada, Mexico also asked for an update on the process for review and entry into force of the regulation. In addition, Mexico asked whether Chile considered redefining the phrase "high in ..." in order to describe the concentration of the product using another, similar formulation, so as not to scare consumers.

3.126. The representative of <u>Brazil</u> recalled that Brazil had expressed its concerns during the March 2014 meeting of the TBT Committee and was engaged in bilateral talks with Chile on this issue.

3.127. The representative of <u>Switzerland</u> commended the openness of the Chilean legislative process, which allowed the bill to be improved and the reaching of a final version of the regulation containing warnings that were more neutral and that allowed the use of stickers. While Switzerland shared Chile's concerns on the prevalence of obesity and other diseases, it nevertheless considered that such measures could be made less trade restrictive if they were more in line with international standards and did not discriminate according to the selling method. Switzerland had been informed that the legislation was being reconsidered. While this could be an opportunity to

reduce certain effects on trade, it was important to continue to engage with international partners and ensure that previously raised comments remained taken into account in any amendment.

3.128. The representative of <u>Costa Rica</u> indicated that they shared the concerns raised by other Members and welcomed an update on the current status of the regulation.

3.129. The representative of <u>Guatemala</u> joined the delegations of Mexico and Canada in reiterating concerns regarding the measure and requested that Chile provide information on the status of the Regulation, in particular on the internal processes, changes that would be introduced, and as the entry into force of the Regulation.

3.130. The representative of <u>Australia</u> supported Chile's right to implement measures to provide consumers with information to make appropriate dietary choices and reduce the risk of diet related non-communicable diseases, provided that such measures were implemented in a manner that was consistent with Chile's WTO obligations. There could be other measures available to promote consumer health, which could achieve Chile's objective and which were being considered by other countries, including Australia. Australia appreciated the clarification provided by Chile that the warning label would no longer take the form of an octagonal "STOP sign" and that it would instead be a "coloured hexagon", the size of which would be established in relation to the size of the total area of the products. Australia was pleased that Chile had modified the proposed front of pack labelling requirement based on suggestions it had received by other Members, including Australia. However, in Australia's view, the labelling scheme was still mandatory for some food categories including some dairy foods. In addition, there were some inconsistencies between the requirements for imported and domestic products. Australia also sought clarification as to whether the regulation came into force on 17 June 2014, i.e. six months after its publication in the Official Journal of Chile, which had occurred on 17 December 2013.

3.131. The representative of Chile said that child obesity and related non-communicable diseases had taken on epidemic proportions in Chile in recent years. Law 20.606 on the nutritional composition of food and on food advertising and its implementing regulations were one of the first regulatory steps Chile had taken to address this countrywide problem, whereas other strategies of a promotional nature had been in place for years. As mentioned in the March 2014 meeting, on 17 December 2013, the final version of the regulations that implement Law 20.606 - Ministry of Health Decrees 12 and 28 - was published in the Official Journal. However, in March 2014 a new government had come into power and the new Health Authority in Chile, after analysing both the aforementioned regulations, had decided that they needed to be revised, mainly, but not exclusively, because Decree 12 was highly inconsistent with the Sanitary Regulations for Foodstuffs and other internal regulations. The Ministry of Health had issued two decrees, published in the Official Journal on Saturday 14 June 2014, which postponed the entry into force of Decrees 12 and 28 by one year. Additionally, the Ministry of Health had created a multidisciplinary committee composed of skilled professionals in the areas of food advertising and the nutritional labelling of food and representatives of other government agencies, for the purpose of revising current regulations and drafting new regulatory proposals. These proposals, expected to be ready in July or August 2014, would be duly notified to the WTO, with a 60 day period granted for comments in accordance with Article 2.9 of the WTO TBT Agreement. Any comments received during this process would be duly analysed and answered.

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

3.132. The representative of <u>Canada</u> said that while her delegation supported Peru's objective of reducing obesity and other non-communicable diseases, it was nevertheless concerned that this measure might be more trade restrictive than necessary to achieve this objective. She asked whether Peru had considered less trade restrictive alternatives to pursue its objectives and whether the proposed regulations were based on international standards and sound science. She also inquired when the regulations would come into force and encouraged Peru to provide a transition period to allow industry time to adjust to any new labelling requirements.

3.133. The representative of <u>Mexico</u> supported the comments made by Canada and recalled the concerns Mexico had already expressed at the previous meeting. She welcomed the notification of the technical regulation and requested an update on its status.

3.134. The representative of <u>Switzerland</u>, endorsing the remarks made by Canada and Mexico, inquired about the scope of the regulation and the level at which a product needed to be labelled with a warning saying that it was "detrimental to health". Switzerland was concerned with use of negative warning messages and the multiplication of uncoordinated parameters on them.

3.135. The representative of <u>Peru</u> said that the Peruvian Law to Promote Healthy Eating Among Children and Adolescents, notified as G/TBT/N/PER/59 on 20 May 2014, was a draft technical regulation establishing parameters for determining whether an industrially processed food product or non-alcoholic beverage had a high sugar, sodium or saturated fat content and providing for the gradual reduction of trans fats. Comments received until the deadline of 18 August would be reviewed by the multi-sectoral commission drafting the technical regulation.

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

3.136. The representative of <u>Canada</u> supported Indonesia's objective of reducing the risk of noncommunicable diseases. However, according to information available, Canada was concerned that the regulatory proposals might have a significant impact on trade and were likely to be more trade restrictive than necessary. She asked whether Indonesia had considered less trade restrictive alternatives to pursue its objective. At the March 2014 meeting, Indonesia had indicated that testing for sugar, salt and fat content must be conducted by accredited in country laboratories. She asked whether Indonesia had considered opening up such testing to foreign laboratories and if not, whether this would be considered. Canada welcomed an update regarding when the regulation would enter into force and what type of transition period it would provide for industry to adjust.

3.137. The representative of the European Union welcomed the clarifications received from Indonesia on 10 June 2014. However, the EU remained concerned about certain provisions of the notified Regulation and considered that further explanation was needed with respect to the new mandatory nutrition labelling requirements. The EU recalled that implementing regulations, which Indonesia intended to issue to address product coverage in detail, needed to be notified to the TBT Committee while still in draft form, providing sufficient time for Members to comment on them. The EU was also interested in receiving an update on the guidelines to be developed by the Indonesian Ministry of Health and the National Agency for Drugs and Food, which would regulate other details of the Regulation and which would also need to be notified. The EU reiterated its concerns with respect to the mandatory warning message on salt, sugar and fat content that would have to be included on the label of all processed food products and invited Indonesia to consider whether the objectives of the Regulation could be achieved with less trade-restrictive means. In particular, the way of placing of nutrition information and related health warning, the conduct of risk assessment related to non-communicable diseases, as well as testing methods for nutrition levels, still required Indonesia's clarification. The EU was interested in receiving more detailed information on how the Indonesian authorities were going to address a possibility for accepting test results issued by laboratories other than those accredited by the Indonesian National Accreditation Body (KAN). The EU also reiterated that compliance with the Codex Alimentarius Guidelines on nutrition labelling would require also the amount of saturated fat and sodium or salt to be labelled. Lastly, Finally, the EU deeply regretted Indonesia's confirmation that it will not allow stickers placed after importation of the products, and before their being placed on the market in Indonesia – for instance, in customs warehouses – as means to show compliance with the Regulation. This would have been a sound alternative to labelling in the country of origin that would allow Indonesia to fulfil its legitimate objectives in a non trade restrictive way.

3.138. The representative of <u>Switzerland</u> said that, as various other Members, Switzerland was concerned that the measure deviated from the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev. 1 - 1993) and other recommendations building on that guideline, whereby labelling should not lead consumers to believe that there was an exact quantitative knowledge of what individuals should eat to maintain good health, but rather convey an understanding of the quantity of nutrients contained in the products. He also asked why the conformity assessment procedure required the approval of the label by an authority. Switzerland urged Members to adopt less restrictive measures, which were consistent with international standards, guidelines and recommendations and invited Members to share experiences in this regard.

3.139. The representative of the United States welcomed Indonesia's plans to take into account Members' concerns during the three year transition period and hoped this process would take place effectively. She asked how the trade impacts of this particular approach were evaluated to ensure that it was no more trade restrictive than necessary to achieve Indonesia's public health objectives. She also inquired whether Indonesia had considered using the Codex Nutrient Reference Values for labelling purposes for sodium and saturated fat, which provided another means for consumers to identify foods "low" and "high" in nutrients of concern and the Codex "low" claims, "no added sugars" claims, and other conditions for health claims. In addition, she asked for more information on the research Indonesia had conducted to assess how consumers would receive and understand the information communicated by the mandatory health message. The US also continued to seek clarification of the testing provisions set forth in Article 6 of MOH Regulation 30/2013, which seemed to establish a strict testing procedure that would not allow minimum normal variations between batches and would possibly include unnecessary shipmentby-shipment inspections. Such a high level of oversight was, in the view of the US, unnecessary given the low risk posed to consumers by the inclusion of nutritional information. Random testing and sampling was sufficient for monitoring and enforcement of the accuracy of nutritional declarations. In order to conserve limited regulatory resources, the US suggested that Indonesia consider using existing international tools, such as the nutritional databases maintained by FAO, the International Union of Food Science and Nutrition, and the industry-driven eatright.com, which helped verify the accuracy of nutritional declarations without additional testing.

