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Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 6-7 MARCH 2013

CHAIRPERSON: MR. SALIM LAHJOMRI

NOTE BY THE SECRETARIAT[1]

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1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in WTO/AIR/4073.

2 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

2.1 Statements from Members under Article 15.2

2.1. The Chairman said that the list of statements submitted under Article 15.2 of the TBT Agreement was contained in document G/TBT/GEN/1/Rev.12, dated 18 February 2013. In total, since 1995, 128 Members had submitted at least one Statement on Implementation under Article 15.2. He recalled that this information was available, and regularly updated, on the TBT Information Management System (the "TBT IMS"[2]).

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

[2] http://tbtims.wto.org.

2.2 Specific Trade Concerns

2.2.1 New Concerns

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

2.2. The representative of Japan requested that India postpone the enforcement date of the Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order 2012. He noted that Article 3 of the Order prohibited manufacturing, storing for sale, importing, selling or distributing products which did not conform to the Order after the enforcement date of 3 April 2013, which was six months from the date of publication in the Official Gazette. However, Japanese industry estimated that it would take more than nine months to comply with all requirements in the Order. He additionally noted a lack of testing laboratory capacity in relation to the Order; India had designated only four testing laboratories, all of which were located in India. For these reasons, the representative requested that India postpone entry into force to 12 months from the date of publication in the Official Gazette, at the earliest.

2.3. He requested that the Order apply only to products imported to India after the entry into force of the Order, and not to products imported prior the enforcement date. The representative noted that in many countries new rules are applied to only those products that are imported after the relevant enforcement date. Furthermore, he explained that Japanese exporters supplied "Goods" listed in the Order's "Schedule" to various Indian dealers, and thus, it was nearly impossible to trace these complex supply chains. Should product stock in the market place be subject to the Order, it would place additional burdens on Japanese exporters and Indian dealers and retailers, namely: collecting products from markets; opening product packaging; replacing labelling affixed to the product; conducting quality control; and, repackaging the modified products. He also requested India to accept certificates issued by Japanese Certification Bodies. According to the BIS Rule 16B (3), test reports were required from one of the four national testing laboratories designated by BIS. Given that India was a member of IECEE CB Scheme, he asked India to accept CB certificates issued by foreign certification bodies.

2.4. The representative of the United States echoed the concerns expressed by Japan. She expressed confusion as to whether the Order was a proposed or final measure, given that the published measure included an entry into force timeframe and did not specify a final or revised measure being issued before then; the Order was published in the Official Gazette in September 2012 with a public comment period until December 2012, and it was notified as G/TBT/N/IND/44 in October 2012. The representative further asked how comments would be taken into account given the April implementation date, and that this raised questions regarding India's implementation of its notification obligations under Articles 2 and 5 of the TBT Agreement.

2.5. Regarding testing, she noted that the BIS had identified only four recognized laboratories, each of those labs authorized to test only a small subset of products on the list. These laboratories did not appear prepared to handle the volume of products that would need to be tested, and she expressed concerns that this could lead to significant delays in placing products on the market. Moreover, it was unclear why in-country testing was required, and she asked why India deemed foreign labs inadequate to address product safety concerns. She understood that BIS was a signatory to the IECEE CB Scheme, and said that the four designated laboratories had no scheme categories in their scope for the office products regulated under the Order; moreover, it was not consistent with the CB Scheme requirement that signatories must agree a priori to accept reports of other signatories.

2.6. The representative said the scope of products subject to the Order remained unclear, and that the FAQs on the BIS website did not address concerns on this issue. In particular, the coverage of "automatic data processing machines" was unclear, and if this was intended to include large servers used by industrial consumers, her delegation questioned whether product safety concerns warranted in-country testing. Given, the confusion over many technical aspects of the Order, and testing issues, she strongly encouraged India to delay entry into force until such time as comments received from interested parties were fully taken into account in a revised final measure.

2.7. The representative of the European Union supported the concerns raised by Japan and the US, and raised a further fundamental concern about the necessity and proportionality of the proposed compulsory registration system for the 15 types of electronic and information technology goods listed in the Annex to the Order. Mandatory third party testing by a laboratory approved by the BIS appeared excessively burdensome, and more strict than necessary, given the low risk nature of the products concerned. Examples of covered products included laptops, printers, scanners, wireless keyboards, telephone answering machines, automated data processing machines, video game machines, CD/DVD players, and televisions, which were unanimously considered as very low risk products giving rise to a very low number of accidents.

2.8. He invited India to consider a lighter conformity assessment procedure that would rest on a supplier's declaration of conformity, without any mandatory third party intervention. This would provide manufacturers freedom of choice regarding the laboratory where any relevant test would be carried out, including the possibility to use in-house testing facilities at the manufacturing premises. He reiterated concerns raised by other Members about delays and costs imposed by the Order and asked for clarification that the new rules would be applicable only to products placed on the market after the entry into force of the Order, and those products already on the market would not be affected. Further, he requested confirmation that test reports and certificates issued by members of the IECEE CB schemes would be accepted, and likewise that applications from foreign conformity assessment bodies to carry out the testing required by the Order would be accepted. He noted with appreciation bilateral discussion with India prior to the meeting, and his delegation welcomed further formal confirmation on the points raised.

2.9. With respect to frequency of testing, the representative of the EU said that the notified text required that testing be repeated every two years even when the product had not been modified, which appeared excessively and unnecessarily burdensome. His delegation believed that testing should be repeated only if the product had been substantially changed in such a way that its safety properties were affected. He also noted that Indian Standards were referenced for each product category listed in the Annex to the Order; compliance to these standards was mandatory. The representative understood that there were corresponding international IEC standards for each product category, and he asked about the relationship between the referenced Indian Standards and the corresponding IEC standards.

2.10. Regarding the registration procedure, he noted that the manufacturer would have to send the test reports to BIS for scrutiny, but it was not clear from the notified text how this procedure would be implemented, how long it would take, or if there was a time-limit within which BIS was required to give feedback to the manufacturer. This was important for providing predictability and legal certainty so that businesses could plan the time to market of their products.

2.11. The representative of Korea aligned his delegation with the concerns raised by other Members. He understood that this Order referred to Indian Standards that were harmonized with relevant international standards. He also noted that the Order exempted manufacturers that adopt Supplier's Declaration of Conformity from on-site inspection by the competent Indian authorities, and he thanked India for reducing the compliance burden. His delegation respected the efforts of the Indian Government to protect consumer safety in respect of electronics and information technology goods. Korean companies, he said, would try to fulfil those requirements.

2.12. However, Korean companies were struggling with compliance due to a small number of designated testing labs as compared to the high demand for testing, and the resultant processing delays by designated laboratories. He further noted the need to register products with the Indian authorities after testing, and that it was impossible to complete these steps prior to 3 April 2013. He recalled that Article 2.12 of the TBT Agreement required Members to provide a reasonable time interval between the publication of technical regulations and enforcement, and he requested India to provide a six month grace period. If the entry into force could not be postponed, he asked India to accept test report in accordance with the IECEE CB Scheme.

2.13. The representative of Switzerland said his delegation shared the concerns of other Members regarding the Order. In particular, he encouraged India to clarify if the standards being used corresponded to international standards as per Article 2.4 of the TBT Agreement. Further, his delegation was not convinced that the conformity assessment procedure chosen was justified under Article 5.1 of the Agreement as necessary or proportional, since all the products mentioned in the Order were low-risk consumer electronics. He believed that a less burdensome system

based on Suppliers' Declaration of Conformity could equally achieve the purposes of the legislation.

2.14. The representative requested that India treat registration as definitive, and thus that tests would be valid as long as products did not change, which could reduce the burden on importers and avoid disruptions for products awaiting confirmation. In any case, he invited India to streamline the process by accepting conformity assessment according to the IECEE CB Scheme and other relevant international schemes for test results.

2.15. The representative of India stated that the Order would come into effect on 3 April 2013, and that a seven-month adaptation period had been provided from the date of publication of this order in the Official Gazette. He noted that many of the queries raised by Members had been discussed with Indian authorities by the multinational companies representing concerned Members, and on this basis the Department of Electronics and Information Technology had prepared FAQs and guidelines for series approvals, and shared these on its website. The representative believed that many of the queries raised by Members are answered in the FAQs, given these were the exact questions asked by the multinational companies during the consultation process.

2.16. He was of the view that this registration system was a more trade facilitating conformity assessment procedure than the previous third party testing system. He asked Members to take into account the fact that most developing countries did not have well-developed post market surveillance systems, and that this registration system helped to fill this gap. He said that the Order was only applicable for products manufactured or imported after the Order's entry into force, as stated in the FAQs. Regarding testing every two years, his delegation believed that this was a proven norm for ensuring compliance. He stated that the five testing laboratories recognized under the scheme would be able to handle the workload. The BIS was examining other applications from laboratories, including foreign laboratories. He observed that compliance should not be a problem for most exporters, since the Indian Standards were based on equivalent IEC standards.

2.17. Regarding the issue of international systems for conformity assessment and accreditation, he recalled a very healthy debate on this topic during the Sixth Triennial Review, and said this debate should continue. In his view, it was clear that Members with substantial imports and poor post market surveillance, especially developing countries, needed to develop their own testing laboratories. The registration system under discussion fits with this purpose, because even under the current IEC CB Scheme, he noted that most of the laboratories were concentrated in developed countries.

2.2.1.2 United Arab Emirates - Conformity Assessment Procedure for Automobile Tyres (G/TBT/N/ARE/116) (IMS ID 368)

2.18. The representative of Japan expressed concerns about this measure, which entered into force on 1 September 2012. He noted that automobile tyres exported from Japan to the United Arab Emirates (UAE) had already satisfied the requirements of the Gulf Cooperation Council Standardization Organization (GSO) regulations, of which the UAE is a member. Under the GSO system, Japanese tyre manufacturers were required to renew the GSO certification every year, and that this was one of the most stringent certification systems in the world. His delegation was of the view therefore that it was not necessary for the UAE to introduce a duplicative conformity assessment procedure in addition to the GSO system, and he requested an explanation of the rationale and objectives behind this additional procedure.

2.19. The representative of the European Union echoed Japan's concerns, and said her delegation had sent written comments on this notification in October 2012 regarding divergences between the notified text and relevant requirements under UNECE Regulations. The UAE was asked to consider removing the ban on the importation of those retreated tyres which were certified as complying with UNECE Regulations 108 & 109, and to refrain from adopting a measure which would be disproportionate to the objective it aims to achieve. She requested that the products complying with UNECE Regulations for tyres be accepted on the market of the UAE, and requested an update on the state of play and the timeline for the revision of the measure.

2.2.1.3 Thailand - Certificate Requirement and Administrative Measure Relating to Importation of New Pneumatic Tyres of Rubber into the Kingdom of Thailand B.E. 2555(2012) (G/TBT/N/THA/413)[3] (IMS ID 369)

2.20. The representative of Japan voiced concerns on Thailand's import regulation for automobile tyres, published on 11 January 2013 and entering into force on 12 January 2013. The measure obliged tyre importers to submit "Standard Assurance Certificates" and "Certificates of Origin" issued by the "competent authority of exporting country", with the stated objective of the regulation to ensure economic stability and public safety.

2.21. He expressed four concerns; first, regarding the fact the regulation did not provide information on relevant standards. His delegation thus believed that this regulation was unnecessarily trade restrictive, and he requested that Thailand temporarily postpone entry into force. While his delegation had recently learned that Thailand was postponing entry into force until 13 March 2013, he nevertheless believed this time frame was still insufficient to allow for adaptation to this new regulation. Second, he expressed concerns about preparation of Standard Assurance Certificates for tyres, as Japan did not adopt technical regulation for tyres. Instead, he asked that Thailand accept a copy of a UNECE Regulation Compliance Statement which was issued by a Designated Administrative Department of the United Nations. Third, he flagged concerns about application of the regulation to new tyres for research. According to the Article 6 of the regulation tyres for research were exempted. However, Thailand customs authorities have required Japanese industry to provide Standard Assurance Certificates and Certificates of Origin in respect of these tyres. His delegation requested Thailand to guide its customs authorities as to the exemption for new tyres for research. Fourth, he noted the date of entry into force of the regulation was just one day after the publication. This measure should have been notified by Thailand, and sufficient lead-time should have been provided. He requested that Thailand at the very least take Japan's concerns into account in implementing the regulation, and respond promptly to Japanese industry enquires regarding the regulation.

2.22. The representative of the European Union supported Japan's concerns, and noted that this measure contained provision falling under the TBT Agreement, but as it had not been notified WTO Members were denied the opportunity to analyse the draft and to comment. Moreover, the measure entered into force one day after publication, meaning that no transitional period was provided for implementation. She invited Thailand to notify the measure, and to postpone entry into force of the measure in order to allow sufficient time for exporters to adapt to the new requirements.

2.23. She noted that Article 4 of the Ministerial Announcement required Standard Assurance Certificates issued by the exporting country, and she asked for clarification on the relevant standards subject to the required Standard Assurance Certificates. In particular, her delegation enquired as to whether certificates of compliance with applicable UNECE Regulations would be accepted by the Thai authorities. The representative expressed the view that the duties of importers outlined in Article 5 were unnecessarily burdensome, in particular, the storage requirements and monthly reporting obligation. She asked whether similar duties applied to domestic producers. Finally, she sought clarification from Thailand about the purpose of the measure and the legitimate objectives pursued.

2.24. The representative of Thailand explained that her country was facing problems due to importation of low standard tyres. Her authorities deemed it necessary to urgently establish a measure to solve problems arising from the import of the tyres which did not comply with the relevant standards, so as to avoid risks associated with loss of life and assets. This technical regulation of the Ministry of Commerce was considered as the means to solve these urgent safety problems.

2.25. However, she announced that the date of enforcement of this technical regulation would be postponed to 13 March 2013, and that in the meantime the measure had been notified to the TBT Committee. Her delegation offered to provide copies of the technical regulation upon request. On the other concerns raised, she would consult with her capital for an appropriate response.

[3] Listed as "Thailand- Import Regulation for Automobile Tyres" in JOB/TBT/45.

2.2.1.4 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) (IMS ID 370)

2.26. The representative of the United States expressed concerns with Chile's proposed regulation implementing Law No. 20,606 on nutrition and composition of food and its advertising. Her delegation was of the view that the draft regulation lacked critical information needed to assess trade impacts, such as: explanation of application to foods served in restaurants; application to existing commercial inventory; and, whether imports can comply through the use of supplemental labels or stickers. She noted that this measure addressed the definition of serving and portion size, and that this was related to nutrient limits – on which Chile had recently submitted a notification.

2.27. US industry had voiced concerns with this proposed measure: on its mandatory nature; stringent requirements for the critical nutrients; and, the large number of products that could have to bear front-of-pack (FOP) icons and undergo relabeling. Her delegation believed this was the most onerous proposed measure of its kind to date, and that it may constitute an unnecessary obstacle to international trade. She asked if Chile had considered less trade restrictive approaches to promoting healthy diets, and if Chile had fully considered the potential impact of the proposed labelling and related criteria on the range of foods affected.

2.28. The representative noted alternative approaches contained in Codex guidance, which provide consumers with information to make appropriate dietary choices and reduce their risk of diet-related Non-Communicable Diseases. She cited for example, the Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) and the Codex Guidelines on Nutrition Labelling (CAC/GL2-1985), which establish conditions for voluntary "low", "free", or "no added" claims in tandem with mandatory nutrition labelling. As a result of Codex work to implement the WHO Global Strategy on Diet, Physical Activity, and Health, the mandatory list was recently expanded to include saturated fat, sodium, sugars (and consideration of trans fatty acids in countries where this nutrient is a public health concern).

2.29. Since Chile already maintained requirements for mandatory nutrition labelling, she suggested a further option of expressing the nutrient content of a food as a percentage of food label daily intake reference values, which was common practice in other countries. She explained that this approach, in conjunction with mandatory nutrition labelling and nutrition education, helped consumers understand that all foods may be consumed in the context of a total diet, but those high in certain nutrients may need to be limited. Moreover, Codex had recognized the important role of Nutrient Reference Values (NRVs) for labelling purposes in implementing the WHO Global Strategy on Diet, Physical Activity, and Health, evidenced by recently proposed NRVs for sodium and saturated fat in the Codex Committee on Nutrition and Foods for Special Dietary Uses.

2.30. She referenced Codex Guidelines on Nutrition Labelling (CAC/GL2-1985), Section 5 recommendations in on Supplemental Nutrition Information: "Supplementary nutrition information is intended to increase the consumer's understanding of the nutritional value of their food and to assist in interpreting the nutrient declaration. There are a number of ways of presenting supplementary nutrition information to consumers that may be suitable for use on food labels". Furthermore, she cited Codex Guidelines on Nutrition Labelling (CAC/GL2-1985): "The use of supplementary nutrition information on food labels should be optional and should only be given in addition to, and not in place of, the nutrient declaration." She asked Chile to explain why existing mandatory nutrition labelling requirements did not meet its public health objectives, how a mandatory supplemental label would address lack of understanding among consumers, and whether Chile had undertaken consumer studies to support their proposal.

2.31. On the current timetable for implementation by July 2013, she said this did not leave sufficient time for industry compliance or discussion of trading partners' concerns. Her delegation requested that Chile delay finalization and implementation of its regulation to allow: adequate dialogue and consideration of comments from stakeholders; a discussion of the rationale, details and potential impact of this proposed regulatory approach, as well as alternative approaches considered; and, Chile's assessment of the costs and benefits associated with the proposed mandatory labelling requirements.

2.32. The representative of Mexico voiced her delegation's concerns with the measure. These are contained in full in document G/TBT/W/361.

2.33. The representative of the European Union was concerned that the overarching Law No. 20,606 on the Nutritional Composition of Foods and their Advertising had not been notified, and hence WTO Members did not have the opportunity to comment. Article 5 of the Law established that the Ministry of Health would determine categories of foods that would need to be labelled as "high in calories", "high salt" or an equivalent designation and would also determine the content, form, size, messages, signs or pictures used for the labels.

2.34. While her delegation fully shared Chile's public health concerns regarding the provision of adequate nutritional information to consumers, she expressed doubt that the approach taken in the notified draft was the best way to achieve these objectives; or moreover, if the approach was proportional to the aim pursued, which was to empower consumers to make informed dietary choices in order to foster effective competition and consumer welfare. She expressed that "high in" warnings, such as those proposed by the Chilean legislation, should be avoided, as they are not foreseen by the applicable Codex guidelines on nutrition labelling, and they risk demonizing some foods whose consumption in moderation can be part of a healthy diet. The representative explained that Chile's approach would have a discriminatory effect on foreign manufacturers, which would need to adapt their packaging for the Chilean market only. Her delegation invited Chile to consider less trade restrictive information measures.

