WORLD TRADE ORGANIZATION

RESTRICTED

G/TBT/M/57
18 September 2012

(12-5032)

Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 13-15 JUNE 2012

Chairperson: Mr. Salim Lahjomri

Note by the Secretariat[1]

I. ADOPTION OF THE AGENDA

1. The Committee adopted the agenda contained in WTO/AIR/3942.

II. ELECTION OF CHAIRPERSON

2. The Committee elected Mr. Salim Lahjomri (Morocco) as chairman.

III. IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

A. STATEMENTS FROM MEMBERS UNDER ARTICLE 15.2

3. The Chairman said that the list of statements submitted under Article 15.2 of the TBT Agreement was contained in document G/TBT/GEN/1/Rev.10, dated 22 February 2011. He noted

[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.

that, since the last meeting of the Committee, Ukraine (G/TBT/2/Add.100/Rev.2) and Malaysia (G/TBT/2/Add.9/Rev.31) had submitted revisions to their original statements. In total, since 1995, 126 Members had submitted at least one Statement on Implementation under Article 15.2. He recalled that this information was available, and regularly updated, on the TBT Information Management System (hereafter "the TBT IMS"[2]).

B. SPECIFIC TRADE CONCERNS

(a) New Concerns

(i) European Union – Draft Implementing Regulations amending Regulation (EC) No. 607/2009 laying down detailed rules for the application of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products (G/TBT/N/EU/44)

3. The representative of South Africa had previously expressed his delegation's concerns regarding the allergen labelling regulations for wine, including by joining the World Wine Trade Group. As Europe was a very important market, South African producers should be informed of the detailed labelling requirements within a reasonable timeframe to ensure compliance. Unfortunately, no clarity had yet been provided on the language to be used in each EU member with regard to the allergens concerned, nor was it clear whether pictograms were sufficient when accompanied by a statement in one language, or whether the pictogram should be in black and white or grey scale. The 30 June 2012 deadline was problematic for South African producers because the 2012 wine harvest had already been completed in the southern hemisphere and labelling had already commenced. Furthermore, consignments of wine could take over a month to ship from South Africa to Europe. Without guidance and clarity on the labelling for individual EU member states, it would be difficult for exporters to comply with the current deadline. Once the regulation was clarified, exporters would still require between three and six months to source compliant labels. The fact that the measure would be implemented just three days after publication in the Official Journal of the European Union was likely to cause significant trade disruption, and all label stock not affixed by 30 June 2012 would have to be destroyed, causing significant financial losses. Article 2.12 of the Agreement required a "reasonable interval" between the publication of technical regulations and their entry into force. Furthermore, Ministers decided at the Fourth Ministerial Conference in Doha, that the phrase "reasonable interval" shall be understood to mean normally a period not less than 6 months, a decision also adopted by the TBT Committee.

4. He recalled the "special and differential treatment" provisions in Article 12.3 of the TBT Agreement. South Africa, therefore, requested the postponement of the implementation date for the labelling regulation of at least six months to allow a reasonable chance of compliance by South African exporters.

5. The representative of New Zealand stated that the EU had the responsibility to ensure that its rules were applied transparently thus allowing for commercial certainty. Since a prior exemption was extended in late 2009, it was known that wines labelled after 30 June 2012 would be required to bear compulsory allergen labels. Despite multiple attempts by both government and industry, no information on how these regulations would be implemented had been obtained until the notification to the TBT Committee on 25 June 2012 - only five weeks prior to implementation. This was significantly less time than the minimum period of six months recommended by the Committee under Article 2.12. Only now was New Zealand aware that limits of detection were specified. However, the required ELISA testing kits to analyse wines for detectable limits of Casein and Ovalbumin were not commercially available in New Zealand and could not be ordered and delivered before 30 June.

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

Furthermore, the components of these tests have biosecurity implications. This meant that even wines with safe levels would nevertheless have to be labelled as allergenic.