3.140. The representative of <u>Australia</u> supported Indonesia's implementing measures to help its citizens make informed dietary choices, so as to reduce their risk of developing diet related non communicable diseases. However, the proposed measure could be modified and implemented differently, such that there was no unnecessary impact on trade. For example, Indonesia could consider other less restrictive measures to promote consumer health, which were being considered by other countries, including Australia. As the proposed nutrition declarations needed to be based on tests carried out by accredited labs, Australia asked what methods would be used for the tests verifying the nutrition declarations and whether tests performed by foreign laboratories or in house laboratories of companies would be accepted. Australia also wished to know how these requirements would apply and how the gradual implementation of the Decree would take place, in particular how the risk of the products with respect to non-communicable diseases would be assessed. Moreover, Australia asked where the nutritional information and related health warning needed to be placed on the label and whether Indonesia would allow stickers to be placed after importation, and before being placed on the market in Indonesia.

3.141. The representative of <u>Indonesia</u> underlined that the labelling requirements involved health messages, not health warnings. Further, the regulation did refer to the Codex Standard for Labelling. Indonesia also clarified that it did not intend to prevent or prohibit the public from consuming particular foods. The legitimate objective of the regulation was to increase consumers' awareness on the importance of knowing the amount of sugar, salt and fat in the processed food they consumed and the recommended daily intake. Such awareness was important to control the risk factors that contributed to non-communicable diseases. Indonesia was now preparing technical regulations for the implementation of the Regulation, which would clarify all aspects that were currently not specified in the Regulation, which would be notified to the WTO.

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

3.142. The representative of <u>Mexico</u> expressed concerns relating to the process leading to the registration of pesticides and the re-classification of compounds as endocrine disruptors on the basis of a regulatory focus, which did not seem to be risk-based. Mexico asked for an update on the status of this proposal.

3.143. The representative of the <u>United States</u> reverted to concerns previously raised in 2013 and 2014 in the Committee on DG Environment's proposal. The EU had released its roadmap for the impact assessment on defining criteria for identifying endocrine disruptors in the context of plant protection regulation two days earlier. This document, which outlined the four policy options that would be analysed with respect to the attainment of the EU's health and environmental objectives as well as their economic impact, would be reviewed by the US in light of the concerns articulated in previous meetings. The US reiterated its request for active public participation and transparency, including the opportunity for public comment on draft impact assessments,

proposed regulatory actions and the supporting scientific opinions, which would be taken into account in finalizing any measure.

3.144. The representative of the <u>European Union</u> said that the EU would carry out a comprehensive impact assessment that would analyse different options for defining criteria for the identification of endocrine disruptors and their corresponding health and socio-economic effects once incorporated in different pieces of EU legislation. In this context, the European Commission had published two days earlier a roadmap outlining the impact assessment structure and the options to be assessed and would be organizing a three-month public consultation and comment period. The European Commission would present proposals for introducing criteria to identify endocrine disruptors in different pieces of EU legislation only after the conclusion of the impact assessment.

3.2.3.20 China – China Food and Drug Administration (CFDA) EMC Enforcement Notice for medical devices of 19 December 2012 (IMS ID 387)

3.145. The representative of the <u>European Union</u> said that their concerns on the issue had been addressed under specific trade concern number 4.

3.146. The representative of the United States was concerned with China's plans to restrict electromagnetic compatibility testing (EMC) for medical devices to CFDA approved facilities in China and require retesting of medical devices. The US said that this would significantly increase both cost and time to market for the products at issue and might create unnecessary trade barriers. She noted that China no longer accepted EMC test reports generated outside of China by qualified international laboratories, including IECEE CB scheme laboratories. Referring to Article 9 of the TBT Agreement, she asked why China considered it necessary to mandate domestic testing, given the serious potential impact on trade associated with costs and burdens to foreign producers of duplicate and redundant testing. She inquired whether China had concerns about the quality of CB Scheme test reports and whether China had conveyed these concerns to IEC and planned to participate in the IECEE CB Scheme in a manner that would address those concerns. She also noted the option of CFDA acceptance of test reports from foreign laboratories accredited by signatories of ILAC. Further, the US requested clarity on the IEC standards referenced in these measures as the notifications appeared to reference outdated versions of the relevant IEC standards. Finally, she expressed concern with China's failure to notify these conformity assessment procedures to the Committee and take comments into account, as required by Article 5.6 of the TBT Agreement.

3.147. The representative of <u>China</u> said that YY 2012 0505 Medical Electrical Equipment Part 1 2: General Requirements for Safety, EMC standard Requirements and Test Standards for Medical Devices Industry, was an identical transposition of the IEC international medical electrical equipment electromagnetic compatibility test standard IEC 60601 1 2, which was set to ensure a safe environment for medical devices so as to protect public health. As IEC 60601 1 2 was a recognized international standard used widely by WTO Members, China did not expect the promulgation of YY 2012 0505 to have a significant impact on international trade.

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

3.148. The representative of the <u>United States</u> said that Peru's November 2012 implementing regulation for the moratorium on planting genetically engineered crops needed to be notified to the WTO in accordance with the TBT Agreement, as had already been expressed during previous Committee meetings as well as Peru's November 2013 Trade Policy Review. The Implementing Regulations of the Biotech Moratorium would require the National Agrarian Health Service (SENASA) at the Ministry of Agriculture and Irrigation to conduct conformity assessment procedures (i.e., testing to ensure that there was no presence of genetically engineered materials in the seeds) to confirm compliance with the moratorium. In light of the fact that the measure's conformity assessment procedures were not in accordance with the relevant guides and recommendations issued by international standardizing bodies, and given that it might have a significant impact on the trade of WTO Members, she asked why the measure had not been notified. She also asked Peru, in case it had considered that the measure was in accordance with guidelines and recommendations issued by international standardizing bodies, to identify them.

She said that, in addition to the unclear, potentially trade disrupting conformity assessment procedures, the implementing regulations included penalty provisions that were overly restrictive. The US disagreed with Peru's assertion that the moratorium was not a technical regulation and considered it to be a measure designed to protect the environment. The US also disagreed with Peru's position that such notification was not necessary due to an exception under Article XX of the GATT as this provision did not relieve Members of their notification obligations under the TBT Agreement.

3.149. The representative of <u>Peru</u>, referring to their inputs already provided during earlier Committee meetings, reiterated the view that the Moratorium on Planting Genetically Engineered Crops did not need to be notified to the TBT Committee as it was not a TBT matter, but rather an environmental matter related to biodiversity.

3.2.3.22 Ecuador – Resolution No. SENAE-DGN-2013-0300-RE relating to post entry control of imported alcoholic beverages (IMS ID 394)

3.150. The representative of Canada said that on 9 August 9 2013, Ecuador had approved a new customs regulation on spirits imports covering whisky, vodka, tequila and rum, which had been published in Ecuador's Official Registry No. 86 on 23 September 2014 and, as Canada understood, had entered into force 30 days thereafter. Canada was concerned that the regulation might be in violation of Articles 2.1 and 2.2 of the TBT Agreement since it applied only to imports and because its Article 4 stipulated that liquor that was not properly labelled at its origin could be returned to the country of export. However, standard practice in the internationally traded spirits industry was to apply, in the country of production, generic front labels providing mandatory information and to affix, in the import market, various other market-specific information on the back or secondary label. In this respect, Canada was concerned that Ecuador's requirements to label at the point of origin might be more trade restrictive than necessary to fulfil a legitimate objective and thus not in compliance with Article 2.2 of the TBT Agreement. In addition, Canada was concerned that transition period provided did not comply with article 2.12 of the TBT Agreement. According to the information received, the came into force after its publication on 23 September 2013. The resolution did provide for a transitional provision, but with a deadline of only four months from its publication, after which no imported alcoholic beverages could be sold in the Ecuadorian territory without the new required labelling.

3.151. The representative of the <u>United States</u> associate herself with the concerns expressed by Canada and referred Members to the US intervention under specific trade concern number 11.

3.152. The representative of <u>Ecuador</u> said that the resolution was a customs measure implemented by the National Custom Service of Ecuador (SENAE) with the aim of reducing the illegal entry of alcoholic beverages into the country, in light of the high rates of contraband in these products. Ecuador was of the view that the TBT Committee was not the right forum to address this issue. Nevertheless, the customs authority of Ecuador had been revising the measure with the aim of looking at other mechanisms that would achieve the same objectives without affecting trade flows.

3.2.3.23 China – China Food and Drug Administration (CFDA) Notice 191 of 16 December 2013 – Free Sales Certificate for Imported Cosmetics (IMS ID 415)

3.153. The representative of <u>Canada</u> noted that, as previously expressed by Canada and other WTO Members, China's new interpretation regarding "Free Sale Certificates" (FSC) required that licensing applications submitted to Chinese evaluation centres for imports of cosmetic products prove that the products had been sold or manufactured in the country of origin. This requirement was contrary to China's previously accepted interpretation where the certificate of free sale only had to state that a cosmetic product was permitted to be sold in the country of origin. Canada was concerned that Chinese manufacturers were exempt from premarket registration, which could result in a more accessible and preferential market access for domestic manufacturers, as this additional demand caused significant delays to the launch of new products and increased costs for importers. The discriminatory treatment also had a negative impact on Chinese consumers and reduced their timely access to innovative and safer cosmetics products. He asked China to explain the necessity for requiring FSC from importers but not from its own manufacturers.