2.35. She noted that an obligation to provide nutritional information was already established by Article 2 of Law No. 20,606, and she thus enquired as to the rationale for imposing additional warnings, and to compatibility with Article 2.2 of the TBT Agreement. She recalled that Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) state 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 to convey an understanding of the quantity of nutrients contained in the product". She noted that no nutrient thresholds have been established by Codex for the nutrients targeted by the Chilean legislation. Moreover, while her delegation recognized that for certain nutrients there was evidence of a positive association between intake and the risk of developing a disease or disorder, there was no scientific evidence suggesting an identifiable threshold above which the risk exists. Rather, the risk increased continuously when the nutrient intake was above the levels recommended by nutritionists.

2.36. The representative said that with respect to portion sizes the EU was currently analysing Chile's recent notification, and it would submit comments in due time. Also, according to the notified draft amending food safety regulation, the warnings would need to be placed in the middle of an octagonal icon (a STOP sign) which must: occupy not less than 20% of the main face of the packaging; be located in the upper right corner; and, have a size of at least 4 square centimetres. These burdensome requirements raised concerns regarding the labelling of small packages; furthermore it was not clear if stickers would be accepted in order to comply with the regulation. Her delegation asked for clarification of these issues, and, should the additional warnings eventually be imposed, asked Chile to consider less restrictive size and placement requirements – the current proposal would entail re-design of the packaging of a large majority of products concerned by the warning sign.

2.37. Finally, she asked Chile to share information on the foreseen deadlines for the entry into force of these requirements; Law 20,606 was scheduled to come into force on 6 July 2013 according to Article 11. She stressed that adaptation to the new requirements would require significant investment for manufacturers, and a redesign of the packaging for some categories of products which were not yet defined. Therefore, her delegation requested that Chile postpone the entry into force, and provide a reasonable implementation period in accordance with Article 2.12 of the TBT Agreement. For example, EU legislation on nutritional labelling was adopted in 2011, but would only come into force in 2014.

2.38. The representatives of Argentina and Colombia echoed concerns expressed by the US, Mexico and the EU; Argentina stressed in particular that the measures were not in line with Article 2.2 of the TBT Agreement and would affect negatively the bilateral trade. Argentina announced that it would submit comments to the notified drafts.

2.39. The representative of Guatemala, while sharing Chile's objectives of providing consumer information and adequate health education to mitigate problems such as obesity, voiced serious concerns. He said that the measures in question would not fulfil their legitimate objectives, and that they thus constituted an unnecessary obstacle to international trade under Article 2.2. Additionally, he was concerned about transparency and opportunity to provide comments. Chile rejected two requests from Guatemala for an extension of the comment period, and Guatemala continued to have a number of questions, such as the international standards that were taken as the basis for the measure. He again asked Chile to reconsider the possibility of extending the comment period to give opportunity to his delegation to comment, and also that Chile re-examine the measures to ensure that they do not create unnecessary trade restrictions.

2.40. The representative of Canada was concerned that this regulatory proposal would have a negative impact on Canada's significant food exports to Chile. In particular, she expressed the view that it had not been properly notified, deviated from international standards, had no apparent scientific basis, and was likely to be more trade restrictive than necessary. Her delegation supported Chile's policy objective of promoting healthy dietary choices and reducing obesity and related non-communicable diseases, but she encouraged Chile to consider a less trade restrictive alternative. Additionally, due to the lack of transparency, the representative reiterated other Members' requests for an extension to the comment period.

2.41. The representative of Peru echoed concerns of other delegations, and requested that Chile reconsider her delegation's request for an extension of the comment period. Moreover, she was concerned about the upcoming entry into force of the measures, and asked Chile to reconsider the implementation timeframe.

2.42. The representative of Chile said that the proposed amendment to the Food Health Regulations, Supreme Decree No. 977/96 sought to solve intractable health problems. Her country was experiencing an obesity epidemic, especially amongst young people who consume a large amount of these food elements. She explained the amendment would communicate specific health information and provide a warning that would be easily understandable for consumers, and guide them to the best consumption choices based on available information. Her delegation was holding meetings with public and private sector bodies on this matter, and she said that concerns of Members, especially regarding the time-frame for entry into force, would be communicated to her capital based authorities.

2.2.1.5 Korea – Proposed SAR Values or EMF exposure in cell phones (G/TBT/N/KOR/393) (IMS ID 371)

2.43. The representative of the United States reported that American industry had submitted comments on Korea's proposed labelling regime for cell phones. She sought clarification as to the rationale for requiring two labelling categories for the Specific Absorption Rate (SAR) for cell phones, when both categories of products covered by the measure had already met Korea's safety requirements. Moreover, she was not aware of any scientific evidence or basis for differentiating between the two categories of products on health criteria. Finally, she noted that this regulation had not advanced in some time, and she asked for clarification about its current status, and whether her delegation's comments would be taken into account.

2.44. The representative of the European Union voiced concerns with Korea's "Proposed enactment of the rating of electromagnetic waves for mobile phones and radio stations". Her delegation had submitted comments on this notification on 14 November 2012, but had not yet received a reply. While her delegation fully shared the objective of better informing consumers of SAR, she believed that the requirement to label the SAR on the packaging of mobile communications wireless equipment, personal portable phone wireless equipment and portable wireless devices used in proximity to the ear, could be replaced by less trade restrictive measures such as user manuals or information websites. The representative enquired as to the scientific justification for classifying products as Level 1 or Level 2 on the basis of SAR value; her delegation was of the view that there was no need for specific labelling by levels since both fell below internationally accepted thresholds ensuring safe use of the products.

2.45. The representative of Korea explained that its mandated SAR threshold for mobile phone was 1.6W/kg, which was identical to that of the US. However, he noted that since the WHO had

pronounced in May 2011 that electromagnetic waves emitted from mobile phones had the potential to cause cancer, health concerns had significantly increased worldwide, including in Korea. He noted a consumer survey conducted by Korea Communications Commission, which showed that 82% of consumers were concerned about the dangers of electromagnetic waves.

2.46. In response, a proposed SAR Grading Scheme was designed to help consumers better understand SAR values. His authorities did not intend to arbitrarily discriminate between products by grade, or to mislead consumers. He explained that mobile phones satisfying the 1.6W/kg threshold would have no problems accessing the Korean market. However, taking into account the concerns of interested parties, he said Korean authorities were reviewing this proposal, including the display methods and grace period. The representative would deliver other concerns raised to the competent authorities.

2.2.1.6 Russian Federation – Alcoholic Beverages Storage Technical Conditions Order Number 59n (IMS ID 372)

2.47. The representative of the United States recalled her delegation's November 2012 intervention on this measure[4], and noted that American exporters were still encountering difficulties. She encouraged Russia to perform inspections and licensing of alcoholic beverage warehouses in a timely and transparent manner, with clear instructions available. Moreover, her delegation believed that businesses should be allowed to renew licenses well before expiration. She requested a response to US comments on this measure, sent 28 August 2012. Finally, she hoped that Russia would act consistently with the TBT Agreement, and adopt measures that do not create unnecessary obstacles to trade.

2.48. The representative of the Russian Federation explained that this Order set requirements for warehousing of alcohol products. The legislation was currently being finalized, in compliance with WTO rules. He said the comments of the US had been carefully examined, and additional clarifications and discussions could continue on a bilateral basis.

2.2.1.7 India – Proposed Amendment to 2008 Hazardous Waste Law (IMS ID 373)

2.49. The representative of the United States noted that India's Ministry of the Environment and Forests was considering adopting a "Fifth Amendment" to its 2008 Hazardous Waste Rules, the draft of which was provided selectively to members of the Indian industry for their input. Her delegation was disappointed that the previous four amendments to the Hazardous Waste Rules were not notified to the TBT Committee. She expressed regret for such an approach which, besides disadvantaging foreign competitors, was unlikely to help India meet the objectives underlying the Hazardous Waste Rules since the Indian market relied on imports for many of the products covered by these Rules, such as electronic and electrical equipment. She hoped the Fifth Amendment would be notified to the TBT Committee, giving stakeholders an opportunity to provide comments.

2.50. The representative of India replied that if India did proceed with an amendment to this law, it would be notified at the draft stage to the WTO.

2.2.1.8 Ukraine - Amendment to Law on Advertising, Law of Ukraine No. 3778-VI of 16 March 2012 (G/TBT/N/UKR/89) (IMS ID 374)

2.51. The representative of the United States thanked Ukraine for notifying this measure, which was commented on by the US industry through the Enquiry Point. She asked whether Ukraine planned to take into account the comments received. She also sought specific updates on, first, the implementation of the provisions of this measure with respect to alcoholic beverages and, second, on the rational and objective of extending to alcoholic beverages the application of a measure that targeted primarily tobacco.

2.52. The representative of Ukraine explained that the Ministry of Health of Ukraine had notified the new Law amending a number of advertisement laws and regulations. The Law prohibited direct and indirect advertising, sponsorship and promotion of tobacco products. In addition, the Law also

[4] G/TBT/M/58, Page 26, paragraph 2.133.

included some limited specific obligations relating to alcohol advertising. The comprehensive ban on tobacco advertising was a necessary element of Ukraine's tobacco control policies and confirmed Ukraine's commitment to the protection of public health in general and the reduction of smoking prevalence in particular. Advertisement bans for tobacco products have been adopted by many countries in the world and were supported by a body of evidence that they were able to genuinely contribute to the protection of public health. Ukraine's Law, however, drew an important distinction between advertising, on the one hand, and the legitimate use of validly registered trademarks on tobacco products to which they were to be applied, on the other. Trademarks themselves, when used on the product or the packaging, were not advertising and were thus not affected by the Law. However, what was prohibited by the Law was advertising that used signs including trademarks to promote the product. For example, the Law banned indirect advertising by placing images of tobacco products or tobacco trademarks on consumer goods not related to the use of tobacco products.

2.53. The representative of Ukraine explained that the Law protected the use of trademarks on tobacco products or their packaging, while ensuring that all direct and indirect forms of advertising for tobacco products were prohibited. Trademarks served the important function of distinguishing lawfully available products. They merit special protection in that function and are protected also under the Law (that was why the Law only prohibited the placement on tobacco products, or their packaging, of words, drawings or other images other than aspects of protected trademarks). The Ukrainian Law banning tobacco advertising was a legitimate public health measure that balanced effective health protection, on the one hand, and appropriate protection for trademarks and market access rights, on the other. Therefore, Ukraine considered that this Law, unlike other tobacco control measures previously discussed in the TBT Committee or the TRIPS Council, did not act as an unnecessary obstacle to trade and was consistent with the TRIPS Agreement, thus complying with Ukraine's obligations under WTO law. Further, the few specific requirements relating to advertising for alcoholic beverages introduced by the Law were similarly consistent with Ukraine's obligations under WTO law. In fact, the alcohol-related requirements in the Law concerned advertising and were thus not subject to the disciplines of the TBT Agreement given that these advertising requirements did not relate to product characteristics or the labelling or packaging of alcoholic beverages. Additionally, the requirement that alcohol-related trademarks were not allowed to be placed on products that were not similar to alcohol, or not associated with alcohol, did not apply to an "identifiable product or group of products" but rather concerned a very broad range of widely diverse products and the prohibition on indirect advertising for alcohol was thus not a technical regulation. Incidentally, this was the approach adopted by the WTO Appellate Body in EC Asbestos and EC Sardines: a technical regulation was a measure that applied to an identifiable group of products, for which it imposes certain product-related requirements compliance with which was mandatory (Appellate Body Report, EC – Sardines, Para. 176). Thus, the prohibition on indirect advertising for alcoholic products, which already existed in a less comprehensive form before the new Law, did not constitute an unnecessary obstacle to trade in non-alcoholic products. This requirement was rather an accepted way of curbing indirect advertising for alcohol products. The same reasoned justification that existed for banning indirect advertising for tobacco products - a measure that was widely accepted in the international community as an effective, proportionate and legitimate means of addressing a public health concern - would apply with equal force to indirect advertising for alcoholic products.

2.2.1.9 Canada - Improved food inspection model: The Case for Change (G/TBT/N/CAN/365, G/TBT/N/CAN/365/Rev.1, G/TBT/N/CAN/365/Rev.1/Add.1, G/TBT/N/CAN/365/Rev.1/Add.2)

2.54. The representative of China requested the Canadian authorities to base any changes in their measures on relevant international standards, such as Codex standards. His delegation looked forward to receiving the notification of this measure and the opportunity to send comments.

2.55. The representative of Canada explained that Canada was developing a more consistent and comprehensive inspection approach that could be applied across all foods. Canada was consulting with Members and Canadian stakeholders on ways that its site-based inspection system could be enhanced to best manage current food safety challenges and emerging trends. Canada had already provided two opportunities for Members to comment on items related to this initiative. The first opportunity, in June 2012, sought comments on the document called "The Case for Change" - which outlined the proposed core components of an improved inspection model in G/TBT/N/CAN/365. Canada thanked both China and all the other Members for reviewing and

considering this concept document and for providing comments. These comments were taken into account when developing the draft improved food inspection model. The second opportunity, in August 2012, sought feedback on the draft improved food inspection model in G/TBT/N/CAN/365/Rev.1. During this second round of consultations Canada received comments from various Members. Canada intended to notify a second draft of the improved food inspection model for comments shortly.

2.2.1.10 Korea - Draft amendment of Ordinance and Regulation of Motor Vehicle Control Act (G/TBT/N/KOR/342 and G/TBT/N/KOR/342/Add.1) (IMS ID 375)

2.56. The representative of the European Union noted that Korea had not responded to comments on this notified draft sent by her delegation on 1 March 2012. This notified draft announced the introduction of a system of self-certification of certain car parts. The manufacturers or importers of these parts would have to: (i) be registered with the relevant Korean authority (the Ministry of Land, Transport and Maritime Affairs - MLTM); (ii) submit their products for testing by a testing facility designated by the MLTM; and then (iii) apply the self-certification mark on the product before placing it on the Korean market. However, there were no details as to how the registration, testing and self-certification procedures would be carried out, or as to the certification mark itself. She recalled that in its comments of March 2012, the EU requested that car parts certified as complying with UN Regulations, and marked with the "E-mark", be accepted on the Korean market on the basis of UN certification and marking, without the need for an additional Korea-specific mark, in accordance with Article 2.4 of the TBT Agreement.

2.57. She also noted that her delegation had learned that additional implementing legislation to the Motor Vehicles Control Act – MLTM Notice no. 2013-70 on "Guidelines for Motor Vehicle & Vehicle Parts Self-Certification" - had been published by the MLTM on 22 February and entered into force on the same day. This Notice specified the details of the registration, testing and self-certification procedure. It also stipulated that the products should be marked with the Korean KC mark in an indelible manner, and that stickers would only be allowed if the part was too small or if the engraving of the KC mark affected the parts' performance. The EU requested Korea to notify these Guidelines to the TBT Committee, in accordance with its obligations under Article 5.6 of the TBT Agreement, and suspend their application until Members have had an opportunity to provide comments, which should be taken into account. It also requested Korea to provide a reasonable period - of at least six months - between the publication of the Guidelines and their entry into force. The EU reiterated its request for Korea to accept UN certification and marking as an alternative to the KC mark and, in the meantime, to allow the affixing of the KC mark by means of a sticker in all cases (i.e. not only when the part was too small or its performance was affected).

2.58. The representative of Korea explained that the purpose of this measure, which was similar to those from other Members, including the EU, was to protect customers from low graded and defective products. Regarding the notification, he recalled that the EU had consistently requested Korea, according to the provisions of the EU-Korea FTA, to accept parts with E-mark which meet the safety standards instead of KC-mark. However, given that there was no provision regarding the recognition of E-mark, Korea was unable to accept this request. In order to ease the burden of automotive parts manufacturers, Korea allowed manufacturers not only to carve the KC mark on the parts but also to print it or mark it indelibly. Moreover, in the case where the size of the parts was too small that self-certification could not be marked over 1.5mm of length, stickers were also allowed. A 3-month-grace time was also granted to give enough time to manufacturers to adapt. He also informed that the final regulation of self-certification for automotive parts was promulgated on 22 February 2013 and had since entered into force. Furthermore, after notifying the regulation on December 2011, Korea believed that it had made significant transparency efforts with respect to this measure by: (i) informing domestic and international manufactures about the regulation; (ii) reflecting comments of other Members for two years; (iii) granting a 3-month grace period so as to ease the burden of manufacturers and give enough time to adapt.

2.2.1.11 European Union - Tobacco products, nicotine containing products and herbal products for smoking. Packaging for retail sale of any of the aforementioned products (G/TBT/N/EU/88) (IMS ID 377)

2.59. The representative of Nicaragua said that his delegation was concerned with the proposed directive. He wondered whether the high level of protection sought by the draft measure was proportional to the legitimate public health objectives and whether it was not more trade

restrictive than necessary to attain such goals. The EU imposed strict obligations with respect to disclosure of ingredients which must be met before a tobacco product can be marketed. The draft directive provided that manufacturers should not only provide all of the toxicological information with respect to the product concerned but also should present a report on the inclusion of such ingredients. Nicaragua asked the EU to explain the rational of such requirements. The draft directive also provided that Member states may require manufacturers or importers to carry out other tests to assess the health effect of substances bearing in mind the problems of addiction and toxicity. Nicaragua considered that the imposition of other non-specified tests was not in line with the goal of harmonizing legislation in the EU. What were these "other non-specified tests"? Would the tests for addiction and toxicity impact, *inter alia*, what proof would be necessary? How would the EU ensure that these other non-specified tests within EU member States not constitute arbitrary and unnecessary barriers to trade? With such obligation of disclosing ingredients, the EU would endanger industrial secrets and other confidentiality of producers. In this respect, Nicaragua asked what was the public health objective pursued by forcing manufacturers to provide internal and external studies on marketing and with respect to other groups of consumers on ingredients and forcing manufacturers to provide volume sales for each product and for each member State.

2.60. Nicaragua also asked what scientific evidence was used by the EU to justify the ban on all tobacco products with characteristic flavours as there seemed to be no indication anywhere that these products, in particular those with regular flavour, were harmful to health. Nicaragua also asked what would be the maximum levels of additives with respect to the preparation of a positive list of prohibited additives. Additionally, what scientific evidence was used as a basis to impose a strict ban on these specific additives, irrespectively of whether they impart a characteristic flavour? In fact, certain additives did not impart a characteristic flavour and there was no evidence that they increase the toxicity or dependence on the product. What was thus the basis for banning such additives? What was the reason for providing a similar prohibition for characteristic flavours of cigars, and other tobacco products, which were currently exempt from the measure? Would it simply be because the market quota for these particular tobacco products had increased by a given percentage? He also noted that the proposed directive, purportedly based on the Appellate Body report in US - Clove Cigarettes, covered all flavoured tobacco products, including "menthol" and "clove". He also noted that the analysis of the Appellate Body in that case, which led to a finding of *de facto* discrimination under Article 2.1 of the TBT Agreement, were, however, based on the specific circumstances of the domestic market of tobacco products at issue.

