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Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 20-21 MARCH 2012

Chairperson: Ms Denise Pereira (Singapore)

Note by the Secretariat[1]

[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.

I. ADOPTION OF THE AGENDA

1. The Committee adopted the agenda contained in WTO/AIR/3896.

2. The Chairperson drew delegations' attention to the agreed recommendations made by the Committee on Budget, Finance and Administration to the General Council concerning savings to be made in documentation, as well as in meeting organization (contained in WT/BFA/128). In light of these, she informed the Committee that, as of 1 April 2012, TBT notifications would be available online only.[2] At the same time, the Secretariat would continue to enhance and further develop its information management system for TBT notifications (the TBT IMS), including with respect to the on-line submission of TBT notifications.

II. IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

A. STATEMENTS FROM MEMBERS UNDER ARTICLE 15.2

3. The Chairperson said that the latest list of statements submitted under Article 15.2 of the TBT Agreement is contained in document G/TBT/GEN/1/Rev.11, issued on 29 February 2012. She noted that, since the last meeting, Namibia (G/TBT/2/Add.108) had submitted its statement under Article 15.2 and South Africa (G/TBT/2/Add.60/Rev.1) had submitted a revision to its original statement. In total, since 1995, 125 Members had submitted at least one Statement on Implementation under Article 15.2. She recalled that this information was available, and regularly updated, on the TBT page of the WTO website and in the TBT Information Management System (http://tbtims).

B. SPECIFIC TRADE CONCERNS

1. Specific Trade Concerns

(a) New Concerns

(i) Russian Federation – Draft on Technical Regulation of Alcohol Drinks Safety (published on 24 October)

4. The representative of Mexico recalled comments sent by her delegation in December 2011 expressing concern about the compatibility of this measure with the TBT Agreement. She appreciated the removal of the definitions of tequila and mescal from the technical regulation, since they were not considered generic products. Nonetheless, she requested information about how these products would be categorized and whether they would be acknowledged as having undergone a process of protection in the context of their denomination of origin registration by the Russian Federation. Her delegation considere0d certain requirements of the measure - state registration, declaration of conformity, as well as of import and circulation licences for alcoholic beverages - to be excessive (in terms of notification) and duplicative (of existing regulations). She requested that the accreditation of laboratories, and the results of laboratory tests conducted by those laboratories, be acknowledged by Russian Federation customs authorities, given that tequila already complied with a complete system of certification and guarantee.

5. With regard to the commercial information to be included in labelling, the delegation of Mexico believed that the requirements were very broad, and that the measure was more restrictive

[2] Documents related to a specific meeting can be downloaded from the WTO website at: http://docsonline.wto.org/gen_meetings.asp.

than necessary to achieve its legitimate objective. Furthermore, she asked that product specifications established by the measure not apply to tequila and mescal, since these products bore a denomination of origin and complied with the specifications of relevant Mexican rules. Finally, the representative requested further information about the technical regulation from the Russian Federation, as well as a formal answer to Mexico's comments.

6. The representative of the European Union announced that should this draft regulation be adopted in its current form, a considerable number of EU exports of wines, spirits and other alcoholic beverages would no longer be allowed on the Russian market. In addition, she was concerned about the establishment of several new administrative requirements with no added value for health protection. She urged the Russian Federation to amend the draft regulation and to not impose requirements regarding production processes nor transport of products when circulating outside the Customs Union. The representative stressed that controls carried out by European authorities should be deemed sufficient, and asked that EU certification be accepted. She further requested that laboratory tests not be carried out on each single consignment; this would create serious delays at customs given the substantial trade flows of these products.

7. Additionally, the EU requested the Russian Federation to remove the notification procedure, which was more stringent than necessary to fight counterfeit products. Further, labelling provisions should be fully aligned with Codex Alimentarius, especially the definitions and analytical parameters of alcohol products. Also, steps should be taken to duly protect EU geographical indications. She noted that a number of bilateral technical meetings had taken place, and that her delegation had submitted detailed technical comments in December 2011. Her delegation hoped these bilateral discussions would continue, and that EU comments would be taken into account before the adoption of this technical regulation.

8. The representative of the Russian Federation (Observer) stated that development of these technical regulations was carried out in accordance with transparency provisions of the TBT Agreement, and in accordance with transparency provisions of Working party report on the Russian Federation accession to WTO. He said that all interested parties had the opportunity to participate in a two month public discussion period (which ended December 2011), and that WTO members had the opportunity to submit comments. Comments were being consolidated, and an improved draft of this technical regulation was under preparation, which would be available on the official website of Customs Union and Minister of Industry and Trade of the Russian Federation after completion.

(ii) Dominican Republic – Draft of the Technical Regulation "Categorization of Alcoholic Beverages" (G/TBT/N/DOM/143 and G/TBT/N/DOM/143/Add.1)

9. The representative of Mexico noted her delegation's written comments expressing concern over the compatibility of this measure with the TBT Agreement, particularly because tequila had not been acknowledged as a denomination of origin. However, she announced that her delegation had received a positive response from the Dominican Republic, acknowledging tequila as a denomination of origin, and that the definition proposed by Mexico had been included in the draft regulation.

10. The representative of the European Union reiterated concerns expressed in her delegation's written comments. She raised concerns and requested clarifications regarding the definitions of beer, wine, fortified wine, sangria, whisky, vodka, grapa, pisco, tequila, gin and distilled gin, blended spirits, liqueur, sambuca, cream liqueur, and pastis. With regard to the definition of "tolerance", the representative stressed that a negative tolerance below the minimum alcohol level should be accepted, as was the case in EU legislation.

11. In addition, the EU called for the draft regulation to be aligned with the Codex Alimentarius. At present the draft did not allow the use of processing aids, and it prohibited the use of sweeteners

for some beverages, both of which were permitted under Codex. Furthermore, the draft did not allow the bottling of beverages outside the factory, which could be problematic for bulk imports. In terms of labelling, the representative stressed that this draft regulation created uncertainty for marketing of products that did not fit into listed categories. She also expressed concerns with the requirement of a preferred "used by" date for wines, which was not in line with the Codex Alimentarius. Furthermore, the health warning: "Consuming alcohol is harmful to health" was too generic and misleading for consumers.

12. The representative of the Dominican Republic clarified that this draft regulation was based on 28804, which was a modification of no. 11 94 of the code of the Dominican Republic establishing consumption taxes on alcohol, and which included elements related to the general characteristics of alcoholic beverages and the designation of each category. He indicated that his delegation had responded to Mexico's comments, and had taken into account most points therein, particularly those that referred to tequila, and those related to Articles 2.11.11, 2.11.7 and 6.1.7. Finally, the representative said his mission had not received the EU's comments, and he presumed that they had been sent directly to capital.

(iii) 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 (G/TBT/N/EEC/246, G/TBT/N/EEC/246/Add.1)

13. The representative of Brazil referred to Directive 62, which introduced requirements regarding the process of importation of the so-called “active substances”, with the aim of preventing the introduction of falsified medical products in the supply chain. According to these new rules, active substances to be imported in the EU had to comply with two requirements: produced according to Good Manufacturing Practices (GMP) equivalent to those of the EU; and, be accompanied by a written declaration of the competent authority of the exporting country to this effect. The second requirement was not applicable to some exporting countries indicated in a list contained in Directive 2001/83/CE, but he noted Brazil had not been included in this list. He believed this regulation was not in accordance with international practices regarding the certification of GMP. If implemented in its current form, it could create an unnecessary barrier to the trade of medicinal products in the context of Article 2.2 of the TBT Agreement.

14. Brazil was not aware of any other WTO Member that required a regulatory authority in an exporting country to confirm that a medicinal product was in accordance with the requirements of the importing country. He recognized that Members had the right to establish necessary requirements to attain their legitimate objectives. However, the kind of certification required by the EU had to be conducted by the regulatory authority of the EU, or by an accredited body. This certification would be an unjustifiable burden for the regulatory authorities of the exporting country, who could only certify that the products complied with their own regulations or with the existing relevant international standard: the Technical Report 37/2003 of the World Health Organization. This report, which was widely acknowledged by Members, provided relevant international reference regarding the certification of GMP. In this context, the representative requested clarification on a series of questions:

(a) Why the EU has decided to modify its procedures in this area?

(b) Why was it necessary for the certification to be issued by the Regulatory Authority of the exporting country?

(c) Does the EU have the intention to certify the products imported in the EU?

(d) Would the EU be willing to certify that the European medicinal products complied with the Brazilian requirements for certification of GMP?

(e) Does the EU acknowledge that the WHO Technical Report 37/2003 is a valid reference for this issue?

(f) To what extent did the EU requirements deviate from those established by the WHO reference?

(g) What does the EU mean by "confirm that the standards of good manufacturing practice applicable to the plant manufacturing the exported active substance are at least equivalent to those laid down by the Union"?

(h) What kind of document did the EU expect a Regulatory Authority of an exporting country to issue?

(i) Will the EU be responsible for verifying the equivalence or compatibility between the requirements of the exporting country and its own requirements?

(j) What were the criteria for a country to be included in the exception list of Directive 83, and why had Brazil not been included in that list?

15. The representative of China raised further concerns following a previous bilateral meeting with the EU. He noted that Directive 2011/62/EU had been notified on 6 February 2009 (G/TBT/N/EEC/246), and had mentioned GMP. However, the concept paper *Implementing Act on the Requirements for the Assessment of the Regulatory Framework Applicable to the Manufacturing of Active Substances of Medicinal Products for Human Use*, dated 7 December 2011, which was the final concrete conformity assessment procedure for this measure, had not been notified, denying Members the opportunity to have their comments into account. This was especially important given the existence of WHO GMP guidelines, which had not been followed in the measure. He understood that Directive 2011/62/EU had been published to prevent the entry of falsified medicinal products into the supply chain. However, the EU failed to provide evidence of falsified medicinal products originating from China. It also failed to consider other less trade-restrictive measures, such as specific measures targeting particular falsified products, before requiring that all imported medicinal products comply with the Directive. Therefore, he argued it created unnecessary obstacles to international trade, as per Article 5.1.2 of the TBT Agreement.

16. Furthermore, according to Directive 2011/62/EU, EU holders of preparation-manufacturing authorization were only required to review GMP equivalence of producing and manufacturing of Active Pharmaceutical Ingredients (API) procured, while API importers had to review GMP equivalence and ask the authority of the exporting Member to provide a written equivalence confirmation. He explained this would subject suppliers of like products originating from other Member countries to less favourable conditions. In addition, the representative of China explained that according to Article 46b(2) of Directive 2001/83/EC, active substances shall only be imported *inter alia* if they were accompanied by a written confirmation from the competent authority of the exporting country. In practice, competent authorities regulated enterprises by their respective GMP standards. The obligation to fulfil the GMP requirement fell upon importers rather than exporting Members. The EU was urged to follow international practice in this regard.

17. He also noted that the EU failed to follow relevant GMP guidelines of WHO on API. His delegation understood that the EU considered the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH GMP) requirements as an equivalent. Yet, the representative explained that ICH was a platform that brought

together the regulatory authorities and the pharmaceutical industries of Europe, Japan and the US only, to discuss scientific and technical aspects of drug registration. It was neither an intergovernmental organization nor an international standardization body according to: *Decision Of The Committee On Principles For The Development Of International Standards, Guides And Recommendations With Relation To Articles 2, 5 And Annex 3 Of The TBT Agreement.* The representative said that HS codes did not distinguish between API, intermediate products and chemicals. Indeed, many API HS codes were integrated codes, thus custom officials could not regulate API exports separately. The fact that Directive 2011/62/EU had neither specified its coverage of API products, nor established concrete measures to identify API at EU customs, would, according to the representative, lead to increased costs and burden upon exporters. He argued this Directive was not practicable, and expressed hope that the European Union would adopt less trade-restrictive alternatives to achieve its legitimate objective.

18. He announced that China had been implementing its newly revised GMP for medicine, which referred to and were equivalent to WHO, EU and US GMP guidelines. Furthermore, several GMP guidelines - of United States Food and Drug Administration, United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) and WHO - recognized the newly revised Chinese GMP guidelines. To prove equivalence between Chinese API GMP and those of WHO, the State Food and Drug Administration (SFDA) was ready to issue written certificates for exporters, or for specific products exported, as per the WHO certificate format. He hoped that the EU would explore the possibility of accepting a WHO format API GMP certificate under its requirements. Given that imported API made up approximately 80 per cent of the EU market, and that analysis had not been finalized on WHO GMP equivalence, he urged the EU to provide a reasonable interval before entry into force, as per Article 5.9. He also asked that the written confirmation requirement be suspended to maintain supply stability.

19. The representative of the European Union indicated that the Directive had been notified to the TBT Committee in February 2009 (G/TBT/N/EEC/246), and neither Brazil nor China had issued written comments at that time. After agreement between the European Parliament and the Council of Ministers, the Directive was published in the Official Journal of the European Union on 1 July 2011, and will be applicable as of July 2013. The Directive addressed *inter alia* manufacturing (in the EU) and the importation (into the EU) of API for medicinal products for human use. She explained that manufacturing of API in the EU had to comply with GMP, and that Member States were therefore required to ensure that manufacturers of API in their territory followed GMP. With respect to importation, she said API had to be manufactured in accordance with standards of GMP at least equivalent to those that applied in the EU. The Directive established that, in the case of imports, the competent authority of the exporting country had to issue a written confirmation stating that the standards of GMP applicable to the plant manufacturing the API were at least equivalent to those of the EU; this written confirmation had to accompany imported API.

20. In relation to the use of international standards for GMP of API, she explained that the EU GMP rules were fully in line with the Guidelines of the International Conference on Harmonisation (ICH). Her delegation was assessing whether the World Health Organisation GMP guidelines for API, based on ICH guidelines, were equivalent to those of the EU and ICH. The EU had also been exploring the possibility of using a WHO-formatted API GMP certificate. A draft template for the written confirmation was being prepared and would be shared with main trading partners. She noted that the EU had discussed this issue repeatedly, and organised awareness-raising sessions with third countries. Her delegation had also discussed this issue bilaterally with China and Brazil on the margins of the TBT Committee, and remained open to discussing any further issue bilaterally.

(iv) China – Measures for the Administration of Certification Bodies (G/TBT/N/CHN/798 and G/TBT/N/CHN/798/Suppl.1)

21. The representative of the European Union expressed concerns regarding the measures for the administration of certification issued by China's General Administration of Quality Supervision and Inspection and Quarantine (AQSIQ), and Certification and Accreditation Administration (CNCA). The measures took effect on 1 September 2011 and aimed to implement a State Council regulation on certification and accreditation from 2003. According to their scope, the measures applied to the activities of both domestic and foreign invested certification bodies within China, regardless of whether such activities were related to products destined for the Chinese domestic market or export markets. The measures laid down rules on the establishment and approval of certification bodies as well as on the opening of representative offices of foreign certification bodies.

22. The representative of the EU reported that his delegation had a written exchange with Chinese authorities, and had also held bilateral talks in the framework of regulatory dialogue between DG Enterprise and AQSIQ. In these talks, the Chinese authorities had clarified the scope of the measures as also covering activities carried out in China through temporary presence of natural persons - i.e. in the absence of any permanent establishment or representative office by foreign certification bodies approved by foreign regulators. This meant that measures would apply, extra-territorially, to conformity assessment bodies (CABs) located outside China when these bodies acted in the framework of mandatory conformity assessment procedures set out in foreign regulations. According to this interpretation, if a foreign CAB had received an application from a Chinese manufacturer and the relevant conformity assessment procedure applicable in the importing country of destination required some activities to be carried out in China (e.g. factory inspection), the foreign CAB was required to either: i) to open a subsidiary in China; or, ii) to sub-contract the activities in question to certification bodies established in China. The EU was concerned about the impact of these new measures on the ability of the foreign CABs located outside China, and approved by foreign regulators, to fulfill their obligations regarding the certification of Chinese products intended for export. China's approach was unique, and without precedent in any WTO Member.

23. He stressed that the activities referred to were carried out in accordance with legal requirements of the importing country, rather than of China. He asked the Chinese delegation to explain the objectives of this new interpretation and how these could be reconciled with any of the objectives identified in Article 5 of the TBT Agreement. Moreover, his delegation had noted that the definition of conformity assessment procedures in Annex 1.3 of the TBT Agreement also covered approval of CABs.

24. The representative of the United States reported bilateral engagement with China's CNCA on this issue, and had raised several questions. Despite this, the intent of the various provisions in the measures, including the provisions suggesting extraterritorial application of the Chinese rules, remained unclear. She encouraged China to engage in further dialogue with interested foreign parties.

25. The representative of China said this measure was notified on 21 March 2011 (G/TBT/N/CHN/798), published on 20 July 2011, and entered into force 1 September 2011. It was based on relevant international standards such as ISO IEC 17021, ISO IEC Guide 65, ISO/IEC 19011, as well as China's relevant laws and regulations, including the License Law and Regulations on Certification and Accreditation. In accordance with Article 9 of the Regulations on Certification and Accreditation of China, he noted that domestic and foreign certification bodies were not allowed to carry out certification activities within Chinese territory unless approved by the competent Chinese authority. In this regard, the measure in question did not exceed the requirements of the Regulations on Certification and Accreditation of China, promulgated in September 2003. Furthermore, the measure did not differentiate between domestic and foreign certification bodies. Foreign certification bodies could establish wholly owned or joint venture bodies in China. The representative stated that

legally established foreign-wholly owned and joint venture certification bodies that obtained approval would enjoy the same rights and obligations as domestic certification bodies.

(v) Kingdom of Saudi Arabia – Motor vehicles[3]

26. The representative of the European Union requested information on the state of play of several notifications from Saudi Arabia. Her delegation had sent written comments on five notifications from Saudi Arabia in April 2010, highlighting differences between the notified texts and requirements under different UNECE Regulations. The EU received a positive reply from Saudi Arabia on 8 December 2010 announcing that comments had been taken into account and modifications would be introduced in the final measures. Since then, the EU TBT Enquiry Point had tried at several instances without avail to obtain information about the notified texts, and on the modifications introduced, from the Saudi Arabia Enquiry Point. During 2011, the EU TBT Notification and Enquiry Point were made aware of two other new measures that were not notified under the TBT Agreement, and enquiries had been sent by email to the Saudi Arabia Enquiry Point. Several of these enquiries remained unanswered, and the representative reminded Saudi Arabia of its obligations under Article 10 of the TBT Agreement, and requested a better flow of information.

27. The representative of the Kingdom of Saudi Arabia clarified that three of these notifications[4] were made in January 2010, and had been approved as voluntary standards, rather than technical regulations. The other two notifications[5] were still in draft form. The representative noted that his delegation had replied to the EU, inviting them to provide comments on the latter two drafts. Additionally, he reported exchanges of emails between the Saudi Arabia and Omani Enquiry Points, and the EU regarding this subject. An informal bilateral meeting had taken place, and his delegation had clarified questions. On another matter, regarding a notification on kitchenware, he clarified to the EU delegation that it was not a technical regulation, and that his delegation was not prepared to answer questions which it viewed as originating from a private certification-related company.

(vi) Egypt – Two Decrees of the Minister of Industry and Foreign Trade of Egypt (626/2011 and 660/2011) related to the import requirements for leather, footwear and textile products

28. The representative of the European Union noted two Egyptian Decrees of the Ministry of Industry and Foreign Trade[6] that modified the import requirements for leather, footwear and textile products. Both decrees introduced a new certification procedure that mandated certain information about imported products, and certified that products complied with Egyptian rules. By introducing the new conformity assessment procedure, the Decrees rendered the Egyptian standards mandatory. The representative therefore requested that both Decrees be notified under Articles 5.6 and 2.9 of the TBT Agreement, and further requested that Egypt postpone implementation until notifications were carried out and other WTO Members had the opportunity to comment. No responses had been received from Egyptian Enquiry Point on why the Decrees had not been notified. In addition, she asked whether the new certification requirements applied only to imported products or whether similar requirements existed for domestic products. Finally, she requested detailed information on the specific Egyptian standards that were made mandatory through the new certification procedure.

29. The representative of Egypt was not present at this meeting. Through the Chairperson they offered to provide a response to the EU promptly.

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[3] G/TBT/N/SAU/121, G/TBT/N/SAU/122 G/TBT/N/SAU/123, G/TBT/N/SAU/124, G/TBT/N/SAU/125.

[4] G/TBT/N/SAU/121, G/TBT/N/SAU/122, G/TBT/N/SAU/124.

[5] G/TBT/N/SAU/123, G/TBT/N/SAU/125.

[6] Ministerial Decrees: No 626 on textiles, published 17 November 2011; and, No 660 on leather and footwear, published 24 November 2011.

(vii) European Union – Safety evaluation of childcare cosmetic products

30. The representative of China explained that in April 2010, AFSSAPS (*Agence Française de Sécurité Sanitaire des Produits de Santé*) issued advice for safety evaluation of cosmetics for children under three years old. As there was no such EU regulation, he wondered whether this measure would be mandatory within France or within the EU, and if it were mandatory he asked why it had not yet been notified.

31. The representative of the European Union said that the new Cosmetics Regulation[7] was adopted in 2009 and will enter into force in July 2013. As explained to China bilaterally, work on its implementation was on-going, including on guidelines for product safety management, which were scheduled to be ready before the entry into force of the Regulation. With respect to the safety evaluation of childcare cosmetic products, the representative stated that there were no harmonized EU level specific childcare cosmetics safety management guidelines. However, EU harmonized guidelines on safety management of cosmetics *in general* were being developed, and some sections would be dedicated to products for children under 3 years old. These guidelines would be published before July 2013. The representative flagged her delegation's on-going concerns on the registration of baby care cosmetics in China, for which there had been a complete standstill in approvals since April 2010. The European Commission and SFDA had discussed this issue bilaterally the previous week, and hoped that these bilateral exchanges would help solve this longstanding trade concern.

(viii) European Union – Alternatives to animal testing and new cosmetic regulations

32. The representative of China indicated that the European Parliament and the Council had, in its 2009 cosmetics regulations, clarified the possibility of using Alternatives to Animal Testing (AAT) to ensure safety of cosmetics, and had set a deadline. China supported the principles of reduction, replacement and refinement, and in this regard, China's State Food and Drug Administration (SFDA) on 2 March 2012 notified *Test Method of In-Vitro 3T3 NRU Phototoxicity for Chemical Raw Materials Used by Cosmetics* (G/TBT/N/CHN/886). However, at present some AAT were not mature, and China had raised concerns about their impracticability in previous meetings. He urged the EU to explain the rationale for its 2009 cosmetics regulations, in particular with regard to AAT.

33. The representative of the European Union explained that the regulation provided for a robust, internationally recognized regime, which reinforced product safety and took into consideration the latest technological developments, including the potential use of nanomaterials. The implementation of the Regulation was being prepared. The ban and strict regime aimed at phasing out animal testing had not been modified. In fact, a full testing ban in the EU had been in place since 2009, as well as a marketing ban in relation to some testing "endpoints". In relation to three remaining endpoints (repeated-dose toxicity, reproductive toxicity and toxicokinetics), the marketing ban would enter into force on 11 March 2013. Despite intense efforts and considerable research progress on alternative methods, validated alternative methods for the three endpoints would not be available by 2013, and therefore the EU was analysing the impacts of the marketing ban. She mentioned that the European Commission and SFDA had discussed the Regulation's provisions and the details on animal testing in Beijing in March 2012, and her delegation remained open to discussing this issue bilaterally.

(ix) European Union - Provisions on limit values for allergenic substances in children's products (2009/48/EC) (G/TBT/N/EEC/184 and G/TBT/N/EEC/184/Add.1)

34. The representative of China shared the EU's objective of protecting children's lives and health, such as through Directive 2009/48/EC which regulated in detail the use of chemical substances in toys. However, he was concerned that the Directive had not established corresponding testing

[7] Regulation (EC) No 1223/2009.

methods. With a view to effectively implementing the regulation, the representative suggested that a testing method and standard for carcinogenic, mutagenic or reprotoxic (CMR) substances and allergenic aromatic substances be determined. If no such testing methods were made available, he suggested delaying the implementation of the directive until such time as they were formulated.

35. The representative of the European Union provided an update on standards that had been developed to support the new toy safety directive. Even though it did not specifically concern the aspects raised, he referred the Chinese delegation to the most recent publication of standards, published in the official journal of the European Union in October 2011. As for the Chinese delegation's concerns on the testing for CMR substances and allergenic fragrances, he recalled that Article 18 of the new toy safety directive had foreseen an explicit obligation for manufacturers to carry out a safety assessment for the purposes of conformity assessment. Safety assessment consisted of an analysis of all the chemical, physical, mechanical, electrical flammability, radioactivity and hygiene hazards that a toy may present as well as an assessment of the potential exposure to them - i.e. whether there was risk arising from the use of any prohibited or restricted substance in a toy. Therefore, manufacturers were required to assess the likelihood of the presence of a particular prohibited or restricted substance in a toy, and the scope of any possible testing would have to be based on that assessment. Given the high number of substances involved, it had not been feasible to foresee a testing procedure for each specific substance. On the contrary, he underscored that any possible testing should be focused on instances when an actual risk has been assessed to exist in view of the actual exposure to particular substances in a toy.

36. He referred the Chinese delegation to a comprehensive guidance document[8] on how to perform the safety assessment and any subsequent testing, which had been prepared by toy safety experts. The EU had discussed this issue with China in detail and organized training events in 2011 and 2012 for Chinese manufacturers in China. He noted that requirements related to CMRs would only apply as of 20 July 2013. CEN, the relevant European standardization body, was reviewing relevant standards concerning chemical substances. As new standards became available in 2012, or early 2013, useful guidance could be derived from certain standards on organic chemical compounds, which had been developed under the old toy safety directive. A reference to these standards was contained in the aforementioned guidance documents. Concerning allergenic fragrances, the representative specified that in general the Directive permitted traces of a fragrance, provided that its presence was technically unavoidable in GMP and did not exceed 100mg per kg. In this regard, useful guidance could be derived from the relevant European and international standard for GMP, EN ISO 22716. His delegation remained available for bilateral discussions and clarifications.