6. The implementation date of 1 July fell during the normal bottling season for New Zealand and other Southern Hemisphere producers. It would take weeks to redesign labels, which were generally ordered 3 months prior to bottling. Some bottles could be labelled before 30 June, but consumers in the EU might find it confusing that the same wine could appear on shelves with or without the warning labels depending on when they were bottled. The EU's failure to provide adequate information in good time would cause significant commercial injury to New Zealand's wine industry and to other Southern Hemisphere producers who were operating in the EU market in good faith. This injury would happen because: (i) the considerable expense of having to re-label bottles to comply with the new guidelines with only five weeks' notice; (ii) Southern Hemisphere products would be the first on the market with these allergen labels and would bear the brunt of any adverse consumer reaction; (iii) the relevant ELISA tests were not yet available in the Southern Hemisphere, which meant that producers in that part of the world would not be able to demonstrate that their products did not contain detectable allergens (whereas the tests would likely be widely available for EU producers when they release their 2012 vintage wines, creating a source of considerable prejudice to Southern Hemisphere producers since they would have to label products that their EU counterparts would not); and (iv) the EU producers would still be entitled to an exemption for unlabelled products that were "in the market" after 30 June 2012, an exemption that effectively covered all "stock on hand" (whether or not it was bottled or labelled). Like the tests, the application of this exemption would be highly prejudicial since Southern Hemisphere producers would not be able to take advantage of it except in the very limited case where bulk wine had landed in the EU before 30 June. Given shipping time, no Southern Hemisphere producer would be able to take advantage of this exemption by shipping bulk wine after notice of the new regulation had been provided because these products would arrive too late in the EU market.

7. Thus, the only way to avoid significant prejudice to non-EU producers would be to exempt all wine produced before 30 June 2012 until stocks were exhausted. This would be no more than an application to third country producers of the "stock on hand" exception that already applied within the EU market, in line with the national treatment obligations. This prejudice was levelled at New Zealand producers despite repeated attempts to comply in good faith with the regulations. New Zealand urged the EU to push back the implementation date of this regulation to a reasonable interval of not less than six months.

8. The representative of Australia noted that in 2011 Australia exported over 363 million litres of wine to the EU and had a significant commercial interest in this market, so it was vital trade not be disrupted. Australia was therefore interested in the European Commission's proposed labelling requirements for allergens in wine. Australia acknowledged the importance of providing accurate information to consumers regarding allergens in wine as Article 2 of the TBT Agreement provided for measures to help protect human health. However, Australia was also concerned with the lack of transparency surrounding the EU's approach to these new requirements for various reasons: (i) the 30 day comment period was half of what WTO Members normally provide; (ii) the proposed date of adoption - June 2012 – allowed wine producers in third countries almost no time to amend their labels before the regulation took effect; (iii) such an approach was inconsistent with the decision of the TBT Committee in 2002 that Members should normally provide a period of not less than 6 months before bringing a technical regulation into force so as to allow time for producers to adapt their products or methods of production to the requirements; (iii) Article 2.9.2 of the TBT Agreement required that notifications take place at an early appropriate stage, when amendments could still be introduced and comments taken into account.

9. Australia was particularly concerned with the impact this regulation would have on wine producers in the Southern Hemisphere, where the entire 2012 southern hemisphere harvest was

already completed and labels were already prepared for wines that were made and not yet bottled. The uncertainty of these labelling requirements under the EU measure was likely to cause a disruption to trade for wines from this region. Australia asked whether the information the EU was seeking must be provided in multiple languages, or whether the indicated pictograms were sufficient when accompanied by a statement in one language. Australia also noted the uncertainty of the labelling or certification requirements for non-vintage wines under the proposed EU regulation and asked for clarification.

10. Australia recalled it had already sought from the EU information and clarification on the requirements in the proposed regulation on numerous occasions, both individually and as a member of the World Wine Trade Group. However, to date no such clarifications had been received, so Australia urged the EU to provide them as soon as possible. Given the significant impact that this regulation would have on wine producers in third countries, coupled with the late notification of the content of the regulation, Australia requested that the EU delay its implementation by between three to six months.