2.61. With respect to the requirement for a health warning, he observed that the EU mentioned, as a basis, a 2009 report, which was commissioned by the EU itself. The EU proposed measure was also based on the experience of other countries that use major graphic health warnings. This however did not show if the use of such warnings had made a material and quantifiable contribution to the objective of protecting human health. Nicaragua asked the EU for other studies and evidence that, in the EU's view, would constitute new scientific evidence to support a direct causality between the requirement for the warning and the objective of providing a high level of health protection. Additionally, Article 12 of the proposed directive prohibited any information in the labels and packaging of tobacco products that promoted these products by means that were "false, misleading, deceptive or likely to create an erroneous impression about [their] characteristics, health effects, hazards or emissions". However, the proposed directive did not define "misleading", what was particularly confusing and deserved a more precise definition. Further, with respect to the draft directive's prohibition of symbols, marks or other signs in the packages of certain tobacco products, Nicaragua asked whether the EU had considered its obligations under the TRIPS Agreement when devising such obligation. More specifically, Nicaragua asked what "false, misleading and deceptive" meant with respect to registered trademarks for tobacco products that include in them reference to the flavour of these products. Would the product prohibition ban in Article 12 of the proposed directive apply in such cases? Another element of concern was the prohibition of "misleading colours" in Article 12(2) of the proposed directive. In this respect, Nicaragua asked the EU to clarify, first, how misleading and non-misleading colours would be differentiated, and, second, to provide scientific evidence supporting the claim that banning the use of colours contributed to the achievement of the legitimate human health objective. Nicaragua also asked for the scientific evidence that supported the rule in Article 12(2) of the proposed directive, according to which "cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading." Why did this presumption applied only to slim cigarettes and not, for instance, also to cigars ("puros") with identical diameter? Nicaragua also asked the EU to explain the basis for requiring that cigarette packages be cuboid in shape. In Nicaragua's view, there was no evidence showing that the shape of the package protected human health. Finally,

Nicaragua asked the EU for detailed information on the scientific evidence justifying the distinction made between, in one hand, cigarettes and "roll-your-own tobacco", and, on the other, cigars and other tobacco products. What was the scientific evidence showing that smoking cigars was less harmful than smoking cigarettes?

2.62. The representative of the Dominican Republic expressed serious concern about the impact of the measures proposed by the EU with respect to their consistency with the TBT Agreement. The full statement is contained in G/TBT/W/358.

2.63. The representative of Indonesia associated his delegation with the concern expressed by the Dominican Republic and Nicaragua. Indonesia noted that while the proposed measure exempted certain tobacco products, such as cigars, cigarillos and pipe tobacco, from some provisions (such as the prohibition of products with characterizing flavours), such exemptions shall be removed if there would be a substantial change of circumstances in term of sales volume or prevalence level among young people. In this regard, Indonesia asked the EU to clarify what would be the amount of volume actually defined for these exemptions.

2.64. The representative of Guatemala stated that his delegation shared the policy objectives of the EU to improve public health by discouraging people from using tobacco products. However, it was not clear to Guatemala how the proposed EU measure would achieve the purported legitimate objectives. In any case, this measure appeared to be more trade restrictive than necessary to achieve such objectives. The EU should therefore consider less trade restrictive alternatives.

2.65. The representative of Malawi expressed serious concern about the impact of the measures proposed by the EU with respect to their consistency with the TBT Agreement. The full statement is contained in G/TBT/W/360.

2.66. The representative of the Philippines associated her delegation with the concern expressed by the Dominican Republic and Nicaragua. She noted that the proposed measure would ban certain tobacco products with a characterizing flavour and that there were exemptions to this ban. Like Indonesia, the Philippines sought clarification and further information on the criteria for the threshold to be used on the surge in the consumption of the exempted products. Further, with respect to the criteria for the regulation of ingredients pertaining to characterising flavours, particularly as it related to tobacco products currently exempted from the ban, she noted that cigarettes made of several types of tobacco contained several additives. These additives, however, were not used to give characterizing flavour to the product; rather, they were used as an essential component to mitigate the strong flavour, like in the case of burley tobacco, where natural sugars and flavours were destroyed by the curing process.

2.67. The representative of Honduras expressed her delegation's commercial interest in this matter, in particular the answers to the questions posed to the EU by the preceding delegations during this meeting.

2.68. The representative of Mexico asked for more clarification about the proposal's prohibition of misleading information in its Article 12, a rule linked to the use of trademarks. She also asked the EU for the scientific and technical justification to require that tobacco products be sold in packages of at least 20 units and that a unit packet of "roll-your-own" tobacco contain tobacco weighing at least 40g. She further noted that the proposed directive required that all cigarette packages and "roll-your-own" tobacco contain a single, EU-wide "tracking and tracing system" and a "common security feature". Mexico asked the EU to further explain the reason for such measures, including the costs for their implementation. Mexico was concerned that this proposed directive could be more trade restrictive than necessary within the meaning of Article 2.2 of the TBT Agreement since there could be other less burdensome means to achieve the legitimate objectives of protecting human health. In this respect, Mexico asked the EU for any scientific and technical evidence supporting the approach taken to deal with the attraction to the public of tobacco products when packaged. She recalled that Article 2.8 of the TBT Agreement provides that Members must base their technical requirements "in terms of performance rather than design or descriptive characteristics". This draft measure may not comply with such provision since it dealt with the packet itself rather than restricting the use of tobacco.

2.69. The representative of Norway stated that public health and tobacco control were topics of particular interest to her delegation, and that Norway supported the EU in its efforts of combatting the tobacco epidemic. She praised the EU for having notified the proposed measure at such an early stage in the process. In Norway's view, it was within the right of each WTO Member to adopt measures which were necessary to protect public health, as long as they were consistent with the WTO Agreements. It was Norway's firm opinion that the FCTC and the relevant WTO Agreements were mutually supportive, and that it was therefore possible to implement measures intended to regulate the packaging of tobacco products in line with both sets of binding obligations.

2.70. The representative of New Zealand reiterated his delegation' view that Members had the right to regulate the protection of human health and safety, in particular in the important area of tobacco control. New Zealand trusted that the EU would regulate in a manner that would be consistent both with EU member States obligations under WTO Agreement and with their obligations under the FCTC.

2.71. The representative of Cuba stated that her capital was still reviewing the EU draft and reserved the right to intervene subsequently on this matter.

2.72. The representative of Zambia stated that her delegation shared the concerns raised by the previous delegations. While Zambia shared the public health objectives outlined in the EU notification, it believed that the proposed measures seemed to be excessive and could potentially have implications for the EU's obligation under the WTO Agreements. Zambia asked the EU to explain the draft measure's prohibition of additives and its relation with health benefits. She also asked whether there was a list of such prohibited additives and what measures and comparators EU intended to use in order to determine the degree of toxicity or addictiveness.

2.73. The representative of Nigeria stated that her delegation associate itself with the concerns raised by several delegations on this EU proposal with respect to the prohibition of tobacco products containing any additives as flavours to cigarettes.

2.74. The representative of Zimbabwe was concerned with EU proposed measure's restrictive effects on trade from, and negative impact on tobacco producing of, developing countries.

2.75. The representative of Australia said that, according to the WHO, approximately one person died every six seconds due to tobacco. Tobacco killed nearly 6 million people each year. Unchecked, tobacco related deaths could increase to more than 8 million per year by 2030. Given these facts, Australia welcomed the EU's notification on tobacco products directive proposal. In addition to mandating increased graphic health warnings, under the proposal, Australia understood EU member States were allowed to implement plain packaging of tobacco products as far as compatible with the directive and EU law. The proposed EU directive was, in Australia's view, a legitimate measure designed to achieve a fundamental objective: the protection of human health, in particular the protection of young people against smoking initiation and uptake. Like Australia, the EU was a strong supporter of effective tobacco control and both shared common goals as parties to the WHO FCTC. In this respect, Australia noted that one of the objectives of EU proposal was precisely the implementation of the FCTC. Finally, Australia was of the firm view that Members had the right to implement measures necessary to protect human health while complying with relevant international treaty obligations, including the TBT Agreement.

2.76. The representative of the European Union explained that the new proposal, which was put forward by the European Commission on 19 December 2012, was meant to replace the current Tobacco Products Directive 2001/37/EC. It had been notified to this Committee as notification G/TBT/N/EU/88 on 18 January 2013, and WTO Members were being provided 90 days to comment on the draft, i.e. until 18 April 2013. After this period, the proposal would go through the EU's legislative process, in which both the European Council and the Parliament give their approval in order for the proposal to be adopted. Once adopted, the Directive would become applicable 18 months later, and products not in compliance with the Directive would be able to be placed on the market for an additional 6 months.

2.77. The representative of the EU explained that, as its name suggested, the current applicable EU legislation, Directive 2001/37/EC, had been adopted over 10 years ago. During this time, there had been various scientific and international developments in the area of tobacco control, as well

as changing trends in the market for tobacco products and in consumption patterns. Most notably, in the international context, the WHO Framework Convention on Tobacco Control (FCTC) had entered into force in 2005; the EU, as well as its member States, were parties to the FCTC, and committed to implement it in their legal frameworks. There had been repeated calls from numerous EU stakeholders, as well as the European Parliament and Council, to strengthen tobacco legislation in line with these developments. At the same time, the EU was not only the world's leading importer of raw tobacco, but also the largest exporter of tobacco products. Growing and manufacturing of tobacco was an activity that, while decreasing in importance, still employed thousands of people in the EU. Social aspects were also duly considered, as well as the economic costs of tobacco addiction for private businesses and for the State. The European Commission had carefully balanced the need to put in place a comprehensive tobacco control policy, including the implementation of FCTC commitments, with economic and trade considerations, on the basis of the Commission's assessment of the specific circumstances prevailing in the EU. Consistency with international rules had been ensured, including with regard to WTO provisions. The proposal was therefore the result of thorough consultations and in-depth analysis, and provided for a broad range of measures which were both non-discriminatory and proportionate to the legitimate health objectives pursued. The draft Directive was fully consistent with the EU's international commitments, including its obligations under the TBT Agreement, and throughout the legislative process, WTO aspects would be duly be taken into account.

2.78. The proposal joined a broad array of legislative and non-legislative initiatives (such as excise duties, public awareness campaigns, bans on smoking in public places, prohibition of advertising), at both EU and Member State level, to increase awareness of tobacco risks, reduce the appeal and attractiveness of tobacco products, and therefore contributed to a decrease in smoking rates and smoking initiation, particularly among youngsters. While the overall number of smokers in the EU had decreased in past decades, a significant number of EU Member States have witnessed an upward trend since 2008. At present, 28% of EU citizens were smokers, 70% of which had started before the age of 18. Tobacco consumption was the single most important avoidable health threat for EU citizens, and was responsible for 700,000 deaths each year in the EU. The Commission developed the new proposal over a long period of time, carefully balancing the interests of all stakeholders, and providing numerous consultation opportunities along the way. For instance, a public consultation, held in 2010, garnered over 85,000 submissions, while targeted discussions with stakeholders – such as consumer groups, non-governmental organizations, as well as tobacco growers, distributors, upstream suppliers, manufacturers, and pharmaceutical companies – had taken place throughout the legislative development process. The impact assessment underpinning the Commission's proposal was also a very comprehensive exercise – for instance, several external studies had been commissioned to provide input into the Commission's own assessment, which had been complemented by two additional opinions by the EU's independent Committee on Emerging and Newly Identified Health Risks, on smokeless tobacco and, respectively, on additives.

2.79. The new proposal covered several policy areas, including ingredients, packaging and labelling, traceability, novel tobacco products, and cross-border distance sales. In the area of ingredients, the Commission had proposed a ban on cigarettes, "roll-your-own" and smokeless tobacco products with a characterizing flavour (in other words, a distinguishable aroma or taste other than tobacco, such as fruit, herb, candy, menthol or vanilla). The use of additives which were essential for the manufacture of tobacco products was not prohibited, as long as those additives did not result in a product with a characterizing flavour. As regards labelling and packaging, the proposal foresaw a mandatory combined warning (picture + text message) on 75% of the two main surfaces of cigarettes and "roll-your-own" products, as well as a ban on promotional and misleading elements. The proposal did not set limits on the use of trademarks or branding on the remainder of the pack – in other words, it did not mandate cigarettes to be sold in plain packaging. With regard to the concerns expressed by some delegates on the treatment of cigars, the she explained that that all tobacco products, including cigars, were covered by the proposed Directive, as well as under the current Tobacco Products Directive. However - unlike cigarettes and "roll-your-own" tobacco products, which accounted for over 95% of the tobacco market and were generally the products of choice for young people - cigars were considered niche products, which accounted for a fraction of the market and did not contribute to smoking initiation. Therefore, to ensure proportionality and avoid unnecessary burdens for SMEs both in the EU and abroad, the proposal placed less stringent requirements on these products – for instance, they did not have to display picture warnings, and cigars with characterizing flavours would not be banned.

2.80. With respect to process, the representative of the EU explained that the proposal would now go through the EU's legislative process, in which both the Council of the EU and the European Parliament would have to give their approval in order for the proposal to be adopted. Once adopted, the Directive would become applicable 18 months later, and products not in compliance with the Directive would be able to be placed on the market for an additional 6 months. The EU was confident that the information provided in this meeting had been helpful in clarifying the context and various aspects of the proposal, and remained open to address any remaining questions bilaterally. The EU also invited Members to provide their comments in writing to the TBT notification by the deadline of 18 April 2013.

2.2.1.12 Ecuador - Draft Technical Regulation of the Ecuadorian Standardization Institute (PRTE INEN) No. 080: "Labelling of footwear" (G/TBT/N/ECU/94) (IMS ID 378)

2.81. The representative of Colombia thanked Ecuador for responding to Colombia's written comments on this draft measure. However, his delegation still had some questions, particularly the requirement for third-party conformity certificates for the labelling of footwear, which normally was a requirement found in technical regulations. Colombia requested more information on this requirement, including on how it related with Andean Community rules.

2.82. The representative of Ecuador informed that he would respond this concern together with the subsequent concern, also raised by Colombia.

2.2.1.13 Ecuador - Labelling of articles of apparel, household linen and clothing accessories (G/TBT/N/ECU/7, G/TBT/N/ECU/7/Add.1 G/TBT/N/ECU/7/Add.2) (IMS ID 379)

2.83. The representative of Colombia thanked Ecuador for responding to Colombia's written comments on this draft measures. Like the previous concern, Colombia requested more information on the requirement for third-party conformity certificates for the labelling of the products covered by this draft measure.

2.84. Replying to both concerns raised by Colombia, the representative of Ecuador expressed his delegation's concern that discussing this draft measure at the present TBT meeting was premature given that these drafts were still in the consultation phase, in accordance to the TBT Agreement and that responses had already been sent to Colombia on 4 March.

2.2.2 Previously Raised Specific Trade Concerns

2.2.2.1.1 European Union - Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)[5] (IMS ID 88)

2.85. The representatives of India, Australia and the Philippines reiterated concerns expressed at past meetings with respect to REACH. The representative of India, in particular, recalled the REACH Regulation's second deadline this year, and listed a number of outstanding issues: the opaque and arbitrary functioning of the Substance Information Exchange Fora (SIEF), including the prohibitive costs associated with them; definitions of a micro, small and medium size enterprise (SMEs); the cost associated with hiring an Only Representative (OR); and the request for merchant importers to directly undertake registration.

2.86. The representative of the European Union recalled replies to these questions provided at previous meetings. She informed Members that the Commission report on the review of REACH, adopted on 5 February 2013, had confirmed that it was functioning well, but also identified the need to reduce its impact on small and medium-sized enterprises (SMEs). In view of the new registration deadline of 31 May 2013, all substances manufactured or imported at, or above, 100 tonnes per year, would have to be registered. She referred to efforts made by the European

[5] The relevant notifications and documents are: G/TBT/N/EEC/52 and Adds.1-7; Add.3/Rev.1, G/TBT/N/EEC/295, G/TBT/N/EEC/295/Add.1; G/TBT/N/EEC/297, GG/TBT/N/EEC/297/Rev.1, G/TBT/N/EEC/297/Rev.1/Add.1; G/TBT/N/EEC/333, G/TBT/N/EEC/333/Add.1, G/TBT/N/EEC/334, G/TBT/N/EEC/334/Add.1; G/TBT/N/EEC/335, G/TBT/N/EEC/335/Add.1; G/TBT/N/EEC/336, G/TBT/N/EEC/336/Add.1; and, G/TBT/W/208.

Chemicals Agency (ECHA) and the European Commission to inform companies about their REACH obligations. ECHA had been offering a series of activities, including conferences, workshops, webinars and other training opportunities such as a workshop on the functioning of SIEFs and data sharing industries.

2.2.2.1.2 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/Rev.1) (IMS ID 133)

2.87. The representative of Japan enquired about the present status of Clause 10.2 of the revised "Agreement for the Grant of BIS Licence" (hereafter BIS Agreement) that required only foreign tyre manufacturers to provide a bank guarantee fee of USD10,000. This clause appeared to reflect discrimination between Indian and foreign tyre manufacturers; it unfairly modified conditions of competition – it needed to be corrected so as to apply the same conditions to Indian and foreign companies. Furthermore, Japan called for a revision of the ISI Marking Fee calculation method that was calculated according to the total number of ISI marked tyres, including tyres destined for export from the Indian market. Japan was of the view that these tyres should be exempted as the Indian Government need not guarantee the quality of products sold outside of India.

2.88. The representative of the European Union reiterated the longstanding concerns about the Indian Quality Order on Pneumatic Tyres and Tubes for Automotive Vehicles, which included a certification procedure with mandatory marking for tyres, including the requirement regarding the bank guarantee of USD10,000 for the payment of royalty fees (contained in Article 10.2 of the BIS Agreement) and whether this was applied in the same way to domestic and foreign producers. She reiterated particular concern about the royalty fees to be paid on the total production of tyres marked and produced with ISI marking, and not only those which were actually imported to India. She urged India to remove the royalty fees, or to modify their calculation to limit them to tyres which were *de facto* exported to India, as they were extremely burdensome and more trade-restrictive than necessary in their current formulation.

2.89. The representative of Korea reiterated concerns regarding marking fees. He said that the manner in which marking fees were calculated – on the basis of the total number of tyres produced and marked with the ISI symbol – was unfair and needed to be reviewed; it needed to reflect the total number of ISI-marked tyres imported to India. Compared with similar marks issued by other countries, fees were considerably higher for the ISI system, and in general most countries did not charge marking fees for tyres. Korea requested India to repeal the USD10,000-Performance Bank Guarantee that was only required for foreign manufacturers outside India. He cited Article 5.1.1 of the TBT Agreement, stipulating that conformity assessment procedures be applied so as to grant access for suppliers of like products originating in the territories of other Members under conditions no less favourable than those accorded to suppliers of like products of national origin originating in any other country.