(x) United States – Test procedures for high density discharge lamps[9]

37. The representative of China appreciated that these technical regulations aimed at energy saving, nevertheless, he hoped they would be based on scientific norms and not create unnecessary obstacles to bilateral trade. With regard to the requirements on testing methods, he explained the measure required that HID (high-intensity discharge) lamp efficiency of voltage be controlled within 0.1 per cent of the related voltage reference balance. However, the IEC international standard specified that deviation within 0.5 per cent from the voltage reference balance was acceptable. He requested the US to explain this difference, and asked that the measures follow international

[8] "Guidance document on the application of Directive 2009/48/EC on the safety of Toys", in English: "http://ec.europa.eu/enterprise/sectors/toys/files/tsd-guidance/tsd_rev_1-4_explanatory_guidance_document_en.pdf; and in Chinese: http://ec.europa.eu/enterprise/sectors/toys/files/tsd-guidance/tsd_rev_1-3_explanatory_guidance_document_chinese.pdf".

[9] G/TBT/N/USA/669, G/TBT/N/USA/669/Add.1 and G/TBT/N/USA/649, G/TBT/N/USA/649/Add.1, G/TBT/N/USA/649/Add.2, G/TBT/N/USA/649/Add.3.

standards. On the issue of aluminum maintainers measured at 40per cent and 70per cent of service life, he explained that discharge characteristics, frequent switching, as well as vibration during testing would negatively influence measured parameters. Furthermore, at the end of life, aluminum maintainers may speed up malfunction of discharged lamps, so frequent aluminum testing was neither recommended nor worthwhile. Finally, the representative of China noted the measure required the execution of annual recertification and review at the price of USD5000 - USD8000. As per Article 2.2 of the TBT Agreement, he suggested a review or recertification only occur if there was a change in product design, structure, raw material, production equipment or process. Such review and recertification would either be related to a specific model, or an expert would determine, through a pre-review, that such change had no impact on efficiency and thus no review or recertification was required.

38. The representative of the United States indicated that the United States Department of Energy (DOE) maintained an extensive program to improve the energy efficiency of a range of products under the amended Energy Policy and Conservation Act of 1975. The program consisted of four parts: (i) testing; (ii) labelling; (iii) Federal energy conservation standards; and, (iv) certification, compliance, and enforcement. Testing requirements consisted of test procedures that manufacturers of covered products would use as the basis for certifying to DOE equipment compliance with applicable energy conservation standards under Energy Policy and Conservation Act (EPCA), and for making representations about the efficiency of this equipment. She noted that these test procedures also provided the protocols upon which the Federal Trade Commission based its energy guide label for these products. She further explained that DOE's review of specific test procedures for lamps was part of the requirement to review procedures and standards every seven years. With respect to G/TBT/N/USA/669, submitted on 11 December 2011, DOE had issued a notice of proposed rulemaking to add new types of lamps - namely HID lamps - to its existing energy efficiency program. The representative noted the comment period on this notification had closed 28 February 2012. Under the proposed rule, testing had to be conducted by a facility accredited by the National Voluntary Laboratory Accreditation Program (NVLAP), or by an organization recognized by NVLAP. Additionally, she reported NVLAP was a signatory to the ILAC MRA and had accredited many laboratories in China relevant to this regulation.

39. She further explained that DOE interpreted the language in this rule as it does with regard to all products covered by the NVLAP; allowing testing by any laboratory accredited to the appropriate scope by any accreditation body signatory to the ILAC MRA. Since China's accreditation body was a signatory to the ILAC MRA, test laboratories in China could seek accreditation through this body. She asserted there were likely many laboratories in China and worldwide that met the requirements set out by DOE for NVLAP. With respect to China's suggestion on conditions under which recertification and review were required, she was unsure whether China referred to the recertification of test labs or to manufacturer certification of product. If it was the latter, she indicated that manufacturer certification requirements were specified in another regulation (10CFR part 4.29), and not in this notification.

40. The DOE allowed testing by any laboratory accredited by ISO IEC 17025, and accredited to the proper scope by an ILAC MRA signatory. The rule stated that manufacturers' or importers' own laboratory, if accredited, may be used to conduct the applicable testing. This was consistent with DOE's directive to ensure that its standards, test procedures and other requirements were technologically feasible, economically justified and resulted in significant energy savings. She assured the Committee that DOE had chosen trade facilitative arrangements. Finally, she noted that Members, including China, could recognize conformity assessment bodies outside of their territories and accredited by IAF to meet their regulatory and other program needs. She welcomed the productive bilateral discussion with China on this matter, and looked forward to further exchanges.

(xi) European Union – Regulation (EC) No.1222/2009 Labelling of Tyres, Commission Regulation (EC) No.228/2011, No.1235/2011[10]

41. The representative of Korea reported a bilateral meeting with the EU. His delegation was aware that this regulation had already been published after receiving public comments, nevertheless, he reiterated concerns that these regulations could act as barriers to the Korean tyre exports to the EU. According to Article 2.2(g) Regulation (EC) No. 1222/2009, he said the regulation did not apply to tyres fitted with additional devices to improve traction properties, such as studded tyres. Korean tyre manufacturers shipped studded tyres with the stud pins detached, as stud pins could easily damage tyres during the loading and shipping process. In this regard, he requested the EU to accept C1 and C2 studded tyres without pins - the same as studded tyres with pins - and to allow studded tyres with stud pins detached temporarily for transportation purposes to be imported without any labelling requirement during customs processes. He was aware that detaching pins to avoid tyre damage was common practice during the transportation of studded tyres.

42. On the subject of Regulation (EC) No. 228/2011, he understood that the Standard Reference Test Tyres (SRTTs) used for the wet grip index were different from those used for the General Safety Regulation (EC/661/2009); the former were 16-inch tyres and the latter were 14-inch tyres. His delegation requested an explanation for this discrepancy, since according to UNECE Regulation No. 117 there was only one type of SRTTs. He asked the EU to unify SRTT size for both regulations, or otherwise justify this divergence. The representative recalled that Regulation (EC) No. 1235/2011 was published on 29 November 2011 and would apply to tyres produced after 1 July 2012. Since the necessary wet grip tests were carried out at temperatures ranging between 5 and 35 degrees Celsius, it was impossible for manufacturers to begin testing until April. Thus, manufacturers would not have sufficient time to comply with the regulation. Additionally, since Michelin was the only manufacturer of C3 SRTTs, other manufacturers had to order them from Michelin for the purposes of testing, and would not acquire them on time. Therefore, he asked the EU to provide stakeholders with sufficient time to comply with the regulation and to postpone implementation by six months.

43. The representative of the European Union informed the Committee that studded tyres were not within the scope of Regulation (EC) No 1222/2009; normal tyres intended to be fitted with studs are not mentioned. Her delegation would look into this issue, and inform Korea under which conditions tyres intended to be studded would be excluded from the scope of the Regulation (EC) No 1222/2009. She confirmed that ASTM 16 reference tyre needed to be used in the test method for measuring wet grip braking performance under Regulation (EC) No 1222/2009, and that the methods developed were meant to improve upon those laid down in UNECE Regulation No. 117. The use of ASTM 16 reference tyres was necessary to limit the variability of the testing procedures, and the representative clarified the ASTM 16 reference tyre was closer to the current market average rim, rather than the ASTM 14 reference tyres prescribed in the UNECE Regulation No. 117.

44. She indicated that the transitional period was considered sufficient and provided a level playing field for all business actors irrespective of size and location. The Regulation was adopted on 29 November 2011, and the labelling scheme would be mandatory from 1 November 2012 for all tyres for passenger cars, and for tyres for light and heavy commercial vehicles produced from 1 July 2012. She observed the time between publication of the measure and its applicability was at least 7 months, which was in compliance with the Committee's recommendations regarding Article 2.12 of the TBT Agreement. Finally, all three Regulations referenced were notified under the TBT notification procedure, with a comment period of either 60 or 90 days; no comments from WTO members were received. Since all three Regulations were adopted, they would be difficult to change.

[10] G/TBT/N/EEC/241, G/TBT/N/EEC/241/Add.1, G/TBT/N/EEC/338, G/TBT/N/EEC/338/Add.1, G/TBT/N/EEC/374, G/TBT/N/EEC/374/Add.1.

(xii) Colombia – Draft Resolution of the Ministry of Transport Issuing the Technical Regulation for public transport (G/TBT/N/COL/164, G/TBT/N/COL/164/Add.1)

45. The representative of Korea reported a bilateral meeting with Colombia to discuss this issue, and he reiterated his concerns in hope that his requests would be taken into account. The Korean government respected the efforts of the Colombian government to improve services for people with reduced mobility and/or ability to communicate. However, Korean industry was concerned about the regulation's possible negative impact on trade. Korea submitted comments on 16 January 2012, but had not received a reply. According to Article 2.4 of the WTO TBT Agreement, members had to use relevant international standards. The representative said UNECE Regulation No. 107, which excluded vehicles used for school transportation, was considered the relevant international standard in this case. In Colombia, there were schools for children with special needs, which also had specially equipped buses, and it was therefore unnecessary for all school buses to have these features. The representative requested Colombia to harmonize the scope of the new regulation with UNECE Regulation No. 107, and thus exclude vehicles used for school transportation. Additionally, he asked Colombian authorities not to enforce these regulations until these updates and modifications were reflected, and also asked for information on the current state of play.

46. The representative of Colombia would send Korea's concerns to the competent authority, and hoped to be able to provide an official response to Korea promptly.

(xiii) European Union – Wine and Grape Juice Certification (G/TBT/N/EU/5)

47. The representative of the United States noted that this draft regulation was notified in January 2012. Her delegation supported its goal of simplifying the existing regulation and reducing administrative burdens for operators by revising certification requirements to vine products. She noted that the US had raised this issue with the EU on multiple occasions, including in the EU/US bilateral wine meetings in March 2011 and November 2011. She recalled the requirement for a VI 1 wine making certificate for grape juice had been in place in the EU since 1985, yet grape juice from non-European countries could not be made or blended into wine per Council Regulation (EC) No 479/2008. The purpose of the certificate - to ensure the safety of wine products - was not furthered by the inclusion of grape juice in this certification requirement. If the stated objective of this draft regulation was to simplify the existing regulations and reduce the administrative burdens for operators, she inquired as to rationale for requiring wine making certificates for grape juice of non-European origin, if such grape juice was not to be used for European wine. In February 2012, her delegation sent a letter requesting the removal of the wine making certificate requirement for US grape juice, and she asked for information on the status of this request.

48. The representative of Brazil expressed concern with some aspects of this measure, including insufficient adaptation time provided to traders. He believed certain requirements of the measure had the potential to create additional difficulties for exporters, despite the objective of facilitating trade. He said this issue would be discussed bilaterally with the EU following the meeting.

49. The representative of the European Union announced that the draft Commission Regulation was intended to modify two previous Commission Regulations[11], in particular regarding the documents accompanying consignments of wine products across the EU (so-called "accompanying documents"). The draft Regulation aimed to rationalize and simplify the requirements applicable to such accompanying documents, reducing administrative burden for economic operators. She explained the provisions of this Regulation did not modify the rules currently applicable to trade relations between the EU and third countries. Consequently, wines from the US still fell under the

[11] Commission Regulation (EC) No 555/2008; and Commission Regulation (EC) No 436/2009.

procedures established by the EU-US Wine Agreement; namely, wines could enter the EU on the basis of a commercial document issued in the US.

50. The Regulation, it was explained, sought to specify the chain of responsibility and the links between the certificates issued by third countries or authorized operators (VI 1, simplified VI 1, or commercial documents) and the accompanying documents required for the movement of products in the EU market after importation. By not requiring new analyses after importation, the EU expected to improve traceability and facilitate the free circulation of goods on the internal market. Specifically, the Regulation required that the accompanying document for wine products imported from a third country make reference to the certificate drawn up in the country of origin (including, e.g., the number and date of the certificate, and the name and address of the authority of the third country which issued the document or authorized its completion by a producer). Regarding the issue of grape juice raised by the US, she highlighted that the requirement to present a certificate of analysis had previously existed and had not been introduced by the Regulation under discussion. She took note of the request of the US, and indicated that the EU would examine the possibility of introducing specific rules for those products in the context of future modifications to the scope and procedures applicable to the certificate of analysis. The EU would continue to discuss this issue with the US under the framework of their bilateral agreement. Finally, she informed the US that a reply to their comments was under preparation and would be submitted promptly.

(b) Previously raised concerns

(i) European Union – Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)[12]

51. The representative of India reiterated his delegation's concern about the definition of small (micro) and medium enterprises (SMEs) in the Regulation because it did not account for labour intensive industries in developing countries like India. The use of staff head count in addition to annual turnover and balance sheet ceiling would classify many of India's micro enterprises as large under REACH despite meeting the annual turnover or balance sheet ceiling. This went against the spirit of Art. 12.3 of the TBT Agreement as it created unnecessary obstacles to developing country exports. Secondly, the absence of any regulatory mechanism governing the creation of SIEFs and consortia which, although non-mandatory, were a de facto reality for exporters and put a high burden specifically on SMEs. Problems associated with SIEFs and consortia included the opaque functioning, high joining fee, penalties for late joining with no clear timelines, yearly maintenance fee, consultancy costs and the non-uniform rules for consortia, high fees of the lead registrants, the refusal of members to take in participants, and the prohibitive cost of the letter of acceptance. Thirdly, the EU-based Only Representative (OR), a reality for compliance with REACH, was burdensome for many Indian SMEs and added to the cost. He asked the EU to review the provision to permit direct registration by exporters. The delegation of India appreciated the principles in ECHA's guidance document specifically on the conditions of cost of sharing data at an early stage. But implementation under REACH remained poor since exporters were informed about the cost by the consortium late which left no option but to pay the amount requested. Also, what was the rationale for registration of the entire tonnage of a substance in an article if less than 100 per cent was intended

[12] G/TBT/N/EEC/52, G/TBT/N/EEC/52/Add.1, G/TBT/N/EEC/52/Add.2, G/TBT/N/EEC/52/Add.3, G/TBT/N/EEC/52/Add.3/Rev.1, G/TBT/N/EEC/52/Add.4, G/TBT/N/EEC/52/Add.5, G/TBT/N/EEC/52/Add.6, G/TBT/N/EEC/Add.7; G/TBT/N/EEC/295, G/TBT/N/EEC/295/Add.1; G/TBT/N/EEC/297, G/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.

for release upon use. This increased the tonnage band for registration, therefore putting a greater burden on the registrant.

52. The representatives of Argentina, Australia, Thailand and China reiterated their previously stated concerns in the hope that the EU would provide satisfactory responses. They referred Members to the minutes of previous meetings for details.

53. The representative of the European Union first responded to a previously raised question on whether an OR can apply for authorizations for certain substances under the REACH regulation. This question had appeared due to a lack of express provisions in the regulation. She explained that based on the text of the REACH regulation and the principle of non-discrimination, the European Commission took the view that the OR should not be denied the right to apply for authorization. This opinion was confirmed on the ECHA website on 25 Jan 2012 in the updated Q&A section, and the webforms had been revised to allow the OR to send its application. She added that the other concerns were answered in detail in previous Committee meetings. On India's request to permit direct registration by exporters, she explained again that the REACH registration obligation applied to manufacturers and importers in the EU only. It did not apply to manufacturers or traders outside the EU because enforcement actions, such as inspection and fines, could not be carried out. The EU importer, not the foreign manufacturer, had the registration obligation. Manufacturers or trading companies did not have to, but also could not, in consequence, register their substances directly. In cases where the foreign manufacturer did not wish to reveal the information to the EU importer, REACH gave the foreign manufacturer the possibility to appoint an OR to carry out the registration. The appointment of an OR remained an option, not an obligation for the non-EU manufacturer. Consequently, under Article 8, traders or merchant exporters were not allowed to appoint an OR. This was in line with the reasons that prompted the role of the OR, i.e. the protection of confidential business information concerning the substances imported into the EU which remained with the manufacturer of the substance, the formulator of the preparation, or the producers of the articles, not with trading companies that would need to request the information from the manufacturer.

54. Her delegation had replied to the concerns about the functioning of the substance information action, fora and the consortia previously, and had presented the considerable efforts made by the European Commission and the ECHA while it was up to the substance exchange forum participants to organize themselves. She informed that new data sharing guidelines would be published. On the claim that REACH was too burdensome, especially for SMEs, and the concerns about the functioning of the SIEFs, the Commission continued to assist companies in their activities in the substance information exchange forum and in their preparation for the next registration deadline in 2013. ECHA was offering in this respect a series of support activities including workshops in 2012, a series of webinars and other training opportunities on the functioning of the SIEFs and data sharing. ECHA had published a preliminary 2011-2013 schedule for the webinars on its website. These would be video recorded and subsequently published on the ECHA website. She invited Members to inform industry about these upcoming possibilities so that companies, especially SMEs could carry out their new registration obligations

(ii) European Communities – Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE)[13]

55. The representative of Korea said that industry continued to be concerned about the revised directive. For some of the materials listed in Annex III (to which the restrictions in Article 1 did not apply), alternative materials still had not yet been developed. In other cases, although alternatives

[13] G/TBT/N/EEC/247, G/TBT/N/EEC/247/Add.1, G/TBT/N/EEC/247/Add 2.

materials had been developed, their reliability was uncertain. For instance, although there was a substitute for cadmium in the production of colour-converting II-VI LEDs for solid illumination and display systems, manufacturers considered the cadmium-free product so unreliable that they could not apply it in commercial production. Additionally, his delegation had been informed that the technical requirements for CE certification had not been published yet. In the absence of published technical requirements, industries would have difficulty complying with the regulation. It was the EU's duty to publish them and invite comments from stakeholders. His delegation requested the EU to allow a longer transition period for economic operators to develop alternatives to restricted substances and to comply with CE certification.

56. The representative of the European Union said that the concerns expressed today and in past meetings on this agenda item related to the RoHS Directive; the EU suggested that the reference to Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) be removed. As mentioned previously, the RoHS Directive had been published in the Official Journal of the European Union on July 2011. However, the current RoHS Directive continued to apply until the new Directive was transposed by all EU Member States into national law by January 2013. As the scope of the Directive had been extended, the new Directive introduced transitional periods for the new products of up to 8 years. It was considered, therefore, that sufficient transitional periods were provided.

57. The new Directive would continue to restrict 6 substances. However, as of 2014, the list of restricted substances may be periodically reviewed. Any review would be duly notified to the Committee and would be based on scientific evidence, detailed impact assessment and would take into account availability and reliability of possible substitutes. The European Commission was preparing a FAQ document that would be available to stakeholders by mid-2012. She noted that, according to Article 5 of the Directive, decisions on exemptions and on the duration of exemptions would take account of the availability of substitutes and the socioeconomic impact of substitution. A manufacturer, an authorized representative or any economic operator in the supply chain could apply for an exemption or renewal of an existing exemption. Annex V of the RoHS Directive listed the information that needed to be provided in this regard. On the new requirement of CE marking, according to Article 15, the requirements to affix the CE marking applied only to finished electrical and electronic equipment. Spare parts, as defined in Article 3.27 of the Directive, did not need to be CE marked. Article 7, 8 and 9 of the Directive detailed the obligations of manufacturers, of authorized representatives and of importers in this respect.

(iii) European Union – Regulation on Certain Wine Sector Products (G/TBT/N/EEC/264)

58. The representative of the United States maintained its concerns regarding EU measures that severely restricted the ability of non-EU wine producers to use common, descriptive, or commercially valuable terms to describe their products, on the grounds that those terms are traditionally associated with European wine. Some of these terms did not have a common definition across EU member states nor was her delegation aware of efforts to monitor or limit the use of those terms within the EU. This cast doubt about any uniformity in consumer perceptions across the EU on the meaning or use of traditional terms. The EU's approval of the terms by third countries through its bilateral agreements further rendered suspect the notion of a general consumer perception regarding terms traditionally associated with European wines. US producers experienced significant losses from the 10 March 2009 termination of the three-year derogation for use of such terms on the labels of US wines sold in the EU, and from the EU's recognition of so-called traditional expressions in trademarks.

59. Her delegation was concerned that applications by wine America submitted on 19 June 2010 had thus far no response from the EU. She asked the EU for its meaning of "promptness" in Article 5, noting that those US suppliers that used those terms remained unable to ship their products even while the EU had granted approval for the use of these terms through its bilateral agreements with other countries. Her delegation was further disappointed that the European Court of Justice had expanded

the scope of these measures; contrary to the assurances provided by the EU officials, the traditional terms were now protected in languages other than the one for which protection was identified. In addition to TBT related aspects of the EU regulation, her delegation was concerned about the provisions of the regulation regarding protection of trademarks and intellectual property, and sought information from the EU on the status of its request.

60. The representative of the European Union recalled that it was still examining the applications filed by US industry for the use of traditional terms. Her delegation was providing information regularly to the US on the status of these applications, and remained open to continued bilateral discussions, notably in the framework of the bilateral wine Agreement between the EU and the US.

(iv) India – Pneumatic tyres and tubes for automotive vehicles[14]

61. The representative of the European Union recalled India's indication at the last Committee meeting that its Government had given positive consideration to changing the requirement that the ISI marking for tyres could not be used on tyres sold outside India and that the change was now only subject to certain approvals. Since the last TBT Committee meeting, the EU had not heard confirmation of a modification of Article 6.3 of the BIS Agreement. She asked India to report on new developments in this respect. The EU reiterated its concern about the royalty fees which were calculated on the basis of the total number of tyres produced and marked with the ISI marking, and not on the total number of ISI marked tyres de facto imported into India. The lack of accredited laboratories both inside and outside India available to carry out the required tests, and the absence of recognition of tests also remained a concern for the EU.

62. The representative of Japan had raised concerns about Article 6.3 of the BIS Agreement which prohibited export of the BIS marked tires to countries other than India. In the previous meeting, India had responded that India had positive consideration to the removal of Article 6.3 which was only subject to certain approvals. However, according to his information, India had not removed the Article. Prohibition of the exportation of BIS-marked tires to countries other than India discouraged Japanese tire manufacturers from making BIS-marked tires and distorted the conditions of competition. This was an unreasonable technical barrier to trade and his delegation requested immediate deletion of Article 6.3.

63. The representative of Korea continued to have concerns about Article 6.3, marking fees, time-consuming procedures, excessive paperwork, and the term of validity for ISI certification. Korean industry bore an undue cost burden because Article 6.3 of the BIS Agreement prohibited exports of ISI-marked tyres to other countries. Korea requested that the Indian authorities repeal Article 6.3 and also review the marking fees. These were unfairly calculated because they were based, not on the total number of ISI-marked tyres imported to India, but on the total number of tyres produced and marked with the ISI symbol. Compared with similar marks issued by other countries which did not charge marking fees for tyres, fees were considerably higher for the ISI. Furthermore, the administrative procedures and excessive paperwork from application to the issuance of the certification took almost one year. Other countries could process certification in 45 and 90 days.

64. Considering the long process time to obtain the certification, Korean tyre manufacturers considered the one year validity too short; manufacturers had to renew their certification as soon as they had received it. Since other countries granted 5 years or a permanent term of validity, his delegation requested that India simplify its administrative procedures and extend the term of validity to at least five years or an indefinite term. Additionally, his delegation requested India to accept test results carried out in in-house laboratories in Korea. It was common global practice in the tyre

[14] G/TBT/N/IND/20, G/TBT/N/IND/20/Add.1; G/TBT/N/IND/40, G/TBT/N/IND/40/Rev.1.

industry that if the test laboratories of companies were verified according to international standards, the results from these laboratories should be accepted by the tyre certification body.

65. The representative of India reiterated that the BIS and the Ministry of Consumer Affairs were seriously considering the removal of Article 6.3 of the BIS Agreement which had created problems for some suppliers of automotive tyres and tubes. The marking fee charged in India was equitable in terms of the unit cost of tyres for both domestic and foreign manufacturers and, on a comparative basis, India was probably at the lower end *vis-a-vis* other countries. Most of the applications made for certification by tyre companies had been cleared, and those pending were because information was sought from companies. The latest information showed 93 licenses granted to foreign manufacturers. It would transmit Korea's concerns about the cumbersome procedures and the validity of the certificate to its regulators.

(v) Canada – Cheese Compositional Standards (G/TBT/N/CAN/203, G/TBT/N/CAN/203/Add.1)

66. The representative of New Zealand recalled that this was the 15th TBT meeting to deal with this issue. New Zealand considered that the Canadian requirement that for certain cheese varieties to be labelled as 'cheese' they must be produced with a percentage of proteins to be sourced directly from "raw milk" - i.e. from domestic milk suppliers had the effect of limiting the amount of protein that could be sourced from powdered (i.e. imported) dairy ingredients. These ingredients, including milk protein concentrates, milk protein isolates, whey protein concentrate and skim milk powder, were widely used and accepted as cheese ingredients in many countries. Further, the compositional standards were inconsistent with Codex standards, which did not prescribe limitations on the sourcing of milk proteins for use in cheese manufacture. New Zealand's bilateral discussions did not give rise to confidence that Canada intended to provide more clarity about how its cheese compositional standards complied with Codex standards or to address New Zealand's concerns. No further efforts had been made by Canada to address these issues since November 2011. The Dairy Farmers of Canada had lobbied the Canadian Government for a yoghurt standard. Like other WTO members, New Zealand was concerned that any compositional standards for yoghurt would also be inconsistent with Codex standards, and encouraged Canada to adhere to the Codex standard when making decisions on any future federal dairy regulations or standards for yoghurt and other processed dairy products. Her delegation would continue to monitor these developments closely.

67. The representative of Australia shared New Zealand's concerns on this issue.

68. The representative of Canada reiterated that there was no evidence that these regulations had constrained the overall usage of milk ingredients such as milk protein concentrates; his information to date suggested that all imported cheeses in Canada had been deemed to be compliant with the revised standards and no complaints had been received. His delegation had also not initiated any regulatory processes to establish similar standards for any other dairy products.

(vi) India – Drugs and Cosmetics Rules 2007 (G/TBT/N/IND/33)

69. The representative of the European Union asked if the entry into force of this legislation was still April 2012 or was a revision of the notified text under consideration by India. In particular, was India considering increasing the validity of the importing licences to bring it in line with the validity of domestic licences, i.e. from 3 to 5 years? Also, was India considering accepting test reports carried out in foreign laboratories as an alternative to local testing? Finally, the EU asked if India would accept labelling to be carried out in bonded warehouses instead of in the country of origin.