- 41 -

3.154. The representative of the European Union recalled its previous interventions that these new FSC requirements were problematic, in particular with respect to certain cosmetic products that were designed and produced to satisfy Chinese consumer needs and were therefore not necessarily placed and marketed in the origin market, even though they respected the highest safety standards. A FSC attesting sale in the country of origin was therefore not available in such cases. For other products that were innovative and to be soon marketed in the country of origin, requiring a FSC to initiate registration in China would delay entry of the product in the Chinese market. In a fast developing market, it was of crucial importance that cosmetics manufacturers could start approval procedures in different markets, in parallel, as soon as possible and without having to wait for the approval in the country of origin. The EU asked if China had considered alternatives to the FSC for these particular cases and if it considered that its FSC requirement would be in line with the provisions of the TBT Agreement regarding conformity assessment procedures. A practical short term solution would be for the CFDA to accept submission of the marketing statement at a later stage in the evaluation process. In the longer term, the EU asked China to suspend the implementation of Notice 191 and reconsider the need to provide FSC for cosmetics. The EU considered that the Chinese cosmetics legislation seemed to be developed enough, with rigorous procedures that provided adequate consumer protection levels without having to rely on foreign approvals. Finally, the EU welcomed China's efforts to provide advice to companies, which had helped them find practical solutions and the bilateral dialogue between CFDA and DG SANCO on the matter.

3.155. The representative of the United States said that China had sent a Notice to evaluation centres to require, in licensing applications for imported cosmetics, that a certificate be submitted to prove that the product had been sold in the Country of Origin (COO) or country of manufacture. This had resulted in a sudden re interpretation of Chinese regulatory requirements, which had long accepted CFS statements that the product was "permitted to be sold" in the COO. The US strongly disagreed with the China's assertion that the measure had little influence on international trade and questioned how this re interpretation enhanced safety to Chinese consumers. CFS had never been intended to be, or presented as, a proof of marketing of the product in the country of origin and China had always and consistently accepted foreign CFS on this basis. The US also disagreed with China's claim that this action prevented Chinese consumers from being used as test cases for ingredients not used elsewhere. Cosmetics products manufactured in the US needed to comply with all relevant US safety and other regulations, and then undergo extensive mandatory testing and assessment programs by Chinese authorities. These requirements were far more strict and burdensome than regulations applied to Chinese domestic products (in the case of "non special use" products). The US requested an immediate suspension of this new interpretation for at least six months and asked how China planned to take comments submitted by the US industry into account. The US also asked China to notify this change to the WTO Secretariat so as to allow for Members to provide written comments and take those comments into account, in accordance with TBT obligations and the Committee's decisions and recommendations. She noted that the immediate implementation of this re interpretation, with no prior notice, had already greatly impacted US companies as many hundreds of applications had been rejected by CFDA.

3.156. The representative of <u>China</u> said that Notice 191 was only a reiteration of Articles 3 and 4 of Provisions for the Administration of Cosmetics Application Acceptance (G/TBT/N/CHN/821). CFDA had already approved a large number of denied applications after submission of the required documents within a 90 day period. As of the release of Notice 191 until 16 April 2014, CFDA had approved 2,914 imported cosmetics applications, which was higher than the average number for the same period over the past four years.

3.2.3.24 Ecuador – Ministry of Public Health Executive Decree (Agreement) No. 00004522 amending the Sanitary Regulations for the Labelling of Processed Foods for Human Consumption (IMS ID 416)

3.157. The representative of <u>Canada</u> indicated that while Canada supported Ecuador's objective of reducing the risk of non-communicable diseases, it was concerned that the regulatory proposals might have a significant impact on trade and be more trade restrictive than necessary. In addition, in accordance with Article 2.9 of the TBT Agreement, Canada strongly recommended that Ecuador notify the measure, along with a copy of the full text of the proposed regulation, to the WTO and allow for a comment period. Furthermore, she asked whether the measure had already entered into force, possibly on 29 May 2014, as some reports indicated. If so, Canada was concerned that Ecuador had not provided trading partners the appropriate transition period prior to the entry into

force of the measure, as required by the TBT Agreement. She invited Ecuador to provide an update on how Members' concerns were being taken into account in any amendments to this regulation.

3.158. The representative of the <u>United States</u> associated herself with the concerns expressed by Canada on this issue and referred Members to the US intervention under specific trade concern number 14 (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.)

3.159. The representative of Ecuador explained that the Decree's objective was to better regulate the labelling of processed foods for human consumption in order to guarantee the constitutional right of citizens to appropriate, clear, precise and non-misleading information about the contents of these foods, thus allowing them to make right decisions when purchasing and consuming such products. The Decree amended technical regulation RTE INEN 22 on labelling of processed and packages food products, which had been notified as G/TBT/N/ECU/19/Add.1 on 29 April 2010. The amendment introduced a graphical system, which described "high", "medium" or "low" content with regard to the following three ingredients: salt, sugar and fat. This graphic system was designed on a per 100mg/100ml measurement basis. The reason why the amendment did not use measures in terms of "portions" was to avoid be consistent with the objective of giving consumers clear information about what they were consuming, in particular in the case of "snacks", "soft drinks", and "sweets" containing high levels of the three ingredients listed above, and which might cause harmful health effects. Ecuador explained that using "portions" to express nutritional content would require providing such information in terms of proportion. This, could, in turn, confuse consumers and lead them to believe that it would not be problematic to eat many small portions given that, individually, each portion had low levels of salt, sugar or fat. He also informed that the amendment included requirements with respect to the declaration of transgenic content and non-caloric colorants. Transgenic labelling would be required, in accordance to the parameters found in INEN 334/1, if transgenic content corresponded to at least 0.9% of the product's overall ingredients. Without prejudice of further revisions and amendments, Ecuador informed that the measure was expected to enter into force in August 2014.

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

3.160. The representative of Canada remained concerned that the Decree may create unnecessary obstacles to international trade, contrary to France's WTO obligations, and may not achieve its environmental objective. She requested the EU to clarify the exact meaning of the TRIMAN mark as the written response from the EU was that: "the TRIMAN logo pursues a different objective than ... the 'green dot'... [which] means that the person who puts ... products on the market for household use has contributed to the costs of recovery and recycling." Canada had understood the TRIMAN mark to signal that the product was subject to extended producer responsibility, and was therefore duplicative of the intention of the "green dot". She suggested that the TRIMAN mark, even if intended to guide the consumer to recycling practices, may not serve any purpose beyond that conveyed by the internationally recognized "Mobius" recycling mark. Canada was of the view that the TRIMAN mark may be an indicator that the packaging was recyclable, but conveyed no further detail to help the consumer on how or where to recycle. Citing Articles 2.2 and 2.4 of the TBT Agreement, Canada requested the EU to clarify why the TRIMAN mark was needed when an internationally recognized symbol would serve the same purpose. Furthermore, it was unclear how France could, in accordance with its most favoured nation obligations under Article 2.1 of the TBT Agreement, extend an exemption to other EU member states in the application of the TRIMAN mark where alternative marks existed, and not to other WTO Members.

3.161. The representative of the <u>United States</u> reiterated concerns previously raised concerning this proposed measure and asked if France had considered whether the cost to implementing it would be disproportionately high as compared to the stated policy objectives of simplifying waste sorting activities and increasing the recycling rate. The US also asked how requiring most products be labelled solely for the French market would be compatible with Articles 34 and 36 of the Treaty on the Functioning of the European Union Treaty. The US was of the view that this proposed

measure would effectively block free movement of trade within the EU for products that were legally labelled and traded within the rest of the single market. The US was particularly concerned with the lack of a harmonized approach to sorting waste in France with some regions and municipalities more advanced than others. In the least advanced regions, she said, where there was no provision of different waste bins to sort household waste, the relevance of giving sorting instructions to the consumer without a specific consumer education programme was questionable. France was therefore urged to consult with producers and manufacturers from other countries for alternative options that would be less costly and increase recycling rates. She asked if there were any consumer education programmes in place or planned for the future as France could achieve the same policy objective by developing a consumer education programme with a systemic long-term impact on recycling habits without negatively impacting trade.

3.162. She also said that, while the US was pleased that "glass" was specifically exempted from the scope of the proposal in the law published on 3 January 2014, it understood that other packaging, including outer packaging and aluminium and plastic closures, would still be subject to the recycling logo requirement. From a practical standpoint, the US was unclear on how companies would be able to comply with some of these requirements. She asked whether the logo would be required to be included on the product label, indicating that it was referring to the closure, if it was not possible for the logo to be on the packaging and how this information would be made clear to the consumer. It was also unclear at what point in the supply chain the labels could be affixed: in the country of origin or in a bonded warehouse. The US also asked for clarification on where the logo was required to be placed and how large the logo was required to be. Given the potential disruption to international trade, the US encouraged France to allow further comment and consideration of the proposal taking specific account of the concerns relayed by trading partners and the difficulties and costs this measure would add to products being exported to France. The US was concerned with the proposed requirements' compliance with the obligations under Article 2.2 of the TBT Agreement, as it would likely create an unnecessary obstacle to international trade and be stricter than necessary to meet the objective pursued.

3.163. The representative of <u>Mexico</u> stressed her country's interest in this issue and in the replies to be submitted by the EU.

3.164. The representative of the <u>European Union</u> said that detailed explanations of the French draft decree had already been provided at the TBT Committee meeting in March 2014 (G/TBT/M/62). The EU stated that the legislation was still at a draft stage and that there had been certain changes in the draft aimed at simplifying the obligations in the measure. For instance, in the case of tyres and furniture, the TRIMAN logo may be affixed on the packaging of the product or on the accompanying document of the product and not on the product directly. The exemption for glass packaging was also maintained.