11. The representative of Canada associated his delegation with the previous concerns and asked the EU for more clarification as to how precisely the labels would be presented and the languages applied under the measure: would a producer just use one language or it could use one language together with the pictogram.

12. The representative of Argentina stated that, as a member of the World Wine Trade Group, Argentina had asked the European Commission, on different occasions and with due anticipation, for clarifications on the implementation of the measure. These questions concerned the form, written style and idiom to be included in the bottle's pictograms and about whether wine bottled prior to the entry into force of the measure would be exempt from such requirements. He explained that such clarifications were necessary so that the Argentine wine industry would be able to adapt to these requirements with sufficient time. This was particularly important given the timing of the 2012 Southern Hemisphere grape harvest and this new EU label had to be ready at least one month before the date of entry into force of measure. However, the lack of response on the part of the EU to these clarifications, he said, resulted in a situation under which the regulation to be applied as of 1 July 2012 would constitute an unnecessary barrier to imports of Argentinean wine into the European market, in violation of Articles 2.9.2, 2.9.3, 2.12 and 11 of the TBT Agreement.

13. Argentina therefore asked the EU to postpone the entry into force of the measure establishing labelling information requirements for allergens in wines until the European Commission clarified the above-indicated clarifications. Taking into account that Southern Hemisphere grapes had already been harvested this year, Argentina also asked that wine produced (either totally or partially) with those grapes, be exempt from the measure's new label requirements so as not to disrupt wine exports to Europe.

14. The representative from the United States said that the draft implementing regulation would require statements with respect to allergens to appear on the label for wine in which sulphites milk or milk-based products, and egg or egg-based products were used in the making of the beverage. The measure also allowed the statement to be complemented by a pictogram. She asked the EU in what language must the allergens statement be made: could it be done in English on all labels? Was there a minimum size for the pictograms?

15. The representative of the European Union noted that the obligation to label allergens, when the ingredients used during production were still present in the final product, was not new: it existed since 2007. However, in order to allow producers sufficient time to adapt, a transition period to comply with the new labelling requirements was provided until 31 May 2009. This transitional period was extended for wines twice (most recently, in December 2010) and an additional extension

was provided by Commission Regulation 1266/2010 for products placed on the market or labelled before 1st July 2012, until stocks were exhausted. She explained that one of the objectives of this latest exemption was to allow the European Commission and the European Food Safety Authority to examine the requests received from the wine industry for exemptions of certain milk and egg-based ingredients from labelling rules. The European Food Safety Authority, in its opinions of October 2011, found that wines containing these ingredients could trigger adverse effects in persons who suffer from an allergy to those ingredients. As a result of these findings, the Commission rejected the requests for exemptions. Furthermore, no additional transitional period (beyond 30 June 2012) was foreseen.

16. She also explained that the draft implementing Regulation, which was notified as document G/TBT/N/EU/44, intended to clarify the applicable rules with regard the labelling of allergens in wine, in particular by providing: (i) the terms concerning sulphites, milk and milk-based products and eggs and egg-based products, which shall be used, and; (ii) the pictograms that producers could use if one or more of the allergens were still present in the product sold to the consumers. The measure also clarified which products were covered by these requirements. In particular, the draft Regulation indicated that only wines produced with grapes harvested as from 2012 and labelled after 30 June 2012 were concerned by the compulsory labelling of milk and egg allergens. The reason for this short period of time for comments on this notification was because such requirements were not new. Further, the adoption of the Regulation until 30 June 2012, the date when the exemption from labelling was set to expire, was important in order to avoid trade disruptions for those wines which were not covered by this labelling requirement.

17. She informed the Committee that the European Commission had had numerous bilateral exchanges with countries concerned over the past few months, including with Australia and New Zealand, and had taken their concerns into account when developing the draft Regulation – most notably by clarifying that wines from grapes harvested before or in 2012, which were labelled or placed on the EU market before 1 July 2012, would not be concerned by these requirements. Finally, the EU invited all interested delegations to submit comments to the TBT notification until the deadline of 24 June 2012.