70. The representative of the United States shared the EU's concern on the validity of importing licences. She also asked India to clarify its statement at the November Committee meeting suggesting that there were differences between the attestations required for the certificates and licences for

foreign versus domestic producers. Also, she recalled that at the November meeting India responded that enforcement was postponed until April 2012the difference in terms between domestic and foreign firms (i.e., 3 years versus 5 years) was necessary due to technological changes and the fact that domestic manufacturing licences were not imposed on imports. She asked India to clarify the nature of the technological changes. She also asked India to provide an update on its consideration of the US request to hold a technical level discussion on these issues. Technical level discussions were sought quickly to clarify longstanding issues on transition periods for suppliers, registration fees, the question of providing stickers or supplementary labels, and import registration numbers. Her delegation also urged India to consider allowing producers to conduct the required test in the country of origin in accordance with internationally recognized methods of testing common throughout the industry.

71. The representative of India confirmed 1 April 2012 as the date of implementation. The validity of the registration certificate for importers was three years because importers, unlike domestic manufacturers, were not subjected to the comprehensive inspection of documents, premises, manpower, equipment and capability. He informed Members that he had word from his capital that labelling, specifically the name and address of the importer and the import license numbers, could be carried out in a declared place approved by the licensing authority after import.

(vii) Colombia –Draft Decree Establishing Provisions to Promote the Use of Biofuels[15]

72. The representative of Mexico reiterated her delegation's concern on establishing compulsory percentages of blends of ethanol, the increase of these percentages in the future and the restrictions to trade they might generate. Mexico believed that the percentages should be decided and based on an international standard and scientific evidence. She asked for information on the state of implementation of the draft decree and a response to Mexico's previously submitted questions. She also requested confirmation that if the percentages were increased that obligations of the TBT Agreement be fulfilled and notification be made to the Committee within a reasonable period of time.

73. The representative of Colombia confirmed that the measure was currently in force but that any future modification made to the percentages of fuel blends for ethanol and biodiesel would be notified to the TBT Committee.

(viii) India – Mandatory Certification for Steel Products (G/TBT/N/IND/32)

74. The representative of the European Union had sent written comments on 6 September 2011 to the Indian Enquiry Point concerning the second addendum of 22 July 2011 to notification G/TBT/N/IND/32 announcing that certain intermediate steel products would be subject to a mandatory third party certification. It had not received a reply to these comments. India had promised at the last meeting to provide a reply at this meeting. The EU was therefore disappointed to learn that India had adopted the proposal on 12 March 2012. The EU still questioned the necessity of the third party certification for intermediate steel products in an area where international standards were recognized and used internationally. India also imposed factory audits and did not seem to recognize any test results from foreign laboratories. Moreover, the EU remained concerned with the difficulties and backlogs that companies were encountering with the existing certification procedure for galvanized steel and urged India to provide for steel products for a more rapid and efficient procedure.

75. The representative of Japan expressed support for the EU statement. It was not necessary to impose mandatory standards on intermediate goods, such as steel products because protection of

[15] G/TBT/N/COL/96, G/TBT/N/COL/96/Add.1, G/TBT/N/COL/96/Add.2, G/TBT/N/COL/96/Add.3, G/TBT/N/COL/96/Add.4, G/TBT/N/COL/96/Add.4/Rev.1, G/TBT/N/COL/96/Add.5, G/TBT/N/COL/96/Add.6.

human health or safety could be attained only through safety regulations on final products, as the regulation in Japan.

76. The representative of India noted surprise with the EU concern for transparency since the final measure was based on deliberations carried out on the draft regulation notified 5 years ago, on 5 February 2007. Five years was more than a reasonable amount of time for industry to adapt to mandatory certification on steel products. His delegation considered that intermediate products, like ingots and bellets, were critical for the safety of the final building and were covered under the mandatory certification procedures and had to conform to the desired composition and property. Moreover, products such as high string deformed steel bars, wires, hot rolled medium and large size string structures, and sheet steel were essential for building safety and other load bearing applications.

(ix) Thailand – Health warnings for alcoholic beverages (G/TBT/N/THA/332 and G/TBT/N/THA/332/Add.1)

77. The representative of the United States continued to have concerns and questions on this measure and hoped that Thailand would favorably consider the US comments submitted. Her delegation was concerned about the size of the warnings on the label, relative to the bottle, which may detract from the brand name and render the label more subject to counterfeiting. She asked that Thailand modify its alcohol warning label to ensure that implementation would minimally impact trade; if Thailand continued to require warning labels, her delegation asked that they did not cover trademarks.

78. The representatives of Chile, the European Union, Mexico and New Zealand joined the US in recalling its concerns and asked if any developments had taken place since the previous Committee meeting.

79. The representative of Thailand informed the Committee that the regulation still remained a draft. According to the Department of Disease Control of the Ministry of Public Health, a sub-committee to study the impact of the draft regulation is to be appointed, but he had no additional information on the appointment and the enforcement had not been envisaged as yet.

(x) United States – Hazardous Materials: Transportation of Lithium Batteries (G/TBT/N/USA/518 and G/TBT/N/USA/518/Add.1)

80. The representative of the European Union asked for an update on this measure. He recalled that the measure went beyond the UN Recommendations on the Transport of Dangerous Goods and the Technical Instructions on the Safe Transport of Dangerous Goods of the International Civil Aviation Organization. The issue had recently been discussed in the International Civil Aviation Organization, new rules enhancing the control of shipments of Lithium Batteries had been agreed, and work had started to amend the relevant Annexes to the Chicago Convention. The EU urged the US to align its proposal to the requirements agreed in the ICAO, and to refrain from a unilateral approach.

81. The representative of Korea supported the EU's comments.

82. The representative of Japan understood the importance of maintaining transportation security. However, Japan was concerned that this measure was inconsistent with the United Nations (UN) Recommendation on the Transport of Dangerous Goods and the International Civil Aviation Organization (ICAO) Technical Instructions, and had an the impact on trade. Japan sought consistency with the UN Recommendation and with the ICAO Technical Instructions. If the purpose of a regulation was to ensure safety, its scope should not extend to goods for which safety had been assured. Japan reiterated its request that the comments and concerns expressed by Members and

private enterprises be fully taken into account although the final rule would be set to be released in May 2012 according to a website.

83. The representative of the United States confirmed that a revision of the notified measure has been under review since 5 October 2010. Since that time, the Federal Aviation Administration and the Pipeline and Hazardous Material Safety Administration had participated extensively in several multilateral discussions through the dangerous goods panel of the ICAO. UN member state technical representatives and various aviation and battery industry groups also participated. ICAO's final draft guidance document was under consideration and anticipated to be finalized soon. There was a proposed implementation date of January 2013. The proposal would increase the number of battery shipments subject to full hazardous materials labelling and handling information, but also included an exception for some smaller shipments of bare lithium batteries. This was a departure from previous ICAO proposals which would have required full hazardous materials labelling and handling requirements for all shipments of bare lithium batteries. She noted that the current draft of the ICAO guidance did not include batteries "packed within equipment" or consumer electronic goods with an installed battery. She concluded that the US was considering various regulatory alternatives but the timeline of finalization of changes to domestic rules in this area was still uncertain.

(xi) Turkey – New conformity assessment procedures for pharmaceuticals

84. The representative of the United States continued to find aspects of Turkey's decree for pharmaceutical imports problematic, and urged Turkey to take steps to restore market access for safe, high quality pharmaceuticals. While the US was not opposed to inspection requirements for pharmaceutical manufacturing facilities, it was concerned that the measure was neither published in Turkey's official gazette in proposed form nor notified to the WTO. She noted that other measures on medical devices, biotechnology labelling, and inspection procedures for medical devices and IT products were also published in final form without any WTO notification or possibility to comment. She urged Turkey to re-evaluate its internal procedures for transparency and WTO notification to ensure that future measures were properly notified to the WTO

85. Secondly, Turkey had provided the US with a list of recalled pharmaceutical products which it claimed was the impetus for the GMP decree. The US considered product recall as a critical aspect of ensuring that concerns regarding the safety of a pharmaceutical product were addressed promptly and effectively. The fact that some US products had been the subject of recalls should be viewed as a sign that the current system was working to protect consumers. Her delegation urged Turkey to consider not applying the GMP requirement retroactively, giving priority to innovative drug applications that provided new medicinal therapies to Turkish patents, and allowing the integration of GMP inspection into the marketing authorization process. This would alleviate the current blockage of pharmaceutical imports. While pleased with the positive bilateral discussions held on GMP, she noted that the number of pharmaceuticals that awaited marketing authorization in Turkey had reached over 500 products. This was an urgent market access issue for US companies seeking to export to Turkey as well as for, Turkish patients who would benefit from these products. Her delegation urged Turkey to take steps to restore market access for imported pharmaceuticals.

86. The representative of the European Union shared the US concerns and urged continued bilateral discussions to find a solution to the considerable backlog of registration of medicines in Turkey.

87. The representative of Switzerland echoed the EU and US. Swiss Medic and the Turkish Ministry of Health had a bilateral dialogue in 2011 where common ground was identified. Her delegation looked forward to continuing this dialogue this year.

88. The representative of Turkey said that the GMP certification of pharmaceuticals had been explained in detail at the previous Committee meetings. Turkey discontinued its unilateral acceptance of GMP certificates issued by other countries because the Turkish Ministry of Health had concerns that automatic recognition of GMP certificates of other countries, without having access to the relevant background documentation, posed serious risks to human health. The Ministry of Health conducted GMP inspection in accordance with its "GMP Guidelines for Pharmaceutical Products", which were in conformity with the World Health Organization guidelines. In addition, the Ministry used a classification system based on therapeutic priorities for pharmaceuticals. These priorities were determined on scientific criteria and responded to public health concerns. Turkey's current GMP inspection system was implemented on a non-discriminatory basis and, after two years since modification, worked effectively.

(xii) European Union – Directive 2004/24/EC on Traditional Herbal Medicinal Products (THMP)

89. The representative of India requested the EU to put in place a simplified, specific alternative application dossier for registration of traditional products based exclusively on traditional use with references made to the national pharmacopeia for all compliances for specification and quality parameters. India would also request the EU to consider applicants with 30 years of traditional use in the country of origin instead of 15 years of traditional use in the EU in order to establish the efficacy of the medicinal product. Also, the common technical document under the directive was inappropriate for multi-component traditional medicine formulations, given that it was almost an impossible task to provide information with respect to such traditional formulations. India urged the EU to look at recognition of GMP certificates from developing members such as India in this particular directive, and to notify this regulation to the Committee.

90. The representative of China supported India's concerns. According to the Directive 2004/24/EC, TCM products that entered the EU market after 1996 did not have the opportunity to prove they were safe medicine products since they could not be sold in the EU for 15 years after the Directive formally entered into force from 1 May 2011. Meanwhile, registered TCM products needed EU GMP certification before they were distributed. Many Traditional Chinese Medicine enterprises obtained TGA (Australian Therapeutic Goods Administration) certification. Since both Australia and EU were PIC/S members (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme) and recognized each other's results of conformity assessment procedures, he asked why the EU refused to accredit TCM enterprises that already acquired TGA certificate. He asked the EU to explain what fell into mutual recognition among EU and other PIC/S members.

91. The representative of the European Union reiterated that this Directive introduced a lighter, simpler and less costly registration procedure for traditional herbal medicinal products as compared with medicinal products falling under the full market authorization procedure (Directive 2001/83/EC). Herbal products that did not fulfill the definition of medicinal product did not fall under the registration scope. On the specific request for the EU to accredit enterprises that had already acquired a GMP certificate from other Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) members, the EU noted that PIC/s was an organization for cooperation on inspections. The GMP certificates issued by PIC/s Members could only be recognized in the EU if the Members were EU Member States. The EU also recognized GMP certificates from countries with which the EU had a mutual recognition agreement on GMP for sites on the territory of the country in question. The inspection for GMP compliance was a national competence so China and India should contact the Member States where the medicinal products would be placed on the market.

92. The Common Technical Document (CTD) was an internationally agreed consistent format produced to overcome delays in the submission of applications to the different International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) regions and it had facilitated the exchange of information between medicinal

products' regulatory authorities. She advised Members to refer to minutes of previous TBT Committee meetings and to bilateral meetings with India and China where, among other issues, the directive's scope and the eligibility criteria were discussed. Her delegation was happy to continue bilateral discussions on other subjects if necessary.

(xiii) Korea – KS C IEC61646:2007 Standard for Thin-film Solar Panels

93. The representative of the United States reiterated its view that Korea should adopt the IEC 61646 standard in its entirety without limiting application to only thin filmed solar panels produced by Korean industry. She urged Korea to complete its deliberations internally as expeditiously as possible so that companies be allowed to complete all necessary pre-testing of thin film solar panels according to IEC 61646. , KEMCO would have all the necessary input to provide certification expeditiously once this issue had been resolved.

94. The representative of the European Union joined the US' concerns and asked for an update from Korea on the study on the environmental impact of thin-film solar panels.

95. The representative of Korea reiterated that the related certification system was not mandatory. Currently, non-amorphous silicon types of thin film solar panels - Cadmium Telluride (CdTe) and Cooper Indium Gallium Selenide (CIGS) - did not have problems entering the Korean market without certification. The feasibility study was due by the 30 May 2012, following which the competent authorities would decide whether these two types should be included in KS IEC 61646. Updated information would be provided when ready. She added that if and when Korea enabled panels IEC61646 to receive KEMCO certification, Korean authorities could not allow pre-testing because factory inspection results were required beforehand. The other points would be sent to her authorities.

(xiv) Colombia – Shelf life Requirements for Milk Powder[16]

96. The representative of the European Union was concerned that the extension of minimum shelf life for imported milk powder to at least 12 months at import, which was already six more months than was required previously was not notified when the measure was adopted in 2010 and could impair EU exports of milk powder to Colombia. Although the proposed revision established a similar requirement for milk powder manufactured in Colombia, it was discriminatory because it did not take into account the time necessary for getting the product in the Colombian market. It was thus more favourable to Colombian manufacturers. No reply had been received from Colombia to the EU's written comments. She asked Colombia to clarify the risk its authorities sought to address by extending the required shelf life of milk powder, and to provide an update on the draft text.

97. The representative of Colombia hoped to have a technical response as soon as possible which it would submit to the EU delegation.

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

98. The representative of the European Union had remaining concerns with the revised telecom network security regulations and their accompanying template agreement on "security and business continuity" between telecom network operators and equipment suppliers. With regard to the

[16] G/TBT/N/COL/67, G/TBT/N/COL/67/Add.1, G/TBT/N/COL/67/Add.2, G/TBT/N/COL/67/Add.3, G/TBT/N/COL/67/Add.4, G/TBT/N/COL/67/Add.5.

requirements for in-country testing of network elements as of 1 April 2013, the EU failed to understand to what extent the obligation to carry out testing domestically could enhance security. How could state security justify such drastic discontinuation of the acceptance of test results from foreign, internationally accredited laboratories? The EU requested India to postpone or, not enforce, the requirement for in-country testing and hoped that bilateral dialogue could lead to a satisfactory solution.

99. The EU welcomed India's statements that it remained fully committed to honouring its obligations under the Common Criteria Recognition Agreement (CCRA) for the acceptance of certificates issued by other members to that agreement. The EU asked India for assurance that the requirements for in-country testing would, in any event, not affect India's current acceptance of certificates issued under the CCRA. He also requested confirmation that testing and any further security evaluation would be made in accordance with the relevant international standards, such as the ISO IEC Common Criteria standard and, for mobile phones, the international standard for third generation mobile phones. Finally, the EU drew attention to its earlier request that vendors' legitimate commercial interests be adequately protected in inspections and checks and that, consequently, sensitive propriety information need not be disclosed. In that regard, the EU reiterated its request that mandatory testing be limited to those elements that were essential for ensuring the security and integrity of the system.

100. The representative of the United States shared the EU concerns. While appreciating improvements made in the revised telecom network security regulations, the US still had remaining concerns, in particular why the in-country security assurance testing was necessary to address India's security concern. Recalling India's signatory status to the common criteria recognition arrangement (CCRA), she asked India whether the test performed in labs according to the common criteria arrangement would be sufficient for its needs. The US also encouraged India to reconsider the scope of products subject to the in-country testing requirement. Although the current license amendment appeared to apply to all telecom equipment, further examination of India's security concerns may reveal that such an onerous requirement could only add value to specific subsets of telecom equipment that raise those concerns. The US understood that India had begun the process of establishing some labs in-country that would perform the necessary testing of telecom equipment, and had invited the private sector to work with the government setting up those labs. The US expressed concern about the role of those private actors in running the labs where they were also manufacturers of telecom equipment. This created obvious potential for conflicts of interest, raising questions about the ability of a manufacturer to protect intellectual property and the confidentiality of other business proprietary information. The US noted that the requirements for running a competent and independent laboratory were set out in ISO/IEC 17025, and the assessment of whether labs met the terms of that international standard was done through accreditation by peer-reviewed accreditation bodies. In this respect, the US noted Article 5 of the TBT Agreement, which contained the obligation to use international conformity assessment standards backed by international systems, such as ILAC, consistent with Article 9.

101. The US requested India to postpone the implementation date of its measure. The establishment of labs would take time, especially ones that were accredited and internationally recognized. India would therefore need to establish adequate safeguards to assure foreign manufacturers that their intellectual property would not be jeopardized as a result of requiring testing in a test lab done by a competitor. Additional bilateral discussions were welcome to explore commercially viable options in order to meet India's legitimate security concerns.

102. The representative of Japan shared concerns raised by the EU and the US. It was still concerned with India's regulations on the licensing conditions for telecom services, announced on 31 May 2011. The representative of Japan stated that Japan would also maintain interested in these regulations and their future improvement. As mentioned at the previous TBT meeting in November

2011, Japan thought that this approach might not be in accordance with the CCRA because the new rules starting in April 2013 dictated that only network elements approved by Indian certification agencies would be allowed. Japan recalled that India had accepted the CCRA scheme. Furthermore, he asked India to ensure that their telecom regulations did not impede market access for foreign companies.

103. The representative of India stated that India would continue to recognize the process based on performance tests conducted by international laboratories for general guidelines on products covered by the CCRA. India would continue such recognition notwithstanding the fact that it was not a complete member of the CCRA and despite the fact that India's own tests were not recognized by other Members. India also reiterated that these were security testing guidelines of telecom equipment and, as such, they called for the application of other parameters different from the general guidelines, technical regulations and conformity assessment procedures. At the same time, India wished to make this measure as trade facilitating as possible. He understood the concerns expressed and the request for extending the measure's timeline, and would communicate them to his authorities.

(xvi) Brazil – Instructions for Registration for Labels of Imported Products of Animal Origin[17]

104. The representative of the United States appreciated bilateral discussions and was pleased with Brazil's indication that it would consider a Food Safety Inspection Service (FSIS) proposal, to be sent by letter as soon as possible, addressing the concerns of both countries.

105. The representative of Brazil noted that the bilateral videoconference allowed Brazilian experts to better explain to their US counterparts the requirements of the Brazilian regulation. Brazil remained open to receiving the US proposal.

(xvii) Indonesia – Labelling Regulations (Ministry of Trade Regulation 62/2009 and 22/2010) (G/TBT/N/IDN/47)

106. The representative of the European Union thanked Indonesia for explaining, at the last TBT Committee meeting, that the approval procedure of labels and the obligatory labelling in Indonesian of certain imported goods before entering the Indonesian customs area were necessary for consumer information and to carry out pre-market surveillance of imported goods. However, the EU found these measures burdensome for importers and encouraged Indonesia to re-consider the need for the approval procedure and to provide at least the possibility of re-labelling products in a specific zone *after* entering Indonesian customs, a common practice in many WTO Members. Sufficient market surveillance actions could still be ensured under this option and it would ensure a less burdensome and less trade-restrictive procedure for importers, while still fulfilling the control and consumer protection objectives. The EU also asked for clarification on whether Indonesia would reconsider the possibility that importers had to use *stickers* for the re-labelling.

107. The representative of the United States requested that US food products be allowed into Indonesia; supplemental labels would be applied in a facility under the importer's control, subject to the Indonesian Government's approval. The re-labelling of goods would subsequently be subject to BPOM's inspection before entry into commerce, as was a common practice for many WTO Members. The US requested Indonesia to indefinitely delay any implementation date until the issue was resolved; the US sought resolution to the matter in a way that would meet the two countries' shared objectives of informing consumers and continuing their trading relations. This was an important trade issue for the US, affecting approximately $430 million worth of processed food exports to Indonesia.

[17] G/TBT/N/BRA/385, G/TBT/N/BRA/385/Add.1, G/TBT/N/BRA/385/Add.2, G/TBT/N/BRA/385/Add.3, G/SPS/N/BRA/654, G/SPS/N/BRA/654/Add.1, G/SPS/N/BRA/654/Add.2, G/SPS/N/BRA/654/Add.3.

108. The representative of Australia shared the concerns expressed. Australia's preference was to allow exporters to use labelling stickers upon the entry of a good into the market. Australia encouraged Indonesia to ensure that any labelling standards be consistent with international standards, such as the Codex Alimentarius, which provided guidance on using a secondary label in a country.

109. The representative of Indonesia explained to the EU that the pre-import labelling obligation was imposed to protect the consumer by providing clear information, facilitating the implementation of monitoring and enforcement of custom in the reign of custom excise, and minimizing the entry of illegal import and circulation of illegal goods. Indonesia would revert to the EU for further bilateral discussions on this issue. The US requested that Indonesia allow supplementary labels for processed food products supplied at an importer-selected warehouse, and or in approved locations. He referred to the regulation HK0315121109955 of 2011 of the Indonesian national agency for drug and food control intended to process food registration and labelling requirements. Articles 35 and 36 of this regulation require that processed food should comply with quality, nutrition and labelling criteria. He added that distributed processed food should comply with staff-approved labels at the time of registration into Indonesia. Article 36.1 requires that registration be done by an approved manufacturer, or other party which had the approval as an importer pursuant to the regulation and had authorization from the company. When the processed food entered Indonesia, the label must fulfil these stated requirements.

(xviii) Italy – Law on "Provisions concerning the marketing of textile, leather and footwear products" (G/TBT/N/ITA/16)

110. The representative of India asked the EU for an update on the implementation of this law. It covered a large number of regulations and required provision of information at each stage of processing, which created difficulties for industries premised on global and multiple sourcing.

111. The representative of the European Union reiterated that Italian authorities had decided to postpone the application of this law. It depended on the adoption of implementing measures for which no adoption date was foreseen.

(xix) Turkey – Communiqué SUT 2010 regarding documentation requirements for medical devices

112. The representative of the United States urged Turkey to eliminate the Social Security Institution (SGK) documentation requirements in communiqué SUT 2010 so that suppliers of medical devices could continue to place their products on the Turkish market, provided that they met the requirements of the Medical Device Directive and the Ministry of Health. As this measure was not notified to the WTO, interested stakeholders had no notice nor opportunity to comment on the measure in draft form. Since the measure went into effect only seven days after publication, suppliers did not have a reasonable interval for implementation. The purpose of requiring companies, and only selected medical devices used in 3 specific areas, to provide these additional documents was unclear, given that Turkey's Ministry of Health, which is the regulatory authority responsible for ensuring the safety and efficacy of medical devices, does not require companies to provide such documents. She asked if these documentation requirements were being reviewed since they posed problems for producers. She asked for an update on the review by Turkey's reimbursement authority of these requirements.

113. The representative of Turkey explained that medical devices were regulated, as in the EU, under three different pieces of legislation in Turkey: (i) the Regulation on Medical Devices; (ii) the Regulation on In-Vitro Diagnostic Medical Devices; and (iii) the Regulation on Active Implantable Medical Devices. A requirement for market entry into Turkey was that medical devices must comply with the applicable technical regulations which were indicated by the "CE" marking. Therefore, any medical devices, either imported or produced domestically, could enter into the Turkish market freely

if it bore this marking. While the Ministry of Health regulated the entrance of medical devices into the market, SGK decided which devices would be reimbursed. SGK's primary objective was to serve public interest and protect public health by assuring that the most efficient medical devices were provided to patients; while also keep expenditures within its pre-set budgetary limits. The SGK did not regulate market-access conditions for the Turkish market; companies could decide to sell their products to this institution by accepting its reimbursement policies. Additionally, SGK's documentation requirements were neither excessive, nor discriminatory.

(xx) Brazil – Draft Resolution No. 112, 29 Nov 2010; maximum levels of tar, nicotine and carbon monoxide permitted on tobacco products and prohibition of additives (G/TBT/N/BRA/407)

114. The representative of the European Union asked Brazil for an update on this proposal, as the EU had learned that a text had been adopted and published on 16 March 2012 as ANVISA Resolution 14/2012. The EU also asked Brazil to provide an outline of the changes contained in the adopted Resolution, compared to the notified draft, and a timeline of implementation of the measure. She reiterated her request for Brazil to reply in writing to the EU's written comments.

115. The representative of Mexico associated her delegation with the EU's statement regarding possible breaches to the TBT Agreement in this draft technical resolution. She asked Brazil for a formal response on Mexico's comments on the draft resolution presented on 31 March 2011.

116. The representative of Honduras considered that the Brazilian measure seemed to be incompatible with the TBT Agreement; Article 2.1 of the Agreement required that technical regulations not discriminate against domestic and like imported products. Depending on market conditions, the prohibition on the use of components may be incompatible with this obligation because it would be a *de facto* prohibition of traditional US-blend cigarettes, whereas Virginia-type cigarettes would not be similarly affected. Article 2.2 of the TBT Agreement provided that technical regulations not be more trade restrictive than necessary to fulfil a legitimate objective and that they must take into account the risks of non-fulfilment. This provision also stated that in evaluating these important elements, the following elements should be relevant when assessing such risks: available scientific and technical information; related processing technology; and intended end use of products. Brazil had been unable to explain how its legislation would fulfil such requirements. In particular, it seemed that the Brazilian measure was not based on scientific evidence or any impact assessment.

117. Article 2.8 of the TBT Agreement stated that, wherever appropriate, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics. Other WTO Members had adopted a standard based on performance that only prohibited those cigarettes that truly had a fruity or sweet characteristic flavour. Brazil was seeking to regulate the design of the product and the components of cigarettes without taking into account how such components affected the performance; in other words the characteristic flavour of the product. The focus based on characteristic flavour was a lot more specific and targeted than an approach prohibiting a list of additives in any amount, regardless of their effect on the end product. Article 12.3 of the TBT Agreement required Members to ensure that their technical regulations would not create unnecessary barriers to exports from developing country Members. By affecting tobacco leaf markets, Brazil's measure may be creating a barrier in violation of this provision.