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

3.165. The representative of the European Union recalled that amendments to this technical regulation were still under development and no precise date was provided for the adoption and implementation of the notified draft. The EU was still concerned with the ban introduced by the draft technical regulation of "artificial or synthetic leather". The EU stated that the concept of "artificial or synthetic leather" did not exist because leather was defined as "a product of animal origin" by the International Council of Tanners. The EU was of the view that a lack of clear understanding of materials defined as "artificial or synthetic leather" could lead to potential misinterpretations. Regarding the absorption requirement for certain first layer articles for sporting purposes, the EU reiterated that properties of synthetic fibres allowed these articles to keep the body dry, and hygroscopicity testing should not be required. The EU also considered the wide range of labelling and marking requirements in the technical regulation to be excessive when compared to the information needed to be provided to the consumer. In this respect, the EU invited Russia to consider limiting mandatory labelling requirements to only absolutely essential elements, such as the composition of the product, with other information left to the discretion of the producer or distributor. Concerning conformity assessment procedures, the EU recalled that the technical regulation allowed for compliance to be demonstrated through certificates of conformity or declarations of conformity, depending on the product. The EU considered textile, clothing, leather and footwear to be low risk products. It would therefore follow that compulsory third party conformity certification would, in this case, create unnecessary barriers to trade in the

form of additional burdensome and onerous requirements. The EU suggested that, instead, a selfdeclaration by the manufacturer be deemed sufficient proof that these products were safe. The EU sought clarification on which standards were being referred to in the technical regulations and if GOST standards would continue to apply. Finally, the EU again stressed that its concerns related to technical requirements and conformity assessment procedures were the same with regard to the Customs Union's technical regulation on "safety of light industry products", notified as G/TBT/N/RUS/31 on the same day as G/TBT/N/RUS/29.

3.166. The representative of <u>Norway</u> associated herself with the statement and concerns raised by the EU and looked forward to updates and written replies from Russia.

3.167. The representative of <u>Ukraine</u> said that, like previous delegations, Ukraine also considered that because textile, clothing, leather and footwear were low-risk products, the conformity assessment procedures established under the Russian measure were too time-consuming and costly for producers and, consequently, constituted unnecessary barriers to trade. He also said that the global practice was to ensure safety of input materials rather than imposing mandatory conformity assessment procedures through compulsory third party certification. He said that the stated objective of the regulation, such as safety and consumer protection, would hardly be achieved through such compulsory requirements. He added that both of these technical regulations included certain sanitary requirements to footwear which were the same as that in the mandatory Customs Union common sanitary, epidemiological and hygienic requirements to products of 28 May 2010. Given the forgoing, he asked Russia to clarify the need for these requirements. Ukraine also expressed concern with the wide range of labelling and marking requirements included in Article 9 of the technical regulation on the safety of products for children and adolescents. Ukraine considered this requirement to also be more trade restrictive than necessary to fulfil the objective of consumer protection.

3.168. The representative of the Russian Federation welcomed the comments of the EU, Norway and Ukraine on the amendments to the Customs Union technical regulation on the safety of products for children and adolescents. Concerning the timelines, he said that the technical regulation entered into force in 2012 with a transition period for economic operators that expired in 2014. In practice, implementation of the technical regulation had revealed the need for liberalization of certain requirements applied under the measure. Amendments to the technical regulation were developed and notified as G/TBT/N/RUS/29. Public hearings on amendments to the technical regulation started in December 2013 and, based on requests from WTO Members, were extended until April 2014. Comments from interested parties had been received and were being considered in the draft amendments currently under development. He added that procedures for the introduction of amendments to technical regulations were similar to those for the introduction of the regulation itself. He stated that the amendments were at the stage of internal coordination and would probably be adopted no earlier than September 2014 and would enter into force around March 2015. He cautioned, however, that this was only an estimate and clarified that the existing technical regulation would continue to be applied before the amendments entered into force.

3.169. On the substance of the measure, he clarified that it only applied to products used by children and adolescents and that products used by adults were less stringently regulated by another technical regulation on the safety of light industry products. Russia was of the view that more stringent requirements for products used by children were necessary for attaining the legitimate objective of ensuring their safety and health. It also served as scientific justification for corresponding stricter conformity assessment procedures. Russia also explained that a number of international standards were included in the list of standards attached to the technical regulation and that compliance with these standards, such as ISO standards, was equal to compliance with the technical regulation. Russia clarified that there was no ban on "artificial leather". Instead, Annexes 14 and 15 to the technical regulation simply established some additional requirements for "polymer based" or "artificial leather". More strict requirements had also been established in the technical regulation for "first layer articles" that had contact with skin. For other goods, in the "second" or "third layer", the requirements were not as strict. He said that labelling requirements were mandatory and were established by the technical regulation for consumer protection. According to paragraph 1 of Article 9 of the technical regulation, a manufacturer could choose to meet the labelling requirements in different ways: by placing the label on the product itself, or by attaching the label to the package of the product or group of products, or by inserting a card to the product. He also said that the mandatory sign of distribution marking in the markets of the member states of the Customs Union represented compliance with the requirements of the Customs Union technical regulation.

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

3.170. The representative of Canada stated that as of May 2014, India's Food Safety and Standards Authority (FSSAI) had apparently banned the marketing and labelling of canola oil. The High Commission of Canada to India had been notified that the product be labelled and marketed as: "imported refined rapeseed oil - low erucic acid" and canola oil as an additional trade name could be used. Previously, canola oil products had been labelled as canola oil and "ingredients: imported refined canola oil" and had entered India for several years without incident. She said that India's seemingly irrevocable decision to impose new labelling requirements to shipments directly and immediately affected export, marketing and sale of canola oil in India. In Canada's view, India was in violation of the TBT Agreement for having failed to notify to the WTO the changes to its labelling regulation and because this regulation was more trade restrictive than necessary to achieve a legitimate objective. Canada also expressed concern that the labelling requirements for canola oil contained in India's Food Products Standard and Food Additives Regulation 2011 did not conform to the relevant international guidelines recommended by the Codex Alimentarius Commission, as Codex standards deemed canola oil and low erucic acid rapeseed as synonyms. India's labelling requirements appeared to discriminate against the legitimate term canola oil. Since India's regulation differed from this relevant international standard from the Codex, Canada was of the view that India's regulation also violated Article 2.4 of the TBT Agreement. She noted that the FSSAI was not allowing suppliers to comply with the new labelling requirements by way of temporary use of stickers as an alternative solution and importers were required to re-export the shipments in bond with no exception.

3.171. The representative of <u>India</u> said that Canola oil was an edible vegetable oil produced from rapeseed bearing low erucic acid. Canola oil had been imported to India for several years, mostly from Canada. For India, canola oil was nothing but a given trade name. Consistent with the way this product was listed in the Codex standard, the appropriate marking for imports into India was "imported rape rapeseed low erucic-acid oil (canola oil)" or "imported refined rapeseed low erucic acid (canola oil)". The objective of this marking was to ensure that consumers could make an informed choice. This was only a simple change of product declaration on the labels. Instead of writing only the trade name, suppliers were now required to declare the actual ingredient on the product label for the purpose of informing consumers. In India's view, this would not be characterized as a measure more trade restrictive than necessary. Since this was an old regulation, dating back to 2011, India urged Canada to start following it as any previous non-adherence to the regulation did not imply that such situation could continue in the future.

3.2.3.28 Egypt – Bottled water (IMS ID 421)

3.172. The representative of Turkey said that Turkish bottled water exporters were unable to obtain import permission from Eqypt's Supreme Committee for Water in the Ministry of Health for the following reasons: (i) bottled water could not be imported into Egypt as periodic control of its source could not be maintained based on Egyptian Standard No. 2007/1589; and (ii) bottled water could only be imported from producers based in EU member states that had applied the HACCP system. He recalled that although in June 2013 Egypt had explained that the mandatory Egyptian food product standards were being revised in accordance with "Codex Standard 227-2001" and "WHO Guidelines for Drinking Water Quality, 2011", no further explanations had been provided thereafter. Exporters were still unclear about certain aspects of the measure. For example, if any conformity assessment procedures existed for the export of bottled water to Egypt, such as the steps to be taken for the control of water at its source, they should be published and notified to the Committee, consistent with Article 5.6 of the TBT Agreement. Turkey was also of the view that this current Egyptian practice was contrary to the principle of non-discrimination and also constituted an unnecessary obstacle to international trade, contrary to Articles 2.1 and 2.2 of the TBT Agreement. He invited Egypt to cooperate with Turkey on this matter and bring its legislation and implementation into compliance with TBT Agreement rules.

3.173. The representative of <u>Egypt</u> said that imports of bottled water were subject to the Egyptian Standard No. 1589/2007, mandated by the Ministerial Decree No. 130/2005, which was notified to the TBT Committee as G/TBT/N/EGY/1. She said that this standard was publicly available at the Egyptian Organization for Standardization and at their website (<u>http://www.eos.org.eg</u>). Egypt

applied this decree equally to domestic bottled water companies. Her delegation stated that the Egyptian standard was in conformity with the relevant CODEX standards and WHO guidelines. Therefore, it was fully compliant with Article 2.1 of the TBT Agreement. Furthermore, she said that compliance with this Egyptian standard was not more trade restrictive than necessary as the measure was necessary for consumer health, safety and protection. Finally, Egypt confirmed that the requirement that bottled water may only be imported from EU producers applying the HACCP system had been removed.

3.2.3.29 Italy - Testing requirement on import of steel cutlery products (IMS ID 395)

3.174. The representative of <u>India</u> noted that Italy did not allow utensils and cutlery made of grade 200 stainless-steel and only accepted items made of grade 202 and 304 stainless steel. India stated that grade 200 stainless-steel contained 13% chromium and was considered food safe. Moreover, other EU member states, such as France, Germany and the UK, allowed the import of utensils and cutlery made of grade 200 stainless steel. He added that the stainless steel grades from India had passed three tests (N1, N2 and N3) prescribed by the Bureau of Indian Standards but these tests were not acceptable in Italy. The testing method in Italy was rigorous. It required a serving tong be kept in acid for more than four days to determine its food-safeness. India considered this testing method to be inappropriate and more trade restrictive than necessary to fulfil its objective given that serving tongs held food for only a short time. These requirements had created an unnecessary obstacle goods exported from India. He therefore requested to be provided with the scientific justification for maintaining such technical requirements. India was also concerned by the lack of harmonization among the EU member states in this matter.