(ii) Spain – Ministerial Order of the Government of Spain IET/822/2012, published on 21 April 2012 and in force as of 22 April 2012

18. The representative of Argentina expressed concern with the prohibitive and distorting trade impacts of the Spanish measure, which *de facto* prohibited imports of biodiesel produced outside the EU by allowing the use of biodiesel produced exclusively in plants situated in Spain or in any other member State of the EU. This prohibition was established by the Spanish measure (Ministerial Order IET/822/2012) by regulating the allocation of biodiesel production volumes in order to comply with the mandatory biofuel consumption objectives of the EU. For this purpose, the Order established a certification procedure to certify that the biodiesel was totally produced in plants located within EU territory. This measure affected Argentina in particular because Argentina was Spain's principal supplier of biodiesel. It was remarkable that the measure was only applied to biodiesel and not to other biofuels, especially given that Directive EC/2009/28 (which dealt with the promotion of renewables and was the basis of the Spanish measure) covered various sources of renewable energy, such as biogas and bio-ethanol. Since Argentina was the Spanish market's principal biodiesel supplier, it is clear that the measure's main objective was to keep Argentina out of that market. This was therefore a measure that unjustifiably discriminated between biodiesel from EU/Spain and from any other origin, in violation of the most basic principles of the multilateral trade system - National Treatment and MFN - which were enshrined in Article 2.1 of the TBT Agreement. Additionally, the measure also violated Article 2.2 of the Agreement by creating an unnecessary obstacle to the international trade in biofuels.

19. He recalled that while EU Directive EC/2009/28 established certain biofuel sustainability criteria, it did not restrict, much less ban, market access to suppliers of such fuels. Nor did such Directive require that the supply of biofuels be only made by EU producers. Thus, the Spanish measure was in contradiction with the EU rules. He also noted that Argentina followed the conception and evolution of this European Directive and gave the EU sufficient scientific evidence showing that Argentina's biodiesel clearly complied with the sustainability criteria included therein. Therefore, Argentinean biodiesel and biodiesel produced in Spain and in other EU members were "like product".

20. He also expressed concern with the fact that Spain did not notify this measure given that it would have a significant impact on international trade. Thus Spain violated Article 2.9 of the TBT Agreement. As a result of the lack of notification, Spain did not grant other Members time to make comments or begin discussions with its authorities. Further, given that the main suppliers of biodiesel to Spain were developing countries, Spain did not comply with the special and differential treatment provisions of Article 12 of the TBT Agreement, especially Article 12.3. In this respect, Argentina noted that the measure would have the effect of stopping developing countries' exports from ascending the value chain. Indeed, the measure would limit these countries to the role of mere raw material providers, thus imposing serious obstacles for their industrialization.

21. He concluded by stating that the measure was a technical barrier to trade the sole objective of which was to protect Spanish producers while unjustifiably discriminating against non-EU biofuel producers. Argentina noted that this measure was adopted, without any scientific justification, based on a supposedly environmental objective. However, given that the measure evidently did not pursue any such objective, but rather to harm argentine biodiesel exports, Argentina expressed concern with a growing tendency of Members enacting protectionist measures with the pretence of having environmental objectives. Argentina asked Spain to take immediate steps to respond to these concerns so as to comply with its WTO obligations and requested the EU to ensure that its member States complied with WTO obligations.

22. The representative of the European Union stated that the Spanish Ministerial Order related to the allocation of production volumes for calculating compliance with the objectives set by the Renewable Energy Directive. These allocation procedures fell outside the scope of the TBT Agreement and therefore this Committee was not an appropriate forum for either discussing this issue or providing a reply to Argentina's questions.