118. The representative of Guatemala supported previous comments and expressed concern that the measure might have an impact on the trade of US blends cigarettes using burley tobacco. As the Resolution was recently published, Guatemala was still looking at its possible impact on the marketing of tobacco products. Guatemala was concerned that banning certain kinds of additives that were necessary to make the US blend may result in a *de facto* ban on the marketing of this kind of cigarettes. Because of the way it was cured, burley tobacco had to use certain additives in order for the cigarette to retain moisture and recover the sugars that were lost during the curing process. This

measure would therefore have an impact on the growing of burley tobacco and would seriously affect small countries like Guatemala where the production of this type of tobacco accounted for approximately 98per cent of its domestic tobacco production, generating 1,000 direct jobs and some 4,000 related jobs. Guatemala's tobacco exports in 2011 reached $54 million US. While Guatemala recognized Members' right to adopt standards for the protection of human health and safety, in so doing the criteria established in Article 2.2 of the TBT Agreement, in particular the obligation that technical regulations shall not be more trade restrictive than necessary in order to fulfil their legitimate objectives, must be respected. She requested Brazil to explain how it took into account Members' concerns raised in this Committee and to indicate whether Brazil felt that its resolution would allow for production and consumption of American blend tobacco. In particular, how would each of the ingredients of American blend be covered by Article 7 of the Resolution?

119. The representative of Dominican Republic supported the concerns raised by other Members and reiterated its previously stated concerns.

120. The representative of Indonesia reiterated its request that Brazil reply in writing to the letters from the Indonesian Minister of Trade, sent in March and April 2011, related to this draft resolution.

121. The representative of Nigeria associated herself with the previous speakers and asked for an update on the public health consultation process. Given that the resolution would ban the use of additives with no reasonable justification, Nigeria encouraged Brazil to ensure that any final decision be based on scientific and technical evidence.

122. The representative of Zimbabwe stated that his delegation was still waiting for Brazil's written responses to the written comments it had sent before the November TBT meeting.

123. The representative of Australia welcomed Brazil's decision to implement tobacco control policies and preventive measures aimed at reducing the attractiveness of certain tobacco products, particularly to children and youth. Each Member had the right to implement necessary measures to protect public health. Australia would follow Brazil's implementation of these measures with interest and was prepared to continue to defend the right of members to protect public health while complying with relevant international treaty obligations.

124. The representative of Chile asked about the resolution's status. At the last meeting, Brazil said that it was reviewing all comments received and would respond to these before the resolutions' adoption. Chile sought these responses as the resolution would affect developing countries which export tobacco products.

125. The representative of Colombia reiterated previous concerns that this measure would be contrary to the TBT Agreement and would have an impact on Colombian tobacco products by restricting the American blend marketing based on oriental and burley tobacco. Recently Brazil published a new version of the resolution, similar to the previous one, restricting the import and sale of tobacco products containing ingredients that were indispensable for the American blend. The exclusion of sugar in the most recent version of the resolution would not substantially change the situation for American blend cigarettes. Other banned ingredients were required for this blend, and it was likely that sugar would be banned in the future. Colombia was concerned that the resolution would infringe Article 1.2 of the TBT Agreement, establishing less favourable treatment of international products by banning cured tobacco and sugar, of which Brazil was the main producer. He asked for the date of the new resolution, whether it had been notified, and if not, when it would be.

126. The representative of Zambia asked Brazil to confirm that it had enacted a final resolution on tobacco additives and, if so, whether it intended to notify it to the TBT Committee. Did Brazil intend to take into account the special development, financial and trade needs of developing countries in the

application of this technical regulation, as provided for in Article 12.3 of the TBT Agreement? Brazil had not provided peer reviewed scientific evidence that the banning of additives would address its stated health objectives and the imposition of such measures could create trade barriers, more so because the legislation would ban additives on a selective basis. This measure would have far reaching implications for countries like Zambia as its implementation would make it impossible to blend tobacco, especially the type produced in Africa. Zambia considered that there were more balanced approaches to meeting Brazil's policy objectives than the current measure. The regulation of ingredients should not be deemed an effective measure to reduce the threat posed by tobacco. Because it was naturally addictive with or without ingredients. Efforts should focus therefore on measures that had proven effective on the consumers' behaviour.

127. The representative of Turkey supported the concerns expressed. While committed to the protection of human health consistent with the WHO Framework Convention on Tobacco Control and respectful of the measures taken by Members based on that Convention, Turkey was concerned that some Members could use areas of this Convention for commercial interests. The Brazilian regulation containing a list of additives to be prohibited in all tobacco-related products in Brazil, was an issue for Turkey, one of the major Oriental tobacco producers. Some of the prohibited additives were essential components of the blended type of cigarettes, in which both Oriental and Burley tobacco were used. The TBT Agreement prohibited discrimination between "like products". The Brazilian Resolution would ban the production and sales of blended cigarettes, leaving the market to the Virginia type products. He noted that Brazil was one of the main producers of the Virginia type tobacco. Additives did not give any characterizing flavour to tobacco products and this decision was made without considering the effects on final products. Turkey asked Brazil to indicate scientific evidence proving that the prohibited additives would pose increased risk to human health. There was no difference with respect to the "end use" between blended and the Virginia types, and Brazil had not provided a satisfactory explanation for discrimination between these two types. Turkey requested Brazil to respond to its comments and to amend the Resolution in accordance with the TBT Agreement.

128. The representative of Norway informed Members that Norway had implemented measures to combat smoking and would continue to follow the Brazilian tobacco regulation closely. Norway believed that it was within a Member's right to implement necessary measures in order to protect public health and that this was not in contradiction with a Member's trade obligations.

129. The representative of Brazil informed Members that on 16 March 2012, ANVISA, the Brazilian Health Surveillance Agency, published the final regulation on maximum levels of tar, nicotine and carbon monoxide for cigarettes and on the restriction of additives in tobacco products. The measure would be notified to the TBT Committee. A draft regulation had been notified and a four-month period for comments was provided. Further, ANVISA promoted several rounds of public debate all along the process. In December 2011, Brazil held a public hearing on the issue and in February and March 2012, the board of Directors of ANVISA discussed the draft measure in open meetings, with the participation of industry, governments, civil society, academia, etc. Comments received were carefully examined by the Brazilian authorities who were working on a consolidated answer for all Members. Companies now had 18 months to adapt their products to the new requirements; those that did not comply could be sold for 24 months only. The main difference between the draft and the final measure was that *sugar* had been removed from the list of prohibited additives in tobacco products. The use of sugar as an additive would only be allowed to restore the sugar lost during the drying process of certain tobacco leaves. Arguments about a possible discrimination against traditional blends produced with burley tobacco did not stand since sugar would be allowed for this process.

130. In Brazil, 200,000 people died every year due to diseases caused by tobacco consumption. The objective of the measure was to protect public health by reducing tobacco products' attractiveness, especially on children and the youth. Studies showed that the risks of tobacco

addiction were significantly higher when people start smoking as children or teenagers; the Brazilian regulation was therefore intended to reduce the incentive for first experimentation since flavoured products had evident appeal to the youth. A recent study conducted by the Oswaldo Cruz Institute in Brazil, surveyed more than 17,000 thousand students in several Brazilian cities. It found that more than 50per cent of young smokers preferred flavoured cigarettes. The Brazilian regulation also prohibited the use of additives used to reduce the harshness of tobacco smoke and to potentiate the effect of nicotine which reduced the natural rejection to tobacco products and increased their addictive characteristics. Brazilian authorities had taken into account the FCTC "partial guidelines" to the implementation of Articles 9 and 10 as a basis for the regulation. Brazilian authorities had also taken into account the extensive scientific literature on the properties and effects of additives in tobacco products and had produced a compilation of the scientific references on this subject, which had been shared with several Member. Brazil is willing to continue to share it with other interested Members. Moreover, in defining the flavouring additives covered by the regulation, Brazil had taken into account the work of the Joint FAO/WHO Expert Committee on Food Additives and of the Flavour and Extract Manufacturers Association. Finally, the measure did not differentiate between national or foreign producers.

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

131. The representative of the European Union reiterated his delegation's concerns and requested an update on the timeline for the revision of the regulation on commercial encryption products managed by OSCCA. He sought assurance that the process would be transparent and allow for consultation by interested parties. In this regard, the EU considered that the publication of the final text by the State Council Legislative Office before promulgation of the regulation would be too late in the domestic regulatory process and would not allow stakeholders a meaningful opportunity to comment. The EU sought assurance that the draft would be notified to the TBT Committee at an early draft stage, when amendments could still be introduced and comments taken into account, as required by Article 2.2 of the TBT Agreement.

132. The EU also recalled that the Multi-Level Protection Scheme (MLPS) had an impact on commercial sectors of economic significance such as banks, financial institutions, public transport and energy. He requested more transparency and predictability on the classification criteria used to establish the level of security sensitivity of IT systems, and that the concept of critical infrastructure be construed so as to only include IT systems that were essential to national security. The concept should not be subject to an extensive interpretation that could encompass systems involving activities that should normally not be covered by the national security exception.

133. The EU was also concerned with standardization practices in the area of information security (detailed in the EU's submission G/TBT/W/344 in China's last Transitional Review Mechanism), in particular those carried out by the Information Security Standardization Technical Committee (TC 260) managed by the China Electronics Standardization Institute (CESI). The procedures of this Committee did not allow foreign companies, or even foreign invested companies established in China, to participate directly in the standardization process. As these standards could impact commercial products and applications, the EU requested more opportunity for the participation of non-domestic companies in this process. He requested an update on the six draft information security standards issued for consultation by TC 260 in July 2011, on which comments had been made by the EU and European industry.

134. Another concern in the field of standardization was a new draft standard issued for public consultation by Standards Committee 17 of China National Information Technology Standardization (NITS) on 19 January 2011. This standard concerned radio frequency based mobile payments - on-

line payments made by mobile phones. Recently, European industry had submitted concerns via the European Chamber of Commerce in China. A general concern was the process which did not allow foreign invested enterprises to participate, and did not allow foreign technology to be included in the patent pool from which the Standards Committee could draw upon when deciding the encryption technology and the algorithm to be used. Specific concerns regarding this standard included the fact that the draft standard referred to an algorithm ("Algorithm E") which was to be used, without providing any additional information about its content. The EU requested clarification about the accessibility of the algorithm and, in particular, whether the content of the algorithm would be publicly released and made accessible on fair terms to all market players, including foreign invested enterprises. The EU recommended that the implementation of this standard be delayed to allow that all players not only be given access to all required information, but also benefit from an adequate period for product development and interoperability testing. In addition, regarding this draft standard, some important divergences had been observed with respect to the relevant international standard in this field, i.e. ISO IEC 14443 Type A, as regards the data frame, coding and security aspects. Unlike China's draft standard, the ISO IEC standard clearly defined the algorithm to be used.

135. Mobile payments were another example of a purely commercial application not related to state security. The production of mobile payment applications and products incorporating these applications should therefore be open to all enterprises, domestic and foreign invested ones. This could only happen if the algorithm needed to apply the standard was made available to all. The EU requested that European industry comments be taken into account. On the relationship between these standards and the regulatory framework being discussed, i.e. the OSCCA regulation and the MLPS, the EU requested clarification as to the way the standards were going to be used and referenced for the purposes of implementing the OSCCA regulations and the MLPS. Greater dialogue among all market players was in the mutual interest of all parties concerned.

136. The representative of the United States supported the EU statement. Her delegation had raised these concerns both in this Committee and bilaterally, including on transparency and information security testing practices, such as requirements for the use of Chinese-only intellectual property in the core components of IT security products. She urged China to ensure that future implementation of the MLPS regime take a least trade restrictive approach to regulating information technology products.

137. The representative of Japan supported the EU and US statements. Various schemes and regulations within China regarding information security continued to pose difficulties for the future of trade in information security products, as these schemes could not be regarded as being in line with global norms and approaches. Japan would closely monitor this issue.

138. The representative of China noted the bilateral meetings with the US and the EU on this measure and that China was studying the concerns expressed by them and by Japan on the draft Commercial Cryptography Administrative Regulation by the State Commercial Cryptography Administration. Concerning the Regulation on Classified Protection of Information Security, he referred to China's responses contained in the previous Committee minutes. China invited Japan to explain the global norm in information security. China's electronic standardization institute had received comments from the EU delegation to China and Mongolia and from the European Chamber of Commerce in China. The institute had contacted the European Chamber of Commerce twice, most recently in February, however, due to scheduling conflicts, they did not meet. On the procedures of standards relevancy, the institute would collect and record the comments from relevant stakeholders before making its final decision. As China did not receive the comment about the drafting standard on radio frequency mobile payments earlier, he asked for it in writing to forward to his capital.

(xxii) China – Administration on the Control of Pollution Caused by Electrical and Electronic Products[18]

139. The representative of the European Union, asked for information on the state-of-play of the measures, particularly on the progress of discussions on the certification procedure. The EU remained concerned about mandatory third party certification.

140. The representative of Korea also asked for an update on the measures and for detailed information on the requirements for certification bodies and laboratories for State Recommendation Voluntary Certification on Electric Information Products, which had entered into force on 1 November 2011.

141. The representative of Japan, while also asking for the state-of-play, recalled previous discussions and the TBT notification indicating that the Administration itself was mandatory, while the Management Catalogue was voluntary. However, it was not clear if the Administration referred to the Management Catalogue and thus made listed products subject to mandatory certification, like in the previous Administration. If the combined regulation of the revised Administration and Management Catalogue became both a mandatory and a voluntary certification system, Japan asked China to stipulate SDoC in "nationally recommended voluntary certificate system". This would contribute to reducing the burden of manufacturers in China and in other Members.

142. The representative of China said that the Administration on the Control of Pollution Caused by Electrical and Electronic Products was still being finalized, and after its publication, the Management Catalogue and the correspondent conformity assessment procedure would be determined. The state-recommended Voluntary certification under Administration on the Control of Pollution Caused by Electronic Information Products was to be launched and enterprises would be free to choose qualified certification bodies.

(xxiii) Indonesia – Draft Decree of Minister of Industry on Mandatory Implementation of Indonesia National Standard for electrolysis tin coated thin steel sheets (G/TBT/N/IDN/46)

143. The representative of Korea asked Indonesia to update the Committee on the status of this draft measure. He requested that Indonesia only regulate final products, not intermediate ones.

144. The representative of Japan supported Korea's statement, stated that finished products rather than intermediate materials would be responsible for protecting human health and safety. Japan expressed concern about the possible further expansion of mandatory standards to cover steel imported from Japan which was already produced under a strict quality management system at ISO 9001 certified steel mills. If the scope of mandatory standards was extended further, it would add to the time and cost required to receive and maintain certification. This would have serious implications on foreign trade, such as increasing distribution costs and delaying deliveries for specific industries in Indonesia. It might even make industries in Indonesia less competitive in global markets.

145. The representative of Indonesia said that Indonesia was currently in the preparation stage of revising the national standard SNI for electrolysis tin coated steel sheets. When ready, it would be notified and Indonesia would then provide more information. Regarding Japan's question on the ISO 9001 standard, the product certification was not similar to the management system of certification. Therefore, manufacturers certified with ISO 9001 must comply with the product certification or SPPP SNI. Indonesia welcomed continued bilateral discussion on the issues raised by Japan and Korea.

[18] G/TBT/N/CHN/140, G/TBT/N/CHN/140/Add.1, G/TBT/N/CHN/140/Rev.1.

(xxiv) Korea – PVC flooring material and Wallpaper and paper linoleum, and toys[19]

146. The representative of the United States referred to previous discussions on this matter. In a bilateral meeting in May 2011, Korea informed the US of a study on the release of phthalates in construction materials. The US asked Korea for a copy of this study in a letter of June. The response from Korea in July stated that the results of the safety assessment study for PVC flooring and wallpaper had been conducted from July to October 2010. She asked for an actual copy of the study so that her delegation could better understand how the results were obtained and compare them to other studies. This information had again been requested in September 2011. In exchanges with Korea, Korea had asked the US to share studies with respect to phthalates regulations. The US Environmental Protection Agency (EPA) had published an action plan on phthalates given a generalized concern on this material. However, there were no EPA studies or surveys and the EPA was not contemplating taking any action with respect to PVC flooring and wallpaper. The US was unaware of any other scientific or technical data supporting the Korean hypothesis that children would be exposed to phthalates in PVC flooring and wallpaper.

147. The representative of Japan supported the US comments and asked about the status regarding Korea taking into account of comments received from stakeholders in the previous TBT committee.

148. The representative of Korea said that the proposed measure could help protect children's health from the three phthalates. Most Korean houses used PVC flooring materials and wallpaper. As toddlers and children play on the floor and against the walls, they tend to suck and rub against these parts of the house, necessitating regulation of PVC flooring materials, as in the case for toys. KATS, the competent authority, had changed the total amount of contents in PVC flooring material, taking into account other countries' comments. In PVC flooring material for Ondol (a Korean floor heating system), the total amount of DEHP, DBP and BBP contents of upper part would now be no more than 1.5 per cent and that of lower parts no more than 5 per cent. In PVC flooring material for non-Ondol, the total amount of their contents of upper part would be no more than 3 per cent and that of lower part no more than 10 per cent. The revised regulation had been notified under G/TBT/N/KOR/303/Rev.1. Korea would send the other points or requests made to its competent authority.

(xxv) Colombia – Alcoholic beverages[20]

149. The representative of the European Union thanked Colombia for its January 2012 reply to its comments and its efforts to address them. The EU continued to have concerns on the notified text which were not resolved with the amendments proposed in Colombia's reply. He outlined these concerns, which would be sent to Colombia in writing. First, the EU still had some problems with the definition of "Gin", in particular, the definition of "London Gin". Secondly, the EU stressed that fixing labels at the origin could be problematic, in particular for imports of low volume. For imported products, labelling in warehouses was explicitly accepted as an alternative to labelling at the origin. This would guarantee that consumers were properly informed. Thirdly, the EU asked if the requirement for the issuing of a sanitary inspection certification, based upon the presentation of a quality certificate issued by the manufacturer and complemented by physical sanitary checks would be also applicable to locally produced goods. If not, the EU requested that for imported alcoholic beverages this requirement be substituted by the presentation of a quality certificate supplemented by random physical sanitary checks when deemed necessary.

[19] G/TBT/N/KOR/303, G/TBT/N/KOR/303/Add.1; G/TBT/N/KOR/304, G/TBT/N/KOR/304/Add.1.

[20] G/TBT/N/COL/121/Add.1, G/TBT/N/COL/121/Add.2, G/TBT/N/COL/121/Add.3, G/TBT/N/COL/121/Add.4.

150. The representative of Colombia said previous comments were based on a questionnaire regarding this measure. Given that Colombia was hearing new comments for the first time during this meeting, he would relay them to the competent authorities for the appropriate answer.

(xxvi) China – Provisions for the Administration of Cosmetics Application Acceptance (G/TBT/N/CHN/730, G/TBT/N/CHN/730/Suppl.1 and G/TBT/N/CHN/821)

151. The representative of the European Union recalled previous concerns on China's new requirements for the approval of cosmetics products, which had been posing difficulties to EU manufacturers for the past two years. The EU shared China's legitimate objective of providing for consumer protection. However, in its current form, the registration procedure was considerably more burdensome than necessary to achieve this objective, particularly for smaller companies. The EU considered that further efforts were necessary to streamline and hasten the registration process. In particular, the registration of products with new ingredients was in a complete standstill. The EU noted that since April 2010 there had not been a single new product accepted by China that contained a new ingredient. During the same time period, thousands of new products had been safely marketed in the EU and exported elsewhere, including to all regions that required pre-market registration. The EU considered this trade interruption extremely disconcerting for a fast moving product sector that was driven by constant innovation and asked the Chinese State Food and Drug Administration (SFDA) to provide more information on the steps being taken to solve this problem. The EU reiterated its commitment to further enhance its bilateral cooperation with China to effectively address these issues and appreciated the constructive attitude of the SFDA in the regulatory expert dialogue with the European Commission's Directorate General for Health and Consumers, most recently in March in Beijing. The EU also thanked China for the recent reply provided to its comments to notification CHN/821.

152. The representative of Japan welcomed China's intention to ensure the safety of cosmetics. However, it was still concerned with aspects of the measure. Article 3.(2), 2, (2) of the national guidelines for application and evaluation of new ingredients for cosmetic products required the safety evaluation of single substances. It stipulated that "[t]he safety evaluation of a new ingredient should be carried out with single substances, solvents, stabilizers and carried substances which are technically unavoidable and irremovable are excluded from this scope. Natural ingredients should be single substances, and information on the parts used for extraction should also be submitted." The scope of exclusion of solvents in these guidelines was not clear. Plant extracts were generally compounds of chemical substances which could not be isolated. Even if isolation was possible, the isolated substance would be different from the one contained in the original extract due to the chemical reaction in the isolation process. Therefore, the evaluation of isolated substance was not appropriate. Japan requested China to revise the guideline so that a single substance in a natural ingredient was excluded from the test, and also to clarify the scope of this requirement at the earliest opportunity.

153. Japan also reiterated its concern that Article 3.3 of the guidelines required a summary and flow chart of the manufacturing process of new ingredients. Japan requested China to review the implementation of the guidelines because according to Japanese industry, in implementing this provision based on the opinion of the Examination Committee in August 2011, Chinese authorities sometimes required the disclosure of information not necessary for the test, such as trade secrets related to the manufacturing process, including reaction processes and reaction temperatures. In June 2011, SFDA published new ingredients on its website, which were thought to be approved ingredients. According to industry, SFDA disclosed the related trade secret such as the name of the original ingredients, including the name of the raw materials, and also part of these applications. Because trade secrets were very important in marketing, Japan requested improved methods of publication to avoid disclosing trade secrets. Japan was also concerned with delays in the review of applications. In some cases applications for new ingredients which were duly submitted waited more

than one year for an "examination postponed" notice, without any additional feedback. Japan requested China to notify the applicants of the current status of such examinations. Japan had submitted comments to the Chinese notification G/TBT/N/CHN/821 on 2 August 2011 and expressed its concerns in the November 2011 Committee. Since then, Japan had not received any response and it urged China to reply to its comments and concerns

154. The representative of China stated that China had replied to the EU comments of 22 September 2011 to the EU Enquiry Point on 16 March 2012. Although the Guidance for Application and Evaluation of New Cosmetic Ingredients did not provide 60 days for comments, both EU and Japan had learned about it and were able to have effective exchanges with SFDA. The EU had reached consensus with SFDA at the Third Meeting of the Sino EU Cosmetic Working Group in June 2011. In July 2011, the SFDA organized training activities, to which L'Oreal, Unilever and Nivea from the EU, Amore from South Korea and Pola from Japan participated. At the EU-China technical exchanges, held in November 2011 and March 2012, experts from the EU and China discussed more details about the Guidance. Currently, application and evaluation of new cosmetic ingredients were being carried out smoothly. He added that Japanese companies could also exchange their technical concerns with SFDA, but questions as to whether plant extracts were solvents, stabilizers, or carriers due to inevitable technical constraints; or any technical problems on natural ingredients and formula ingredients, were questions that had to be resolved on case-by case basis. The SFDA encouraged these issues to be discussed through bilateral technical exchanges. Natural extracts, like plant extracts, should be applied with relevant information on ingredients (information on active ingredients with known structure in plant extracts, for example) in the applications. For plants whose whole bodies were approved for use as cosmetic ingredients, the concentration limit of the whole plant was not applicable to extracts from certain parts of that plant. For ingredients accepted and being evaluated, the Guidance for Application and Evaluation of New Cosmetic Ingredients should apply. Applicants who provided materials involved with confidential intellectual property information should make this point clear in the application. According to SFDA regulations, applicants could log onto the following website to check the status of the evaluation of applied new ingredients via usernames and passwords: http://123.127.80.6/enterprise/index.jsp.

(xxvii) Korea – Good Manufacturing Practice requirements for cosmetics (G/TBT/N/KOR/301)

155. The representative of the European Union reiterated previously raised concerns. In the last meeting, Korea confirmed that the Korean Food and Drug Administration (KFDA) was reviewing whether KCGMP certification for foreign manufacturers could be made possible to provide equal treatment to domestic and foreign manufacturers of cosmetics in accordance with Article 2.1 of the TBT Agreement. The EU asked for an update on this, particularly since this issue was not covered by the new Enforcement Regulation to the Cosmetics Act, adopted in February 2012. The EU also asked for confirmation that the KCGMP did not substantially deviate from the international cosmetics GMP standard ISO 22716, and whether KFDA would accept assessments performed or certificates issued by independent third parties proving compliance with ISO 22716, or self-certification by cosmetic manufacturers, as was the case in the EU and other major cosmetic markets.

156. The representative of the United States supported the remarks of the EU on the issues of ISO 22716 and certification. The US was concerned with the Korean cosmetic trade association's (KPTA) participation in the customs clearance process for imported cosmetics. In that capacity, KPTA was responsible for reviewing conformity assessment and other documentation provided by foreign competitors. The US asked for clarification on KPTA's role in this review process because it was concerned that there could be a serious conflict of interest.

157. The representative of Korea explained that the Cosmetic Act would be amended to revoke the "Cosmetics Standards and Test Methods". This would mean that foreign manufacturers could receive equal benefits to manufacturers with KCGMP certification. The Enforcement Regulations of

Cosmetic Act was amended to allow manufacturers to self-select testing items during quality inspection of final products. Under Article 2.1 of the TBT Agreement, both domestic and foreign manufacturers must receive an independent KFDA certification even if they had third party certification from an overseas certification body. For import clearance, the submission of a frame formula and sales certificate (submitted if the product was imported for the first time) to KPTA via EDI system was the minimal requirements to access the Korean market. Furthermore, the Enforcement Regulations provided an exemption if there was an import history, and the submission of an ingredient list to manufacturers that received an import declaration through the EDI system.

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(xxviii) Australia – Tobacco Plain Packaging Bill (G/TBT/N/AUS/67, G/TBT/N/AUS/67/Add.1, G/TBT/N/AUS/67/Add.2)

160. The representative of Mexico requested an update and an official response to its comments sent on 22 July, 31 May and 22 July 2011.