2.90. The representative of India reiterated that the marking fee and overall fees were equitable, in terms of the unit costs of tyres for both domestic and foreign manufacturers. The overall fee charged by India was comparable or even lower than those charged by other Members for similar schemes. The bank guarantee clause (Article 10.2) under the Foreign Manufacturers Certification Scheme (FMCS) had been inserted to obviate any legal complications that might arise out of deletion of Article 6.3 of the BIS agreement that had been removed at the request of some delegations.

2.2.2.1.3 India – Mandatory Certification for Steel Products (G/TBT/N/IND/32, G/TBT/N/IND/32/Add.1; G/TBT/N/IND/32/Add.2) (IMS ID 224)

2.91. The representative of the European Union voiced concerns in view of the entry into force on 31 March 2013 – for certain steel products – of India's mandatory third party certification under the Steel and Steel Quality Products Order. The EU enquired about the implementation of mandatory third party certification, given that the European industry continued to report significant difficulties during the certification procedure, including long delays for issuing certificates, extensive and detailed information to be provided, the lack of feedback on reasons for refusal of applications, and the lack of recognition of test results carried out by foreign laboratories. The EU invited India again to take measures to ensure equal treatment for domestic and foreign manufacturers. She called on India to institute a more expeditious procedure for the steel products submitted to third party certification including clear deadlines and possibilities to

challenge the refusal of the application. The representative asked India to consider suspending implementation beyond 31 March 2013 to allow already submitted applications to be processed. She reiterated the EU view that third party certification was inappropriate and too burdensome for intermediate steel producers.

2.92. The representative of Japan reiterated three concerns with regard to the technical regulation. First, he considered that technical regulations were not needed for intermediate products such as steel products, and the objective of securing consumer's health safety should be achieved by safety regulations for final products. Second, Japan restated concerns about the undefined scope of the technical regulation, and asked India to clarify the covered products. If put into effect as scheduled, this would create unnecessary obstacles for customs procedures, disrupt Japanese high-quality steel supply, and could cause a negative impact on the Indian manufacturing sector. Japan asked India to postpone the commencement of operation and implementation of the regulation until its scope of application was clarified.

2.93. The representative of the China also reiterated previously stated concerns related to this measure, and asked in particular for a clarification on the scope of products subject to the certification scheme.

2.94. The representative of India reiterated that the regulation on nine steel products, initially subject to mandatory BIS certification under the quality order of 2012, had been amended on February 15 leading to the situation where the date of entry into force for some of these products had been extended from 12 September to 31 March 2013. In terms of product coverage (the nine steel products covered) the HS codes, titles and Indian standard numbers had been provided. Regarding the measure's applicability to intermediate products, it was noted that the regulation applied to intermediate products because this affected the performance of the final product.

2.2.2.1.4 United States – Hazardous Materials: Transportation of Lithium Batteries (G/TBT/N/USA/518, G/TBT/N/USA/518/Add.1, G/TBT/N/USA/518/Add.1/Corr.1) (IMS ID 262)

2.95. The representative of the European Union welcomed the second addendum to notification G/TBT/N/USA/518 of 16 January 2013, which indicated that the 2013-2014 ICAO Technical Instructions had now been implemented by the US. The EU sought confirmation that a shipment of lithium batteries in compliance with the 2013-2014 ICAO Technical Instructions could be transported to the US without any further unilateral requirements. Moreover, with regard to the US second addendum on whether to provide shippers and carriers with the flexibility to choose the most appropriate method of compliance for the transportation of lithium batteries, her delegation enquired on requirements that could possibly be imposed by shippers and carriers other than the ones laid down in the 2013-2014 ICAO Technical Instructions.

2.96. The representative of the United States recalled that, as of 7 January 2013, the US regulations authorized the use of the 2013-2014 ICAO Technical Instructions for transportation of hazardous materials to, from, or within the US as an alternative to the US Hazardous Materials Regulations (HMR). Lithium batteries prepared in accordance with the 2013-2014 ICAO Technical Instructions could be offered, accepted and transported. Specific to lithium batteries, a difference from the ICAO Technical Instructions (USG 2) was maintained in that lithium metal batteries (UN3090) were forbidden for transport aboard passenger carrying aircraft. Apart from this exception, the provisions contained in the 2013-2014 ICAO Technical Instructions applicable to lithium batteries were in most cases more stringent than the current HMR. On 11 January 2013, the US had notified WTO Members that PHMSA[6] had issued a Notice of Proposed Rulemaking soliciting additional comments on the positive or negative impacts of adopting the 2013-2014 ICAO lithium battery provisions. PHMSA was currently evaluating the impacts of amending the appropriate sections of the HMR consistent with the 2013-2014 ICAO Technical Instructions, which, if adopted, would have the practical effect of enacting the ICAO Technical Instructions for domestic transport of lithium batteries. No amendments more restrictive than the current ICAO Technical Instructions were being considered.

[6] Pipeline and Hazardous Materials Safety Administration.

2.2.2.1.5 Turkey – Conformity Assessment Procedures for Pharmaceuticals, Circular issued by the Directorate General of Drugs and Pharmacy of the Ministry of Health re "Important Announcement regarding GMP Certificates" (IMS ID 264)

2.97. The representative of the United States recalled previously raised concerns on this issue in 2010, 2011, and 2012. The US thanked Turkey for alleviating the growing backlog of inspections by allowing for a parallel submission process. She referred to her delegation's request for additional steps to be taken by Turkey to address the backlog, such as as the recognition of GMP (Good Manufacturing Practices) inspections conducted by FDA or other members of the PIC/S (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme), as well as opportunities to discuss the trade concerns in more detail and to establish targets for reducing inspection delays.

2.98. The representative of Turkey said that Turkey's GMP certification process for pharmaceuticals had been explained in detail during previous meetings. He said that there was no comparative numerical data proving that backlogs claimed to occur during the GMP certification process in Turkey exceeded those in other WTO Members. Nonetheless, he informed the Committee that the Turkish Ministry of Health (MOH) was working on a method that would enable simultaneous acceptance of GMP inspection and license applications. He said that Turkey was ready to work constructively with interested Members.

2.2.2.1.6 Brazil - Health Products Good Manufacturing Practices (GMP) Requirements for Health Products (G/TBT/N/BRA/328) (IMS ID 233)

2.99. The representative of the United States recalled previously raised concerns on this issue in 2010, 2011, and 2012. She noted the National Health Surveillance Agency's (ANVISA) work with other regulatory agencies such as the US FDA (Food and Drug Administration) to develop a single auditing programme to help address the backlog through work-sharing and developing criteria for accreditation of third parties that would be implemented in 2014. As the inspection backlog continued to grow, her delegation had requested that ANVISA work with trading partners to develop interim steps. Recently, the US had noted that ANVISA had developed and published a strategy for 2013-2016 expanding its focus from health, safety, and cost effectiveness to also considering domestic market and industry impact for suppliers for medical products. She requested further information on this proposed change and voiced concerns about the potential impact on trade.

2.100. The representative of the European Union asked Brazil to provide an update on the situation as regards the Good Manufacturing Practices (GMP) inspections for medical devices and noted that a number of measures had been taken to accelerate inspection capacity. The EU asked if those measures were reflected in a concrete reduction of the backlog and if ANVISA was now in a position to guarantee that inspections were carried out within three months after the request had been filed. In case reasonable inspection deadlines could not be complied with, the EU invited ANVISA anew to rely on and take into account quality management system audits conducted by accredited auditing bodies such as EU Notified Bodies, and to consider accepting products authorised in the EU or in other major markets, pending the completion of ANVISA inspections. She invited ANVISA to consider subcontracting overseas inspections to accredited auditing bodies such as EU Notified Bodies, which would inspect EU facilities on behalf of ANVISA and allow for a reduction of the current backlog. The EU enquired if Brazil was considering these suggestions.

2.101. The representative of Brazil said that several measures had been adopted to improve the inspection capacity of ANVISA, such as the augmentation in the number of GMP inspectors. Measures included the relocation of experts from other areas of the agency, the enabling of experts from state and/or municipal level to act as international inspectors, and the publication of draft resolution No. 2 of 8 January 2013, still under public consultation, which aimed at, *inter alia*, optimising conditions for the concession of GMP certificates. To his knowledge, there had been no case of interruption of trade caused by the processing of GMP certification. He recalled that Brazil had joined the International Medical Device Regulators Forum (IMDRF). Brazil had taken note of the suggestions made by the EU with a view to finding a temporary solution – but these did not seem feasible in the context of the legal framework of Brazil, which required GMP certificates to be issued by ANVISA. In this sense, the representative of Brazil invited the EU and other Members to consider an alternative previously suggested by Brazil: the confidentiality agreements between health agencies in Brazil and other Members to exchange inspection reports.

2.2.2.1.7 European Union - Directive 2004/24/EC on Traditional Herbal Medicinal Products (THMP) (IMS ID 265)

2.102. The representative of India said that despite repeatedly raising this issue in past Committee meetings, it remained unresolved. He briefly restated his delegations core concerns, including: non-notification to the WTO; the need for review of the Common Technical Document (CTD), which was not appropriate for multi-component traditional medicinal formulations; expansion of the definition of herbal medicinal products to include non-herbal biological and non-biological ingredients; and the need for references to national pharmacopeia for all compliances on specification. Due to impediments in the Directive, India had hardly undertaken any exports under the scheme.

2.103. The representative of the European Union noted that extensive technical clarifications had been provided in previous meetings of the Committee. She reported that a number of meetings between EU and Indian experts had been held, notably to discuss: issues of eligibility criteria, scope of the Directive, registration procedures and documentation to be provided. Her delegation remained open to discuss any further issues bilaterally at expert level.

2.2.2.1.8 India – Telecommunications Related Rules (IMS ID 274)

2.104. The representative of the United States noted improvements in India's telecommunications related regulations, such as the May 2011 amendment that removed the source escrow requirement. However, she raised three concerns: (1) the requirement for telecommunications equipment vendors to test all imported network elements in India; (2) the requirement to allow the telecommunications service providers and government agencies to inspect a vendor's manufacturing facilities and supply chain, and to perform security checks at any time during the supply of the equipment; and (3) the imposition of strict liability and possible blacklisting of a vendor for taking inadequate precautionary security measures. The US also reiterated concerns with respect to the requirement that foreign firms bear additional costs of in-country testing, and with respect to the 1 April 2013 entry into force of the measures.

2.105. The representative the European Union echoed the concerns raised by the US. In particular, the representative of the EU raised concerns about the deadline for the entry into force of the measures, and for the absence of any appointed laboratory to process the testing applications. Additionally, he expressed concerns for the absence of final guidelines on the applicable standards and for the actual scope of testing, which he suggested be limited to critical elements only. He also reiterated the EU request to maintain the current level of acceptance of test results and certificates issued by foreign laboratories approved under the Common Criteria Recognition Arrangement (CCRA). With regards to the testing methods, he reiterated the EU request that relevant international standards for information security be referenced in the final guidelines. Moreover, he requested clarification on the relationship between the draft guidelines on the certification of telecommunications equipment, which had been put out for public consultation in the spring of 2012, and the security clearance requirements to enter into force on 1 April 2013. Finally, he underlined the need for economic operators to rely on a predictable framework that provided legal certainty and allowed other adequate planning for the marketing of products, and invited India to consider any measures that may be necessary in order to avoid any market disruption.

2.106. The representative of Japan was also concerned that the Indian regulation might not be in accordance with the CCRA, since only network elements approved by Indian certification agencies would be allowed in the market. He noted that India had accepted the CCRA scheme, and hoped India would ensure the regulations did not impede market access for foreign companies.

2.107. The representative of India said that there was no intention of not recognizing the process based conformance tests conducted by the laboratories under the CCRA, but that for security considerations, testing had to be conducted in the designated laboratories.

2.2.2.1.9 China – Requirements for information security products (including, *inter alia*, the OSCCA 1999 Regulation on commercial encryption products and its on-going revision and the Multi-Level Protection Scheme (MLPS) (IMS ID 294)

2.108. The representative of the United States recalled previous statements in the Committee and noted China's commitment to the obligations of the TBT Agreement's Code of Good Practice, in particular, to the requirement for a 60-day public comment period.

2.109. The representative of the European Union also recalled previously raised concerns on this issue. He emphasized the need for increased transparency in the development of regulations and standards, including access by foreign stakeholders - that needed to be treated on equal terms as Chinese companies when established in China. He echoed the concerns of the US with respect to compliance with the Code of Good Practice by Chinese central government bodies in charge of developing the relevant standards. The EU also requested an update on the regulation on commercial encryption products managed by the Office of State Commercial Cryptography Administration (OSCCA), on the six information security standards developed by the China Electronic Standardisation Institute (CESI), and on the standard for radio frequency based mobile phone payments developed by the China National Information Technology Standardization (NITS) Technical Committee. The latter standard raised issues of accessibility of the encryption algorithm, whose content and licensing conditions were for the OSCCA to determine. The EU representative requested that the algorithm be accessible fairly to all interested companies. In addition, he recalled previous concerns on the Multi-Level Protection Scheme (MLPS). Finally, the EU also raised a new concern regarding an announcement by the People's Bank of China that all banking financial payment systems would need to integrate Chinese algorithms. In this respect, the OSCCA had published 14 standards on its website related to the implementation of this policy. He inquired whether these algorithms would be mandatory and, if so, under which conditions they would be available to non-Chinese information security product suppliers to the banking systems.

2.110. The representative of Japan echoed the concerns of the US and the EU. In particular, he expressed concerns over the encryption of the OSCCA regulations and the Multi-Level Protection Scheme (MLPS), and requested China to provide information on how to introduce these measures.

2.111. The representative of China reported that the regulation on commercial encryption products had been listed in the 2013 legislative work plan of the State Council of China, and that it was being drafted in line with the Legislation Law and Rules on Formulation of Administrative Laws of China. She stated that OSCCA would undertake scientific evaluation and public consultation to ensure openness in the legislation process. She also explained that the essence of the MLPS aimed at safeguarding the information network and important information systems, to ensure national security, and to protect public interest. China had attached great importance to the security of information systems in banking, education, healthcare, transportation and other public utilities, due to their close relationship with citizen welfare. Therefore, she explained, the importance of information systems was not necessarily decided by the sensitivity of that industry, but by the possible damage it could cause to national security, social order, economic development and the public interest. In addition, it was noted that these systems would only cover a very limited portion of all information systems in China. Therefore, it was very unlikely that the regulations would have a significant effect on international trade. China had repeatedly stated that, in terms of intellectual property protection and government procurement, all enterprises within China would be treated equally in accordance with the non-discrimination principle of the TBT Agreement.

2.112. The representative of China welcomed the relevant technical suggestions from other foreign enterprises in developing the information security standards promulgated on 31 December 2012 by SAC. With respect to the five standards on radio frequency based mobile payment, he stated that they were voluntary and that algorithm E was only a symbol for text description. As for the new concern of the EU regarding the 14 standards, the representative said she would bring this issue to her authorities.

2.2.2.1.10 China – Provisions for the Administration of Cosmetics Application Acceptance (G/TBT/N/CHN/821; G/TBT/N/CHN/937) (IMS ID 296)

2.113. The representative of Japan noted that more than three years had passed since this regulation had been published in November 2009, and that he was aware of only three applications for a new ingredient which had been approved over this period. He requested China to

speed up the examination and to provide more specific guidelines on the review process. He also noted that many applications for registration of new plant extracts and ferments by the Japanese industry had been rejected because safety evaluations had not been carried out on a single substance. These new ingredients, already found in products in the Japanese market after safety evaluation clearance, had not caused any problems for consumer safety. Japan was of the view that some plant extracts and solvents could not be isolated, and that due to the nature of the isolation process, even if isolation was feasible, the isolated substance could have different properties from the one contained in the original substances. Therefore, he was of the view that the best way to evaluate the safety of such substances was to carry out testing of the substances as used in the final products.

2.114. Japan also raised a new concern with regard to the labelling requirement notified on 21 December 2012. He stated that pursuant to this labelling requirement, the manufacturer's name, address, hygiene license number, cosmetic product approval document number, or filing number were required. This information was already required by AQSIQ Ordinance No. 100. Therefore, it appeared that the implementation of the labelling requirement would bring a situation of duplicative regulations that was not necessary to fulfil the Chinese regulatory objective.

2.115. The representative of the European Union expressed appreciation for the constructive regulatory dialogue between the European Commission services and China's State Food and Drug Administration (SFDA). She said that this dialogue had contributed to progress on a number of issues of bilateral interest. However, she also stated that the approval of new ingredients and of products with new ingredients continued to pose difficulties for European companies operating in China. She hoped that the SFDA's efforts to make the registration scheme more operational would deliver results soon. She hoped that the on-going revision process of the Chinese Cosmetics Hygienic Management Rules would provide a more systemic solution to these issues, and bring Chinese legislation closer to international standards. Like Japan, the EU was concerned about G/TBT/N/CHN/937 which stipulated labelling requirements for cosmetics; she requested the Chinese authorities to coordinate with one another in order to ensure that there was no duplication or conflict between the requirements. Furthermore, the representative considered that the three-month period foreseen between adoption and implementation of the new rules was too short for industry to comply. The EU had submitted comments to China on this notification, and she invited China to provide a written reply.

2.116. The representative of the United States supported the comments made by Japan and the EU. She also encouraged China to consider approaches that were less burdensome and more commensurate with the risks involved in cosmetic products, such as post-market surveillance and internationally recognized good manufacturing practices. She requested clarity on the lists of approved substances SFDA had recently published and on how they related to SFDA approval requirements.

2.117. The representative of China noted that China had been cooperating closely with their trading partners in the implementation of the regulation. She said there was a bilateral meeting going on in Beijing between China and the EU on this issue, and that China had provided various training and information sessions to the industry. With regards to the labelling requirement, she said China was processing and analysing the comments received by Members, and that due to the considerable amount of comments, the proposed date of adoption and of entry into force of the regulation might be postponed.

2.2.2.1.11 France – Loi No. 2010-788: The National Commitment for the Environment (Grenelle 2 Law) (IMS ID 306)

2.118. The representative of India reiterated concerns about the lack of transparency and predictability of the Grenelle 2 Law. In particular, he expressed concerns about: the absence of a TBT notification; the lack of clarity on the international standard on which the measure would be based; the scope of the measure; the methodology for computation of the carbon footprint; the lack of a risk assessment analysis; and, the work on consultations carried out with developing countries. He also said that there was still no ISO standard on carbon footprint.

2.119. The representatives of Argentina, Brazil and China echoed India's concerns. Argentina and China requested more information about the results and current status of the "pilot stage"; and Brazil requested the EU to notify the Grenelle 2 Law to the TBT Committee.

2.120. The representative of the European Union reiterated that the Grenelle 2 Law did not contain technical regulations but provided only for an experiment concerning environmental labelling. She invited concerned Members to refer to the minutes of previous meetings with regard to the objective and scope of the experiment. She also said that the results of the experiment would be shared once evaluated.