3.175. The representative of the European Union stated that this requirement was not harmonised at the EU level and therefore the EU member states could maintain or adopt national rules in accordance with Article 6 of Regulation No. 1935/2004 of the European Parliament and Council on materials and articles intended to come into contact with food.. He added that the Italian Decree of 21 March 1973, as amended, set up a "positive list" of components (plastics, rubber, cellulose regenerated paper and cardboard, glass and stainless steel) that could be used in the manufacture of packaging, containers, utensils that came into contact with foodstuff or in substances for personal use. The import of grade 200 stainless steel was not allowed in Italy because it was not included in the authorised list of this Italian legislation. The EU said that, at the request of stakeholders, the lists could be updated with new substances or materials after an evaluation by the National Health Institute of Italy and an opinion of the High Council of Health of Italy. The documentation to be submitted with an application for inclusion in the list was also defined in the Italian legislation. Migration tests had to be conducted on the steel that was the subject of an application, and the tests had to be performed by laboratories operating to the standard EN ISO/IEC 17025 ("General requirements for the competence of testing and calibration laboratories"). The steel designation name had to be specified in accordance with internationally recognised rules, such as the standard UNI EN 10088 1:2005. If the steel could not be matched with these rules, a statement with the complete casting chemical analysis to identify the stainless steel concerned had to be provided. In reply to the Indian authorities stating that grade 200 stainless steel was not allowed in the Italian market in spite of meeting the Italian requirement of 13% chromium and being food safe, he said that this had to be underlined in the request by the applicant for the inclusion of grade 200 stainless steel in the "positive list". He added that the stainless steel also had to comply with the overall and specific migration limits established in the Italian Decree of 21 March 1973 for chromium, nickel and manganese.

3.2.3.30 India – Drugs and Cosmetics Rules 2007 (G/TBT/N/IND/33) (IMS ID 167)

3.176. The representative of the <u>European Union</u> recalled that the India's Drugs and Cosmetic Rules were published in the Gazette of India in May 2010 and its implementation, initially scheduled to take place as from April 2011, was deferred to March 2013. On 2 January 2013, the Indian Government had issued Guidelines on the Registration of Imported Cosmetics. These Guidelines had established that the label of imported cosmetics had to bear the registration certificate number of the brand and the name and address of the registration certificate holder. The EU welcomed the fact that these same Guidelines established that the "stickering of labels containing the registration certificate number of the brand and the brand and the name and address of the registration certificate holder may be allowed to be carried out after import at a suitable place approved by the licensing authority". However, the EU requested India to confirm whether providing information via stickers at customs-bonded warehouses to all aspects of cosmetics

labelling, including the listing of cosmetic ingredients or any other information for the consumer, was also allowed. He said that allowing information to be provided after import in customs-bonded warehouses was an important trade facilitating measure that did not jeopardise India's legitimate health and safety objectives. This was relevant for manufacturers that exported in small quantities and found it difficult to adapt the labels to different geographical region requirements. The EU hoped that India could take this suggestion into account and amend the January 2013 Guidelines on the Registration of Imported Cosmetics.

3.177. The representative of <u>India</u> said that the Drug and Cosmetics (Amendment) Rules 2007 for the import and registration of cosmetics were finalized vide GSR No. 426(E), dated 19 May 2010. As per this notification, registration of cosmetics was to be made effective as from 1 April 2011. Subsequently, via GSR 733(E), dated 29 September 2012, the Rules for import and registration of cosmetics were implemented with effect as from 1 April 2013. He informed that, to date, about 400 registration certificates and 190 product endorsements had been issued. There were no major issues reported regarding the registration procedure for the import of cosmetics. His delegation, however, had noted the concerns and suggestions of the EU regarding the labelling requirement. These would be forwarded to the concerned capital-based authorities and their response would be communicated to the EU in due course.

3.2.3.31 Ireland – Proposal to introduce standardised/plain packaging of tobacco products in Ireland (G/TBT/N/IRL/1)

3.178. The representative of <u>Nicaragua</u> noted that, as indicated in a study undertaken over three decades by the Institute for Health Metrics and Evaluation at the University of Washington, evidence showed such kind of measures did not succeed in getting people to give up smoking. Nicaragua also considered that it would be premature to implement such a tobacco packaging measure while the TBT and TRIPS consistency of a similar measure by Australia was currently been challenged before the DSB by four Members, with forty Members acting as third parties to the dispute. Nicaragua therefore encouraged Ireland to abstain from adopting the measure until the report of this panel was finalized. He stressed that plain packaging measures would have a negative effect on the Nicaraguan economy, which largely depended on the production and export of tobacco products, with 35,000 direct employees and many more that indirectly benefited from the tobacco industry, including in the tourist industry. While Nicaragua shared the objective of protecting human health by using effective tobacco control measures, it opposed the attainment of such objectives by regulations that were more trade restrictive than necessary and which would be inconsistent with international law.

3.179. The representative of the <u>Dominican Republic</u> supported the statement made by Nicaragua and also urged Ireland to suspend the application the measure until the DSB had ruled on the case against Australia.

3.180. The representative of <u>Guatemala</u> supported the statements made by Nicaragua and the Dominican Republic. She encouraged Ireland to consider less trade-restrictive measures while allowing for the achievement of its legitimate objective.

3.181. The representative of <u>Australia</u> reiterated his delegation's strong support for the decision by the Irish Government to legislate for mandatory plain packaging of tobacco products and welcomed the recent decision by the Irish cabinet to approve draft legislation which would require tobacco products sold in Ireland to be plain packaged and carry graphic health warnings. Australia, he said, 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 the fundamental objective of the protection of human health. This approach was endorsed by leading health experts as well as the WHO and supported by extensive peer review and research. Concerning the Australian measures that were currently before the DSB, he said that his country was vigorously defending its measure within the mechanisms of the WTO. It was therefore inappropriate for the complainants in ongoing WTO disputes, including this one against Australia, to invoke those proceedings as an attempt to delay or discourage other Members from developing or implementing their own legitimate tobacco-control measures, particularly when a number of those Members had delayed the prosecution of those very dispute settlement proceedings. 3.182. The representative of <u>Cuba</u> associated herself with the statements made by Nicaragua, Dominican Republic and Guatemala and reiterated Cuba's concern with the fact that this measure was being implemented while the Australian measure was being challenged before the DSU. The statement delivered by the representative of Cuba is contained in full in G/TBT/W/391.

3.183. The representative of <u>Honduras</u> associated himself with the statement made by Nicaragua and called Members' attention to the five disputes against the Australian tobacco plain packaging measure, the decisions of which would help to give an answer to this matter.

3.184. The representative of <u>Norway</u> commended Ireland on its measures to combat the tobacco epidemic, and said that it was well within the right of WTO Members to adopt measures necessary to protect public health insofar as they were consistent with the WTO Agreements. Norway recalled that plain packaging of tobacco products was the recommended measure under the Framework Convention on Tobacco Control (FCTC). It was the opinion of Norway that the FCTC and the relevant WTO Agreements were mutually supportive, and that it was possible to introduce measures for the regulation of tobacco products in line with both sets of obligations.

3.185. The representative of <u>New Zealand</u> supported Ireland's decision to commence the process of introducing a plain packaging regime for all tobacco products. There was an extensive and growing body of international research that established that plain packaging, as part of a comprehensive tobacco control programme, would contribute to the objective of improving public health. The WTO Agreements did not prevent Members from taking legitimate action to protect the health of their citizens. WTO rules, including those in the TBT Agreement, included appropriate flexibilities to enable WTO Members to regulate for health and other public policy purposes. New Zealand was therefore confident that Members would be able to introduce plain packaging regimes in a manner consistent with their obligations both under the WTO Agreements and the commitments undertaken under the WHO FCTC.

3.186. The representative of <u>Zimbabwe</u> associated his delegation with the concerns expressed by Nicaragua, Cuba, Dominican Republic, Guatemala and Honduras. While Zimbabwe appreciated the efforts made by Ireland to protect public health, the proposal appeared to be inconsistent with Article 2.2 of the TBT Agreement as this technical regulation would be more trade restrictive than necessary to fulfil its stated legitimate objective. Furthermore, the measure would impact negatively on employment, economic performance and poverty alleviation efforts in Zimbabwe, where tobacco farming was the major economic activity and source of livelihood for many farmers. Tobacco contributed significantly to Zimbabwe's GDP and was a major export.

3.187. The representative of <u>Chinese Taipei</u> said that his delegation shared Ireland's objective with regard to public health and the fight against tobacco. Chinese Taipei followed with great interest the ongoing Australian plain packaging case in the DSB, and believed that the rules of the WTO, including those under the TBT Agreement, were drafted to balance the interest in liberalization of world trade, in one hand, with the right of each Member to pursue public health policy objectives, on the other.

3.188. The representative of <u>Uruguay</u> was of the view that the Irish plain packaging measure was compatible with WTO rules. In implementing such a measure, Ireland would be merely exercising its sovereign right to protect public health by giving effect to the obligations it had undertaken as a party to the WHO FCTC, in particular its Article 11 and relevant implementing guidelines. His delegation supported the statement made by Australia that ongoing DSB cases should not have any bearing on Members adopting measures in favour of public health.