161. The representative of Dominican Republic reiterated her delegation's concerns expressed in this Committee and in the TRIPS Council. Australia had only provided concerned Members with partial preliminary responses that showed a lack of scientific basis for such a radical measure. The measure would affect the competitive advantages of tobacco products, in general, and cigarettes, in particular. It would result in negative effects to developing countries, such as the Dominican Republic, which had invested heavily in the development of high quality tobacco products. Her delegation believed that the measure was not in conformity with several WTO disciplines. By prohibiting the use of special designs and by requiring tobacco products to be sold in essentially identical packages, the measure would eliminate all means of differentiation between products. This, in turn, would prevent consumers from having access to essential information about tobacco products, creating confusion in the market. As a consequence, the competitiveness of these products would be affected as would their intellectual property rights be violated. The measure would not attain the legitimate stated objective of protecting public health; on the contrary, it could result in unintended negative effects. For example, eliminating differentiation between tobacco products could result in lowering tobacco product prices, which, would lead to an increase in their consumption. Australia had not explained how this consequence would contribute to attaining the measure's stated objectives.

162. Australia considered the measure to be a technical regulation under the TBT Agreement and thus accepted that it had to be compatible with Article 2.2 of the TBT Agreement and its

jurisprudence. This meant that Australia accepted that the measure could not be more trade restrictive than necessary to attain its policy objective, and that it could only be maintained if less trade restrictive alternatives were not available. The measure, however, did not respect these conditions for several reasons. Firstly, Australia contended that the measure was justified by public health objectives, referring to a number of studies. However, the scientific evidence underpinning the measure had been challenged in public documents submitted to the Australian Government, and Australia had not yet fully explained the scientific basis of its measure. Secondly, Australia had at its disposal other measures that would be more effective to attaining the stated objective without being detrimental to the competitive opportunities of imported tobacco products. In this respect, Australia had never satisfactorily explained why such alternative measures had never been contemplated. Finally, her delegation urged Australia to reconsider its position and honour its WTO obligations.

163. The representative of El Salvador stated that while her delegation endorsed the measure's objective of protecting human health, it had doubts as to its compatibility with the TBT Agreement. For instance, how would the measure comply with Article 2.2 of the TBT Agreement, in particular the requirement that the measure not be more trade restrictive than necessary to attain its objective and that it should not constitute an unnecessary obstacle to trade. El Salvador would continue to monitor the development of this discussion both in this Committee and the TRIPS Council.

164. The Representative of Honduras noted that her country was also a party to the Framework Convention on Tobacco Control (FCTC). While Honduras understood the public health objectives of the measure, it still harboured concerns. Article 2.2 of the TBT Agreement required that technical regulations not constitute unnecessary obstacles to trade and be as least trade restrictive as possible to attain a certain stated objective. Given the lack of evidence that plain packaging would influence consumer behaviour, the measure would burden producers and exporters and restrict trade without attaining its stated legitimate objective of reducing tobacco consumption among youth. It would result in disproportionally high negative financial and competitive consequences to tobacco producers, including making their brands less valuable. Brands were important to differentiate various tobacco products and a brand's reputation was only gained after many years in the market.

165. The plain packaging provision of the FCTC was not mandatory and its implementation should be in conformity with the WTO disciplines. The FCTC itself required that when parties went beyond minimum obligations, like with plain packaging, they should do so in accordance with "international law", which clearly included the WTO Agreements and the Paris Convention. Finally, the Australian measure, in contravention with Article 12.3 of the TBT Agreement, would create unnecessary barriers to the exports from developing countries, like Honduras, which depended on tobacco cultivation.

166. The representative of Nigeria stated that her delegation recognized Australia's right to take appropriate measures to protect its citizens' health and welfare. However, Nigeria was concerned with the compatibility of the measure with WTO disciplines, in particular, the TBT Agreement. The measure would remove all distinguishing designs, logos, colours and other similar marks from the packaging of branded tobacco making it virtually impossible to identify any specific branded product. This would make it difficult for foreign manufacturers to enter the Australian market. She requested scientific and technical information demonstrating that plain packaging would reduce the number of smokers in Australia and how the measure would comply with Articles 2.2 and 2.4 of the TBT Agreement. She urged Australia to take into account Members' views and concerns and to produce an alternative measure that would ensure compliance with Australia's WTO obligations.

167. The representative of Colombia shared the concerns expressed. It reiterated its concerns expressed at the June 2011 meeting and was still waiting for Australia's official responses.

168. The representative of Hong Kong, China noted the number of substantive concerns on the consistency of the legislation with the TBT Agreement, despite a wide recognition of Australia's right

to adopt measures to protect public health. He also noted that a tobacco manufacture company with its Asian headquarters in Hong Kong, China was making a claim against the Australian Government under an agreement on the promotion and protection of investments concluded between these two economies. Discussions and mediations were being arranged on this claim. He trusted that Australia had taken its international obligations seriously and hoped that the parties to that dispute would find an amicable and satisfactory solution, so that the impact of the measure on trade would be minimized.

169. The representative of Chile stated that while his delegation shared Australia's goal of protecting public health, it also shared the view expressed that measures should not be more trade restrictive than necessary. He asked when Australia would reply to comments received.

170. The representative of Cuba supported the points raised. While acknowledging the transparent consultation process held by Australian public health authorities, in which Cuba participated, she regretted the lack of Australian responses to Cuba's questions raised in document G/TBT/W/338 of June 2011; made via the TBT enquiry point; and posed to the Australian Ministry of Health. Previously, Cuba had emphasized the additional barriers that plain packaging would create for cigars; Australian law established that the "ring" on top of each cigar should have the same plain packaging characteristics. In other words, the "ring" should be olive green without any distinctive sign of the brand. In order to comply with this requirement, an additional process would be performed by hand, which, in turn, would produce an adverse impact on cigar producers because the outside packaging was fragile and the "ring" was part of the cigar. Cuba asked Australia to show the scientific basis for this additional requirement and to explain its contribution to the measure's policy objectives.

171. She was also concerned that the measure would stimulate illegal trafficking of tobacco products; under the plain packaging measure false products would be more easily produced because identical packaging would make it more difficult to distinguish between illicit and legal products. Unlike in Cuba, there would not be any official stamps, denomination of origin stamps or other marks affixed on imported tobacco products. In addition to intellectual property rights, the measure would have an impact on Article 2.2 obligations of the TBT Agreement which required measures to not be more trade restrictive than necessary to achieve a legitimate public health aspiration. While the measure would reduce the attractiveness of tobacco products, it would also make the continued sale of many cigars impossible in the Australian market. This would not only produce adverse consequences to Australian consumers, but also to the small developing countries which produce and export cigars. Cuba asked Australia to take these concerns into consideration and to provide a satisfactory reply.

172. The representative of Nicaragua noted that his delegation had expressed concerns at the TBT Committee and the TRIPS Council, as well as to the Australian Government by an open letter. However, it never received a response from the latter. His delegation did not question Australia's right to regulate the sale of tobacco and efforts to protect health, it was concerned that the measure would infringe Australia's WTO commitments, particularly those under the TRIPS and TBT Agreements. As a tobacco producing and exporting country, Nicaragua considered that there had to be a balance between health objectives and the rights of other WTO Members. Nicaragua asked Australia to provide more scientific evidence on the measure and to reply to the note it sent to Australia's focal point and posted by Australia on its official website.

173. The representative of Canada said that Canada had been a pioneer in regulating packaging of tobacco products and would follow with interest these discussions. It understood the challenge of introducing never before implemented tobacco control measures as it had been in a similar situation a decade ago when it introduced pictorial health warnings on tobacco packages. Canada put in place this measure after extensive research suggesting its effectiveness in increasing public awareness of the products' health effects and hazards. Canada understood that Australia had also conducted serious research to support introduction of its new measure, and considered that information and discussions on the measure would help Members' understanding of this complex matter.

174. The representative of Norway said that public health and tobacco control, in particular, were dear to Norway and it did not see an inherent contradiction between regulating tobacco products and other international obligations. Each Member was within its right to regulate these products so as to take into account the legitimate concern of its people's health needs. Norway believed firmly that the FCTC and the WTO rights and obligations were mutually supportive, and that regulating packaging of tobacco was in line with both sets of binding obligations. Tobacco control policies and preventive measures, such as those proposed by Australia, had the legitimate objective of protecting public health by reducing smoking. Article 11 of the FCTC, and the accompanying guidelines, explicitly mentioned plain packaging as one of the options for achieving this objective. On the question of the scientific basis for this measure, the WHO had previously stated that a strong and irrefutable body of evidence had demonstrated that product packaging had traditionally served as one of the tobacco industry's central vehicles in initiating and maintaining addiction to their lethal products among consumers. Norway believed that regulation of product packaging was vital to reduce tobacco consumption and supported Australia's right to introduce measures necessary to fulfil its obligations under the FCTC to protect public health. Norway trusted that implementation of Australia's legislation would be done in compliance with all international treaty obligations. Norway would follow this matter with interest and was prepared to continue to defend the interests of public health.

175. The representative of Zimbabwe shared previous delegations' concerns that the measure was not consistent with WTO disciplines and did not accord effective protection to trademarks as provided under the TRIPS Agreement. The measure would burden consumers who would no longer be able to readily identify their favourite brand of tobacco products, risking their health as they experiment from one cigarette pack to the next in the absence of full information. This could have possible adverse consequences to the national health budget. The measure constituted an unnecessary obstacle to trade and was more trade restrictive than necessary to achieve Australia's health objective; thereby inconsistent with Article 2.2 of the TBT Agreement. Zimbabwe urged Australia to look for alternative ways to meet its health objective while respecting its WTO commitments.

176. The representative of New Zealand welcomed Australia's plain packaging legislation for tobacco products. The negative effects of smoking could not be overstated; in New Zealand smoking was the leading preventable cause of early death. Australia had given past assurances that it had paid close attention to and respected its WTO obligations in developing its plain packaging proposal. The TBT Agreement recognized that no country should be prevented from taking measures necessary to protect human health. Furthermore, numerous scientific studies had demonstrated that plain packaging could lead to positive public health outcomes by reducing the attractiveness and desirability of smoking and increasing prominence of public health warnings. In a comprehensive suite of tobacco control measures, plain packaging could contribute to efforts to reduce smoking rates.

177. The representative of Turkey said his delegation would comment on the measure later.

178. The representative of Brazil thanked the Australian delegation for clarifications provided previously. Brazil supported the legitimate objectives pursued by the legislation and fully recognized the right of Members, in accordance with the TBT and the TRIPS Agreements, to regulate the tobacco sector to protect public health. Brazil would follow the international developments and Members' regulatory experiences in this area.

179. The representative of Ukraine shared the concerns expressed on this measure. His delegation believed that the measure clearly violated the provisions of the TBT Agreement, and its position was detailed in the minutes of the last TBT meeting.

180. The representative of Guatemala expressed systemic interest in the discussions of this measure. While the measure sought to give legal affect to certain FCTC obligations, it was not clear how it could be reconciled with Australia's obligations under the TBT and TRIPS Agreements. The

WHO and WTO rules contained mandatory international obligations. For international legal coherence, the rules of one system could not be adhered to the detriment of those of the other. Implementation of international health obligations to fight smoking within the WHO must be compatible with WTO obligations, particularly those in the TBT Agreement which recognized Members' rights to ensure the quality of products, protection of the health and safety of humans and animals, preservation of the environment and prevention of deceptive practices at levels they considered appropriate. To fulfill these objectives, Members needed to ensure that in drafting, adopting or implementing technical regulations did not create unnecessary barriers to international trade. Article 2.2 of the TBT Agreement provided that technical regulations should not be more trade restrictive than necessary to full the objective, taking into account the risks of non-fulfillment.

181. In Guatemala's view, the FCTC Guidelines would not justify non-compliance with TBT or TRIPS obligations. Many of those Guidelines were not even mandatory. In particular, paragraph 46 of the Guidelines referring to plain packaging, stated that the parties should consider the *possibility* of adopting measures to restrict or prohibit the use of logos, colors, trademark images or promotional material other than the brand name or the name of the product in ordinary lettering and font, *i.e*. plain packaging. Any WTO Member considering adoption of such measures should consider their international obligations, including those under the WTO Agreements. Moreover, according to paragraph 46 of the Guidelines, plain packaging "enables greater noticeability and effectiveness of health warnings and messages preventing the package from distracting attention from these messages and prevents the use of industrial packaging designs that would suggest that some products are not as harmful as others". Guatemala interpreted this provision as behind the Guideline's legitimate objective. In seeking to fulfill this legitimate objective, WTO Members must take into account that they could not adopt measures more trade restrictive than necessary to fulfill that legitimate objective.

182. The representative of China expressed her delegation's continued interest in this topic which involved both the TBT and the TRIPS Agreement.

183. The representative of the European Union recalled its previous comments and continued interest in this matter, particularly in light of the on-going revision of its own tobacco legislation.

184. The representative of Indonesia recalled a communication send on 8 June 2011 on the impact of Australia's draft regulation (G/TBT/W/336) in which it raised five questions related to the bill's justification. Responses were still outstanding.

185. The representative of Australia informed Members that the Tobacco Plain Packaging Act 2011 and the Trade Marks Amendment (Tobacco Plain Packaging) Act 2011 had been passed by the Australian Parliament and they received Royal Assent on 1 December 2011. The former, which had been passed on 21 November 2011, included amendments to: (i) extend implementation timeframes and provided an additional two weeks for retailers to sell through ("flush-through") any product in non-compliant packaging before the retail offences commence; and (ii) address a technical implementation issue identified by tobacco companies to permit rounded corners to be used on the inside lip of cigarette packs. The associated Trade Marks Amendment (Tobacco Plain Packaging) Bill 2011 passed the Parliament on 10 November 2011. All tobacco products manufactured or packaged in Australia would be required to be in plain packaging by 1 October 2012 (previously 20 May 2012). Moreover, all tobacco products would be required to be sold in plain packaging by 1 December 2012 (previously 1 July 2012). The final regulations related to cigarette products, were revised in response to comments from industry, and approved on 7 December 2011.

186. The representative informed the Committee that the final Tobacco Plain Packaging Amendment Regulation 2012, which incorporated the specifications for non-cigarette tobacco

products, was published on 2 March 2012.[21] The Amendment Regulation was approved in the same form by the Executive Council on 8 March 2012. She said the Australian Government had undertaken two consultation processes in relation to the Amendment Regulation and that submissions made as part of those processes had been taken into account. She also emphasized the open and transparent manner her Government had adopted with its trading partners throughout the process of introducing the measure. Australia had met or offered to meet with all WTO Members that had raised this issue in the TBT Committee and TRIPS Council to explain the purpose and details of the proposed measures and to provide detailed answers to the questions raised. Australia had conveyed information to Members' Ministries of Trade and Health; including substantial information on the evidence underpinning the measures; and had provided substantial written information both electronically and in paper form on the concerns raised. Australia had made detailed statements in various WTO committees. The representative therefore considered that claims that her Government had not responded to questions and requests for further information to be unreasonable and that Australia had indeed met its obligations under Article 10 of the TBT Agreement. Furthermore, Australia had been responsive to comments from trading partners and other stakeholders, including by taking their comments into account, which in turn led to changes to the law where those changes were in line with the Government's policy objectives.

187. The effect of the above-mentioned legislation was that tobacco company branding, logos, symbols and other images that may have the effect of advertising or promoting the use of the tobacco product would not be able to appear on tobacco products or their packaging. On the other hand, the brand name and variant name would be allowed on packaging. Information which would be required by other legislation or regulations, such as trade descriptions and graphic health warnings, would also be allowed to appear. Australia was implementing this legislation in the interest of promoting public health. Tobacco products caused extraordinary harm and required appropriate measures. According to the WHO, tobacco was "the only legal consumer product that kills up to half of those who use it as intended and recommended by the manufacturer". 15,000 Australians died each year as a result of smoking, with some 3 million Australians continuing to smoke, costing Australia's society and economy over A$31.5 billion per annum. Smoking rates were particularly high among disadvantaged groups such as teenage mothers, aboriginal and Torres Strait Islanders, people with mental illness and the unemployed. Tobacco packaging was one of the last remaining forms of tobacco advertising in Australia and this legislation was the next logical step in Australia's tobacco control efforts. It was confident that, as part of a comprehensive package of tobacco reforms, it would make an effective contribution to reducing smoking, and thereby reducing the health impacts of smoking on Australian individuals and the community at large. Plain packaging of tobacco products was designed to: (i) reduce the attractiveness and appeal of tobacco products to consumers, particularly young people; (ii) increase the noticeability and effectiveness of mandated health warnings; (iii) reduce the ability of the tobacco product and its packaging to mislead consumers about the harms of smoking; and (iii) through the achievement of these aims in the long term, as part of a comprehensive suite of tobacco control measures, contribute to efforts to reduce smoking rates.

188. The measure was part of a balanced package of measures designed to contribute to the Government's target of reducing the adult daily smoking rate in Australia to 10 per cent by 2018. Other measures introduced by the Government included: (i) the 25 per cent tobacco excise increase in April 2010; (ii) over A$ 85 million investment in anti-smoking social marketing campaigns; (iii) legislation to restrict internet advertising of tobacco products in Australia; (iv) the extended listing of nicotine replacement therapies and other smoking cessation supports on the Pharmaceutical Benefit Scheme (PBS); and (v) record investments (about A$100 million) in support for indigenous communities to reduce smoking rates. This came on top of a comprehensive suite of tobacco control measures already in place in Australia, including: (i) minimum age restrictions on purchase of tobacco products; (ii) comprehensive advertising bans under the Tobacco Advertising Prohibition Act 1992;

[21] http://www.yourhealth.gov.au

(iii) retail display bans; (iv) bans on smoking in offices, bars, restaurants and other indoor public spaces, and increasingly outdoor places where children may be exposed to environmental tobacco smoke; (v) extensive and continuing public education campaigns on the dangers of smoking; (vi) PBS subsidies for smoking cessation supports; and (vii) quitlines and other smoking cessation support services in each State and Territory to help people quit. The plain packaging legislation related only to tobacco products and retail packaging of those products; the Australian Government was not considering extending the measure to other products. Australia was, and continued to be, fully committed to its international obligations. In framing its policy on plain packaging, Australia had paid full regard to its obligations under the TBT Agreement and would ensure that the new policy would be implemented in a manner consistent with that agreement.

189. The representative of the World Health Organization recalled that its previous interventions providing information on the FCTC, in particularly Articles 11 and 13 of the Convention, as well as the relevant Guidelines. She referred Members to minutes of those meetings. She highlighted the substantial number of States that were both Party to the FCTC and Members of the WTO; of the 174 Parties to the FCTC, 137 of them were also WTO Members. These States were thus subject to obligations under both legal regimes. On 15 and 16 March 2012, the Secretariat of the FCTC hosted a workshop at WHO Headquarters to promote the sharing of knowledge and information among country trade and health representatives on trade-related aspects of tobacco-control measures taken pursuant to the WHO FCTC and its guidelines for implementation. The workshop was held further to a decision of the fourth session of the Conference of the Parties (the supreme governing body of the FCTC) relating to "Cooperation between the Convention Secretariat and the World Trade Organization" (FCTC/COP4(18)) which, inter alia, requested the Convention Secretariat to cooperate with the WTO Secretariat with the aim of information sharing on trade-related tobacco control measures. Representatives from the trade and health sectors of over 65 countries participated in the workshop, including several who travelled from capitals to participate. The FCTC Secretariat intended to continue its efforts to cooperate and to share information. She informed that the negotiation of the draft Protocol to Eliminate Illicit Trade in Tobacco Products was expected to conclude from 29 March to 4 April 2012, and the draft protocol was expected to contain provisions on the tracking and tracing of tobacco products.

(xxix) Viet Nam – Conformity assessment procedures for alcohol, cosmetics, and mobile phones (Notice regarding the import of alcohol, cosmetics and mobile phones, No.: 197/TB-BCT (6 May 2011) and Ministry of Finance No.: 4629/BTC-TCHQ on the importation of spirits and cosmetics (7 April 2011)

190. The representative of the United States noted that Ministry of Finance Document 4629 on the import of spirits and cosmetics and Ministry of Industry and Trade Notice 197 on the import of alcohol, cosmetics and mobile phones involved new conformity assessments procedures. They appeared to have gone into effect in June 2011, to be legally binding and to create new requirements on specific quality control procedures such as submission of a quality control certificate and the designation of specific ports and charge of control. While the US appreciated Viet Nam's written responses to its concerns and willingness to engage in this issue, Viet Nam's view that the measures were not legally binding was creating confusion for US exporters. For example, Viet Nam stated that the measures were not legally binding and did not create any new requirements. How Vietnam did not explain why it chose these particular products to be subject to such procedures and not others, and what its criteria were. Further, Vietnam said that it would provide detailed HS codes that were "subject to" Notice 197, while continuing to argue that the measure is not a normative legal document and does not create new trade measures. Viet Nam also clarified that some component products had been excluded from the scope of the measure, but the responses did not provide any details of quality control entailed for each of these products, nor what the quality conformity certificate mentioned in document 4629 was and who was responsible for issuing it. The US would continue to seek clarification from Viet Nam on these issues and on why consularization was necessary.

191. The representative of Australia shared the US concerns, in particular on the conformity assessment procedures set out in document 4629, including its compatibility with the TBT Agreement. Australia was also concerned that notice 197 was administratively burdensome and having unintended negative trade consequences, particularly on small to medium enterprises exporting small quantities.

192. The representative of the European Union shared the US concerns and asked Vietnam to provide further clarification on the status of these measures. Since Notice 197 was presented as a temporary measure soon to be repealed, the EU wondered whether it was still in place. As for Notice 4629, Viet Nam stated in the last TBT meeting that this was not a legally enforceable document. Thus, the EU asked Viet Nam to clarify what this meant. For instance, were quality checks meant to be applied to all consignments of alcoholic beverages, cosmetics and mobile phones? Should a Quality Control Certificate accompany these consignments and, if so, what entity was in charge of issuing it and what was the timeline for it? Was a template used for issuing the certificate and what quality standards were supposed to be certified by this document? What other information should this Certificate cover? Finally, why was quality control limited to only three sea ports? The EU recalled that previously, Viet Nam indicated that these measures were meant to prevent counterfeiting and smuggling. Had these measures met their stated purpose? Was a drop in counterfeiting or smuggling recorded?. The EU urged Viet Nam to notify these measures to the WTO.

193. The representative of New Zealand thanked Viet Nam for its responses. It continued to monitor these measures from a TBT perspective. New Zealand requested an update as to whether Viet Nam had established, or intended to establish, a new "certificate of quality achievement" process for alcoholic beverages and cosmetics as proposed in MOF Official Letter 4629/BTC-TCHQ of 7 April to MOIT. She asked if Viet Nam intend to notify this process.

194. The representative of Viet Nam recalled its previously provided answers to the concerned delegations. Regarding document 4629, Viet Nam confirmed that this document did not create any new conformity assessment procedures because it was not a legal document and had no legally binding force. Moreover, the Ministry of Finance was not the authority responsible for goods quality control. Regarding Notice 197, although its purpose was anti-counterfeiting and anti-smuggling and the protection of consumer health and safety, the measure was not a conformity assessment procedure specified by particular standards and technical regulations. In recent years, its market had been seriously suffering from smuggling and counterfeiting, especially in cosmetics, alcohol and mobile phones. In 2010, about 12,000 cases of counterfeit products were found, and in the first half of 2011 about 15,000 cases were found; cosmetics, alcohol and mobile phones were the largest categories of counterfeit illegal imports in Viet Nam. As justification for standard and consumer protection, 52 per cent of consumers did not know that the products they had purchased were counterfeited, in particular when the products were foreign brand cosmetics, alcohol and mobile phones. The requirements in Notice 197 supported agencies in their more effective control of smuggling and counterfeiting in alcohol, cosmetics and mobile phone, thus benefiting both consumers and foreign exports. Viet Nam noted Members' comments and welcomed bilateral discussions with interested Members.

(xxx) Malaysia – Draft Protocol for Halal Meat and Poultry Production (G/TBT/N/MYS/23)

195. The representative of the United States appreciated visits from Malaysian officials to the US to discuss the halal requirements with US industry and Government. The US still had concerns, including the requirements that production facilities be dedicated exclusively to halal production. This raised issues of consistency with the Codex halal guidelines and had implications for US industry. She asked for continued bilateral discussions to find a mutually acceptable resolution.

196. The representative of the European Union supported the US concerns, stressing that transparency of import conditions was a key prerequisite for ensuring that trade flows were not

unnecessarily impeded. There had been progress, in particular with the TBT notification in December 2011 of Malaysia's new Trade Description Orders (as notification G/TBT/MYS/27). However, Malaysia' halal related measures were still not aligned to international standards such as Codex, in particular in the way audits were carried out. Their application lacked clarity, transparency and predictability and, as a result, EU exporters faced difficulties meeting these conditions. The EU urged Malaysia to make more efforts to alleviate the impact of its requirements on foreign establishments.

197. The representative of Brazil thanked Malaysia for its written answers but his delegation still had concerns about this measure, especially the requirement that halal production should take place in a facility dedicated exclusively to that kind of production. This contradicted the relevant Codex standard on this issue. Brazil expressed its continued interest in discussing this issue bilaterally.

198. The representative of Turkey said that the use of different standards and conformity assessment procedures in the halal food industry lead to technical barriers to trade, including among Muslim countries. A number of Muslim countries took initiatives under the Organization of Islamic Cooperation (OIC) to develop standards for halal food so as to remove technical barriers to trade through common rules and procedures. To this end, an affiliate body, namely "Standards and Metrology Institute of Islamic Countries" (SMIIC) was established by OIC. SMIIC not only prepared guidelines for halal food standardization, but also published two additional guidelines for certification and accreditation in the area of halal food. Malaysia's Draft Protocol for Halal Meat and Poultry Production envisaged employing additional requirements on halal-related imports without considering common rules and traditions. Conformity assessment bodies would be further limited by the Malaysian Government. Turkey emphasized the importance of the initiative taken by 14 Members of SMIIC. In order to prevent technical barriers on halal products and to promote international trade, common standards should be established with the support of especially Muslim countries. Additionally, mutual recognition of conformity assessment and of accreditation bodies should be maintained. Therefore, Turkey expected Malaysia to reconsider the Draft Protocol in conformity with its WTO commitments and invited Malaysia to become a member of SMIIC and participate in the development of common standards, conformity assessment and accreditation among countries.