2.2.2.1.12 Indonesia - Technical Guidelines for the Implementation of the Adoption and Supervision of Indonesian National Standards for Obligatory Toy Safety Draft Decree of the Ministry of Industry on Mandatory Implementation of Indonesia National Standard and Technical Specification for Toys (G/TBT/N/IDN/64) (IMS ID 328)

2.121. The representative of the United States expressed appreciation for the discussion on the issue that had taken place at the November meeting, but noted that the US industry was still seeking clarifications from Indonesia on a number of issues, including whether the decree would only apply to products placed on the market or imported after the date of entry into force. She requested a written response and a delay on the adoption of the toy safety certification programme until the specific testing requirements were clarified.

2.122. The representative of the European Union also expressed appreciation for the discussions in November 2012 but noted that no progress had been made in finalizing the technical guidelines for implementation, which were supposed to clarify how compliance with the mandatory SNI toy safety standards had to be demonstrated by manufacturers (e.g. testing methods, sampling procedures, etc.). He also stated that no laboratory had been appointed, and urged Indonesia to consider postponing the entry into force and to allow further discussion with foreign industry. The EU also raised concerns about the level of acceptance of test reports issued by foreign laboratories, the modalities for the affixing of the marking of compliance, the validity of the certificates of compliance, and the acceptance of ISO 9001 certificates as proof of compliance with Indonesia's Quality Management System requirements.

2.123. The representative of Indonesia informed the Committee that inputs from all Members had been consolidated by the Ministry, and that information on the requirements for azo dyes, formaldehyde and phthalates, as well as information on the certifications, would be accommodated in the technical guidance for the implementation of the ministerial decree, which was being drafted.

2.2.2.1.13 Russian Federation – Draft Technical Regulation of the Customs Union on alcoholic products safety (G/TBT/N/RUS/2)[7] (IMS ID 332)

2.124. The representative of the United States noted that the notification of the Eurasian Customs Union's Technical Regulation on Alcohol Product Safety designated a date for the comment period which occurred a year prior to the notification. She underlined the importance of the consultation process in transparency commitments to the WTO and recalled that this included a reasonable comment period. The US was also concerned about the technical regulation itself, including with respect to the requirement that whiskies be aged for three years and that alcoholic beverages had to indicate an expiration date. She explained that these requirements would have an impact on US producers and asked Russia to reconsider them.

2.125. The US understood that Russia, along with the other Eurasian Customs Union members, was revising the alcoholic beverages technical regulation – and that this revision required a circulation registry procedure for alcoholic beverages. She recalled that on 30 December 2012 Russia had signed Amendment SF171 (via the passage of Amendments to the State Regulation Law for Alcohol #286-FZ) into Russian Federal law, which created an additional circulation procedure outside of the Custom Union. She said that this additional circulation procedure under law SF 171 appeared to be duplicative to the circulation procedure in the draft Customs Union

[7] Listed as " Russian Federation – Draft on Technical Regulation of Alcohol Drinks Safety (published on 24 October) Eurasian Customs Union Technical Regulation on the Safety of Alcoholic Beverages)" in JOB/TBT/45.

Technical Regulation. Moreover, the circulation procedures appeared to be additional to other numerous and duplicative registration requirements for alcoholic beverages, which included State Registration and a Declaration of Conformity. As the regulation was scheduled to go into effect on 1 March 2013, the US requested Russia to postpone the implementation of SF171 – that the process be clarified, and, where possible, streamlined in the next draft technical regulation. The US looked forwards to receiving replies to comments sent in December 2011 and on 13 February 2013.

2.126. The representative of Australia acknowledged the Russian Federation's efforts to establish technical regulations for alcoholic products that ensured free circulation of these products in the single market of the Customs Union. He emphasized that Australia and Russia shared a commitment to adopt internationally accepted standards for alcoholic products as set out by the International Organisation of Vine and Wine (OIV) which helped to avoid the creation of unnecessary obstacles to trade in wine. Australia appreciated Russia's decision to notify to the TBT Committee its technical regulation on the safety of alcoholic products. On 6 February 2013, Australia had submitted comments on the notification of Russia's technical regulation on the safety of alcoholic products.

2.127. First, on the regulation of the use of additives, the representative of Australia said that a number of commonly used additives and processing aids, as set out by the OIV, which did not affect the safety of the alcoholic product, would either have restrictions placed on their use or would not be permitted for use in wines sold in the Customs Union in accordance with Russia's technical regulation. Second, Australia underlined that restricting the use of – or banning – these oenological practices would limit Australia's ability to continue to provide quality wine to the Customs Union. Third, in the light of this, Australia suggested that Russia consider adopting the OIV list of approved additives and processing aids, as set out in the "International Oenological Codex" and the "International Code of Oenological Practices". In addition, Australia sought clarification 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. If such wines were to be affected, he suggested that Russia would introduce a six-month transition period for these products to enable industry sufficient time to implement the stated labelling requirements. Finally, Australia asked that the requirement for nominated storage conditions be removed from the draft technical regulation, noting that the storage conditions of a wine did not affect health and safety. The representative concluded by welcoming Russia's consideration of these comments and those of other WTO Members and looked forward to receiving a written response to its comments.

2.128. The representative of the European Union expressed her delegation's concerns regarding the procedure of notification of alcoholic products. The information that would be requested for this procedure was duplicative as regards the information that was already provided to Russian authorities to fulfil requirements linked to other administrative procedures such as the 'state registration', the 'declaration of compliance', the system for 'excise stamps' and the 'customs clearance'. In addition, she noted that the circulation of alcoholic beverages would be allowed only after the reception of a notification by an authorized body of a member of the Customs Union. This amounted to a prior authorization for the release of the products on the market with no added value for health and safety. Therefore, the EU requested the withdrawal of the notification system from the draft technical regulation.

2.129. The EU requested confirmation that the production control procedures and conformity assessment procedures suggested in the draft technical regulation would not be applicable to EU production sites as those had already been subjected to production controls by EU authorities. Third, she stated that the labelling requirements were excessive and in some cases could mislead the consumer. For instance, the size and content of the health warnings and the requirement to indicate date of bottling or storing conditions for all types of drinks could be problematic. Regarding wines, she furthermore noted that according to the draft text, the use of 'concentrated must' and 'concentrated rectified must' was banned in wine production for all types of wines except for so-called "table wines". As many EU quality wines were enriched with 'concentrated must' or 'rectified concentrated must', they would need to be classified as 'table wines' when exported to Russia. This was a designation with a certain depreciative connotation. This was valid for the ban on enrichment with sucrose for all wines including wines with geographical indication and "table wines". This would exclude a large number of EU wines from the Russian market unless they were labelled as "wine drinks". She noted that enrichment with concentrated must or rectified

concentrated must or sucrose was an oenological practice that was widely accepted at international level.

2.130. In addition, the EU noted that according to the draft, wines with protected geographical indications and with protected designation of origin would have to be bottled at their origin. Russia was recommended to take a more flexible approach as regards bottling of wines with protected geographical indications or protected designation of origin and spirit drinks with geographical indication as some of them were transported in bulk and were bottled at the country of destination. Moreover, regarding beers, while the EU welcomed the decrease of the compulsory malt content from 80% to 50% which was more in line with international practices, Russia was requested to remove the limit on sugar content of beers to allow for the use of fruits in beers, and to clarify if the use of additives was allowed. Furthermore, there were a number of alcoholic drink definitions missing in the draft or requiring adaptations such as vodka, gin, liqueur, brandy and vermouth. The EU had made concrete proposals for those definitions and stood ready to cooperate with Russia at a technical level. The EU also asked Russia to take measures to adequately protect EU geographical indications such as 'Cognac', 'Calvados' and 'Champagne' in accordance with WTO TRIPS rules. Finally, the representative of the EU recommended that Russia removed the ban on PET packaging from the draft technical regulation. She hoped that the concerns and suggestions of the EU would be taken into account before the final technical regulation on alcoholic drinks was adopted.

2.131. The representative of Mexico endorsed the comments made by the US, Australia and the EU. It was noted that despite exchanges of information with the Russian authorities, many of the concerns had not been taken into account by Russia in the draft regulation. Mexico asked Russia to clarify a number of points, including: to provide information regarding the category for tequila and mescal when entering the Customs Union; clarify the way in which one could register a denomination of origin; whether drinks could be bottled with the name of the category to which they belonged followed by the specific name of the product; and, whether manufacturers would have to register their products in each country.

2.132. In addition Mexico was of the view that the procedure for certification appeared to be incompatible with Art. 5.1.2 of the TBT Agreement. With respect to labelling, Mexico noted that certain requirements to specify information on labels were very restrictive, in particular the requirement to present a sentence "excess consumption of alcohol is harmful to health", which covered 20% of the surface area of the label. Mexico had also questioned the requirement to include the amount of methanol alcohol as well as the total amount of alcohol, which could create confusion for consumers. She said that during meetings of the working group on tequila between Mexico and Russia, held in August 2011, Mexico had asked Russia to take into account the physical chemical aspects of standard 0075 2005 for alcoholic beverages in particular - as well the Mezcal 57SFI 94 standard. Mexico had requested that the levels of methanol be adapted to bring them into line with the tequila and mezcal standards. Finally, Mexico appreciated Russia's withdrawal of the definitions of tequila and mezcal from the draft document.

2.133. The representative of Argentina explained that competent authorities in Argentina were still looking at measures which remained of concern, particularly with respect to the lack of transparency (notification). In accordance with the statements made by the US, he noted that the time period given for comments by Russia had already expired when the notification of the measure had taken place. A period should have been given for Members to provide their comments. He also underlined that it was important to respect the standards set by relevant international bodies, for example with respect to the use of concentrated must and concentrated rectified must in wine production.

2.134. The representative of New Zealand associated his delegation with the comments made by others and noted that comments had been submitted directly to Russia. He noted that the notification procedure did not appear to provide authorities with any additional information that could enhance consumer safety but rather duplicated requirements already found elsewhere. For instance, separate conformity declarations and certification steps were already provided for in the regulations, as was a list of information points to be specified on labels and shipments. He therefore suggested that the notification procedure be reviewed and duplicative elements removed.

2.135. The representative of the Russian Federation explained that the draft was still undergoing inter-governmental procedures that had not yet been completed. As indicated in the notification of the draft, a public hearing had been completed in December 2011, but, at that time, Russia was not a WTO Member. Nevertheless, interested parties had been able to provide their comments within a period of 60 days. He further noted that a number of WTO Members did provide Russia with their comments on the draft technical regulation, and, in addition, Russia had held a series of bilateral consultations, some of which had resulted in solutions covering many issues. In February 2013, Russia had received additional comments from the US and New Zealand which would be examined. He also explained that comments provided by the EU would also be taken into account when received. Finally, he reiterated Russia's willingness to be engaged in bilateral consultations with interested WTO Members, including detailed consultations among technical experts in Moscow.

2.2.2.1.14 European Union - Directive 2009/28/EC, Renewable Energy Directive (EU - RED) (IMS ID 307)

2.136. The representative of Argentina reiterated concerns raised at previous meetings of the Committee with respect to certain specific aspects of Directive 2009/29/EC as it affected exports of biodiesel from Argentina to the EU. He highlighted that the Directive required compliance and certification with sustainability criteria and emission reduction values which had both been imposed unilaterally. He also stated that the default value for emission reduction of greenhouse gases in Annex V of the Directive for soya biodiesel had been established without a solid scientific basis and without consideration of technology, practices or local conditions of production in producing countries. He underlined that the Directive ascribed different values to each type of biofuel which was discriminatory as the products considered were similar. As it did not take into account the real productive practices of producing countries, it did not ensure compliance with a legitimate objective. Argentina had approached the EU several times and provided relevant technical information seeking an amendment of the value of greenhouse gas reductions provided for soya biodiesel in Annex V that reflects a specific GHG emission reduction value of soya produced in Argentina under the system of direct seeding. However, no progress had been made. He furthermore underlined that the Directive foresaw a review by the Commission, but more than three years after coming into force, there had been no such review despite the fact that the Joint Research Centre of the EU had already provided the Commission with revised values based on the analysis of additional information, part of which was submitted by Argentina.

2.137. Regarding the requirements for certification of sustainability criteria imposed unilaterally by the EU, Argentina said that the EU had discouraged recognition of the requirements and national systems for sustainability which were equivalent to those of the EU despite the fact that the Directive itself contemplate this possibility. As a result, the private sector in Argentina presented a voluntary certification scheme but its approval by the European Commission had been delayed. The procedure was still being analysed despite the fact that recently various voluntary certification schemes had been approved for EU and non-EU countries. This created a situation of uncertainty, imbalance and discriminatory treatment with respect to Argentine biofuel suppliers.

2.138. Argentina was also concerned about a presentation made in October 2012 by the European Commission to the Parliament and the Council of a proposal for amendments to Directive 2009/28 and 98/70. He stated that the presentation did not take into account comments by third countries and other actors regarding the lack of scientific evidence supporting the implementation of policies and actions of the so called Indirect Land Use Change impacts of biofuels (ILUC). Argentina was concerned that the proposal contemplated that an estimation of ILUC emissions be included in the report of emissions. This represented a negative future signal for the biofuel industry since the ILUC factor could be included in the content of emissions for 2020. The values for greenhouse gas emissions caused by ILUC with respect to other biofuels could therefore be estimated on the basis of theoretical models which did not take into account scientific evidence and the technologies, practices and local conditions in countries of production. Argentina requested the EU to take into account its comments to eliminate the uncertainty in the biofuel market and to avoid the implementation of measures that result in new unnecessary obstacles to international trade.

2.139. The representative of the European Union explained that these concerns fell outside the scope of the TBT Agreement. The EU therefore considered that the TBT Committee was not an appropriate forum for the discussion. She nonetheless stated that the EU remained open to further bilateral exchanges.

2.2.2.1.15 Viet Nam – Decree regulating the Implementation of Some Articles of Food Safety Law Decree 38 implementing the Food Safety Law (G/TBT/N/VNM/22, G/TBT/N/VNM/22/Suppl.1) (IMS ID 356)

2.140. The representative of Australia noted that his delegation had been following the development of the implementing decree for Vietnam's Law on Food Safety (Decree 38) closely. While Australia supported Vietnam's right to implement measures to protect the health of its consumers, it was important that such measures were no more trade restrictive than necessary. He noted that Decree 38 had formally entered into force on 11 June 2012 but that there was a lack of clarity as to how Decree 38 would operate. Australia encouraged Vietnam to delay full implementation of Decree 38 until the arrangements for implementation had been fully considered and clearly communicated to trading partners. He explained that Australia appreciated Vietnam's notification and encouraged Vietnam to continue to notify the WTO of any technical circulars guiding the operation of the Law on Food Safety. Australia looked forward to working constructively with Vietnam to ensure trade was not disrupted.

2.141. The representative of the European Union recalled concerns about the measure at issue. She noted that Vietnam's notification had been issued seven months after the adoption of the Decree, and six months after its implementation. The EU therefore continued to urge Vietnam to suspend the application of the Decree until concerns of WTO Members had been adequately addressed, and producers had sufficient time to comply with the requirements. She also reiterated concerns on the complexity and unnecessary burden that this Decree would cause due to the multiple declarations of conformity and related documents that had to be submitted to Vietnamese authorities prior to importation, as well as the number of different ministries involved. The EU remained concerned about the impact of this Decree on imports into Vietnam, due to the lack of clarity on the applicable requirements, scope of products covered, and authorities responsible for implementation.

2.142. The EU also wished to point at some specific concerns; for instance, the difference between 'expiry date' and 'use by' date, the overly prescriptive requirement that the font of the name of the product be at least 3 times that of the other information on the label, or the labelling requirements for 'functional foods' and 'foods enriched with micronutrients'. Furthermore, the requirement to provide notarized copies (or copies legalized by the Vietnamese consulate) of the conformity assessment documentation was also of concern. The EU asked Vietnam to eliminate this requirement, which significantly increased compliance costs without having any positive impact on food safety. She also underlined that the EU had submitted comments to Vietnam under the TBT notification procedure on 25 February 2013, and that the EU looked forward to Vietnam's reply.

2.143. The representative of New Zealand endorsed the statements made by Australia and the EU. Given his delegation's requests at previous meetings to notify implementing circulars, he thanked Viet Nam for notifying to Members the draft circular regulating state control of food safety within responsibility and authority of the ministry of industry and trade G/TBT/N/VNM/23 which would give effect to part of Decree 38. He explained that New Zealand would submit comments on this draft through the appropriate channels. He encouraged Viet Nam to notify the Members all other draft circulars and instruments.

2.144. The representative of Viet Nam stated that before being notified in accordance with the TBT Agreement, draft Decree 38 had been notified to the SPS Committee on 25 March 2011 (G/SPS/N/VNM/27) and the final adopted decree had been notified on 11 May 2012 (G/SPS/N/VNM/27/Add.1). At the request of several Members, Viet Nam had notified the Decree to the TBT Committee in November 2012 under Article 2.10.1 and comments received would be considered and replied to as soon as possible.

2.2.2.1.16 European Union – Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to Medicinal Products for Human Use, as regards the Prevention of the Entry into the Legal supply Chain of Falsified Medicinal Products (IMS ID 334)

2.145. The representative of India raised concerns regarding the absence of a notification of the implementation of the EU Directive; the definition of falsified medicine products which did not

include the parameters of quality, safety and efficacy; as well as the need for an adequate time period for compliance for the industry sector. He noted that one of India's primary concerns which had been raised at the last TBT Committee meeting, was about the certification by Indian authorities of the GMP compliance of the EU. He explained that India believed that the EU had changed the format in its new regulation, and requested an update about this, and whether the WHO GMP equivalence would be acceptable by the EU.

2.146. The representative of Brazil noted that his delegation shared some of the concerns raised by other delegations on this issue and he thanked the EU delegation for having provided information on this matter on a bilateral basis. Brazil had applied to be included in the list of countries exempted from issuing a certificate of conformity with the EU requirements. This list considered Members where their regulatory framework was equivalent to those of the EU. He noted that Brazil was concerned that the procedures to be implemented were too restrictive and that the established timelines and procedures to be followed were not sufficiently flexible.

2.147. The representative of the European Union explained that this subject had already been extensively discussed at previous meetings of the TBT Committee and at a bilateral level. The Directive provided that imported active substances had to be manufactured in accordance with Good Manufacturing Practices so as to ensure protection of public health at a level 'at least equivalent' to the one applied in the EU. She noted that the World Health Organisation (WHO) GMP guidelines for active substances were considered to be equivalent to the EU ones. To comply with the Directive's provisions, competent authorities of exporting countries needed to issue a 'written confirmation' that the standards of good manufacturing practice applicable to the plant manufacturing the active substance were at least equivalent to those in the EU. The written confirmation was a simple system building on mutual trust between competent authorities worldwide. A template for the written confirmation, fully in line with the WHO-formatted API GMP certificate, had been shared with key trading partners. In addition, a questions-and-answers-document had been made available for market operators and competent authorities. Some countries had now confirmed that they were ready to issue the written confirmation. Other countries had asked to be listed by the Commission on the list of countries for which the written confirmation was waived. She furthermore noted that all relevant information was publicly available and that the European Commission expected a smooth implementation of the rules by July 2013.