3.189. The representative of <u>Ukraine</u> associated her delegation with the statements made by Members concerned with the measure's consistency with the TBT and TRIPS Agreements. Ukraine considered that this measure was more trade restrictive than necessary to fulfil the stated objective and could, in fact, have the contrary effect of stimulating illicit trade and therefore raising even more health and economic problems. Ukraine also believed that it would be prudent for Ireland to await the outcome of the disputes lodged against the Australian plain packaging legislation before enacting its own similar legislation. Ukraine stressed that Ireland should consider policy options to influence human behaviour that strike a balance between trade and health so that they complement each other.

3.190. The representative of <u>Canada</u> stated that Canada continued to follow with interest ongoing international developments in the regulation of tobacco products and how such measures interacted with both international trade and public health. Canada noted that it had been a pioneer in plain package labelling requirements for tobacco products, and it considered such requirements to be a core component of the right to regulate in the interest of the Canadian public. Tobacco use continued to be a significant problem around the world. This suggested that Members should consider the complete economic picture regarding tobacco control, including whether tobacco was a net economic drain for many countries.

3.191. The representative of <u>Indonesia</u> asked Ireland to defer any final decision on the implementation this measure until the Australian dispute brought by five WTO Members, including Indonesia, had reached its conclusion.

3.192. The representative of the European Union thanked delegations for their detailed comments on Ireland's Public Health (Standardised Packaging of Tobacco) Bill 2014. Tobacco products, he said, were not ordinary commodities given the harmful effects they had on human health. Health protection policies should therefore be given high importance, in particular, those aiming at reducing smoking prevalence among young people. The EU considered, in line with recommendations of the World Health Organization (WHO) that a high level of health protection should be taken as a base for legislative proposals in this area. In this respect, he recalled that Article 2.2 of the TBT Agreement included the protection of human health as a legitimate objective and that any measure pursuant to such legitimate objective must not be more trade-restrictive than necessary or create unnecessary obstacles to international trade. Further, Article XX(b) of the GATT 1994, emphasised the importance of public health by justifying measures "necessary to protect human... health". He informed that the Irish Government had approved the text of the Public Health (Standardised Packaging of Tobacco) Bill 2014 on 10 June 2014, which, in line with WTO obligations, had been immediately notified as a draft measure to the WTO, allowing 90 days for comments. In parallel, Ireland had also notified the European Commission in accordance with internal EU requirements for EU member states. He also noted that, in Ireland, reducing the use of tobacco products had been a public health policy priority for many years, as over 5,000 people died from tobacco related diseases in Ireland annually. This Bill followed a range of measures already adopted in Ireland that aimed at reducing the consumption of tobacco products. A core objective of this Bill was to reduce the attractiveness of tobacco products especially among young people. The Bill was also designed to meet other commitments arising from the EU's recent Tobacco Products Directive. He said both the EU and Ireland looked forward to considering the views of other WTO Members concerning any legitimate trade-related issues or any unintended consequences arising from this public health initiative. In line with Ireland's EU and WTO commitments, the timeline for the legislative process would provide the appropriate opportunity for comment by interested parties.

3.3 Exchange of Experiences

3.3.1 Transparency (Thematic session of 17 June 2014).

3.193. The <u>Chairman</u> presented his report on the thematic session on transparency held on 17 June 2014. In concluding his report, he noted that the presentations had been very informative and helpful in sharing ideas and good practices; they had also showed the challenges involved in implementing the TBT Agreement's transparency provisions. The comments and questions made during the discussion had helped the Committee dig deeper. He encouraged delegations to reflect further on effective means of implementing and benefitting from the transparency obligations of the TBT Agreement. He said that he had found the discussion on regional coordination on transparency particularly interesting; this was perhaps a topic the Committee could consider during the upcoming triennial review in 2015. He also noted that, while not a new issue, different forms of "Alert" systems were growing and becoming more advanced as the examples provided by Kenya and the United States had shown. He drew the Committee's attention to a suggestion from Canada that the WTO could look into developing a centralized alert system for TBT notifications. Finally, the Chairman encouraged Members to continue making use of the on line TBT NSS. The Chairman's full report, including a brief summary of each presentation, circulated in document G/TBT/GEN/167.

3.3.2 The Coherent Use of Notification Formats (G/TBT/35)

3.194. The <u>Chairman</u> recalled that the European Union had circulated a paper in June 2014 entitled "A Coherent Approach to Notification Formats" (JOB/TBT/48) and that a substantial amount of work had been undertaken since then. The Committee had also heard from the SPS Secretariat on related working practices; there had been a number of informal discussions; and, several delegations had tabled written comments. The latest revision of the Committee's draft recommendation was contained in document JOB/TBT/68/Rev.2, circulated on 14 June 2014.

3.195. The representatives of Japan and the <u>United States</u> expressed support, and made some textual suggestions, to the document. Japan, supported by Chinese Taipei, suggested changing the word "full" to "draft" in the first line of the first box (New Notification), while the US suggested some clarifying wording in the box on "Revisions". The representatives of <u>South Africa</u>, <u>Chinese Taipei</u> and the <u>European Union</u> also expressed support to the document. South Africa stressed the importance of tracking the life cycle of TBT measures, while Chinese Taipei and the EU noted, respectively, the balance achieved in this document and that a general level of support appeared to have been reached.

3.196. The <u>Chairman</u> proposed that the Committee adopt the text with the minor modification suggested by Japan.

3.197. The <u>Committee</u> adopted the recommendation as contained in G/TBT/35.

3.3.3 Good Regulatory Practice

3.198. The <u>Chairman</u> gave the floor to the former Chairman of the TBT Committee, Mr. Jingo Kikukawa (Japan) to report on his consultations held during the week aimed at finalizing the work of the Committee on its "Non-Exhaustive List of Voluntary Mechanisms and Related Principles of Good Regulatory Practice (GRP)". The report is set out in full in document G/TBT/GEN/168.

3.199. All delegations that took the floor thanked the former Chairman for his efforts.

3.200. The representative of <u>China</u> said that his delegation valued greatly the GRP document. It was China's understanding that this document was about facilitating an improved implementation of the TBT Agreement; it was expected to provide guidance in improving domestic regulations with the aim of implementing the TBT Agreement. Nevertheless, when reviewing recent DSB cases, such as US Tuna II, questions about the legal implications of this Committee document had arisen, in particular whether the document - once adopted - could serve as interpretative instrument in DSB proceedings. China also noted the view of other Members with respect to how to address these concerns. China stressed that it was open to continue to constructively engage in further discussions.

3.201. China thanked all Members, the Secretariat and the Chairman for efforts made to bring forward discussions on GRP. At the same time, it did not think the "Rev.4" had been intended as the final version of this document. There had been a clear indication that comments could still be made before 30 April 2014 – and there had been no way of foreseeing what those comments would be. China noted that in the comments it had submitted before that deadline (JOB/TBT/93), it had requested, among other things, the insertion of the word "some" in para. 3. China also stressed that it had engaged cooperatively and constructively during the informal meetings. Because the document was of great value, it merited the time invested so as to ensure an in-depth communication on the views of different Members. This approach was, in China's view, necessary in order to reach consensus. Moreover, there were other important topics that needed to be discussed as well, as had been mentioned in the Chairman's summary. China also stressed the fact that there remained opportunities to further discuss these issues.

3.202. The representative of the <u>Republic of Korea</u> expressed deep disappointment that the Committee had failed to achieve consensus on the GRP document. This document, he stressed, had been prepared in accordance with the Committee's mandate from the Sixth Triennial Review Report (G/TBT/32) – and had been the subject of the Committee's work for over one year and a half. He recalled the Chairman's observation that this document had received wide and active engagement by all Members. He noted that although Members had been aware that the document

was up for adoption at this meeting, the membership was now facing a challenge essentially about divergent views on the "legal nature" of the document. Korea stressed that this GRP document was simply intended to serve as guidance, i.e. as a complementary tool to help Members implement the TBT Agreement more effectively and efficiently. It was not, therefore, a treaty. Moreover, the mandate for this work came from the Committee's own Sixth Triennial Review Report. It was this Report that provided a clear legal "umbrella" of the GRP document. There was, in Korea's view, no need for disclaimer about legal nature because the Sixth Triennial Review report clearly specified that the Committee's mandate was to:

"...identify a non-exhaustive list of voluntary mechanisms and related principles of GRP, to guide Members in the efficient and effective implementation of the TBT Agreement across the regulatory lifecycle,..." (paragraph 4(a) of G/TBT/32)

3.203. Korea called Members' attention that the words "non-exhaustive" and "voluntary" in the above text were not mandatory language. He asked why it would be then necessary for the GRP document to have a legal disclaimer in terms of its general interpretation, let alone a specific link to the Vienna Convention on the Law of Treaties. Even if the GRP guidelines were not followed, no Member would go to formal dispute settlement proceeding with a claim of violation of the GRP guidelines which were voluntary in nature. Members could not afford to unnecessarily spend time on never ending negotiations of a text that was voluntary in nature and which was only intended to facilitate implementation of the TBT Agreement. These were not the DDA negotiations. The Committee, he argued, was a forum to seek improvement over practices. For Korea, it was important for the Committee to show flexibility and creativity so as to be able to move forward and finish the remaining task as early as possible.

3.204. The representative of South Africa said that the use of non-committal wording, such as "voluntary", "may" and "could" - instead of "shall" as well as a clear expression that the proposed steps and examples of mechanisms in the document were not legally binding, unless already contained as a legal provision in the TBT Agreement, would address the concerns South Africa had. He was of the view that the document contained a comprehensive, although non exhaustive list of voluntary mechanisms and related principles of GRP that was derived from the best practices of a representative group of WTO Members. The current document provided an excellent guideline for regulators on what good regulatory practice could entail. South Africa was of the view that if regulators incorporated steps outlined in the document in their respective regulatory activities, the technical regulations and conformity assessment procedures developed by such regulators would most likely not create unnecessary obstacles to international trade. This would contribute towards greater compliance with TBT Agreement thereby also reducing the number of specific trade concerns (STCs) discussed in TBT Committee meetings. The representative of South Africa encouraged delegations to finalize the draft document and noted that, once finalized, this document could be revised an updated over time, for instance during the Committee's triennial reviews.