199. The representative of Malaysia took note of the comments and indicated its willingness to continue bilateral discussions with interested Members in order to resolve this issue.

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

200. The representative of the United States indicated that the US government and industry appreciated the objectives of Korea's "Act on Registration, Evaluation, Authorization and Restriction of Chemical Substances" (Public Notice 2011-74) to safeguard public health and the environment and hoped that consultations would continue on developing regulation able to achieve these goals with minimum adverse effects on US and Korean trade interests. It was the US view that the proposed Act had broad implication not only for US industry, but also for producers and importers of chemicals in Korea, by creating significant changes to Korean's current chemical regulatory regime. She noted that the US industry had expressed various concerns with the proposed regulation and that multiple entities including, among other, the American Chemistry Council (ACC), Society of Chemical Manufacturers and Affiliates (SOCMA), the US Council on International Business had submitted comments directly to the Ministry of Energy in Korea. She appreciated the responses provided by Korea to most of these groups, which were still evaluating the replies. She asked Korea to update the Committee on key issues raised at previous meetings regarding the proposed annual reporting requirements and the 0.5 minimum ton thresholds for preregistration and registration. In particular, she wanted confirmation whether it was planned to increase the 0.5 ton threshold to 1 ton.

201. The representative of Korea explained that the announcement for public opinion on the legislation was made in April 2011 and the promulgation of the Act was expected to take place in 2012. The Ministry of Environment of Korea was at the moment taking into account all the comments from Member countries. He further mentioned that no date had been determined for the new legislation to be finalized. In general, Acts and subordinate regulations were enforced two years after the day of their promulgation. Enforcement had been postponed to provide a certain preparation time to the industry. In the case of registration, maximum 8 years of grace period were granted depending on the substance.

202. With regard to the minimum tonnage threshold of 0.5 ton and the annual reporting requirement, he explained that the Ministry of Environment was considering whether to amend these provisions following consultations with the concerned industries. With respect to which chemical substances would be subject to these regulations, studies were under way to determine this and details would be set forth in the enforcement decree. The legislation was in accordance with the provisions of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS), which Korea had adopted for substances on 1 July 2010 and would also apply to mixtures beginning 1 July 2013. He further explained that the Korean ministry would assess the compatibility of the OECD software with the Korean system for data submission. The enforcement decree specified the list of exempted substances, such as certain chemicals used solely for research and development. He also confirmed that reliability was essential for submitting physiochemical data, but the data did not have to be produced under GLP. The remaining points raised in the Committee were conveyed to the competent authority.

(xxxii) Mexico – Energy Labelling Measures (Law for Sustainable Use of Energy, 28 Nov 2008; Regulation of the Law for Sustainable Use of Energy, 11 September 2009; National Program for Sustainable Use of Energy 2009-2012, 27 Nov 2009; and Catalogue of equipment and appliances used by manufacturers, importers, distributors and marketers that require mandatory inclusion of energy consumption information, 10 September 2010) (G/TBT/N/MEX/214)

203. The representative of the United States supported Mexico's effort to raise consumer awareness in the area of energy consumption through a testing and labelling system and noted that similar programs were maintained in the US. She thanked Mexico for notifying the Catalogue in June in response to requests from trading partners and noted the comments that had been provided, including from the US. Her delegation welcomed the idea proposed by Secretary of Energy for Mexico, Jordy Herrera, during a recent meeting with the US Ambassador, Anthony Wayne, for the US-Mexico Working group to start a review process of the products catalogue and consider narrowing products categories. Nevertheless, she was concerned that the current regulation was overly burdensome and not transparent. She noted US industry willingness to comply with the Mexican law and regulations and hoped that the working group could identify product categories that could be removed from the catalogue based on the *de minimis* energy consumption criterion and could also work towards US-Mexico greater alignment in the area of energy consumption and labelling and energy efficiency, including leveraging the existing US Energy Guide, US or international standards for testing and convergence.

204. The representative of Japan appreciated the purpose of the measures in question but remained concerned that some of the provisions of the Mexican measures introduced considerable difficulties with respect to, among other things, compliance for product manufacturers. In particular, the measure regulated products contributing little to their objectives, and the specific procedures and methods of measurement were not clear. It was Japan's view that an inappropriate measuring method could allow low energy efficiency products to claim “high energy efficiency” resulting in confusion for consumers as well as manufacturers. He concluded by requesting the Mexican government to clarify the

measurement method and notify it to the WTO when stipulated in order to provide opportunities for comments by Members.

205. The representative of Mexico pointed out that the new catalogue of equipment and appliances had been notified as document G/TBT/N/MEX/214, on 15 June 2011 and a 60 days comment period had been provided in compliance with the commitments established under Article 2 of the TBT Agreement. The US, Japan, the EU and interested companies that had submitted comments had received a reply from the National Committee for efficient energy use. The comments made by Korea after the expiration of the public consultation period had also been responded to. The delegate of Mexico stressed that on 11 November 2011, the period for submission for formats and requirements for delivery of information from manufacturers and importers of equipment and appliances consuming energy had expired. Since then, the Federal Office for Consumer Protection (PROFECO) and Energy Saving Committee had begun the analysis and review of the information referring to test methods used to measure energy.

(xxxiii) Kenya – Alcohol Labelling: The Alcoholic Drinks Control (Licensing) Regulations, 2010: Legal Notice No. 206: 2010

206. The representative of Mexico asked Kenya to provide information with respect to the implementation of the regulation published on 17 December 2010. She further requested a formal reply from the Government of Kenya to the comments submitted on 12 May 2011.

207. The representative of the United States made several enquiries during her intervention. First, it was unclear why Kenya had notified the regulation under Article 2.10.1 of the TBT Agreement (as an urgent measure). She noted that both dates of notification and adoption were the same, 1 March 2011, and asked Kenya to provide a time period for interested parties to submit comments and take them into account in revising the measure. It was also the US understanding that implementation of some sections of this measure had been postponed due to a pending lawsuit in Kenya. She requested Kenya to notify, pending the outcome of the case, any changes to the labelling section of this regulation to the WTO. The US delegation, like Mexico, was still waiting to receive a reply to the comments submitted on 7 April 2011; she urged Kenya to allow for time to consider changes. Finally, although her delegation appreciated the objectives of Kenya's alcohol labelling, she was interested on the rationale behind the inclusion of pictures in the alcohol warning statements – and how this would ensure that the warning labels would not unnecessarily impact on trade.

208. The representative of the European Union supported the concerns expressed by Mexico and the US. Her delegation was still waiting for a written answer from Kenya to the detailed written comments sent in April 2011. She also asked if Kenya had considered less burdensome alternatives other than mandatory health warnings labelling to modify drinking behavior. She also requested confirmation if the requirement for health warnings to comprise at least 30 per cent of the total area of the package had been amended, as stated during the previous TBT Committee meeting.

209. While the delegate of Kenya took note of all the comments made, he explained that in regards to the on-going lawsuit he was not able to provide a comprehensive response. Appropriate information would be reported to the Committee when available. He confirmed that comprehensive responses to the written comments would be provided at the next Committee meeting.

(xxxiv) Korea – Proposed Cosmetics Labelling and Advertisement Guidelines: KFDA draft Guidelines for Management of Nanomaterials in Cosmetics (G/TBT/N/KOR/308)

210. The representative of the European Union reiterated her delegation's call for the Korean Food and Drug Administration (KFDA) to apply the above-mentioned Guidelines in a transparent and participatory manner, and to regularly discuss their implementation with concerned industries. Her

delegation remained concerned that the Guidelines could pose problems with respect to the control of claims in languages other than Korean, including names of globally marketed products (for instance brand names) if they were to fall within the scope of the Guidelines.

211. The representative of the United States explained that she had previously raised concerns in conjunction with Korea's labelling measures for cosmetics and advertising guidelines as well as KFDA draft guidelines for management of Nano materials in cosmetics. She thanked Korea for their engagement, accepting the comments submitted by the US industry and for amending the guidelines to provide a one-year grace period for new products entering the market to enable adjustments to the new labelling guidelines. However, it was unclear whether the transition time was also allowed for products already available on the market, including those already in the manufacturing and shipment process. She informed the Committee that the US Embassy in Seoul had raised this issue with both MOFAT and KFDA in early February 2012 and had requested, once again, the date of manufacture for the importer and not the one of import to be the enforcement date, because factors, such as shipping times and in transit goods, could impact the ability of importer to comply. She further requested an update as to how the Ministry was addressing concerns raised about the Hangul language requirement on both the primary and secondary packaging.

212. The representative of Korea explained that specific standards for Cosmetic Advertising/Labelling scheme came into effect on 5 February 2012 following the Amendment in Cosmetic Act. Details for methods and procedures would be notified in June 2012 after receipt of all public comments and completing the harmonization process with international standards. He further confirmed that KFDA could not approve exempting foreign languages from the labelling items requiring regulations. The amended cosmetic act was intended to regulate the concerns with a product name written in a foreign language on imported cosmetics that could deceive or mislead consumers to consider this product as pharmaceutical product. The guideline specified the methods allowing importers to modify, correct, delete and over-label the advertisements or labels written in foreign languages in order to comply with the guidelines. Finally, he explained that the guideline for cosmetics containing nanomaterial was currently going through internal review and would be uploaded on the KFDA website once finalized.

(xxxv) Colombia – Draft of the modification of the Resolution 910 / 2008 and Resolution 2604/2009, concerning the emission of contaminant sources for heavy vehicles with a diesel motor.

213. While the representative of Mexico shared Colombia's objective to improve the quality of fuels and contribute to a reduction in air pollution, she expressed some concerns with respect to the draft amendment to the resolutions 910 of 2008 and 2604 of 2009 regarding the establishment of stricter emission limits for heavy vehicles using a diesel motor. It was Mexico's view that the measures could be incompatible with the TBT Agreement by allowing vehicles with a specific diesel engine technology to circulate but prohibiting those with a different technology. In addition, the measure could be a potential unnecessary restriction to trade regarding its potential negative effects on Mexico's manufacturing sector and exports to Colombia. She further noted that the measure had not been notified and her delegation was still waiting for a reply to a request sent on 5 December 2011 followed by a reminder sent on 31 January 2012.

214. The representative of the United States thanked Colombia for the regulator-to-regulator dialogue held recently on this matter and noted that the US is; waiting for a reply to its technical questions following that dialogue, which were sent on 9 February 2012. She estated that the trade impediment issue noted at the last TBT Committee meeting if Colombia would make available 15 ppm sulphur fuel not be an issue, which would allow EPA 2007 and EURO V standards to be used, and enable Colombia to achieve greater environmental and health benefits. , and. She noted that may countries, including in Latin America, had made this transition or were in the process of doing so.

215. The representative of Colombia explained that this measure had not been notified to the Committee, because the draft resolution had yet to be finalized. Preliminary tests were currently drawn up with the participation of all interested parties, including importing firms from Mexico and the US. He confirmed that the final version of the draft would be notified as soon as it was available.

(xxxvi) South Africa – Liquor Products Act of 1989

216. The representative of the United States recalled the difficulties faced by US industry to import liquor since 2009 because of the South African identity standard for liquors requiring a minimum alcohol content of 24 per cent and preventing the US industry to import products with a 17 per cent alcohol content. She noted that this product had been classified as liquor in a number of countries including the United Stated, and a number of countries defined liquor based on raw materials and production processes rather that the chemical composition such as alcohol content. She invited South Africa to provide a status update on the labelling and ingredient documentation application submitted by the US industry as suggested by South Africa in two Committee meetings and to also explain the reason for the delay in responding. She concluded by highlighting the importance of considering revising its standard of identity to provide a category for products such as "Hpnotiq" - product of interest to the US - in order to enable more trade facilitative approach or considering granting a waiver or exemption.

217. The representative of South Africa recalled that two categories under the Liquor Products Act No. 60 of 1989, namely liqueur and spirit cocktail, were relevant to "Hpnotiq", the product the US wished to export. It was South Africa's view that the technical regulations for both products under this Act were based on product requirements, including raw materials, production process and alcohol limits, and therefore fully compliant with the TBT Agreement. The South African delegate noted that alcohol content limits were also referred to in the USA Federal Alcohol Administration Act to define products such as Brandy with more than 40 per cent of alcohol content by volume.

218. According to South African Liquor Products Act, liqueur, whose minimum alcohol limit by volume could not be less than 24 per cent, had to be produced by macerating fresh or dried fruit, or peels thereof, or aromatic plants, or leaves, herbs, roots or seeds in a spirit; by adding flavourants of vegetable origin or extracts thereof, or herbs or natural extracts of herbs, to a spirit; or by redistilling the product obtained in terms of maceration or flavor addition, and thereafter adding thereto a syrup containing honey or sugar derived from cane or grain, and, if applicable, colourant. In contrast, spirit cocktail, whose minimum alcohol limit could not be less than 24 per cent alcohol by volume, had to be produced by the addition of herbs, natural extracts of herbs, other flavourants of vegetable origin or nature-identical, egg or milk flavourants, and sugar derived from cane or grain to a spirit in order to create a distinctive taste and aroma different from that of wine or a class of wine. He further explained that both technical regulations did not differentiate between locally produced or imported liqueurs or spirit cocktails given that both importer and local producers had to comply with the same requirements on production processes, raw material and minimum alcohol. Finally, he reiterated that the products "Hpnotiq" could not be compared with Amarula, because both products specifications, raw materials and production processes were totally different.

(xxxvii) Peru – Draft Supreme Decree approving the regulations governing the labelling of genetically modified foods.

219. The representative of Mexico expressed concerns about Peru's intention to potentially label differently foods containing genetically modified ingredients. Following the notification of the draft measure under G/TBT/N/PER/37 on 27 June 2011, these concerns, submitted as comments on 14 September 2011, were still pending on an official reply by the government of Peru. As had been mentioned in previous Meetings, it was Mexico's view that this proposal could be more trade restrictive than necessary to achieve the legitimate objective. In this respect, she recalled that,

pursuant to Article 2.5 of the TBT Agreement, her delegation had requested Peru to provide a technical scientific justification of the draft technical regulation. She further invited Peru to share the latest update on the status of implementation of the draft decree approving the regulation on labelling genetically modified foods and requested an official reply to the comments submitted.

220. Similarly, the representative of Chile requested an update on the status of the draft technical regulation and a reply to the comments submitted last November. He reiterated the importance of considering extending the timeframe beyond the proposed 180 days to provide sufficient time to enable the Chilean industry to adapt to the new requirements.

221. The representative of Colombia supported the concerns expressed by Mexico with respect to the requirements of different labelling for food deriving from genetically modified organisms and requested an update of the status of the draft measure as well as a reply to the concerns expressed in the Committee.

222. The representative of Peru explained that this draft was still under review as the Peruvian authorities were still reviewing and compiling all the comments received. In particular, no date of publication of the final technical regulation had been specified by the multi-sectoral working group in charge of drafting this regulation. Therefore, further information on any particular changes to the draft would be provided in due time and in compliance with international obligation. According to the Peruvian delegation, the draft regulation did not put into question the safety of genetically modified organisms or genetically modified foods. He explained that the rationale of the technical regulation was to provide consumer with clear and sufficient information on various products and services to avoid any type of potentially misleading practices, as promoted by the Mexican Federal Law on Consumer Protection and the Peruvian Code for Consumer Protection.

(xxxviii) Mexico – Draft Decree Amending Provisions for Drinks with Caffeine

223. The representative of the European Union expressed some concerns about the draft decree amending the General Mexican Health Law and foreseeing a restriction to sell drinks with caffeine to persons of less than 18 years old. She explained that, according to the latest scientific information, moderate consumption of caffeine was unlikely to present any health risk for most consumers, although moderation of caffeine intake was advisable for certain consumers such as pregnant women and children of less than 12 years. It was the EU view that health warnings included in labels of drinks with caffeine constituted a sufficient means to achieve the legitimate objective of protecting human health. The EU delegate requested Mexico to provide the scientific information justifying the sale prohibition of drinks with caffeine to individuals of less than 18 years old and to update the Committee on the state of play of this draft decree and its TBT notification timeline.

224. The representative of Mexico explained that the Mexican Secretary of Economy had received, on 27 September 2011, a communication from the Ambassador of Austria about the concerns that the draft decree relating to warning labels and the establishment of caffeine levels would be approved without discussion and review of available scientific information. She informed delegations that the related official Mexican standard (NOM-218-SSA1-2011) on non-alcohol aromatized drinks, including concentrated products used to prepare them, had been published in the Official Journal on 10 February 2012 and specified sanitary requirements as well as testing methods including technical requirements, warning legends and labelling of drinks with added caffeine. It was Mexico's view that the elaboration of this standard complied with Article 2 of the TBT, including the notification of the draft under G/TBT/N/MEX/207 on 19 January 2011.

225. She confirmed that on 31 January 2012 the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) provided the Austrian Embassy in Mexico, the interested firm and the EU focal point with the scientific evidence used to justify the requirements included in the official

Mexican standard and the draft decree. With respect to the draft decree amending the General Mexican Health Law, she confirmed that the Committees of Health and Legislative Studies of the Chamber of Senators had presented the "Opinion of the Joint Committee on Health and Legislative Studies on the Draft Minutes of the draft decree amending and adding various provisions of the General Health Law, in terms of drinks with added caffeine."

(xxxix) Korea – National Tax Service Notice 2011-17 (Requirements for Radio-Frequency Identification Tags for Imported Whiskeys) (G/TBT/N/KOR/338)

226. The representative of the United States considered that there were less costly or less burdensome methods to achieve Korea's objectives of ensuring brand authenticity, preventing counterfeiting and providing information to the authorities on tax payments. She asked if Korea was considering working with a prototype system before the implementation date. Was Korea concerned that this measure could send a precedent and was it considering applying RFID tracking to other products in the future? Since counterfeit whisky did not pose a significant risk to safety and human health, she requested clarification on the rationale of applying these new requirements, as opposed to other requirements, to whisky. Finally, she requested more information on the testing fees.

227. The representative of the European Union recalled that her delegation had submitted comments to Korea on this notification on 29 February 2012 and was waiting for Korea's reply. While the EU supported appropriate counterfeiting measures, it wondered whether RFID tagging was the most appropriate and cost-effective method. Products were invariably marked with the producer's lot code; in the event of any query, the lot or batch from which the whisky came could be traced back to the producer. Therefore, prohibiting the import of products without the producer's lot code would be an important step towards counterfeiting prevention. Korean authorities could also require all shipments of whisky to be accompanied by the Certificate of Age or Origin issued by the authorities in the country of origin as proof of their authenticity.

228. This measure could bring financial and logistical burdens to small European whisky producers that exported to Korea, or that sought to enter the Korean market. In addition to set-up and unit costs, there were other practical difficulties. The EU suggested that Korea consider making RFID tagging voluntary for imported bottled-at-origin whiskies, or that companies exporting below a certain threshold, for instance under 5 per cent of the Korean whisky market, be exempted. Furthermore, the tags should be allowed to be affixed either at the exporter's choice. For bottles sold in cartons, the tag should be allowed to be placed on the carton. Finally, the EU asked why whiskey, a product which was almost entirely imported in Korea, was subject to treatment different from other spirit drinks.

229. The representative of Korea recalled that his Government had notified the regulation on 28 November 2011. Its purpose was to enable Korean consumers to use mobile phone technology to verify the brand authenticity of each bottle of whiskey being purchased, as well as to prohibit tax evasion related to whisky transactions. It came into effect on 1 October 2011, and presently applied only to domestic whiskey in six areas of Korea, including Seoul, Gyeonggi Province and Jeju Island. As of 1 October 2012, it would apply to all imported and domestic whiskey across the country. The reason for introducing RFID tags instead of barcodes was that RFID provided unique information for a specific bottle of whisky rather than a group of similar products. Regarding cost increase concerns, Korea said that it would provide tax reduction as compensation. The Korean authority had also provided scanning equipment to manufacturers, importers and distributors, and considered providing it to foreign manufacturers as well. As for technical issues such as the possibility of malfunction or the difficulty of tagging very small bottles, the Korean authority would allow the exemption of tags with prior-approval from competent authorities.

(xl) Argentina – Resolution 453/2010 establishing mechanisms in order to eliminate dangers arising from the use of inks with a high lead content in graphic products

230. The representative of the United States had previously expressed concern that this regulation appeared to apply to foreign producers only, and that Argentina's testing capacity was insufficient to perform all the required testing. This, coupled with the inability to test these products in the country of production, would lead to significant delays, cost and burdens for industry. She asked whether Argentina would accept certification by internationally accredited laboratories outside of Argentina and requested that Argentina consider postponing implementation or not enforcing temporarily the requirements in the regulation. Her delegation would submit comments on the regulation and sought discussion on the regulation. Her delegation requested postponing implementation so that Argentina could take discussions into account when reformulating the measure.

231. The representative of the European Union supported the US concerns, noting that "Disposición N° 26/2012", issued on 5 March 2012, implemented Resolution 453 and had not been notified to WTO members. The EU understood that only 2 Argentinean laboratories had been approved for carrying out the tests for the required certification for printed graphic products. The EU requested information on how Argentina would ensure the necessary capacity to handle the high number of potential requests. She asked if test reports, carried out in European internationally accredited laboratories, would be accepted by the Argentinean certification body for the purposes of issuing compliance certificates. If not, she asked for justification as to why tests needed to be carried out locally.

232. The representative of Argentina informed the Committee that Argentina had notified a 7th addendum to this notification on 14 March 2012. Resolution N° 453/2010 gave the National Direction for Internal Commerce the power to dictate the pertinent measures for interpreting, clarifying and implementing the Resolution. Therefore, the National Direction has initiated the issuance of regulations for an effective and efficient implementation and application of the regime established in the Resolution. The 7th addendum established a transition period in which the Argentinian Government would accept a sworn declaration made by the producer or importer that ensured that the product, or group of similar products, complied with the applicable norm, ASTM (ASTM D 3335-85a). The National Direction for Internal Commerce continued to work on the pending issues that required implementation, interpretation or clarification in the Resolution.

(xli) China – Specification for Import and Export of Food Additives Inspection, Quarantine and Supervision (2011 No. 52) - Disclosure of formulas for imported food additives

233. The representative of the United States had had constructive bilateral discussions with China and she provided an update. The three Chinese measures related to labelling are: the 2009 Food Safety Law, the 2010 Chinese Standard for the Labeling and Prepackaged Foods, and the 2011(AQSIQ) Specification No 52 that addressed specifically Food Additives and required the disclosure of formulas which was inconsistent with CODEX guidance in this area and is a serious concern for the US. The Food Safety Law included a provision for prepackaged foods to list the ingredients in a table. In bilateral discussions, China noted an agreement with the US that the Food Safety Law did not require a formula disclosure. This interpretation was consistent with the Chinese Food Safety Law and the 2010 Standard for the Labeling of Prepackaged Foods, the latter being consistent with Codex Standard for the Labeling of Prepackaged Foods, i.e. how to provide information on ingredients on labels.

234. Her delegation was concerned that (AQSIQ) specification No 52 for Food Additives appeared to go beyond the requirement for ingredient listing contained in China's 2010 Standard for the Labeling of Prepackaged Foods . US authorities had received repeated reports that US industry had been asked to declare the amount of food additives in a manner that was equivalent to formula

disclosure. Chinese authorities had requested percentages in the content and dosages of additives in contrast to a simple listing of ingredients. This went beyond the ingredients table approach contained in the Codex Standards as well the approach contained in the Chinese 2010 Standard for Prepackaged Foods and the interpretation of the 2009 Foods Safety Law provided by China in bilateral discussion.

235. Her delegation accepted China's invitation to engage on these technical issues and had started by identifying the specific discrepancies across the measures as well as their application. She suggested issuing interpretation guidance documents on these measures to provide certainty to US exporters that formulas would not be requested for disclosure.

236. The representative of the China said that the US' concerns had already been addressed in previous bilateral and TBT Committee meetings. China reiterated that this "Specification" was mainly a consolidation of China's previous provisions on food additives specified in the relevant laws and regulations, which were being currently implemented. The requirements on mandatory listing of ingredients or components were not new; they had already been specified in Article 42 of China's Food Safety Law, which had been notified to the WTO years ago. The US concerns raised at this meeting could be a misunderstanding of the Chinese measures. China would welcome information from the US on any possible inconsistencies across the Chinese measures.

(xlii) China – GB/T xxxx-xxxx, Information Security Technology -- Office Devices Security and YD/T xxxx-xxxx, High spectrum efficiency and high throughput wireless LAN technical requirements

237. The representative of the United States had highlighted concerns at the last Committee meeting over this draft voluntary standard. She understood that the draft had been released for public comments for a period of 30 days by a standardization institute under China's Ministry of Industry and Information Technology (MIIT), and the China Electronics Standardization Institute, in conjunction with another standardization body, the China National Information Security Technical Standards Committee (TC260, Working Group 5). Since the last meeting, US industry had noted several positive improvements in the recent revisions, such as removing consumables from the product scope and the narrowing of applicable encryption requirements to exclude non-sensitive data.

238. Her delegation, encouraged China to use the relevant international standards with a view to harmonizing conformity assessment procedures on as wide a basis as possible and, where appropriate, play a full part in the preparation of guides and recommendations for assessment procedures by international standardizing bodies. She was concerned about China's plans to implement a national voluntary standard for wireless Local Area Network (LAN) devices, which appeared to diverge from an existing international standard, IEEE 802.11n. On 13 February 2012, China's Ministry of Industry and Information Technology announced on its website the finalization of the standard. The US was concerned that the standard may be incorporated into type approval, CCC mark registration or other certification processes. She encouraged China to include all interested parties in the development of these central government standard and conformity assessments procedures, and urged China to notify the draft of the new conformity assessment procedures, when available, so all WTO members could comment and their comments be taken into account.

239. The representative of Japan supported the US comments. His delegation believed that this standard was being finalized and requested that it be harmonized with international practice. He hoped that the comments submitted by foreign industries would be reflected in the final drafts, and requested China to provide more information on the implementation of recent drafts, including the office device standards, which applied to each Member’s demands.