2.2.2.1.17 China – Testing and Certification Requirements for Medical Devices (IMS ID 143)

2.148. The representative of the European Union recalled concerns about the on-going revision of China's Order 276 on Medical Devices, covering, *inter alia*, requirements related to standardization, product classification and conformity assessment. The EU remained concerned about the fact that medical devices imported into China were subject to duplicative regulatory controls due to the overlapping responsibilities of two Chinese authorities: the General Administration for Control Supervision, Inspection and Quarantine (AQSIQ) and the State Food and Drug Administration (SFDA) in the conformity assessment procedure, pre-market registration and re-registration. She noted that this significantly increased compliance costs for companies without any additional safety benefit. She asked China to clearly indicate in the Order the *single* competent authority in China responsible for the approval of medical devices (which should be the SFDA) and that any check of medical devices at the time of importation would be limited to a verification of the conformity assessment documentation issued in the SFDA approval procedure, without the need for duplicative testing, certification or inspection at the customs clearance stage.

2.149. The representative of the EU also stressed the need for greater convergence of China's applicable mandatory standards to international ones, as well as more flexibility in accepting medical devices on the Chinese market which had been made in compliance with the latest series of international standards. Furthermore, she invited China to provide a sufficient transitional period between the application of a new standard and the abolition of older standards; for example, in the EU, during the transitional period both versions of the standard could be used, allowing industry to adapt more easily. She further requested that China provide for greater acceptance of foreign clinical trial data and foreign test results. She recalled concerns regarding the need for approval of the products in the country of origin or country of manufacture, or the burdensome procedures for re-registration.

2.150. On procedural matters, the EU understood that Chinese authorities would adopt and publish this order in the near future. In this regard, she highlighted the need for China to notify this comprehensive legislation to the TBT Committee and allow WTO Members a reasonable time to provide comments. She also urged China to take Members' comments into account in accordance with China's obligations under the TBT Agreement and its commitment to do so in the context of the 2012 Trade Policy Review. Moreover, the EU underlined the need for an adequate implementation period of at least one year, between the publication of the order and its entry into force. She said that the EU was grateful for the good bilateral cooperation with China in this area, and looked forward to the upcoming meeting of the EU-China Working Group on medical devices. She noted that the EU hoped that these expert exchanges would lead to satisfactory solutions to EU industry market access problems in China.

2.151. The representative of Japan expressed general support for the concerns about China's testing and certification requirement for medical devices delivered by the EU – in particular with the burdensome processes. According to Japanese industry, certain tests and documents that would not be required in other countries were required during the process for marketing authorization in China; including, for example, a test which required that the actual equipment be at the examination center. The representative also recalled that some mandatory standards for medical devices, for instance the standard for CT, were unique in China and not in line with international standards. Thus, Japan requested China to harmonize the test methods and documents required for marketing authorization with international practices, specifically, to eliminate the unnecessary tests and documents that were not required in other countries.

2.152. The representative of Japan also reiterated concerns about the need for certification for marketing authorization in the exporting countries. For Japanese industry, a certification for the marketing authorization in the countries of origin was required in China. Even medical devices solely for export needed to obtain marketing authorization in exporting countries, even in the case that they were not intended to be sold in their countries of origin. Since the SFDA could evaluate efficacy and safety of medical devices, Japan requested China to abolish the requirement of certification for marketing authorization in the countries of origin. Japan was also concerned about the burden of renewal of registration: there was a requirement to renew the registration of medical devices every four years – this imposed a heavy burden on manufactures. Japan invited China to extend the renewal period.

2.153. The representative of the United States associated her delegation with the concerns raised by the EU and Japan and again noted that China had not notified the WTO of Decree 276, first promulgated in 2000, and then significantly amended in 2007, 2010 and again in 2012. She reminded China of its notification obligations and associated her delegation with many of the technical difficulties found in the most recent amendment, including the problematic application of end-product type testing to ensure safety and quality of devices, as well as the burdensome requirements for product re-registration. She nonetheless noted that improvements had been made in the 2012 revisions, such as China's waiver of in-country clinical trials for Class 1 devices or the extension of registration period from 4 to 5 years.

2.154. The representative of Brazil thanked China for its bilateral collaboration on the margins of the last TBT Committee meeting which had led to greater knowledge of China's Order 276 on medical devices. Notwithstanding, he stressed the fact that the Order had not been notified to the TBT Committee, which had resulted in a lack of opportunity to provide comments. He invited China to notify this measure so that the Brazilian companies which imported medical devices to China could be aware and participate with valuable inputs on this issue.

2.155. The representative of China noted that the revision Order 276 on medical devices had started in 2006 and that the State Council of China had been open to public consultations online since September 2010. During this period China had received comments from various organizations and the Legal Affairs Office of the State Council was still revising this regulation while taking into account comments received from stakeholders.

2.2.2.1.18 New Zealand - Proposal to Introduce Plain Packaging of Tobacco Products in New Zealand (G/TBT/N/NZL/62) (IMS ID 361)

2.156. The representative of the Dominican Republic expressed serious concern about the impact of the measures proposed by New Zealand with respect to their consistency both with the TRIPS and TBT Agreements. The full statement is contained in G/TBT/W/359.

2.157. The representative of Guatemala shared New Zealand's public health objective of reducing the appeal of tobacco products and smoking, particularly for young people as well as discouraging them from smoking or using tobacco products. Guatemala was nevertheless concerned with the proposed regulation as it was unclear how New Zealand would reconcile its obligations under the WTO Agreement with the legitimate public health objectives. Also unclear was how this measure would attain such objectives.

2.158. The representative of Honduras associated herself with the statements made by the Dominican Republic. While Honduras shared New Zealand's public health objectives, it was nevertheless concerned with the compatibility of the proposed measure with the obligations under WTO Agreements, in particular the TBT and TRIPS Agreements. Article 2.2 of the TBT Agreement required all Members to ensure that technical regulations were neither drafted, adopted nor applied so as to create unnecessary trade barriers. Article 12.3 of the TBT Agreement required Members to ensure that their technical regulations did not create unnecessary obstacles to exports from developing country Members. Given the disputes currently before the DSB, Honduras hoped that the drafting of similar legislation would wait until the conclusions and guidance from those disputes were available. In this vein, Honduras was pleased with the statement from New Zealand's Prime Minister that the implementation of its plain packaging measure would only commence after the final decisions of those disputes.

2.159. The representative of Nigeria stated that while her delegation acknowledged New Zealand's efforts to take appropriate measures to protect its citizens' health and welfare, it was nevertheless concerned with the compatibility of those measures with WTO disciplines, in particular the TBT Agreement. She asked New Zealand to provide the scientific and technical information demonstrating that plain packaging would reduce the number of smokers as well as to explain how the measure would comply with the Articles 2.2 and 2.4 of the TBT Agreement. She urged New Zealand to take in account views and concerns raised by Members so as to come up with WTO-compliant alternatives.

2.160. The representative of Nicaragua associated himself with the concerns expressed by the Dominican Republic and other delegation. Nicaragua supported the legitimate right of New Zealand to adopt health measures concerning tobacco products provided that such measures were compatible with WTO obligations (in particular the TBT and TRIPS Agreements) as well as other international agreements. Since there was no scientific proof that plain packaging would influence the behaviour of consumers, or reduce tobacco consumption among young people, the adoption of such measures would unfairly restrict trade and would not contribute to achieving the stated objectives. Such measure would thus be trade restrictive and negatively impact the competitiveness of countries such as Nicaragua in international trade. In particular, New Zealand's proposed measure would undermine the economic rise of small countries like Nicaragua, which depend on the manufacture of tobacco products as a key tool for poverty reduction by generating direct and indirect jobs. Finally, Nicaragua welcomed the fact that New Zealand's government had recently decided to wait for the ruling on the disputes currently being litigated in the WTO concerning tobacco before adopting or implementing its own plain packaging measure.

2.161. The representative of Kenya said that his delegation supported New Zealand's proposed plain packaging measure, which it considered to be in line with Article 2.2 of the TBT Agreement, which stated that the protection of human and health and safety was a legitimate objective.

2.162. The representative of Australia stated that WTO Members had to confront the global tobacco epidemic. He recalled that the joint WTO-WHO-WIPO study "Promoting Access to Medical Technologies and Innovation", launched in February by Director General Pascal Lamy, and his WHO and WIPO counterparts, confirmed that tobacco use was the second highest global risk for mortality in the world (behind high blood pressure) and was also responsible for the deaths of almost one in ten adults worldwide. Australia welcomed New Zealand's decision to legislate for

tobacco plain packaging, thus being on track to become the second country in the world to legislate for tobacco plain packaging. Tobacco plain packaging was a legitimate measure, designed to achieve a fundamental objective: the protection of human health. Australia appreciated New Zealand's consistently strong support for Australia's measure, including in TBT Committee meetings. Australia looked forward to supporting New Zealand's on-going development of its own measure. Australia's world first tobacco plain packaging measure had now come into full effect across the country. There were already anecdotal reports indicating that the plain packaging measure was working. The tobacco plain packaging measure was a long term public health investment and the effects of the measure would be seen over the long term. He recalled that Australia and New Zealand were both parties to the WHO FCTC, which recommended the adoption of tobacco plain packaging in the guidelines for the implementation of Articles 11 and 13 of the Convention. Tobacco plain packaging measures were endorsed by leading public health experts as well as the WHO and were supported by extensive research reports and studies. Australia was of the firm view that Members had the right to implement measures necessary to protect human health, while complying with relevant international treaty obligations.

2.163. The representative of Ukraine recalled that in previous meetings of this Committee her delegation had raised concerns about Australia's unnecessarily trade-restrictive and WTO-inconsistent plain packaging measures that appear to violate Australia's WTO obligations. She also recalled that the Australian measure was currently subject to a WTO dispute settlement challenge by Ukraine. New Zealand's proposed plain packaging measure was very similar to the one adopted by Australia Ukraine welcomed New Zealand's decision to wait the outcome of that dispute before proceeding with the adoption of its own proposed plain packaging measure. This was indeed an appropriate way of taking into consideration the concerns expressed by many Members in respect of Australia's plain packaging measure. In terms of the substance of the proposed measure, her delegation requested that New Zealand explain the evidence relied upon in its design of this measure. For example, how did New Zealand's evidence differ from that relied upon by Australia? Had New Zealand examined any alternative, less trade-restrictive measures that would support its public health goals without resulting in the removal of all trademarks and the standardization of the products and their packaging? If such alternatives were examined, could New Zealand indicate why such alternative measures were not preferred? Did New Zealand conduct any study addressing the likely unintended consequences of the plain packaging measure in terms of its impact on prices and on illicit trade? She said that Ukraine was concerned that plain packaging measures, like the ones adopted by Australia and proposed by New Zealand, were more trade restrictive than necessary to fulfil their stated objectives and may thus be inconsistent, among others, with the obligation under Article 2.2 of the TBT Agreement. Ukraine also had serious concerns over the lack of consistency of a plain packaging measure with Members' obligations under the TRIPS Agreement. Ukraine supported New Zealand's public health concerns, and Ukraine had also adopted stringent tobacco control measures that seek to effectively reduce smoking prevalence rates in Ukraine. However, Ukraine considered that any such measures must comply with obligations under relevant WTO Agreements, including the TBT Agreement, and should thus be lawful, appropriately effective and not disproportionate.

2.164. The representative of Cuba stated that her delegation had always recognized the right of Members to address public health problems. However, Cuba had consistently stressed its preoccupation with the economic impact that plain packaging measures could cause in developing country producers of tobacco products. The measure would affect trademarks and geographical indications, the value of which had been built up over many years, even centuries. Such measure could also have a negative impact with respect to the illegal trade of tobacco products. She recalled that Cuban cigars have been subject of falsification throughout the years, forcing the Cuban industry to develop various measures to minimize the counterfeiting of these products. These measures would be voided with the introduction of plain packaging. Cuba was also of the view that such measures would be incompatible with the TBT Agreement, in particular Article 2.1 as well as the TRIPS Agreement, in particular its Article 20 and Article 10bis of the Paris Convention, as incorporated in the TRIPS Agreement. She also recalled that in the TBT Committee session of November 2012, Cuba read out and then sent in writing a series of questions to New Zealand asking New Zealand to show the scientific evidence proving the relationship between the measure and the specific results to be achieved for health purposes.

2.165. The representative of Norway stated that public health and tobacco control were topics of particular interest to her delegation. Each WTO Member, including New Zealand, had the right to adopt measures which were necessary to protect public health as long as they were consistent

with the WTO Agreements. She noted that plain packaging of tobacco products was a recommended measure under the FCTC. It was Norway's firm opinion that the FCTC and the WTO agreements were mutually supportive and that it was possible to implement measures intended to regulate packaging of tobacco products in line with both sets of binding obligations.

2.166. The representative of the Philippines stated that while her delegation shared New Zealand's public health objectives, it also expressed interest in the issue of the relationship between plain packaging's public health objectives and the obligations of Members under the TRIPS and TBT Agreements.

2.167. The representative of Canada said that all Members can benefit from the information that New Zealand provided and its experience with plain packaging would help WTO Members gain a better understanding of the complex issues at stake.

2.168. The representative of Zimbabwe said that her delegation shared the same concerns expressed by the Dominican Republic and other delegations regarding the proposed measures as they could be incompatible with the TBT and TRIPS Agreements. She noted that Tobacco farming had become a major source of livelihood for many farmers in developing countries. In Zimbabwe, over 200,000 families rely on tobacco farming. Tobacco contributed significantly to the country's GDP and was a major export good. New Zealand's measure would therefore impact negatively on employment and economic performance and poverty alleviation efforts. While there was no scientific evident that the measures would influence the behaviour of consumers or reduce smoking amongst youth, it was evident that the measures would result in higher poverty levels and this would compound health challenges that developing countries already face. It was in light of the restrictive effect of the measures on trade and the negative impact on tobacco producing developing countries that Zimbabwe requested New Zealand to consider its concerns.

2.169. The representative of Uruguay stated that his delegation supported New Zealand's proposed measure, which simply implements the FCTC's recommendation on plain packaging contained in its Article 11. These plain packaging measures were not more trade restrictive than necessary to protect public health and constituted the next logical step following a ban on all tobacco advertising. Indeed, the packages were today the last place available for tobacco marketing, where trademarks and colours are used to attract consumers and distract them from the impact the health warning on these packages. In this context, he recalled that the according to the 2010 "Punta del Este Declaration", measures to protect public health, including measures implementing the FCTC and its guidelines, fell within the power of sovereign States to regulate in the public interest, which includes public health.

2.170. The representative of the WHO restated the information provided at the previous meeting of the Committee.[8] She noted that in light of concerns expressed at this meeting regarding illicit trade in tobacco products, Members might find it useful to hear that the first Protocol to the WHO FCTC – the Protocol to Eliminate Illicit Trade in Tobacco Products 5 - was adopted recently. It was opened for signature on 10 January 2013 and had 14 signatories to date.

2.171. The representative of the Dominican Republic thanked the WHO for the information provided on global tobacco control efforts. Domestically, the Dominican Republic had also made use of various tools to convince people to spontaneously stop smoking, such as educational campaigns, high taxes and restrictions in public spaces. This demonstrated that there were various ways to restrict the use of tobacco without affecting countries' international obligations. However, the Dominican Republic could not accept any attempt to force countries to impose restrictions which would eliminate the application of the WTO agreements. He expressed concern with the double-standard professed by certain countries which in one hand promote measures banning smoking, but on the other advocate the legalization of the use of marijuana. Another source of concern was that certain international organisations were adopting positions that could become a new type of "inquisition" against trade. He criticized the purported link these organizations were making between tobacco and illness like diabetes as well as between tobacco and poverty. He was concerned that this line of argument could easily extrapolate tobacco and be also used with respect to other products like alcohol, fast food or red meat.

[8] G/TBT/M/58, Paras 2.22 - 2.25.

2.172. The representative of New Zealand stated that the decision to work towards the introduction of a plain packaging regime was taken to advance New Zealand's public health objectives, and followed a comprehensive and transparent public consultation process, closed on 5 October 2012, which was notified to this Committee in July last year (G/TBT/N/NZL/62). The public consultation process was conducted on the basis of two main documents: (i) the consultation document, entitled "Proposal to Introduce Plain Packaging of Tobacco Products in New Zealand", and (ii) the "Regulatory Impact Statement", which was a domestic legal requirement for new laws. Both of these documents were available on the New Zealand Ministry of Health's website and links to them, and other relevant information, were also found in the Room Document which was available to Members during the meeting.[9] The public consultation process generated a substantial number of submissions from interested parties within New Zealand and around the world. The consultation document specifically sought the views of tobacco manufacturers and exporters, including those within developing countries, on the impact of plain packaging of tobacco products. Several WTO Members submitted comments on the proposal, including developing countries with small economies.

2.173. He explained that the submissions received through the consultation process were used to inform the Government's decision to work towards the introduction of a plain packaging regime for tobacco products. The consultation document and the "Regulatory Impact Statement" outlined the Government's policy objectives and analysed the various different regulatory options to achieve those policy objectives. They also referenced the scientific evidence regarding the effectiveness of plain packaging and summarise the submitted views by both thematic area and the category of the submitter. The Ministry of Health website also featured the submission that was considered by the New Zealand cabinet, and the minutes of the decision made by Ministers. He explained that this decision was part of a long policy development process that would continue for some time yet. This year New Zealand officials would commence the process of developing draft enabling legislation providing for a plain packaging regime. Detailed regulations to implement the regime would be developed subsequently. There would be opportunities during this process for interested parties to express their views on the design of the measure. New Zealand would notify this Committee at an appropriate time in order to facilitate such input. New Zealand considered that making all the above information freely and widely available, demonstrated its commitment to a transparent and robust process that was in full compliance with WTO obligations.

2.174. As to the substance of the proposed measure, he first recalled that his delegation had already responded to many of the points raised on this issue at the present meeting at the previous meeting, in November 2012. Therefore, rather than repeating the statement made at that occasion, he referred Members to page 7 of the minutes of the November 2012 meeting in document G/TBT/M/58. New Zealand also remained ready to meet bilaterally with Members to further discuss the proposed measure, and in that regard he noted that his delegation was delighted to meet with Cuba just before the meeting to discuss the questions they had raised in their communication in G/TBT/W/356.