(iii) United States – Standards of Identity for Pisco and Cognac (G/TBT/N/USA/697)

23. The representative of Chile expressed concern with the proposed amendments to the regulation as it would treat Pisco as a type of brandy, a re-classification which was not in accordance with the existing international definition of Pisco. While brandy and Pisco were both alcoholic beverages, they were fundamentally different wine products with respect to their respective production process. The US standards required that brandy be bottled with at least 40 per cent alcohol by volume. Pisco would then have to meet such condition in order to have that specific label. However, the measure disregarded the fact the Pisco could contain from 32 to 40 per cent alcohol by volume. Chile asked the US to consider in their final version of this measure these comments as well as those made during the public consultation.

24. The representative of Peru stated that on 29 May 2012 his delegation submitted some comments to the *US Alcohol and Tobacco Tax and Trade Bureau* (TTB) with respect to the this proposed measure, which included Pisco as a type of brandy that had to be produced in accordance with the laws and regulations of its country of origin. In its previous comments to the TTB Peru referred to Article 5.22 of the Federal Code (paragraph K3), which indicated that the existing regulation already prohibited the importation and commercialization of products named Pisco unless

they came from the place of origin of Pisco. With respect to the proposed amendment, Peru sought confirmation to its understanding that the labelling approval certificate (under sections 27CFR.5.51 and 5.55 of the Federal Regulation) would be applicable to *both* imported and domestically commercialized products, in conformity with the TBT Article 2.1.

25. With respect to the origin of the name of "Pisco", Peru noted that it already sent this information to the TTB with the objective of explaining the pre-Hispanic meaning of this term in Quechua. "Pisco" was a term used by the Incas to identify a valley, a community and the pottery used to storage distilled spirits. Information was also given about the use of the term "Pisco" by the Spanish as from mid XVI century to designate the river, people and port in the above-mentioned valley. Further information was also given to the TTB about the peculiar making process of Peruvian Pisco, which included the following steps: harvest, marinating, pressing, fermentation, distillation and, finally, the cleaning of the final product. Peru also provided information showing that, according to Peruvian regulations, there were only eight types of grapes that could be used to make Pisco: *Quebranta*, *Negra Criolla*, *Mollar*, *Uvina*, *Italia*, *Moscatel*, *Albilla* and *Torontel*. As a result of all this process, Peruvian Pisco had an average alcoholic volume of more than 40 per cent, which was consistent with the limit included in the proposed US standard. Given the ingredients, the particular production method and the unique characteristics of the final product, Peru suggested the US proposed standard be amended so as to make a distinction between Pisco from Peru and other brandies made from grapes or wine.

26. The representative of the United States clarified that the proposed rule was intended to state that Pisco could only come from Peru or Chile. The US explained why including Pisco as a type within the class of brandy was the most appropriate approach. First, the class for brandy covered alcoholic distillates from the fermented juice, mash, or wine of fruit: Pisco was indeed a distillate of grapes. Therefore, it would not be appropriate to create a new class from a distilled spirit that was derived from an agricultural commodity that was already covered by an existing class designation. Second, the US regulation had recognized Pisco as a brandy since 1933, as evidenced by its listing in 27 CFR 5.22(k)(3) as "Pisco brandy". Third, this allowed the US to specifically state that Pisco must be produced in accordance with the laws and regulations of Peru or Chile, the countries of origin. This addition of a new type of designation for Pisco within an already existing class (Brandy) was also consistent with the recognition in US regulations of other distinctive products of foreign countries (e.g., cognac, Scotch whisky, and Irish whisky). Finally, this addition would clarify that the product may be labelled simply as "Pisco" rather than as "Pisco brandy".

27. She also noted that the Peruvian and Chilean standards for Pisco production allowed Pisco to be bottled at as little as 38 per cent alcohol by volume and 30 per cent alcohol by volume, respectively. However, to be consistent with the US standards of identity for distilled spirits, which required that any neutral spirits (including vodka, whisky, gin, brandy, rum and tequila) be bottled at not less than 80° proof (or 40 per cent alcohol by volume), Pisco bottled below that limit could not be labelled with that type designation. On the other hand, the US allowed, and would continue to allow, products bottled at *less* than 80° proof to be labelled with a truthful and adequate statement of composition or as "diluted". The US believed it was appropriate to apply this 80° proof standard for brandy to products of foreign countries so that the same standard applied to domestic and foreign producers.