3.205. The representative of <u>Indonesia</u> shared the concerns expressed by China about the possible legal implication of the document. Indonesia was of the view that it was important for Members to make clearer the status of the document to prevent possible misinterpretation of the document in the future.

3.206. The representative of <u>India</u> expressed disappointment that agreement had not been possible and associated himself with the concerns raised by the delegation of China. If Members agreed with the fundamental principle that the document did not cast any legal obligation and was voluntary in nature, then there need not be any issue with explicitly stating that the document could not be referred to when seeking any eventual legal interpretation in the future.

3.207. The representative of the <u>European Union</u> noted that the document had almost been brought to a close and regretted that the process had come to a halt. The EU considered important to understand the nature of the concerns raised before deciding whether they were founded. Turning to the text itself, the EU considered that the starting point was that any text had to be interpreted in accordance with the ordinary meaning to be given to the words it contained. The GRP guidelines contained many words which described them as "non-exhaustive", "voluntary", and "illustrative". The text also contained statements to the effect that Members need not follow the suggested steps or that they did not need to follow a defined sequence and that their application depended on their level of development and administrative capacity. Further, any illustrative

G/TBT/M/63

examples given were always preceded by the qualification: "may include, for instance". In other words, said the EU, in no way could it be inferred from the document an intention from the drafter – let alone the TBT Committee itself – to create any binding obligation for Members. Moreover, in no way did the document sought to interpret specific terms or provisions of the TBT Agreement, which would be a fundamental precondition for a Panel or the AB to rely on this document in the interpretation of a term or a provision of that Agreement. Instead, the guidelines set out a non-exhaustive list of practices that Members themselves, based on their own experiences, considered as good practices to ensure / improve the quality of the outcome of the regulatory processes. And this was done without prejudice as to whether the actual outcome of the regulatory processes was in itself compatible with the TBT Agreement. In other words, the Committee was not interpreting the meaning of "not more trade restrictive than necessary". The guidelines merely stated that it was useful to evaluate the impact of proposed initiatives, to evaluate alternative options, to seek the views of stakeholders, in order to ensure and maximize the chances that the outcome would be compatible with the TBT Agreement.

3.208. In response to China's explanation that its concern had arisen from the Appellate Body decisions in US-Clove Cigarettes and US Tuna II, the EU considered that these findings were inappropriate as they took place in fundamentally different contexts. In those cases there was full symmetry between the terms of the TBT Agreement and the language used in the Doha Ministerial Decision (in US-Clove Cigarettes), and the TBT Committee Decision on Principles for International Standards (in US Tuna II). In US-Clove Cigarettes it was about a "reasonable interval" between publication and entry into force of a technical regulation under Article 2.12 of the TBT Agreement and the Ministerial Decision used the wording "should normally be understood as" in order to give meaning to this term. In US Tuna II, the issue was about the term "openness" of an international standardization body under Annex 1.4 of the TBT Agreement, a term which was specifically referred to in the TBT Committee Decision with the language - openness "should mean". In these cases there was no "soft" language, such as "may", "on a voluntary basis", "for instance", "include". In other words, there had to be - in order for a document to be relied on in the interpretation of a provision in a WTO Agreement - the same language used in both documents and a clear expression of the will of the drafters of the other document that that was intended to give meaning or to clarify the meaning of that provision. There was no such indication in the draft GRP guidelines before this Committee.

3.209. On the question of the systemic implications for the Committee's work, the EU noted that Article 15.4 of the TBT Agreement mandated a review of the operation and implementation of the Agreement. Anything that the TBT Committee did clearly had a reference to the TBT Agreement for that was the framework in which the Committee operated. The Committee could not therefore place itself outside of this box. Therefore, the view that documents produced by the Committee did was anchored in the TBT Agreement. This did not mean, however, that it was possible to make the leap to say that any document could be relied on in dispute settlement as for that one would have to check the nature of the document. In the specific case of the GRP Guidelines, the EU considered that there was no indication that they bore specifically on the interpretation of any provision of the TBT Agreement. In fact, these guidelines reflected an agreement among Members that this document should not be binding on Members (i.e., they should be voluntary in nature).

3.210. The EU concluded by inviting delegations that had raised concerns to detail them so they could be better understood. The EU was concerned that this document could be diluted to such an extent that it would undermine current and future work of the TBT Committee. Furthermore, this disagreement on the legal nature of the document itself had prevented the Committee from looking at other important issues in the text; these different discussions needed to take place in parallel.

3.211. The representative of <u>Argentina</u> said that his delegation also regretted the lack of a consensus. However, listening to the different positions, there did appear to be a consensus on the fact that the document was not binding, that it was voluntary, only illustrative, and that there were no new obligations. So, if that was the case, why could a disclaimer, as suggested by China, not be acceptable to all?

3.212. The representative of <u>Brazil</u> said, in regard to the legal status of the document, that the document was a non-exhaustive list of voluntary mechanisms. In this regard, Brazil considered that it did not affect the rights and obligations in relation to the TBT Agreement. It was not

intended to create any additional obligations. Brazil was open to consider options that would give comfort to all Members regarding this point.

3.213. The representative of <u>Chinese Taipei</u> said that the document achieved a good balance between different positions from various Members. He noted that regulatory impact assessment (RIA) was one of the most important tools in GRP and encouraged Members to continue to share their experience in conducting RIAs. He recommended that the Committee to hold a workshop that focused on RIAs to guide Members in an efficient and effective implementation of the TBT Agreement.

3.214. The representative of <u>Mexico</u> associated herself with the comments made by Korea and the EU and expressed her delegation's disappointment with in the lack of consensus over this document that was mandated by the 6th Triennial Review. These Guidelines were entirely voluntary in nature and were not prescriptive in any sense, and, as such, they did not add or diminish Members' rights and obligations.

3.215. The representative of <u>Cuba</u> supported the document and noted that Cuba had made comments on it in three occasions. Nevertheless, if there were Members that had outstanding concerns, these had to be taken into account.

3.216. The representative of the <u>United States</u> associated herself with the concerns expressed by the EU and expressed her delegation's disappointment with the current situation. She noted that her delegation had been engaged both in the WTO and elsewhere – as the ideas applied to all work on in the TBT realm – for a long time. This was, essentially, about helping Members find new ways to strengthen implementation of the TBT Agreement while keeping the guidance voluntary. It was clear to all that this was not a legally binding document. This had always been the spirit of the Committee's work. She recalled and commended the TBT Committee's ability to lay out a task, define the problem, roll up its sleeves and work collaboratively towards an outcome. She reiterated that this was the only Committee that regularly put out 30 page consensus documents that were of value to all.

3.217. She also noted a number or remaining substantive issues had not been addressed because delegations had been held up by discussion on the legal nature of the document. First, the US felt that there was room to breach differences on the subject of Special and Differential Treatment. She recalled that in March 2014, the US had asked countries who would like SDT to explain what they wanted to have in the second column of the document. The US had been asked to provide examples of what it did to take into account the interests of other countries, including developing countries, to operationalise these provisions. The US had thus come forward with several ideas that were practices that the US had in place that could be used and these could be included in the column to illustrate how this was operationalized as a means of addressing the particular needs and interests of developing countries. A second element that the US wanted to see addressed was in Section D, where some points that had existed in previous versions could be reintegrated in a way that could be broadly acceptable. The US remained open to continuing this work. However, the US did need to have from the proponents, those countries that were particularly concerned about the legal interpretative issues of the text, a more specific understanding of what their needs were. In this respect, she expressed her delegation's view that a broad disclaimer that pulled in the Vienna Convention, or a broad disclaiming saying that this current document had no interpretive value, would have serious systemic consequences with respect to Article 15 (as noted by the EU) as well as Article 13 of the TBT Agreement.

3.218. The representative of <u>Canada</u> associated herself with statements form the EU, Korea, Mexico and the US. She recalled that the process employed in the development of the document was very positive as it had engaged a wide variety of delegations, which had been given sufficient time to consider the various versions. Canada had thus expected that the current meeting was simply about making some minor adjustments to the document given that all Members had appeared to be on the same page and the intention was to close the text. This would have enabled the Committee to go forward with new work. What was surprising was that delegations with concerns had not put all its concerns on paper so that these could have been considered beforehand. It was therefore important that delegations followed the established process considering the few meetings that the Committee had. 3.219. The representative of <u>China</u> understood the EU as confirming that the document at hand could indeed serve as interpretative instrument in future disputes, and that the US had agreed with such a view. This was precisely China's concern. While China fully supported the Secretariat's and Chair's work and all the effort Members had employed in this process, this was a point that needed to be addressed. China was of the view that Members could make an interpretation of a particular provision as provided for in Articles IX and X of the WTO Agreement. In the TBT context, most Members shared the view that this document would not be put before the DSU proceedings; indeed, this was the common intention in the Committee. China's objective was therefore simply to make this clear in the text itself. That was the reason for China's comments - and China was disappointed that its comments had not been reflected in the Rev.4 draft. On the systemic concerns expressed by some Members about China's disclaimer on the Vienna Convention - China believed that Members could work on a consensus proposal. If the actual intention was to have a completely voluntary, non-binding document not subject to the DSU, this could be stated.

3.220. The representative of the <u>United States</u> noted that there were key differences, under the Vienna Convention, between various types of documents, such as Committee recommendations or decisions and Ministerial Decisions. A disclaimer of the sort that China was seeking would therefore have a significant impact on the systemic work of the Committee.