240. The representative of the European Union supported the US and Japanese statements.

241. The representative of China informed the Committee that this was a voluntary standard that had not yet been issued. It had been set to ensure the security of user information stored on office devices. During drafting, China had taken into account relevant international standards as well as China's national conditions. Additionally, discussions on some technical concerns with the United States Information Technology Office (USITO) and other stakeholders took place. UHT and EUHT (Ultra High Throughput and Extra Ultra High Throughput) were put online from 10 - 25 August 2011 to solicit comments from Members and observers of China Communications Standards Association. Nokia, VimpelCom, Motorola, Intel, Cisco, Sony Ericsson, Sony and other companies participated. They were again posted online from 20 September to 4 October 2011 to solicit public opinions. On 13 February 2012, UHT and EUHT were formally issued. From 20 September 2011 to 13 February 2012, MIIT had been open to comments from USITO, the European Chamber of Commerce in China, Nokia, Intel, CIAJ[22], JEITA[23], the Korean Chamber of Commerce in China and Euro Digital; 33 comments had been received and taken into account. UHT and EUHT made a complete WLAN system with a physical layer, security protocol, internet management and other technical contents, which enabled UHT and EUHT to support WLAN by itself. UHT and EUHT could be developed together with other WLAN technologies like WIFI. They were implemented as a non-mandatory standard to promote innovative technology and the WLAN industry, and to better satisfy telecommunications demand from the general public. He added that ISO/IEC standard 802.1/b/g had also been adopted, and 802.11ac was in the drafting phase. China would monitor development of these processes.

(xliii) Indonesia – Technical Guidelines for the Implementation of the Adoption and Supervision of Indonesian National Standards for Obligatory Toy Safety

242. The representative of the United States had previously raised her delegations concerns with the May 2010 adoption of the toy safety standard based on the SNI 8124, in particular over the conformity assessment procedures for the toy safety standards. She urged Indonesia to notify any draft conformity assessment measures to the WTO, and to enable the receipt of comments from interested parties. It was important to accept test results from qualified bodies accredited by the ILAC MRA as a trade facilitative measure in implementing any conformity assessment procedures. She asked for an update on this measure.

243. The representative of the European Union requested an update of the expected timeline for the finalization of the draft conformity assessment procedures. He hoped that the process leading to the finalization of this measure would be conducted in a transparent and open way allowing for a meaningful opportunity for stakeholders to provide input. There was some concern regarding the introduction of mandatory testing. In light of a perceived insufficient laboratory capacity in Indonesia, the EU requested that test results from foreign laboratories accredited by signatories of ILAC MRA be accepted as a trade facilitative measure.

244. The representative of Indonesia informed the US and the EU that the regulation was still in a developing stage and that both countries' issues would be taken into consideration in the finalization of the regulation. Subsequently, Indonesia would notify the regulation to the WTO. He welcomed further bilateral discussions on this with both countries.

[22] Communications and Information Network Association of Japan.
[23] Japan Electronics and Information Technology Industries Association.

(xliv) Mexico – Refusal of the National Water Commission to re-certify HDPE pipe products meeting quality/safety standards for piping set out in NOM 001 and NMX 241 (G/TBT/N/MEX/206; G/TBT/N/MEX/206/Add.1 and G/TBT/N/MEX/206/Add.2)

245. The representative of the United States said that she would convey to her capital technical information received in a bilateral meeting with Mexico's National Water Commission.

246. The representative of Mexico confirmed, through the National Commission of Water, that it had never denied the certification of polietileno pipes of high density and structured walls. Mexico had insisted on the application of ISO 21138 in conformity with the TBT Agreement. Mexico had informed the US, in bilateral meeting the previous day, about the following options for accepting such products: a) products had to comply with ISO 21138; b) products had to comply with the US norm ASTM F 894; or, c) products had to comply with norms ASTM F2762 and F2764 once the relevant US authorities accepted them for building sanitary draining. Her delegation was open to analysing other Member's standards. Likewise, the Official National Norm NOM-001-CONAGUA-2011, "Sistemas de agua potable, toma domiciliaria y alcantarillado sanitario-Hermeticidad-Especificaciones y métodos de prueba", had been published in the official national newspaper on 17 February 2012; this norm integrated relevant elements of the ISO standards. This draft regulation was submitted to the Committee on 18 January 2011 (G/TBT/N/MEX/206) for comments from other Members, and was officially published on 17 February 2012 (G/TBT/N/MEX/206/Add.2).

247. In conformity with Article 2.7 of the TBT Agreement, the present regulation contained a paragraph in Article 5 establishing that imported products used for building potable water systems, domestic consumption and sanitary draining coming in from free trading partners, were allowed to apply relevant specifications contained in the norms of the country of origin, provided they were aligned and complied with the objectives of quality and security of these products, as defined in Mexican norms and in the previously mentioned international norms. Therefore, as an alternative to NOM-001-CONAGUA-2011, the National Water Commission accepted foreign norms from the US and other trading partners that so requested, as equivalent standards as long as they complied with the performance and quality conditions required for sanitary draining. The Commission was elaborating a procedure on how to fill in corresponding petitions and how to satisfy the requirements. In order to ease the situation, Mexico may limit the requirements to the following conditions: a) products of importation should have applied the relevant norms of the country of origin, and shown a corresponding laboratory report, b) products should have been used and authorized by competent authorities, and c) products should come with a system of quality assurance.

(xlv) El Salvador – Law on hygienic production of milk and milk products and the regulation of their sale

248. The representative of Mexico shared its concerns with this law with El Salvador, in particular Article 21, on the commercialization of milk, cream and cheese for the reconstitution and re-mixing of milk powder. This Article banned the trading of milk, cream and cheese with additives. Mexico had asked El Salvador to allow for the exportation of products elaborated with milk powder and/or vegetable fat or starch, but had received a negative response. Mexican authorities considered that this ban acted as discriminatory and that it may have violated the TBT Agreement. Mexico requested a formal response from El Salvador with scientific evidence on the need for implementing this measure.

249. The representative of El Salvador reported that since the November 2011 meeting, Mexico and El Salvador had been in bilateral contact. This law was meant to ensure human health and was based on a number of relevant international Codex standards. The provisions of this law did not make any distinction between the national and foreign marketing of milk, cream and cheese resulting from the combination of powdered milk or the use of additives. Thus, it was not discriminatory and was

consistent with Article 2.1 of the TBT Agreement. His Government would continue bilateral discussions with Mexico so as to dispel any remaining concerns.

(xlvi) European Union – Draft Commission Regulation implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for air conditioners and comfort fans (G/TBT/N/EEC/362)

250. The representative of China noted that the EU regulation No 206/2012 had been issued in the EU Official Journal EU on 10 March 2012 and would enter into force on 30 March. Efficiency requirements in *phase one* would be implemented on 1 January 2013. However, the related EU testing standard for judging compliance with the regulation had not yet been formulated, and the relevant ISO Standard was still under formulation. Therefore, it was a great challenge and burden for enterprises to adapt products to the regulation within only nine months as specified in the regulation. Moreover there was no criterion to judge such compliance. The delayed issuance of the testing standard caused much inconvenience to enterprises in conformity assessment and created additional trade barriers. China hoped that the EU would provide the timeline for the formulation of the standard of testing method of air conditioner. In addition, China encouraged the EU to follow other Members' practice (e.g. the US and Australia) by issuing regulations on energy efficiency and testing standards at the same time, when preparing eco-design regulations for energy using products. China would welcome the EU to issue testing methods prior to the development of energy efficiency index.

251. The representative of the European Union stressed that she was aware of the importance of the existence of test and calculation methods for the ecodesign requirements. The EU system required that the European Commission request one of the European Standardization bodies (CEN, CENELEC, ETSI) to develop standards specifying the relevant measurement and calculation methods. She informed that a mandate to that effect had been issued to the European Standardization bodies, CEN, CENELEC and ETSI on 18 February 2011. Pending the elaboration of those measurements and calculation procedures, the European Commission was also in the process of publishing a communication on transitory measurement methods, developed with stakeholders. It was therefore ensured that the necessary measurement methods would be available when the Regulation in question would be applicable.

(xlvii) Norway – Proposed regulation concerning specific hazardous substances in consumer products (G/TBT/N/NOR/17/Rev.1)

252. The representative of Japan examined the Norwegian draft and had some concerns expressed in its comment submitted. Because it was difficult to distinguish between natural lead, which is not derived from manufacturing process and hence unavoidably included,and that from manufacturing processes, the Maximum Concentration Value (MCV) should be set at levels that would be technically possible to protect human health and the environment. Risk assessments consisted of three key items: hazard identification, dose-response assessment and exposure assessment. In Chapter 2.4, some hazard identification data and hazard classification results under EU CLP regulation were mentioned. However, there were no dose-response assessment and exposure assessment data. The lack of analysis of two key items showed that the risk assessment on lead in Chapter 2.4 was incomplete. It should have included the following items: a) the nature of the most significant hazard (primary hazard); b) the level of exposure that was foreseeable from the envisaged sources, and c) whether the envisaged exposure was acceptable or manageable.

253. The representative of Norway recalled that the original Norwegian notification from 2007 was related to the regulation of 18 hazardous substances in consumer products. This regulation had not entered into force on 1 January 2008 as proposed. The draft regulation had undergone a process of review, and as recounted at earlier TBT-meetings, 8 of the substances were removed from the list as a result. It was then concluded in 2010 that four of the remaining ten substances were to be

prioritized for regulation at this point in time. Having taken into account the comments received, revised proposals for regulation and impact assessments were made for the four substances that Japan had referred to in its comments: pentachlorophenol (PCP), lead, medium-chain chlorinated paraffin (MCCPs) and perfluorooctanoic acid (PFOA). As provided for in Article 2.2. of the TBT Agreement, a risk assessment had been performed for the 4 products which was publically available on the website of the Climate and Pollution Agency (http://www.klif.no). She would forward it to Members. The revised proposals had been notified to the EFTA Surveillance Authority in December 2010 and sent for public consultation in the EEA area. They were the subject of a national public hearing (February 2011) and an additional notification in December 2011 (G/TBT/N/NOR/17). Norwegian environmental authorities were in the process of reviewing the proposals in light of the comments received. In the revised notification, 1 July 2012 was proposed as date of entry into force. However, this date would likely not be met. The reviewing process was complicated and resource-consuming; it was unclear when the regulation would be adopted and brought into force. Comments from Japan, received on 8 February were responded to on 22 February 2011. Additionally, a useful bilateral meeting was held and authorities had taken careful note of Japan's comments.

(xlviii) India – Toys and Toy Products (Compulsory Registration) Order

254. The representative of the United States understood that the Ministry of Consumer Affairs' Bureau of Indian Standards (BIS) was to issue a new Toys and Toy Products (Compulsory Registration) Order. The US supported the protection of human health, in particular, children's health in relation to toys and toy products. However, she reiterated her delegation's previous concerns. Though India considered it premature to comment on this unreleased order, the US believed that early identification of potential issues supported the development of quality regulations that could facilitate trade, as stipulated by the TBT Agreement. She urged India to notify the proposed regulation so that Members could provide comments, and she requested an update on the measure's timeline.

255. The representative of the European Union recalled previous concerns raised regarding the potential new measure that would introduce mandatory testing carried out domestically, coupled with registration procedures that would imply the disclosure of extensive information by the applicant manufacturers. He requested an updated timeline for the proposed measure and information on the handling of the procedure by the Indian authority. He supported the US request for a transparent and open process for Members to provide input at an early stage in order to address the potential concerns.

256. The representative of India ensured both delegations that the ASTM and the EU standards for import of toy products were taken into consideration. Extensive consultations had been held by the Department of Industrial Policy and Promotion in which the issue had been raised by both delegations. When the draft guideline was finalized, it would be notified to the TBT Committee.

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

257. The representative of Argentina reiterated his delegation's concerns with the Grenelle 2 Law regarding transparency, discrimination, lack of predictability, exclusion of third party opinions, and subsequently, inconsistency with WTO rules. The representative highlighted three aspects of the lack of transparency: i) the draft law was not notified to the WTO; ii) the lack of notification removed the possibility for Members to submit comments and have them considered prior to the issuance of this law; and iii) answers were not provided to his delegation's questions of June and November 2011. An eventual implementation of this law would generate discriminatory treatment that would alter the conditions of competition between similar products. But similar products should not be differentiated on the basis of unrelated processes and production methods, as it was indicated by this law.

258. According to the EU, addressing these issues in the TBT Committee was premature. Nonetheless, Argentina considered that the fact this law was in a testing phase, should not impede the following clarifications: a) did France have consultations with interested and potentially affected parties, particularly from developing and least-developed countries; b) would this law cover industrial and agricultural products; c) which methodology of greenhouse gas quantification would be employed by the law; and, d) had special and differential treatment clauses been envisaged, as stipulated in Article 12 of the TBT Agreement (e.g. measures to address the development, financial and commercial needs of developing countries and to avoid negative impacts upon their exports)? From the EU's answers provided in June and November 2011, Argentina inferred that there would be no mandatory labelling on carbon footprints of products and their packaging, on the consumption of natural resources nor on their impact on the environment attributable to these products during their lifecycle. Likewise, from the EU's lack of answers to the following topics, it was inferred that developing and least-developed countries were not consulted; that the law would not apply to their agricultural and industrial products; and, consequently. the law would not require a mandatory nor voluntary labelling on carbon footprints during the pilot phase nor at the end; and that the calculation methodology of carbon content of products was not defined. Neither was defined to which products from developing countries this law would eventually apply. He reiterated the need to clarify whether a regulatory impact analysis (RIA) had been performed, and he stressed the need to notify this law, bearing in mind that the fact of having been in a testing period did not exclude France from its obligation of notification..

259. The representative of the European Union highlighted that she had explained at the last two meetings that the Grenelle 2 law did not require mandatory environmental labelling. It foresaw carrying out only a trial phase. This provision had therefore not to be notified under the TBT Agreement, contrary to what Argentina seemed to imply. The trial phase aimed at contributing to discussions on environmental labelling that reflected the concerns and issues expressed in numerous national and international bodies, in relation to the need and means to inform consumers about the environmental impacts of their choices. The French authorities wished to play a leading role in the thinking about environmental labelling mechanisms and hoped to participate meaningfully in the compilation of advanced techniques and methodologies using scientific data underlying implementation of such provisions. They also participated actively in the development of an international standard for the carbon footprint of products (ISO 14067).

260. Given the need to test the calculation methods and implementation of environmental labelling, France had decided to pursue this trial to assess the feasibility of such measures with volunteer companies. 168 companies from different countries had participated in this trial voluntarily and it was therefore not correct, as stated by Argentina, that no consultation had been taking place. The EU was ready to provide information about the trial as necessary, however, the results of the trial would not be known until the beginning of 2013.

(l) United States – California Code of Regulations: Chapter 53 Safer Consumer Product Alternatives (G/TBT/N/USA/579 and G/TBT/N/USA/579/Corr.1)

261. The representative of the European Union said that the proposed legislation laid down a complex system of chemical management that would encourage the redesign of consumer products and manufacturing processes. The proposal seemed to be on hold since November 2010. However, on 31 October 2011 the California Department of Toxic Substance Control published the draft regulations for Safer Consumer Products on its website for informal comments. Main parts of this draft remained similar to the text that had been proposed in 2010. The informal comments received were published on the same website on 20 January 2012. She asked what further steps would be taken with regard to this draft and if a formal public consultation would be carried out. The EU believed that the draft contained technical regulations and should be notified under the TBT Agreement. It laid down rules to set up different lists of chemicals and set out the precise criteria

according to which the lists had to be prepared. In case a chemical was on one of these lists, the draft foresaw important consequences for economic operators, such as the obligation to carry out alternative assessments that would lead to a redesign or a reformulation of a consumer product, a removal of a product, an obligation to set up end-of-life management programs or even product sales prohibitions. While the EU clearly shared the objective of the protection of human health and the environment, it wanted the possibility to comment on the draft and to share with California the experience that the EU had gained from the application of the REACH Regulation. Finally, she asked if any feasibility and impact assessments had been carried out by California.

262. The representative of the United States considered this regulation to be neither a technical regulation nor a conformity assessment procedure under the meaning of the TBT Agreement. There was no draft regulation that specified a particular characteristic or related processes or production method for any products; nor did the regulation call for a particular size, shape, design, function or performance for any product. The legislation called on California's Department of Toxic Substances Control (DTSC) to establish a process by which they could request information from stakeholders on particular substances. Regulators frequently called for data and other types of information but stakeholders were not automatically subjected to notification requirements. She understood that DTSC would likely publish proposed measures in the late spring or early summer and provide a comment period. The EU, like all stakeholders, would provide input through the process of domestic comments. If any subsequent measure fell under the TBT requirements, they would be notified.

(li) Brazil – Health Products (G/TBT/N/BRA/328)

263. The representative of the European Union reiterated concerns regarding timelines for the registration of medical devices in Brazil. As of May 2010, a Good Manufacturing Practices (GMP) certificate had to be presented with the application for registration. A GMP certificate would be issued after the Brazilian Health Surveillance Agency (ANVISA) inspected the manufacturing premises. In the June 2010 TBT Committee meeting, Brazil indicated that inspections were being carried out in a timely manner with no trade disruptions. However, according to information available to the EU, a significant number of manufacturing sites had submitted an inspection request with no inspection taking place. It appeared that the elapsed period between the request and the inspection was on average 20 months. She asked Brazil to update the Committee on the number of facilities for which ANVISA had completed audits and issued GMP certificates, and those for which audits had been requested but not yet completed.

264. She urged ANVISA to take effective measures to reduce current backlog and guarantee that inspections to foreign manufactures would be carried out within a period of three months, particularly due to the relatively short life span of medical devices. If it was difficult to comply with reasonable inspection deadlines, ANVISA could take into account Quality Management System audits conducted by accredited auditing bodies (e.g. EU Notified Bodies). Also, Brazil could consider accepting products that had been authorized in the EU or in other major markets, pending the completion of ANVISA inspections, or consider subcontracting overseas inspections to accredited auditing bodies such as the EU Notified Bodies. Finally, to increase transparency and predictability, ANVISA could regularly inform operators waiting of the expected timing for completion of their registration dossier.

265. The representative of Brazil said Brazilian authorities were aware of the situation and ANVISA had been working to increase the number of GMP inspections. Several measures had been adopted or were under consideration to review procedures and use resources more efficiently. The representative announced that in 2009, when the systematic inspections for medical devices began, ANVISA conducted 39 inspections. In 2011, 226 inspections were conducted, an increase of 579 per cent. Some of the measures adopted by ANVISA to improve its inspection capacity included opening a public consultation number 62/2011, notified as TBT/N/BRA/454, to define criteria for improving the efficiency of international inspections. Another was the establishment of new procedures for

prioritizing inspections, such as enabling inspection teams sent to a certain region to conduct all of the inspections requested by companies of that region. It also hoped to establish a list of priority products for inspection, considering the risk of lack of supply in the Brazilian market, and ANVISA sought to make the best use of its human resources by reallocating experts and forming new teams of inspectors. Another measure considered was enabling local Brazilian governmental experts to work as international inspectors.

266. Brazil remained open to the possibility of promoting mutual recognition agreements in this area, or other arrangements that could expedite the certification process such as confidentiality agreements between ANVISA and the competent authorities of other Members. Finally, Brazil joined the International Medical Device Regulator's Forum (IMDRF), with Australia, Canada, the USA, Japan, the EU and the WHO among others, to work on regulatory convergence with the participating regulatory authorities in the Forum so as to improve its regulatory framework on medical devices.

(lii) India – Prevention of Food Adulteration (G/TBT/N/IND/34)

267. The representative of the United States had concerns about the Prevention of Food Adulteration Act (PFA) and the status of its requirements, particularly those in the 2011 Food Safety and Standards Regulations (FSSR). Did these requirements replace those of the PFA Act? She asked for the expected date of enforcement of compliance with the labelling provisions in the FSSR. Both measures appeared to be in force which created confusion in how to handle their differences. She noted that the US' comments on the FSSR had not been taken into account in the final measure and she was particularly concerned about the lack of consistency with international standards.

268. In November 2011, India indicated that the final regulation had taken into account India's specific needs. The US was interested in exploring what those needs were with respect to Codex recommendations and guidelines, for example: a) why did India require both a date of manufacture and production, along with additional certification of shelf life for certain perishable products, when Codex recommended only the date of minimum durability; b) why did India require for irradiated foods a date, license number of the irradiation unit, and the purpose of the treatment, when Codex only stipulated a statement or use of a symbol to alert consumers; and, c) why did India require a special declaration of colors and flavors when Codex required declaration in an ingredients list. The US questioned India's requirement to add the date of production to distilled spirits when lot identification numbers already provided the information needed if product recall was necessary. She urged India to remove this labelling requirement for distilled spirits as well as the listing of requirements for alcohol. The US delegate was unsure as to why India continued to require the listing of ingredients for alcohol as international practice did not require an ingredient list for non-nutritive products as it provided little useful information to the consumer. Lastly, she noted that India's responses had not provided additional, reliable information on how the elements of this measure improved safety, efficacy, and product quality, or how they met the specific needs of India.

269. The representative of the European Union was concerned that procedurally, since the regulation contained several TBT-related aspects such as labelling and packaging requirements, it should be notified to the TBT Committee. Substantively, she asked whether India would maintain the current temporary practice of allowing labelling to take place in customs bonded warehouses, as an alternative to labelling in the country of origin. This procedure allowed for duly informing the consumer and was more convenient for market operators. In the case of labelling requirements applicable to alcoholic beverages, the EU continued to seek an exemption from indicating the date of manufacture, and the acceptance of "single ingredient status" for the list of ingredients. The EU also suggested that India align its legislation to Codex Alimentarius standards, such as those on food labelling, on cheese and on natural mineral water and bottled water. Finally, the EU had learned that India was drafting a new technical regulation dedicated to alcoholic drinks and she invited India to inform the Committee of the state of play of this draft and the timeline for a TBT notification.

270. The representative of India explained that the new Food Safety and Standards Packaging and labelling regulations of 2011 replaces the old 2008 rules, many of which had been incorporated into the new regulation. India had notified this to the SPS Committee so that Members were aware of the specific regulation in place. India was not aware of the specific questions raised by the US because it did not have a bilateral discussion with the US. He would communicate their concerns to his authorities for a response and would likely have some technical discussions with the US on this issue.

271. In response to the EU's questions, labelling in capital letters had been established for better visual recognition. While not aligned with Codex, this input was provided by Indian regulators. He confirmed that these regulations applied to alcoholic beverages under Rule 2.2.2 of the regulation and flexibility in the regulations allowed for single ingredient status to be acceptable. However, a list of other ingredients shall be declared on the label following the relevant provision. Finally, he was not aware of the new regulation on alcoholic beverages mentioned by the EU but he would consult and revert to the EU on this.

2. Follow-up

272. The Chairperson referred to a Room Document (RD/TBT/3/Rev.1) containing a complete listing of all previously raised specific trade concerns in the TBT Committee. She asked if any delegation wished to report on the status of previously raised concerns, including with respect to the resolution of any such concerns.

273. The representative of Brazil noted that his delegation understood that this item of the agenda was there on a trial basis, and that his delegation was still reflecting on the utility of it. In particular, Brazil had some doubts about the possible implication and value in classifying previously raised STCs as "resolved" or "unresolved". Nevertheless, Brazil could support the idea that this agenda item could be used to provide Members with the opportunity to report on progress and other developments concerning such previously raised STCs.

274. The representative of the United States was still reflecting on discussions that had taken place on this matter.

275. The representative of the European Union noted that keeping track of the status of STCs was important. Nevertheless, the EU considered that providing a progress report that gave an exact picture of the status of an STC was, in most cases, a very difficult exercise in the TBT area. In virtually all cases that had been raised by the EU, he would *not* be able to provide a report that gave a clear reflection of the current status of the STCs. Nevertheless, the EU was not against the approach initially put forward by the Secretariat where some categories would operate by default and other based on voluntary reporting by Members – but there needed to be only very few and clearly identified categories (active, inactive, etc.). Also, it had to be the Member *raising* the concern that did the reporting – and this would inevitably be a subjective assessment.

276. The representative of Canada said that providing updates on previously raised STCs could be a way of flagging continued "concern" while not necessarily re-raising the issue for discussion (if there was nothing new to add), thereby promoting efficiency. There were also situations, Canada had noted, where a Member might raise a concern simply to seek more information or clarification, and, in these cases, there might not actually be a problem to "resolve". It was therefore perhaps not necessary to seek to capture the status of *every* STC, but rather the Committee might consider a mechanism that would provide the Membership option to provide updates on status where relevant.

277. The Chairperson noted that Members needed more time to reflect on this matter.

C. EXCHANGE OF EXPERIENCES

1. Good Regulatory Practice (GRP)

278. The Chairperson recalled the recommendations on good regulatory practice (GRP) contained in the Fifth Triennial Review (paras. 11 and 16 of G/TBT/26) as well as the recent discussions at the Workshop on Regulatory Cooperation between Members (summarized in G/TBT/W/348).

279. The representative of the United States introduced her delegation's submission (a submission on GRP made on behalf of Member Economies[24] of the APEC Subcommittee on Standards and Conformance (SCSC), contained in G/TBT/W/350). She recalled that there had been significant support in the Fifth Triennial Review, for improving the implementation of GRP as a means to improve the ability of Members to meet their regulatory objectives in a manner that facilitated and enabled greater trade and investment in their economies. Many Members, across a wide spectrum of economic development and institutional capacity, had expressed interest in gaining a better understanding of: (i) the body of practices and procedures that were known to improve regulatory quality; (ii) how other Members had instituted these practices, including how practices could be adapted in diverse conditions; and, (iii) how precisely GRP contributed to improving the implementation of the TBT Agreement.