2.175. He stressed that New Zealand's decision to go ahead with this proposed measure was made in order to protect public health. Smoking was the single largest cause of preventable death and disease in New Zealand, with approximately 5,000 New Zealanders dying each year from smoking or exposure to second-hand smoke. In particular, New Zealand's indigenous people, the *Māori*, are overrepresented in all negative smoking statistics, with the prevalence of smoking among *Māori* almost double that of the general population. New Zealand was determined to continue tackling this tobacco epidemic, and took therefore the negative impact on public health of tobacco consumption very seriously. For this reason, in 2010, the New Zealand government adopted the goal of making New Zealand essentially smoke free by 2025, in order to protect and promote public health. New Zealand believed that there was strong evidence that plain packaging, as part of a comprehensive tobacco control programme, would contribute to the objective of improving public health. Details of this evidence were set out in the "consultation package", and interested Members were encouraged to examine it.

2.176. Turning to issues of legal compliance, he underlined New Zealand's commitment to all its international obligations. In developing its policy on plain packaging, New Zealand had closely examined the consistency of its policy with its obligations under the WTO Agreements, including the TBT Agreement. New Zealand would ensure that the development and implementation of a

[9] This document was subsequently circulated with the symbols G/TBT/W/363; IP/C/W/586.

regime for plain packaging would be consistent with the obligations under the TBT Agreement and other relevant WTO Agreements. Additionally, implementing plain packaging measures would assist New Zealand to meet its obligations under the WHO's Framework Convention on Tobacco Control ("FCTC"), including Articles 11 and 13 of the FCTC. In this regard, he recalled that the Conference of the Parties to the FCTC had agreed on guidelines for the implementation of Articles 11 and 13 of the FCTC and those guidelines recommend that Parties consider adopting plain packaging requirements for tobacco products. New Zealand did not think it was relevant, or helpful, to compare New Zealand's tobacco control measures with the regulation of other products. Tobacco products were unique from both a health and regulatory perspective. As the WHO had said: "tobacco is the only legal consumer product that kills up to half of those who use it as intended and recommended by the manufacturer".

2.177. He concluded by noting that New Zealand was a third party in three WTO challenges to Australia's plain packaging measures by Ukraine, Honduras and the Dominican Republic. New Zealand would continue to support Australia in its defence of plain packaging at the WTO. In making its decision to work towards the introduction of a plain packaging regime, the Government of New Zealand had noted that, if necessary, enactment of New Zealand's legislation and/or regulations could be delayed pending conclusion of the Australian cases.

2.2.2.1.19 Israel - Warning Regulations on Alcoholic Beverages (G/TBT/N/ISR/609) (IMS ID 364)

2.178. The representative of the United States reiterated concerns regarding Israel's proposed changes of the placement of warning labels on containers of alcoholic beverages. She especially expressed concerns regarding the outcome of Section 2 of the draft amendment, which proposed to create two distinct warning labels for alcoholic beverages. In accordance with Israel's underlying law, products that contained more than 15.5% alcohol by volume would need to carry a distinct and stronger warning statement. She understood that this would be discussed under the new Knesset and requested an update on this regulation.

2.179. The representative of the European Union had similar concerns with the Israeli draft legislation on the Restriction on Advertising and Marketing Alcohol Beverages (Warning Mark) Regulations, 5772-2012. She underlined that the EU had submitted comments to the Israeli notification on 17 September 2012 to which no reply had been received. She therefore reverted to concerns regarding this measure and requested a written reply. The EU remained concerned about the establishment of two different types of warnings for alcoholic consumption dependent on alcohol content. According to scientific studies, it was the excessive consumption of alcohol that was harmful for health, regardless of the type of alcoholic beverage. The differentiation between strong intoxicating liquors and intoxicating liquors in the warning message could mislead consumers; they might conclude that some alcoholic beverages were more harmful than others. She thus invited the Israeli authorities to consider providing only one form of warning statement against excessive consumption of alcoholic beverages.

2.180. The EU also sought clarification about where, exactly, the warning message would have to be affixed and whether the Israeli authorities would accept additional labels or stickers containing the requested warning to be added in the distribution phase. If the warnings and information would have to appear on the front label, the EU drew the attention of Israeli authorities to the fact that such an obligation would have a burdensome and costly impact on imports as EU producers would be obliged to produce front labels for the Israeli market only. Information for the consumer could be provided with less restrictive requirements; strict provisions related to the colour of the text or to the inclusion of a black frame did not seem justified.

2.181. The representative of Israel said that there was no further information to add to that that was provided at the previous Committee meeting and that he would send the comments made by the US and EU to his capital.

2.2.2.1.20 European Union – Draft Commission Regulation implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to Ecodesign Requirements for Directional Lamps, Light emitting Diode Lamps and related Equipment (G/TBT/N/EU/34) (IMS ID 365)

2.182. The representative of China was concerned about the EU eco-design Directive on certain kinds of lamps. Although appreciative for bilateral contacts, China regretted that the EU had not considered comments provided. For example, China had asked the EU to change the number of samples for testing from 20 to 10 so as to reduce unnecessary burdens for the manufacturer and also to bring the Directive in line with current practice. He also asked for a longer transactional period for developing Members to adapt to the new requirements of the EU Directive. In this regard, he noted that in the final regulation, the original envisioned time frame had to change. He also underlined that his delegation had been informed by the EU that it would revise the regulation no later than three years after its implementation.

2.183. The representative of Korea reiterated concerns about the EU Directive. He underlined that the Korean Government respected the efforts of the EU and its member States to conserve energy. Nonetheless, Korea was particularly concerned about the requirement that specified that "*the luminous intensity in any direction around the tube axis does not deviate by more than 25% from the average luminous intensity around the tube*". At the last TBT Committee, the EU had explained that the requirement specified that a LED tube could be claimed to be equivalent with a fluorescent tube of a particular wattage only if certain conditions were fulfilled. If the conditions were not fulfilled, the LED tube could still be placed on the EU market, provided that the equivalence claim did not refer to particular wattages of fluorescent tubes.

2.184. In Korea's view, the claim that a LED tube was equivalent with a fluorescent tube of a particular wattage could have a significant impact on consumer selection of products. Considering the characteristics of LED tubes, which generated a lot of heat but were influenced in their performance by the temperature, heat emitting function was essential for LED lamps. Accordingly, LEDs had heat sinks mounted on their upper side where it did not need to emit light. However, to comply with the requirements of the EU directive, LEDs would need to emit light in all directions. As a result, this made it difficult to place a heat sink on its upper side. Consequently, this could seriously reduce the longevity of an LED tube due to its reduction of heat emitting performance. The Korean delegation was, therefore, of the opinion that it was technically difficult to comply with the requirement. Korea thus asked the EU to provide data on the possibility of technical implementation of this requirement.

2.185. The representative of the European Union thanked the Chinese and Korean delegations for their interest in Commission Regulation (EU) No 1194/2012, which had been adopted on 12 December 2012 and published in the Official Journal of the EU on 14 December 2012. The EU did not consider it necessary to extend the deadline for application of Stage 2, as it considered that two years was enough to adapt to the new requirements. The representative informed China that the Commission would review the Regulation within three years in accordance with Article 7. Regarding the number of samples to be tested, she stated that 20 was the number of samples required by other EU regulations and standards already in force. She underlined that the EU believed that a lower sample size might not provide a good representation of the normal unit to unit variation in lamp manufacturing. However, for certain parameters, Annex IV allowed for testing fewer lamps than 20. With regard to the suggestion that the parameter for setting the requirement on the energy efficiency of non-directional and directional LED lamps should be unified, the EU agreed with the Chinese authorities that a unification would be desirable in order to simplify the implementation of the Regulation 244/2009 and the currently planned Regulation. The EU was likely to propose an amendment of Regulations 244/2009 and 245/2009 to that effect during the next review of the two regulations.

2.186. Regarding the Korean concerns on the requirement specifying that a LED tube could only be claimed to be equivalent with a fluorescent tube of a particular wattage if certain conditions were fulfilled, she re-iterated that this requirement only referred to affixing the claim of equivalence on the product and in no way hindered the placement on the market of those lamps not complying with the conditions imposed to make such a claim.

2.2.2.1.21 Australia – Joint Governments' Response to the 2010 Independent Review of the Water Efficiency Labelling and Standards Review (G/TBT/N/AUS/71) (IMS ID 366)

2.187. The representative of Korea expressed concern regarding Australia's consultation paper about the Joint Response of the Australian Government, States and Territories to the 2010 Independent Review of the Water Efficiency Labelling and Standards (WELS) scheme. He underlined his government's respect for the efforts of the Australian Government to preserve water resources by reducing water consumption. The Korean Government agreed with, and supported the purpose of the WELS scheme for the protection of water resources.

2.188. Korea recalled that Australia had stated that one of the WELS scheme's objectives (as notified in G/TBT/N/AUS/71) was to improve cost recovery for the operating system. While Korea had not objection to the additional cost that companies pay for the operating system, Korea was nonetheless concerned about the additional burdens implied by the annual registration requirement. The target products of the scheme included several products which had different product life cycles – and this needed to be taken into account in setting registration periods. Therefore, Korea had requested the Government of Australia to set the renewal period to be no less than three years for washing machines and dishwashers. If the Australian government could not accept the Korean proposal to set up another registration period for each product, Korea requested the Australia to amend the registration procedure to allow companies to choose either annual registration or registration according to the desired time period and pay registration fees in bulk.

2.189. The representative of Australia underlined that the changes to the WELS scheme had been implemented to enable it to recover 80% of its costs. Cost recovery was consistent with Australia's WTO obligations. Moreover, registering products annually meant that registrants would benefit from only paying for the period of registration they needed. The rest of the changes had been designed to make the scheme more efficient and simple. A significantly simplified process was now in place (as of 22 January 2013), and once the transition process was fully completed it would deliver substantial efficiency benefits. Feedback from registrants on the process changes had been very positive. Industry feedback, from domestic and international registrants, indicated that the new system had considerably reduced the administrative burden of registering products. The annual re-registration process had been made particularly simple. Businesses were only required to choose the models they wished to renew, indicate any relevant changes to certification, pay the fee, and declare that the information provided was correct. A renewal application did not have to be accompanied by previous certificates of conformity, as so long as those previously provided remained valid. Additionally, only one form was required and covered all the product renewals a business might wish to make in any given year.

2.190. The representative of Australia said that there might have been some misunderstanding that test certificates for products were previously synchronised with the WELS 5-year registrations, which had never been true for all products. The new WELS system relied on a simple process whereby certificates provided at the time of registration were taken into account in applications for renewal, as long as the certificate remained current. Under the old arrangements it was possible for a certificate to lapse early in a five year registration period. In response to comments from Korea, the current system applied equally to all WELS products. It would be administratively burdensome and could be perceived as inequitable for different classes of products to be registered under different arrangements.

2.2.2.1.22 Brazil – Draft ANVISA Resolution on Used, Refurbished, Rented and Lent Medical Devices (G/TBT/N/BRA/440) (IMS ID 362)

2.191. The representative of the European Union reiterated concerns regarding the ANVISA draft resolution on used, refurbished, rented and lent medical devices (G/TBT/BRA/440). The draft resolution prohibited the importation of medical equipment reconditioned overseas and whose last place of installation, before reconditioning, was not Brazil. At the latest TBT Committee meeting, Brazil had informed the Committee that a final draft was not yet available and that a public hearing would be organised. The EU wished to have an update on the situation. The EU was of the opinion that any reconditioned equipment, independent of its place of first installation, should be allowed for importation in Brazil as long as it complied with the health and safety performance requirements established in the Resolution. She also reiterated that several developed countries such as the EU, US and Japan, which also had high health and safety standards, accepted and

used refurbished medical devices. The EU invited Brazil to reconsider its Resolution and find other less trade restrictive means to fulfil its legitimate objectives.

2.192. The representative of Brazil stated that the subject had already been discussed; he recalled that in July 2011, Brazil had notified the public consultation 34/ANVISA of the Brazilian Health Surveillance Agency. A sixty day period had been opened for interested parties to provide their comments on the draft measure. During that period a significant number of comments had been received and they were still being examined and consolidated. He said that one of the main objectives of the draft measure was to avoid the use of medical equipment being exported to Brazil as a means of final disposal of those products. He underlined that another important objective was obliging producers of medical equipment to be responsible for the appropriate disposal of medical equipment. He stated that a public hearing on this issue would be organized so that stakeholders would be able to participate in an open and transparent exchange of views with the Brazilian regulators on this proposed measure which had not yet been implemented.

2.2.2.1.23 Korea – KS C IEC61646:2007 Standard for Thin-film Solar Panels (IMS ID 271)

2.193. The representative of the United States stated that her delegation had raised the issue of the Korean standard for thin film solar panels at every TBT Committee since June 2010, except for in November 2012. Korea required solar panels to be certified by the Korea Management Energy Corporation (KEMCO) to be eligible for government subsidies, which *de facto* limited the Korean market to certified panels. KEMCO's certification standards prevented certain types of thin-film solar panels manufactured by US industry from entering the Korean marketplace. The US had consistently pressed Korea to adopt the relevant international standard: IEC 61646 in its entirety, without limiting its application solely to the type of thin-film solar panel its industry produced. In response to US concerns, the Korea Testing Laboratory (KTL) had conducted an environmental impact review on the use of cadmium in solar panels. KTL released this review to the public at the end of June 2012 and Korea had provided a summary of the study's results at the June 2012 TBT Committee meeting.

2.194. The US had reviewed the KTL study and had significant concerns. The global norm was to set regulatory limits for classifying waste based on standard waste characterization testing. The US observed that non-standard test results, such as those from availability testing in the KTL, should not be used to classify waste. Specifically, the availability test's use of finely ground material and multiple extraction cycles more closely mimicked the recycling process for CdTe PV modules – which had the explicit objective to separate and then recover and reuse metals from end-of-life modules – than the impact on any environmental conditions. The US was also concerned that KTL did not conduct availability testing on all PV technologies (including those that had been certified against KS IEC 61646 and KS IEC 61215 and were sold in Korea) even though previous availability testing in Europe yielded levels of heavy metals (lead) comparable to KTL's availability testing on CdTe PV modules (cadmium). It was not scientific practice to compare results from leaching tests directly against health screening levels (e.g., drinking water levels) without first conducting Fate and Transport Analysis to evaluate the chemical transformations and dispersion of chemicals in the environment in moving from the point of emissions to the point of exposure. Further, many scientific studies on Fate and Transport Analysis had found potential worst-case leaching impacts to be well below health screening levels and background levels in soil, air, and groundwater. Hence, the US reverted to and reiterated the concerns expressed at previous meetings of the Committee.

2.195. The representative of the European Union supported the US concerns and asked Korea for an update on its work on setting up a certification system for CIGS modules. According to the information provided by Korea at the June 2012 TBT Committee meeting, this process would take approximately two years, therefore allowing CIGS modules to be certified for the Korean market by mid-2014. However, according to information at the EU's disposal, the certification system might be made available sooner.

2.196. The representative of Korea underlined his delegation's sympathy for the concerns raised about CdTe modules by the US. He reiterated that the related certification system for thin film solar panels was not mandatory but voluntary, thus there were no restrictions in entering into the Korean market without the certification. Also, as had been explained at the previous TBT meeting, the Korean Government had conducted a two-year, comprehensive feasibility study which involved

Korean test methods for domestic waste as well as US EPA Method 1311 and the EU EN 12457 method. The result of the study showed that when cadmium telluride modules were damaged or discarded, a significant amount of cadmium could be leached into the surrounding environment. The concentration of cadmium leached from these modules was much higher than the allowable levels specified in various national environmental standards. Therefore, Korea did not intend to adopt a certification system for CdTe modules. Korea had decided to adopt a certification system for CIGS modules that satisfied the national environmental standards and was working on setting criteria as well as installing necessary facilities for the certification. These preparations were expected to be completed by the end of 2014. Taking into account the interest of the WTO Members in the certification system, Korea was making attempts to shorten the period of these preparations so as to issue certifications for CIGS modules as soon as possible.

2.2.2.1.24 Colombia – Commercial Truck Diesel Emissions Regulation Proposed modifications to Resolutions 910 of 2008 and 2604 of 2009 on Diesel Emissions. (G/TBT/N/COL/185, G/TBT/N/COL/186) (IMS ID 318)

2.197. The representative of Japan expressed two concerns regarding the "Commercial Truck Diesel Emission Regulation", notified on 14 December 2012 entering into force in September 2013. First, Japan requested Colombia to postpone the enforcement of the regulation. According to the draft regulation, Colombia would adopt the diesel emission regulation that was equivalent to EURO 4 for light-duty vehicles and trucks and EURO IV for heavy-duty vehicles. Currently, Colombia's diesel emission level was equivalent to EURO 2, EURO II, US Tier 1, US 94, etc. Thus, in order to comply with the proposed regulations, vehicle manufactures would need sufficient time to: (i) redesign and remodel cars; (ii) prepare manufacturing; and, (iii) to get certification. According to the Japanese industry, it was estimated that it would take more than 18 months to comply with all requirements in the new regulation. Therefore, Japan requested Colombia to ensure that the new regulation would enter into force 18 months from the date of publication in the Official Gazette at the earliest. Japan also asked Colombia to clarify the timing of the application of the proposed regulation. Japan requested that the proposed regulation should apply only to products imported in Colombia *after* its entry into force.

2.198. The representative of the United States noted that both the US Government and US industry had provided written comments to the amendment of Resolution No. 910 (G/TBT/COL/185). The US requested a discussion of these comments prior to adoption of the final regulation since the US had serious concerns about the short implementation date of this regulation, particularly when normal implementation time frames for vehicle regulations were two to four years. The US therefore strongly urged Colombia to extend its implementation period and reminded Colombia that it had acknowledged a temporary equivalence between Euro IV and EPA 2004. Colombia was also asked to reconsider a permanent equivalency determination between the two standards, similar to Chile's example. She noted that fuel to meet the EURO IV standard would not be commercially available throughout Colombia for many years, which would result in equipment damage and a failure to meet environmental objectives associated with this measure.

2.199. The representative of Mexico reiterated concerns regarding Colombia's proposed modifications to Resolutions 910 of 2008 and 2604 of 2009 on pollutant emissions from heavy vehicles with diesel engines. The full statement is contained in G/TBT/W/362.

2.200. The representative of Colombia explained that the standards at issue, particularly those currently notified to the WTO under G/TBT/N/COL/185 and G/TBT/N/COL/186, were aimed at achieving the legitimate objectives of protecting human health and life as well as the environment. The problem of public health caused by air pollution in Colombia was mainly associated with emissions from internal combustion engines and diesel emissions. According to a World Bank study in 2012, that had been requested by the Ministry for Environment of Sustainable Development in Colombia, the cost of particular matter pollution had increased from 0.8% GDP in 2004 to 1.1% GDP in 2009. Thus, there was a need to implement a strategy in order to achieve an effective reduction of particular emissions.