3.221. The representative of the <u>European Union</u> supported the US statement. There were different kinds of documents at issue. The Committee was working on a document that was a self-addressed guidance on how to strengthen the implementation of the TBT Agreement. Clearly there were different categories of documents. One could not infer from the current document on GRP any intention to elaborate interpretation that could be relied on in a dispute settlement context. In this respect, he reiterated that the EU was not of the view that the intention was for the current document to be relied upon for interpretative purposes in a DSU context. Practical, illustrative guidance on domestic regulatory processes did not lead to any new interpretation of obligations arising from the TBT Agreement that would have implications for DSU. The language that China was seeking was simply not appropriate for this type of document. So, before seeking solutions, it was important to identify the problem. He requested China to articulate its concern. If China was able to demonstrate that it held a valid concern, then the Committee could look into how to best to address it.

3.222. The <u>Chairman</u> noted that there was still significant interest in advancing work on GRP. Indeed – as the former Chair had said – the Committee had a clear mandate from the Sixth Triennial Review to "identify a Non-Exhaustive List of Voluntary Mechanisms and Related Principles of Good Regulatory Practice". It was important not to lose momentum. It could be useful, as suggested by Canada suggested, to take a step back to consider the best approach for reaching a positive outcome on this document. With a view to safeguarding the Committee's processes, and the beneficial work that it could provide, the Chairman said he would be consulting with Members on how the Committee could overcome the present issue.

3.3.4 Other Matters

3.3.4.1 Seventh Triennial Review

3.223. The <u>Chairman</u> noted that, in light of the mandate in Article 15.4, the Committee was scheduled to complete its Seventh Triennial Review of the Operation and Implementation of the TBT Agreement at its last meeting in 2015. While this sounded a while away, it was actually only three meetings down the road. As with previous 15.4 reviews, the process would be driven by substantive proposals from Members against specific deadlines. The Chairman suggested that, guided by previous practice, Secretariat develop a proposed timeline and that the Committee hold a brief informal meeting after the summer break to consider this work programme. This would enable the Committee to agree on an efficient process.

3.224. The <u>Committee</u> so agreed.

3.3.4.2 Next Thematic Session

3.225. The <u>Chairman</u> noted that during 2013 and 2014, following the adoption of the last triennial review, the Committee had held thematic sessions on various cross cutting issues related to the

operation and implementation of the Agreement, including on good regulatory practice, standards, transparency, conformity assessment procedures, technical assistance, and special and differential treatment. The Chairman recalled the mandate for the Committee's thematic sessions derived from the Sixth Triennial Review, paragraph 26 of G/TBT/32:

"Considering the substantive body of recommendations and decisions before the Committee, both existing and those contained in this Report, Members agree on the need to focus and deepen their work. Noting that follow-up is a long-term endeavour, Members see benefit to dedicating time to thematic topics in response to the specific decisions and recommendations in this Report, as well as those contained in previous triennial review reports, in order to press for greater progress on these issues."

3.226. The <u>Chairman</u> noted that the Committee would hold its next thematic session on 4 November 2014, the day before its regular Committee meeting. In 2014, the Committee had been following the 2013 cycle of topics set in the Sixth Triennial Review, as well as submissions from Members.

3.227. The representative of <u>Brazil</u> reiterated his delegation's interest in discussing the topic of mutual recognition agreements (MRAs). Internal consultations were taking place in Brazil on this matter and Brazil might provide a submission on the matter in due time should Brazil pursue this option.

3.228. The representative of <u>South Africa</u> mentioned Special and Differential treatment and conformity assessment as possible topics for the next thematic session, following the cycle established during 2013. In particular, on conformity assessment, the topic of metrology could be worth exploring in more depth.

3.229. The representative of the <u>United States</u> said that perhaps the time was ripe to return to conformity assessment. She recalled South Africa's detailed presentation on MRAs on a previous occasion and she was interested in the Brazil's upcoming submission. There were also other issues of interest in addition to mutual recognition; the US recalled the discussions on international systems for conformity assessment (Article 9) as well as TBT Article 6.4 on national treatment in respect to burdensome and duplicative conformity assessment procedures. The latter was a theme that had come up in many of the interventions related to STCs. The US was also open to discuss transparency. In this respect, she recalled that one of the issues that work on GRP had shown was how important transparency was to preventing unnecessary obstacles to trade. It had also shown the valuable experiences between WTO notification processes and domestic internal process and how these were effectively used and what the processes were to take into account comments.

3.230. The representative of the <u>European Union</u> associated himself with the proposals to revert to conformity assessment; there was scope for diving deeper into the issues that had been discussed at the last thematic session but also to introduce new topics. Looking at the 6th Triennial Review report, there was an interest in understanding how the choice of conformity assessment was linked to the type of enforcement mechanisms in place. In this respect, he referred to market surveillance and product liability systems. He supported going back to the topic of technical assistance as a component of Special and Differential Treatment. In this regard, the EU contribution at previous thematic session had been quite robust and it was now time for others to come forward on their experience in designing effective programmes for TA and success stories.

3.231. The representative of <u>Canada</u> made a proposal in respect of 15.2 Statements. She noted that there were still 32 countries that had not yet made their statement and over 100 that had. If countries were willing – hopefully all 32 – the Committee could work on "twinning or partnering" where a country that had done its 15.2 statement could work with a country that had not. This would avoid only depending on Secretariat assistance. The form of assistance could be one of cooperation without any particular timeline.

3.232. The <u>Chairman</u> thanked delegations and noted that there appeared to be some convergence on the issue of conformity assessment. Other issues had also been raised: MRAs, 15.2 statements, SDT, TA and transparency. The Chairman asked interested Members to communicate any proposals to the Secretariat (or to himself) on the themes to be addressed at the next thematic session by 31 July 2014. After that, the Secretariat would prepare a draft programme based on the input received as well as topics suggested at the current meeting.

4 TECHNICAL COOPERATION ACTIVITIES

4.1. The representatives of $\underline{\rm ISO}$ and the $\underline{\rm ITC}$ updated the Committee on their technical assistance activities. 3

4.2. The <u>Secretariat</u> brought the Committee's attention to the recently published Handbook on the TBT Agreement, available free of charge on the WTO website. The Secretariat also made available a document containing information on the Secretariat's technical assistance activities.⁴

5 UPDATING BY OBSERVERS

5.1. The representative from <u>ISO</u> informed the Committee that his organization was in the process of developing a communication document on using and referencing ISO and IEC standards to support public policy. This publication contained benefits of using international standards, relevant principles and disciplines of the TBT Agreement; methods of using ISO/IEC standards to support technical regulations and other public policy approaches, as well as national policies and examples of using standards in support of public policy. This document would be available by the end of 2014. He also highlighted the 2014 ISO General Assembly, taking place in Rio de Janeiro from 9-11 September where the agenda included a discussion on how international standards can better support global trade in services. Finally, he said, as ISO's current strategic plan would conclude in 2015, consultations had begun with ISO members and stakeholders, on strategic directions that ISO should take for its next five year period (2016-2020). International organizations, including the WTO Secretariat, would also be asked for input, and he encouraged the Committee to involve their ISO Members' perspectives in providing comments to ISO.

5.2. The representative of the <u>IEC</u> updated the Committee on its activities.⁵

5.3. The representative from <u>Codex Alimentarius</u> provided and update on their activities.⁶ She added that, in light of the discussions in relation to Codex Food Labelling Texts, Members might be interested in the upcoming Session of the Committee on Food Labelling which would take place in Rome from 21-24 October. The committee would consider a proposal for new work on the review of the General Standard for the Labelling of Pre-packaged Foods, addressing in particular the issue of date marking. She encouraged Members to follow the discussions on the revision of the General Standard on Labelling in the Committee on Food Labelling.

5.4. The representative of <u>UNECE</u> reminded the Committee that the Working Party on Regulatory Cooperation and Standardization Policies (WP6) was the only UN intergovernmental body that had the promotion of good practice and the development of implementation of technical regulations and standardization policies as the core-standing items in its agenda. She drew delegations attention to the recently shared "Zero draft" of the UN Sustainable Development Goals - when adopted in September 2015, these goals would be the overarching guide of the work of the United Nations. Goal 17 which promoted strong inclusive and sustainable economic growth and decent work for all, contained direct relevance to the work of the TBT Committee "to increase trade-related capacity building assistance to developing countries, including support for building their capacity to meet product regulations and standards".

6 OTHER BUSINESS

6.1 Canada's new regulatory framework

6.1. The representative of <u>Canada</u> updated the Committee on the proposed new regulatory framework for federal food inspection which would bring together federal food inspection regulations in Canada into one overarching system and thereby replacing 13 different food

³ G/TBT/GEN/169 and G/TBT/GEN/172.

⁴ G/TBT/GEN/171.

⁵ G/TBT/GEN/170.

⁶ G/TBT/GEN/173.

regulations with one set of regulations. The new framework for federal food inspection provided an overview of the proposed regulations including draft regulatory text for key elements of the regulations and highlighted some significant regulatory proposals, such as grade standards, labelling and standards of identity, and membership requirements for buyers and sellers of fresh fruit and vegetables. She encouraged Members to provide comments on the proposed framework document by the 31 July deadline. The proposed regulation would be notified for consultation towards the end of 2014, at which time Members would be given the opportunity to provide final comments. The Safe Food for Canadians Act and associated regulations were anticipated to come into force by June 2015.

7 DATE OF NEXT MEETING

7.1. The next regular meeting of the TBT Committee is scheduled for 5-6 November 2014. It will be preceded by a thematic session on 4 November 2014.