280. On the first point, the US was of the view that the Secretariat's compilation was a good starting point.[25] This needed to be a living document, revised periodically to incorporate experiences from WTO Members as well as from multilateral and regional organizations, and other authoritative sources. The compilation, as well as the above-mentioned summary report of the WTO Workshop also addressed the second point: how Members had instituted GRP. On the third point, the representative of the US recalled that during the Fifth Triennial Review, Mexico had expressly indicated an interest in the preparation of a guidance document on good regulatory practices that would include: "(i) recommended procedures that will ensure effective compliance with each of the substantive obligations laid down in the TBT Agreement, and (ii) examples of mechanisms for the fulfilment of such obligations."[26]

281. The idea put forward by Mexico had been discussed in the APEC Subcommittee on Standards and Conformance (SCSC) for some time. In 1997, the SCSC issued a short document "Guidelines for the preparation, adoption and review of technical regulations" which attempted to do this at a high-level of generality. At its 6th Conference on GRP in March 2011 co-sponsored by Japan, Malaysia, New Zealand, Peru and Singapore, SCSC members agreed to go further. Thus a new study was conducted: "Supporting the TBT Agreement with GRP: Implementation Options for Members". This study was authored by a leading authority on regulatory reform, Mr. Scott Jacobs of Jacobs & Associates, in consultation and collaboration with SCSC members. It benefited from the contributions of several Members, including Chile, Malaysia and New Zealand. Chile and Malaysia, for example, had stressed the importance of addressing the issue of how countries that do not currently have institutions or procedures in place that support GRP can understand and evaluate the options for developing and implementing practices and procedures from the array of GRPs. The study not only showed the relationship between various practices and procedures with creating a regulatory environment that facilitated trade and investment, but also pointed out the options that could be implemented both at low cost and yield significant improvements in regulatory quality. She

[24] The APEC members are Australia, Brunei Darussalam, Canada, Chile, China, Hong Kong China, Indonesia, Japan, Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, Peru, the Philippines, Russia, Singapore, Chinese Taipei, Thailand, Vietnam, and the United States.

[25] G/TBT/W/341, 13 September 2011.

[26] G/TBT/W/313, 9 June 2009, para 18.

said said that SCSC members believed that this study, referenced in G/TBT/W/350, was an excellent start in helping policy makers better understand the relationship between TBT and GRP.

282. The representative of Mexico supported the idea of developing a guide on GRP as a means of helping Members comply with the substantive provisions contained in the TBT Agreement. The guide could include recommended procedures for each substantive requirement, as well as examples of mechanisms for compliance. Mexico was of the view that it was particularly important to provide examples of such mechanisms and referred to, as an example, the use of impact assessments to balance benefits against costs when considering the need for government intervention. This could facilitate the work of developing countries, in particular the LDCs as well as recently acceded Members. Mexico intended to make a submission on this subject shortly.

283. The representative of Mexico also expressed her delegation's appreciation for the organization and conduct of the Workshop on Regulatory Co-operation, held in November 2011 (G/TBT/W/348). In her view, it was of important that the Committee continue to exchange experiences on this topic as this was key to increasing the competitiveness of Members, and eliminate unnecessary costs. Mexico suggested that the Committee develop a document covering the results of the seminar and prepare a compilation on the various existing mechanisms in terms of regulatory co-operation, such as in terms of exchange of information, MRAs, technical assistance agreements etc.

284. The representative of the European Union expressed support for the proposal to develop guidance on GRP. He recalled that the Fifth Triennial Review had given the Committee a two-fold mandate: to *identify* principles that were relevant for GRP and, to find examples of *practices*. In the view of the EU there was now a substantial amount of information on the table stemming from: individual papers submitted by Members, the outputs from the Workshops (summary reports) and the Secretariat's compilation of sources of existing guidelines of other international organizations. Hence, there was a need for the Committee to shift its focus to efforts to extract those principles that were most relevant for the implementation on the TBT Agreement. The EU intended to work from this material to try to identify, from its point of view based on its own regulatory policy, the most relevant principles for GRP – this work was underway and a contribution was forthcoming.

285. The representative of India noted that his delegation too was looking at making a specific submission on GRP, primarily by identifying the key elements of GRP – also considering the output from the recent Workshop on Regulatory Cooperation between Members (G/TBT/W/348). This, he said, could be a good background in terms of guidelines for Members. He cautioned, nevertheless, that whatever was being developed by the Committee needed to be framed in terms of best endeavour language.

286. The representative of Cuba also expressed her delegation's appreciation for the Workshop mentioned by India. The exchanges during the Workshop had had demonstrated the wide range of mechanisms that existed for co-operation in the area of regulation. In addition, the exchange during the workshop, also reflected the importance and the need to put together guidelines for GRP also specifically with respect to regulatory co-operation between countries.

287. The representatives of New Zealand and Australia expressed support for the US proposal, noting that they too had been closely involved in GRP work within APEC and said that the Committee's Sixth Triennial Review presented a good opportunity to bring in this body of work.

288. The Chairperson said there was a general willingness to bring the Committee's work forward on GRP in the context of the Committee's Sixth Triennial Review, including by developing guidance in this area.

2. Standards

289. The Chairperson recalled previous work by the Committee in the area of standards and in particular the recommendations contained in paragraphs 25-27 of G/TBT/26.

290. The representative of India recalled that he had introduced his delegation's submission (G/TBT/W/345) on international standards at the last meeting of the Committee.[27] He reiterated that the document considered the Committee's *Decision on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the TBT Agreement* from 2000 (hereafter the "Committee Decision")[28], as well as the TBT Agreement's Code of Good Practice. The submission itself had been developed on the basis of discussions India had held with international standard-setting bodies in Geneva, as well with certain Members and regulators in India. The paper was intended to stimulate discussions in an area that was critical to the TBT Agreement. In particular, standards-setting bodies had a different notion of the principle of consensus as compared to the WTO. The definition of international standards is an important aspect and the only guidance available is the panel report on the EC-Sardines case wherein the Codex standard was stated to the relevant international standard since Codex figures in the SPS Agreement and participation is open to all Members of the WTO. Also the issues of openness, effectiveness, impact assessments and coherence were very important. In the area of development, he noted that many standard-setting bodies had action plans for developing countries and that was critical for participation of maximum number of developing countries in such bodies. He also drew Members' attention to the proposed additional principles contained in the paper. The representative of India noted the concerns expressed by the ISO and IEC (as contained in a room document[29]) and asked them to explain how participation in the technical committees actually worked. He also asked for clarification about the concern on "independent verification" (para 2 of the room document).

291. The representative of Colombia introduced his delegation's submission (G/TBT/W/351). In this submission, Colombia encouraged Members to address the issue of a definition of an international standard in the Sixth Triennial Review. This would help overcome the ambiguity that existed in the TBT Agreement and that had been addressed by India. Indeed, Colombia was of the view that the lack of clarity over whether a standard was "international" or not limited the use of international standards. The explicit designation of relevant bodies – as had been achieved in the SPS Agreement – would facilitate the participation of developing countries and LDCs in the development of international standards.

292. The representative of Mexico concurred that the lack of a definition on international standard generated problems in the interpretation of the TBT Agreement, and therefore also in its implementation. Mexico suggested that a definition be drafted based on the Committee Decision as suggested by India and that the Committee review the principles contained therein.

293. The representative of the United States said that the papers presented a number of important questions. To begin with, it was important to understand just how national standards bodies operated, how they facilitated participation in technical committees at the international level, how they performed outreach to stakeholders and how they interacted with regulators. Participation in technical committees (TCs) was critical and, in the US view, it could be important to further explore Members' experiences in this regard. In one sense, national standards bodies were essentially libraries of standards: they were a resource for regulators – and this was relevant to the issue of how regulators knew what the "relevant" standards were. She noted, in this respect, that there was a broad diversity among Members on how national standards bodies worked. In fact, for many Members national

[27] G/TBT/M/55, dated 9 February 2012, paras. 285 and 286.
[28] The full text of this Decision is contained in Annex B of G/TBT/1/Rev.10, dated 9 June 2011.
[29] Subsequently circulated as G/TBT/GEN/129, dated 2 April 2012.

standards bodies were not *governmental* bodies; hence there was a challenge of being an intergovernmental institution interacting with essentially private sector bodies. The Committee Decision recognized this very clearly in that it did not tell *international standards bodies* to be open, to be transparent, to be relevant,etc.. Instead it told *WTO Members, in their capacity as participants* in international standards bodies to work towards these objectives. This was an important distinction that the Committee needed to maintain.

294. The US was, however, of the view that given the differences among Members, it would not be productive for the Committee to reopen the Committee Decision, or to try to readjust it. The Committee Decision, as it stood, had led to significant and robust reflection among an array of standardizing bodies as to what it meant to be "globally relevant" and to produce standards that facilitated international trade. She stressed that it was not the US government that participated in these bodies, but industry players and private sector entities – the economic operators and stakeholders that had an abiding interest in the technical issues discussed. While the US understood that the diversity of bodies could be source of confusion, the key issue was to focus on how to enable national standardizing bodies to facilitate this exchange among stakeholders. Again, GRP was key: how did regulators become aware of what tools (standards) were available to meet their needs? An important element was the promulgation of draft regulations, public comment and feedback from the industry players and other affected stakeholders.

295. The representative of the European Union stressed the need to be realistic and to stay focused on what could he achieved. He recalled that at the last meeting his delegation had made a detailed statement in this regard.[30] Like the US, his delegation had expressed some caution on whether the Committee could usefully spend time again on the Committee Decision and the definition of "international standard" – this was probably not going to be a fruitful discussion given the different views that existed. On the other hand, there was a prospect for a useful discussion following paragraph 25 of the Fifth Triennial Review[31] in focusing on the *application* of the existing principles. There were two sets of principles. First, those specifically targeting national and regional bodies (contained in the TBT Agreement's Code of Good Practice) and, second, those contained in the Committee Decision which focused on the development of international standards – and which were, in fact, an expression of good practice in standards development.

296. The EU believed, and following the recommendations set out in the Fifth Triennial Review, it would be useful to have a discussion on the effective application of the Code of Good Practice, and in particular the transparency aspects thereto. For instance, this could include giving full effect to the public enquiry stage in standards development, which was a unique opportunity for those stakeholders who were not involved directly in standards development to provide their input on draft standards and to have access to the full text of a draft standard *before* adoption. This was particularly important in those WTO Members where the regulatory system relied on standards as a basis for regulations, and when standards were almost invariably transformed into technical regulations. Likewise, a discussion on the application of the six principles in the Committee Decision could also be useful. Some standardizing bodies had made a genuine effort to integrate these principles as an expression of good practice in standards development in their own operating procedures – this debate was necessary before discussing whether or not the principles needed amendment or revisiting. In sum, the EU was of the view that too little was known about how these principles and the Code of Good Practice were applied and while the EU was willing to embark on a discussion in this area, his delegation was not willing to contribute to a discussion on the definition of an international standard.

297. The representative of India supported Colombia's submission and Mexico's statement but said he remained perplexed at the last two interventions. The whole discussion on international

[30] G/TBT/M/55, dated 9 February 2012, paras. 290-291.
[31] Paragraph 25 of G/TBT/26.

standards was so mired in complexity that it was likely that every organization out there – even India's own national standards body – probably thought they were setting international standards. Clearly more clarity was needed. The principles themselves were not very clear. If this could not be addressed, what would the value addition be from pending triennial review process? This was the backdrop of the NAMA negotiations where actually naming international standards had been the most controversial issue, and why working around the six principles was a useful alternative approach. But now it seemed that some Members were not even willing to consider revisiting the principles? The representative of India stressed the need to consider what the Committee wanted to achieve with the Sixth Triennial Review exercise as a whole.

298. The representative of the IEC noted that, with respect to participation, it was neither ISO nor the IEC that decided on the level of participation from each country in the work of technical committees – it was the country itself. And this depended on capacity and the importance attributed to standards in its economy. Both organizations were endeavouring to involve stakeholders in the elaboration of standards. Similarly, the representative of Codex stressed that all its committees and commissions were open to all its 184 Members.

299. The representative of India noted that there were different levels of participation in the IEC and ISO. He asked if this meant that a particular category of Members decided who participated in the standard setting process, and, in that case – what was the exact procedure? Was this done by voting, for instance with respect to participation in the technical committees? In other words, was a vote held to decide whether or not to allow certain member to participate or not in the technical committees?

300. The representative of the IEC responded that for the IEC any country that was a member of the IEC had the choice to participate in any technical committee. A full member of the IEC could participate in any technical committee either as an observer or as a participating member. Of course, even for very big countries, it was not feasible (or at all necessary) to participate in *all* the technical committees. The country had to select according to its interests and its capacity. As an associate member, the country could participate as an observer and could be a participant member in four technical fields. She reiterated that the level of participation was the choice of the country, not the IEC.

301. The representative of the United States expanded on the point made by the IEC, noting that countries participated in ISO and the IEC in different ways. In fact, it was not necessarily correct to say "countries" it was rather "national member bodies". And a national member body for some WTO Members was a governmental standardizing body or a central governmental body, for others – including the US – it was a private sector entity that actually represented the country. Hence the importance of understanding how national standard bodies worked, meaning how they assured that domestic industry had ample opportunities to participate in standard setting. This was one of the key issues for many developing countries, and in fact an important issue for the US.

302. The representative of Australia referred to the "elephant in the room" as the NAMA negotiations. While this, he said, was readily apparent to those delegations that covered both the TBT Committee and the NAMA Group it was perhaps less obvious to others. In his view, there was a need for some transparency on this matter. He recalled that there had been a discussion that the Chair of the NAMA negotiations had led which had been about the adequate forum to discuss a number of the TBT-related NTB issues: NAMA or the TBT Committee – and this included the debate on international standards. From the point of view of Australia, it was useful to use the technical expertise that existed in the TBT Committee to help inform some of NAMA negotiations as these sometimes occurred in the abstract without the technical expertise required.

303. The Chairperson said that in view of the discussion it would be difficult to bring forward some elements due to the different views among Members. But at the same time, some Members had indicated a willingness to explore ideas that could be brought forward and in this light the Committee needed to further reflect on the matter. In the meantime, the Committee would await any further proposals in this area.

3. Conformity Assessment

304. The representative of the United States again stressed the ambitious nature of the Fifth Triennial Review Report (G/TBT/26, paras 17-19) and the need to build on this work. In this respect she noted that an important part of the Committee's recommendations to date aimed at promoting information exchange on the various aspects of conformity assessment procedures, including on: (i) approaches to conformity assessment; (ii) the use of relevant international standards, guides or recommendations, or the relevant parts of them, as a basis for their conformity assessment procedures; and (iii) facilitating the recognition of conformity assessment results.

305. She said that conformity assessment was a frequent feature of the Committee's discussion on specific trade concerns. The Committee's work on trade facilitative approaches to conformity assessment was therefore a natural outgrowth of its work to prevent and reduce unnecessary obstacles to trade. Promoting greater understanding of the choices associated with different approaches to conformity assessment also served WTO Members' goals of developing and ensuring that their standards and conformance infrastructure supported the effective achievement of the larger economic and social goals of their countries. This infrastructure enabled the achievement of the regulatory needs of governments, but importantly, it also supported the needs of local producers and suppliers seeking to improve in a reliable and systematic way the quality and safety of their products. This, in turn, supported greater exports and could contribute to improved and safer choices for domestic consumers. With respect to laboratory testing, a recent World Bank study[32] concluded: "Given the high cost involved in most laboratory development projects, inappropriate investment decisions often cause a huge waste of resources." And further, "Many investments in public laboratories for food and agriculture are not sustainable, at least from a financial standpoint, and sometimes technically as well.". Hence, while the TBT Committee considered conformity assessment from a trade facilitation perspective, many of these same issues had significant implications as countries sought to support their economic and social goals through the development of their standards and conformance infrastructure.

306. The US submission (G/TBT/W/349) needed to be seen in this light. It showed examples of how the use of elements of the international system of conformity assessment, namely the ILAC MRA and IAF MLA, was helping US regulatory agencies achieve a diversity of goals, and how the US government was working to increase awareness across other agencies that these important tools were available to them. She stressed that the technical infrastructure underpinning US economy was among the most sophisticated in world, so it was particularly instructive that the US regulatory bodies discussed in this paper have chosen to utilize the ILAC MRA and IAF MLA for these programs, rather than mandate the use of national labs or certification bodies.

307. She noted that the regulatory agencies themselves had helped write these cases studies contained in G/TBT/W/349; these ranged across a wide variety of programs - from consumer product safety, to marine and fire safety equipment to ambulances to conserving energy and water usage. Regulators had cited their rationale for using ILAC and IAF – and this could be relevant to agencies in other countries: the need to leverage limited resources; improving trust in, and credibility of, test results; reducing delays and duplicative testing; improving technical competence; enabling links to

[32] "Guide for Assessing Investment Needs in Laboratory Capacities for Managing Food Safety, Plant Health, and Animal Health" can be downloaded from the World Bank website: http://www-wds.worldbank.org.

global supply chains and ensuring that results are recognized beyond national borders. In sum, the US submission gave many good reasons for using the ILAC and IAF, some of which were, in the US view, particularly compelling for economies with limited resources and institutional capacities. Her delegation encouraged Members of the Committee to consider how this might be used in the Sixth Triennial Review to strengthen implementation of Articles 5.4 and 9 of the TBT Agreement.

308. The representative of New Zealand supported the US statement on the value international systems of accreditation could add to regulatory processes. She recalled that New Zealand had submitted a paper in September 2010 (JOB/TBT/5), which had put forward a draft outline for Guidelines on Choice and Design of Trade Facilitation Mechanisms. The paper had been developed in response to the Committee's decision in the Fifth Triennial Review to initiate work on developing practical guidelines on how to choose and design efficient and effective trade facilitation mechanism (G/TBT/26 para 19(c)). In New Zealand's view, more work was needed, and it was timely to proceed on this work in the context of the Sixth Triennial Review, so she urged delegations to revisit this paper and she also urged Members offer case studies and examples, as the US had just done. This was necessary to ensure that the guidelines were rooted in real life experience.

309. The representative of the European Union expressed his delegation's interest in considering the link between GRP and conformity assessment. He intended to provide the Committee with a contribution showing how the application of GRP to conformity assessment could minimize burdens on economic operators arising from conformity assessment procedures. The focus would be on sharing the EU experience in systemizing relevant criteria for the choice of appropriate conformity assessment procedure in a given risk management context. This was an important strand of work for the Committee. Indeed, it was very similar to the work in the GRP context, which was also about identifying mechanisms that could facilitate the acceptance of conformity assessment results without WTO Members privileging one approach over another. For instance, the EU intended to show that by applying GRP in its system it had progressively expanded the areas covered by Supplier's Declaration of Conformity (SDoC), which by definition eliminated any need for establishing formal mechanisms for the acceptance of results (e.g., government to government).

310. The representative of Mexico noted that Articles 5, 7, 8 and 10 of the Agreement established obligations of a both substantive nature and procedural (transparency). Mexico was of the view that the Committee needed to continue its exchange of experiences as this would then serve as a basis to draft guidelines that would contain the requirements that conformity assessment procedures needed to fulfil to comply with the provisions established in the Agreement. Mexico was of the view that the Sixth Triennial Review should produce an outcome that would give preference to technical assistance provided to Members in the area of conformity assessment.

311. The representative of India agreed that the ILAC MRA and the IAF MLA were indeed very useful international systems for conformity assessment, especially in the light of the presentation made by both agencies at an earlier TBT Committee meeting. India nevertheless stressed the importance of focusing on the development dimension. Many existing conformity assessment schemes (laboratory certification agencies and inspection agencies) were, in India's understanding, primarily centered around developed Members. Moreover, the developing country Members who were endeavouring to develop this capacity was faced with a complex choice. Either they needed to join the multilateral recognition arrangement or they had to actually develop their own laboratory infrastructure. Hence, Mexico had touched upon a very important point: the need for technical assistance in order to develop this infrastructure.

312. The representative of Colombia supported Mexico's position, and that of India, on the need to promote the conformance infrastructure in developing countries.

313. The Chairperson said that there was certainly scope to bring work forward in this area and she encouraged Members to come forward with more experiences and ideas.

4. Transparency

314. The representative of Japan noted that his delegation was preparing a proposal on transparency. He wished to highlight some of the points in the forthcoming submission. He stressed that the foremost objective of the submission would be to promote an improvement and strengthening of the implementation of the TBT Agreement's transparency provisions. He noted that Japan sometimes received no responses to inquiries or comments regarding TBT notifications. Members had already shared the importance of responding to comments in the past triennial reviews. One example was paragraph 42(a) of the Fifth Triennial Review (G/TBT/26), where the Committee recommended (on a voluntary basis) that Members respond to comments in writing. Japan wished to reaffirm this recommendation and urge Members to put this recommendation into practice. In addition, in order to enhance transparency, answering all reasonable enquiries in a timely manner needed to be encouraged – and there might be benefit to setting a standard period from receipt of comments to response. In addition, there had been several cases where Members had not answered reasonable enquiries from Japan. From the point of improving transparency, the Committee could recommend that the replies to such enquiries be required.

315. In the area of languages, Japan had experienced situations where their own written comments (in English) had not been accepted because the responding country would only accept comments in Spanish. In such cases, Japan had difficulty in providing a translated comment within the allotted period of time. Based on this experience, it could be beneficial to recommend that if a comment was provided in one of the three WTO official languages and it reached the Enquiry Points within the allotted period for comment, Members would have to accept the translated version of the comment even after the end of the standard period.

316. In respect of the Code of Good Practice and in particular paragraph annex 3-L, which stated: "Before adopting a standard, the standardizing body shall allow a period of at least 60 days for the submission of comments on the draft standard by interested parties within the territory of a Member of the WTO." With a view to enhancing transparency *in standards development*, it would be useful, Japan argued, to share experiences and best practices on the implementation of this provision by Members' standardizing bodies. For instance, the Japanese Industrial Standards Committee (JISC) had the practice of receiving public comments for at least 60 days via a website when planning new standards. When considered these points, it would be a possible recommendation that, through the TBT committee's future work, Members could share and review experiences of implementation of public comment procedures by standardising bodies of Member states.

317. The representative of Mexico emphasized the importance of transparency, and proposed that the Sixth Triennial Review should issue recommendations for the strict compliance with obligations in terms of transparency and an improvement of relevant notifications procedures. In particular, the Committee could consider: improving access to unofficial translations; the creation of a website for comments and answers on notifications; making it an obligation for the responding Member to provide its response in writing within a period of time. A proposal with more detail from Mexico was forthcoming.

318. The representative of the United States also stressed the critical importance of considering transparency in the context of the Sixth Triennial Review and supported ideas that had been put on the table. The US was particularly interested in how governments had put in place mechanisms for consultation that had enabled coordination with other ministries on the process of enquiries and notifications; a good example of this was South Africa's revision of its 15.2 Statement (contained in document (G/TBT/2/Add.60/Rev.1, dated 14 March 2012). This was important not only because

there were obligations on transparency but because transparency was a core element in providing predictability and certainty to economic actors in the market place, and enabling the understanding of the requirements in a given Member or market and thereby facilitating trade and economic growth itself.

319. The representative of the European Union recalled that there was already a substantial body of decisions and recommendations in the area of transparency. Nevertheless, there were still problems in implementation. The EU shared Japan's and Mexico practical experiences and referred, in this regard, to its submission for the Fifth Triennial Review[33]. The EU supported Japan's statement on the absence of written replies from certain Enquiry Points and the refusal to accept comments written in English. It also supported the points made by Mexico and noted that with respect to access to unofficial translations, indeed there were existing recommendations that could be reaffirmed.

320. The EU believed that improvements could be made to the WTO TBT IMS.[34] Transparency and the implementation of existing recommendations could be improved if more effort was put in to this system. Such improvements could, for instance, help avoid certain previous discussions about *when* the 60 day period for comments should start: when the text had been sent to the Secretariat or when it was published and accessible to all Members (on the WTO website)? There had been no agreement on this point in the framework of the Fifth Triennial Review, but the question would be solved in practice if the time between transmission to the Secretariat and the publication on the WTO website would be further reduced. The EU was of the view that it was within the realm of IT possibility to enable Members to notify electronically and the Secretariat to publish a notification at the latest the day after submission. The EU was also keen to find ways to facilitate the work of the enquiry points considering the high number of notifications received. Improvements to the WTO TBT IMS could perhaps be make the process more automatic; avoid having one person checking each notification to identify what products were covered by the notification, or to open every single addendum to see if it covered a new notification that would then have to be circulated to interested stakeholders. Agreeing on a common classification of product categories could enable the IT system to send notifications directly to interested authorities or stakeholders without necessitating any work from the enquiry point. The EU was working on ideas and would submit a paper soon.

D. OTHER MATTERS

1. Sixth Triennial Review: Reminder of deadlines

321. The Chairperson, in concluding the discussion on the exchange of experiences, reminded delegations of the agreed timeline for the preparation of the Sixth Triennial Review (contained in G/TBT/M/55, para. 299). In this respect, she stressed that the deadline for the submission of substantive proposals in the Sixth Triennial Review was 1 June 2012.

III. ANNUAL REVIEW OF THE TBT AGREEMENT (G/TBT/31)

322. The Committee adopted the Seventeenth Annual Review of the Implementation and Operation of the TBT Agreement, as contained in document G/TBT/31.

323. The Chairperson drew the Committee's attention to two lists prepared by the Secretariat to facilitate consideration of matters relating to the operation of the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 of the TBT Agreement. The first list, contained in document G/TBT/CS/1/Add.16, compiles the standardizing bodies that have accepted the Code in the period under review. The second list, contained in document G/TBT/CS/2/Rev.18

[33] G/TBT/W/309.
[34] http://tbtims.wto.org/.

compiles all the standardizing bodies that have accepted the Code since 1 January 1995. Since 1 January 1995, 162 standardizing bodies from 122 Members have accepted the Code of Good Practice. In addition, the Chairman noted that the ISO/IEC Information Centre had prepared the Seventeenth Edition of the WTO TBT Standards Code Directory[35], which contains information received according to paragraphs C and J of the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 of the Agreement.

IV. TECHNICAL ASSISTANCE

324. The representative of South Africa provided the Committee with information on Technical assistance activities undertaken.[36]

V. UPDATING BY OBSERVERS

325. The representatives of the UNECE, Codex and IEC updated the Committee on their on-going activities in developing countries and work related to TBT.[37]

VI. OTHER BUSINESS

326. The representative of the European Union informed the Committee of the change in the nomenclature of its notifications. From 1 November 2011, EU notifications were identified with the symbol G/TBT/N/EU/xxx.

VII. DATE OF NEXT MEETING

327. The next regular meeting of the Committee is scheduled for 13-15 June 2012.

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[35] Available at the ISO IEC Information Centre http://www.standardsinfo.net/info/inttrade.html.
[36] G/TBT/GEN/130.
[37] G/TBT/GEN/131, G/TBT/GEN/132, http://www.iec.ch/about/globalreach/partners/international/pdf_wto/iec_wto_2012_03_en.pdf.