2.201. In light of this, Colombia had taken action to implement an overall public policy to improve fuels and vehicles to mitigate the negative effects of emissions in order to protect the environment and human health. In 2008, laws had been enacted with the effect that from 31 December 2012 onwards, diesel would have a maximum content of 50ppm of sulphur when distributed in Colombia. In order to comply with the new regulations, investments of a sum of $8.5 billion to

update and modernise Colombia's refineries and reduce the content of sulphur in diesel from 4500ppm to only 50ppm had been made. The representative nonetheless noted that Colombia's efforts would be diminished if emission standards were not adopted to take full advantage of the new diesel fuel. For this reason, Colombia began to update its emission standards and the technology required for local and imported diesel vehicles in 2011. When determining the appropriate emission standards in Colombia, the decisive criterion was a standard which would allow for a more efficient use of the new 50ppm sulphur diesel. Following a technical review and in accordance with international regulations in this area, the conclusion had been reached that the only standard which sufficiently met the legitimate policy objective to reduce particular emissions and where 50ppm sulphur diesel could be used, was standard EURO 4. Vehicles that complied with standard EURO 4 emitted up to 87% less particular matter than those vehicles that comply with current standards used in Colombia, such as the EPA 4.

2.202. The representative of Colombia acknowledged the considerable differences between standards and the possible adjustment cost that this measure could have on the market and for importers. The new modifications nonetheless provided an adaption period up to 31 December 2014 for truck and tractor importers. Concerning Mexico's request, the representative noted that there would be a review of conformity assessment procedures.

2.2.2.1.25 Peru - Draft Supreme Decree approving the Regulations Governing the Labelling of Genetically Modified Foods (G/TBT/N/PER/37, G/TBT/N/PER/37/Add.1) (IMS ID 320)

2.203. The representative of the United States requested an update from Peru on the status of the proposed labelling requirements for foods containing ingredients made from genetically engineered (GE) crops. It was noted that the US and other Members had provided comments to Peru on the proposal, highlighting concerns about the potential impacts of the measure on trade. She noted that a mandatory labelling requirement for GE foods that were substantially equivalent to conventional foods could give the false impression that the labelled food or feed was substantively different from, or less safe than, the conventional equivalent. In addition to misleading consumers, labelling would likely also increase costs to industry, consumers, and government authorities. Rather than a mandatory labelling requirement, the US believed that a voluntary approach to GE labelling would allow for consumer choice at a lower cost and with less disruption to international trade. She asked Peru to clarify how it was taking the comments of other Members into account in finalizing the measure. In addition, she requested that, if Peru decided to move forward with implementation of this regulation, it provide clarity on the scope of the requirements as well as the implementing mechanism for monitoring, supervision, and verification of compliance to the labelling regulation. In addition, she asked that the implementation period be extended beyond the currently envisioned 180 days in order to provide sufficient time for industry to adapt to the new requirements.

2.204. The representative of Chile reiterated concerns regarding Peru's draft technical regulation. These concerns had been submitted during the public consultation process; they pointed at the need for interested stakeholders to find out more about the specific requirements found in the regulation, whether the measure allowed certification by foreign producers; and, whether there was a list of approved Peruvian accreditation laboratories. Chile noted that it was important to know the current status of the measure.

2.205. The representative of Colombia referred to the comments submitted by the US and Chile and also recalled that Colombia too had, on a number of occasions, expressed concerns to Peru about this issue. Peru was requested to reply to the questions submitted.

2.206. The representative of Peru underlined that the concerns raised by the US, Chile and Colombia had been addressed at previous TBT Committee meetings. The draft regulations had been notified in June 2011 and Peru was aware of the concerns that had been expressed by these countries. Peru was currently assessing this matter to ensure that the measure was consistent with WTO rules, and in particular with the TBT Agreement. Peru was currently assessing the comments that had been received to see how they could be taken into account in the draft regulation. There was no specific date for adoption of the final technical regulation.

2.2.2.1.26 European Union - Issue with Respect to Honey Containing Pollen from Genetically Modified Maize MON810 (IMS ID 322)

2.207. The representative of Argentina reiterated concerns regarding the European Court of Justice Decision (EJC) of 6 September 2011(Case C-442/09) on honey containing pollen with traces of DNA from the genetically modified maize MON 810. Argentina believed that this decision had created a situation of clear inconsistency with the TBT Agreement as it re-interpreted the scope of regulation EC 1829/2003 on genetic modified foods and feed without technical or scientific justification. According to the ruling, pollen was an ingredient of honey and not a natural component for honey which was in contradiction with Codex standard 12/1981 on revision 2001 and the EU legislation (Annex II of Directive 2001/110 EC and Article 6 subparagraph 2 c) of Directive 2000/2013). In September 2012, the European Commission had presented a proposal to amend the Directive 2001/110 on honey in accordance with the ECJ ruling. This would be discussed at the Environmental Committee of the European Parliament and, at the same time, in the Council of Ministers. In this context it had been mentioned that there was a need for an impact assessment of this proposal, which would actually delay the resolution of this issue for an additional period of 6 months to one year. This situation had generated more concern in Argentina because the current legal uncertainty and its impact on trade would be aggravated and extended in time. Considering that a year and a half had passed since the ECJ ruling, Argentina requested the EU to update the Committee on the current situation and the following programmed steps within the organizational structure of the Community and to promptly adopt all necessary measures to dispel the uncertainties resulting from the ECJ decision so as to eliminate their negative impact for honey exports to the EU, thus avoiding that the implementation measures of the ruling lead to honey export restrictions.

2.208. The representative of Brazil expressed an interest in following the development of this discussion. Brazil was also concerned that the decision of the ECJ introduced legal uncertainty. This ruling established that honey containing pollen from genetically modified maize MON810 was a food product obtained from genetically modified organisms and, by consequence, subject to regulation 189/2003 on GMOs. This ruling seemed to be contrary to Codex standards and also the European Regulation on the subject.

2.209. The representative of Canada expressed concerns regarding the impact of the ECJ ruling on GM pollen and honey. He understood, subsequent to bilateral meetings, that it would be clarified that pollen was a natural component of honey, not an ingredient.

2.210. The representative of Uruguay supported the concerns that had been expressed by other delegations. He urged the EU to take into consideration the economic impact which the measure could have on small family producers. He said that the measure was not scientifically justified and should thus be rejected on its merits and because of its damaging impact on the global food and security situation. In order to meet the challenges of food security in the future there was a need for a competitive and environmentally responsible agriculture – barriers without scientific justification needed to be removed. He concluded that the application of private standards and measures which had an effect on trade and food production raised serious questions about the capacity to respond to the food shortages in the world.

2.211. The representative of the United States supported Argentina and other interested parties on the issue of restrictions towards GE pollen in honey. The US agreed that this ruling appeared to be a serious barrier to trade. This situation demonstrated that the EU GE approval process was overly lengthy and restrictive. Given the scientific data available through numerous food and environmental safety authorities, it was not clear why the process was so laboured. She encouraged the EU to take expeditious action to resolve this trade disruption. In particular, the EU was urged to remove the trade obstacle of treating pollen as an ingredient, as this would be inconsistent with the Codex Alimentarius standard, upon which Directive 2001/110/EC was based - which did not treat pollen as an ingredient.

2.212. The representative of Mexico reiterated concerns regarding the ruling of ECJ in September 2011 concerning honey containing pollen with traces of DNA GE modified maize MON810. She stated that this ruling contradicted what was established in the Codex and the EU standards in Annex II of Directive 2001/EEC and in Article 6 2C of Directive 2013. The prolonged legal uncertainty was affecting honey producers as they could not export their products to the EU.

2.213. The representative of the European Union stated that a detailed explanation on the background and implications of this ruling had been provided at previous meetings of the TBT Committee. In March 2012, Monsanto had submitted an application for the authorization of MON 810 pollen in food and feed and an authorization for the use of genetically modified pollen in honey. The application had been assessed by the European Food Safety Authority and a positive opinion had been issued on December 2012. The decision on the authorization of MON 810 pollen in honey was expected to be taken in April/May 2013. The EU underlined that the Commission had actively worked to ensure the proper implementation of the ruling without unnecessarily causing any disruption to the supply of honey to EU consumers, be it from domestic or imported production.

2.214. In September 2012, the European Commission had adopted a proposal to amend the 2001 Directive on honey in order to clarify the true nature of pollen following the ECJ ruling. The proposal defined pollen as a natural constituent of honey and not as an ingredient. She furthermore noted that the proposed amendment would have two key impacts. First, there would be no need to label pollen as an ingredient of honey as pollen was defined as a natural constituent of honey. Second, as pollen would no longer be considered an ingredient but a natural constituent, the amount of genetically modified pollen would be calculated in relation to honey and not to total pollen. The proposal was now being discussed at the European Council where the majority of member States supported the need to clarify that pollen was a natural constituent of honey and not an ingredient. A vote at the European Parliament was expected during spring 2013.

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

2.215. The representative of the United States recalled previous concerns raised against the above-mentioned EU measure and requested information about the status of the applications that had been submitted by the US wine industry on 19 June 2010. The application process had taken over two and a half years for certain traditional terms and affected suppliers were unable to ship their products. In this context she again stressed that the EU had granted approval to use the terms through bilateral agreements with other countries. She noted that the European Commission was to vote soon on the terms "chateau" and "clos" and would like an update on the applications.

2.216. The representative of Argentina reiterated concerns regarding EC regulations 479/2008 and 607/2009 as they grant the EU Members the exclusive right to use certain traditional expressions in their own languages. He underlined that these rules restricted the rights of third parties to use those definitions on their wine labels, effectively also restricting wine exports from Argentina to the EU. He noted that Argentina believed that this legal regime was not consistent with obligations stemming from the TBT Agreement. These traditional expressions only constituted indications of quality that fell within the scope of the TBT Agreement and not the TRIPs, thus neither registration nor the granting of exclusive rights over these terms was appropriate. He was concerned about requiring said registry when there are diverging definitions of those complementary quality mentions at the European Community level, therefore failing to provide clear, objective and transparent quality parameters for the use of said terms. He also expressed the concern that the EU had given, through bilateral trade agreements, other countries the use of these terms without a registration requirement which amounted to discrimination against the rest of countries with whom the EU had not had bilateral agreements. Nevertheless, for the last 4 years Argentina had engaged in discussions with the European authorities to overcome the obstacles of their regulations so as to continue to use the expressions "reserva" and "gran reserva" in the labeling of argentine wine to the EU. Finally, in March 2012, the dossier submitted by Argentina was approved by the Management Committee for the Common Organization of Agricultural Markets. However, there had already been an unjustified and unexplained one-year delay in including this subject in the agenda of the College of Commissioners. Given that this issue remained unresolved for this additional delay, he again requested the EU to eliminate the unjustified restrictions that harm the argentine wine industry by including this topic in the agenda of said authority and by publishing the relevant regulatory act in the Official Journal.

2.217. The representative of the European Union reiterated that two applications submitted by two American wine associations in 2010, on the terms 'Classic' and 'Cream', had been accepted in

the summer of 2012 and implementing European Commission Regulations had been published to that effect. She noted that the EU was still in the process of examining the other applications filed by US industry for the use of traditional terms and was updating the US on the status of these applications on a regular basis. As for the two applications from Argentina, they had been voted upon by the Single Common Agricultural Market Management Committee, and formal adoption by the Commission was pending.

2.2.2.1.28 China - Draft Mobile Smart Terminal Administrative Measure, Ministry of Industry and Information Technology (MIIT), 10 April 2012 Strengthening the Administration of Network Access of Smart Mobile Terminals (G/TBT/N/CHN/928) (IMS ID 358)

2.218. The representative of Japan expressed three concerns on "Notification on Strengthening the Administration of Network Access of Smart Mobile Terminals" (notified on 21 November 2012). Several industries in Japan had submitted comments to China in January 2013. First, China was requested to clarify the definitions found in the draft: what goods were covered within the term "Smart Mobile Terminals"? What constituted "significant" in the context of Article 5 of the regulation named "Notification Regarding Strengthening Network Access Management for Mobile Smart Terminals"? Second, China was requested to relax its requirement of conditions for filing. Article 5 of the regulation stated that if a Smart Mobile Terminal operating system (OSs) had significant changes in functionality or if new software applications were pre-installed, these changes needed to be filed with the Ministry of Industry and Information Technology. Japan was concerned that such a requirement was more restrictive than necessary to fulfill the objective of securing personal information. While Japan understood that it was necessary to cope with security problems quickly, this requirement could impede timely responses – it needed, therefore, to be removed. Third, Japan was of the view that disclosure and analysis of source code should not be required for the assessment of application software. The relevant document named "Test Methods for Security Capabilities of Smart Mobile Terminals" required source code analysis by testing bodies. In order to assess application software, these testing bodies had to be designated by the Chinese authorities. This requirement would make Japanese industries disclose source code for Smart Mobile Terminals, which could result in leaking confidential business information.

2.219. The representative of the United States appreciated the good work done on this measure, including bilateral engagement with China in April and May of 2012; the subsequent 21 November 2012 TBT notification (G/TBT/N/CHN/928); and, China's earlier action of publishing the draft measure on a Chinese government website soliciting comments. The US appreciated China's bilateral statement at the December 2012 US-China JCCT dialogue that it would modify and improve the notice based on a full consideration of the views of all stakeholders. However, the US was still concerned about the apparent imposition of numerous new obligations, technical mandates, and testing requirements on information technology and telecommunications hardware, operating systems, applications, app stores, and other related services. The scope and mandatory nature of these requirements appeared unprecedented among the major global markets for mobile smart devices. Consistent with commitments made in the JCCT the US respectfully requested that China fully consider the views of Members before it finalized these regulations.

2.220. The representative of the European Union recalled concerns of a more systemic nature on the development of requirements of the MIIT in the ICT sector. He stated that this notification was a good example since it compounded a number of issues that had given rise to concerns of the EU in the past. It laid down additional requirements in the procedure of acquiring a network access license and affected smart mobile terminals (SMT). On a positive note, the EU welcomed the improved transparency of the process, the public consultation in April-May 2012, and the TBT notification, and hoped that this path would be followed in the future. Nonetheless, the measure in of itself was overly prescriptive, and had a potential chilling effect on innovation. It also imposed burdensome test requirements, relied on so-called voluntary standards – i.e. industry standards – but which were mandated through certification procedures. These standards appeared to have been developed by the China Communication Standardisation Association. The EU therefore asked if this standards body, which appeared to operate under the supervision of MIIT, applied the Code of Good Practice. The measure also included extensive disclosure requirements in terms of potentially requiring operators to disclose source codes of their operating system – this was sensitive confidential information so this requirement raised IPR concerns. In conclusion, he underlined that too prescriptive and burdensome requirements might not improve smartphone

security, but would, on the other hand, stifle innovation and prevent timely and effective responses to security threats from malicious software.

2.221. The representative of China underlined that China already became the biggest consumer market of smart mobile terminals. In January 2013, the total number of smart phones and tablet PCs was nearly 221 million. He underlined that China enjoyed the convenience which they brought, but also faced serious problems of leakage of user information. In order to protect user information security and personal privacy, China had developed this method according to relevant Chinese rules and international experience in the field. Based on the Chinese situation, network access management was a proper and effective measure to protect personal privacy, and the purpose was not to establish a new management rule for telecom devices. During the process of developing the measure and the two relevant standards, China had solicited suggestions from relevant domestic and foreign stakeholders.

2.222. In accordance with the TBT Agreement and transparency obligations, China had notified the measure and the two standards to the WTO (G/TBT/N/CHN/928) on 21 November 2012. China had also several times communicated face to face with foreign relevant associations and clarified relevant information which they were concerned about. As regard to the scope of smart mobile terminal, it mainly included smart phones and tablet PCs which contained the mobile telecommunication module. The measure would not require disclosure of patent source code and other sensitive information and they would not prolong the approval of time for network access.

2.3 Exchange of Experiences

2.3.1 Good Regulatory Practice

2.223. Pursuant to the recommendation in the Sixth Triennial Review, the Committee held a thematic discussion on Good Regulatory Practice on 5 March 2013. The Moderator of that Thematic Session provided an oral summary report of the presentations and discussion (G/TBT/GEN/143).

2.3.2 Standards

2.224. Pursuant to the recommendation in the Sixth Triennial Review, the Committee held a thematic discussion on Standards on 5 and 6 March 2013. The Moderator of that Thematic Session provided an oral summary report of the presentations and discussion (G/TBT/GEN/144).

2.3.3 Next Thematic Sessions

2.225. The representatives of Cuba, Ecuador and El Salvador stressed the importance of addressing the topic of special and differential treatment in a future thematic session. Ecuador proposed that a thematic session on both technical assistance and special and differential treatment take place in the October 2013 meeting of the Committee.

2.226. The representative of the United States supported additional discussions on standards – and stressed that submissions from Members would be helpful to focus the discussion, particularly because the discussion during the thematic session had been quite broad. Moreover, the US supported additional work on GRP in June, noting that there appeared to be momentum in that area. For October, the US would support discussions on technical assistance and capacity building.

2.227. The representative of European Union confirmed support for discussions on GRP considering the momentum and noted that the Committee had already agreed on specific follow-up during the current meeting, so further work on GRP in June was appropriate. The EU was comfortable with a combined discussion of the topics technical assistance and special and differential treatment in October. If other submissions were received from Members there was also the possibility of allowing smaller windows during the thematic sessions to address other topics if supported by analytical papers. At this stage there was sufficient substance to justify the discussions agreed.

2.228. The Chairman concluded that for the June meeting, the Committee would continue to discuss in thematic mode the topic of GRP, leaving open the possibility of discussing other matters

depending on submissions from Members. In October, the Committee would discuss: (i) technical assistance and special and differential treatment, and (ii) conformity assessment.

3 EIGHTEENTH ANNUAL REVIEW

3.1. The Committee adopted the Eighteenth Annual Review of the Implementation and Operation of the TBT Agreement as contained in G/TBT/33 and G/TBT/33/Corr.1. Relevant lists of standardizing bodies that have accepted the Code of Good Practice (in line with Annex 3 of the TBT Agreement) are contained in documents G/TBT/CS/1/Add.17 and G/TBT/CS/2/Rev.19.

4 TECHNICAL COOPERATION ACTIVITIES

4.1. The Secretariat provided a document containing information on its technical assistance activities.[10]

5 UPDATING BY OBSERVERS

5.1. The representatives of IEC[11], UNECE[12] and the ITC[13] updated the Committee on their activities. The representative of the BIPM,[14] attending the Committee meeting as an observer for the first time, provided information on their activities relevant to the work of the TBT Committee.

6 DATE OF NEXT MEETING

6.1. The next meetings of the TBT Committee will take place in the week starting Monday, 17 June 2013 and ending on Thursday, 20 June. The Seventh meeting on Procedures for Information Exchange will take place on 18 June 2013.

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[10] G/TBT/GEN/149.
[11] G/TBT/GEN/145.
[12] G/TBT/GEN/146.
[13] G/TBT/GEN/147.
[14] G/TBT/GEN/148.