(iv) Korea – A Draft of Regulation for Measurement of Energy Efficiency of Tyres for Motor Vehicles, and Its Rating and Identification (G/TBT/N/KOR/319, G/TBT/N/KOR/319/Add.1)

28. The representative of Japan stated the Korean measure provided two methods of conformity assessment: by an authorized testing body or by self-measurement. Japanese tyre manufacturers selected the latter approach. However, in either case an appropriate period was necessary, in accordance to Article 5.9 of the TBT Agreement, between the publication and entry into force of the

measure, which was 1 December 2012 for passenger car tyres. Self-measurement required certification for the drum alignment of test facilities in addition to the procedure by the accredited testing body. However, according to Japanese tyre manufacturers, this procedure required several months and it was therefore not possible to deal with this issue by 1 December 2012. Japan thus requested Korea to postpone the entry into force of the measure for passenger car tyres by one year, i.e. until 1 December 2013, and to set a sufficient period to smoothly proceed with the procedures for foreign tyre manufacturers including Japanese tyre manufacturers.

29. He also said that, according to Article 5.2.3 of the TBT Agreement, the information required for conformity assessment procedure was limited to information necessary to assess the conformity and to determine the fees. However, according to Japanese tyre manufacturers, the documents required by the Korean Ministry of Knowledge Economy included confidential and personal information not related to the safety of the products. These Japanese manufacturers had indicated to the Korean Government that they would provide these data upon the event of a factory audit by the Ministry of Knowledge Economy. In response, the Korean authorities stated that an audit could not be conducted unless these documents were submitted, making it therefore impossible to schedule the audit. Consequently, Japan requested Korea to explain why under the measures confidential and personal information was necessary for conformity assessment. Japan also requested that an appropriate guideline for providing information be prepared.

30. Finally, he stated that the reason why Korean tyre manufacturers had almost concluded dealing with the system was because they were able to conduct tests at the accredited testing bodies. If this system would be enforced in its current format, it would possibly constitute a technical barrier given the discrimination between domestic and foreign tyre manufacturers. Taking the above into consideration, the Japanese Government requested the Korean Government to take rational measures.

31. The representative of the European Union shared Japan's concerns and asked Korea for an update on the implementation timeline of the measure as well as to clarify whether testing values would be made public on the website of the relevant Korean authority.

32. The representative of Korea responded that Korea recognized two kinds of testing bodies: "Authorized Testing Bodies" (mentioned in Article 6) and "Independent Testing Bodies" (mentioned in Article 8). As set forth in Article 7, tyre manufacturers, which had their own experts and testing facilities, could apply for approval as Independent Testing Bodies. The Korean government's role would then include the reviewing of applications, performing of an on-site inspection, and the approval of qualified applicants.

33. Regarding the request to extend the implementation date and matching the implementation date with UNECE regulation, Korea explained that the measure was notified on 12 August 2011 and was announced on 14 November 2011 and that it would enter into force in December 2012. Korea therefore believed it granted sufficient time and that there was no need to extend the implementation date.

34. With regard to the concerns with the submission of confidential and personal information, Korea clarified that the Ministry of Knowledge Economy only required minimum information on facilities, manpower status and working procedures in order to review the competence of the testing bodies and the reliability of test results.

35. Finally, with respect to the EU's question on the publication of testing values, Korea responded that, pursuant to the Energy Efficiency Law, it was planning to publish its grade and testing values on KEMCO's website. This practice was applied not only to tyres but also other products such as refrigerators and motor vehicles. This was because Korea believed that customers had a right to information on what they buy. There was therefore no reason to exempt tyres from this practice.

(v) Viet Nam – Regulations relating to liquor production and trading

36. The representative of Australia expressed her delegation's concern that, if implemented, the revised Decree 40 on liquor production and trading could negatively affect exports of Australian wine to Viet Nam, particularly for small and medium sized producers. Australia understood the revised Decree 40 included a requirement for "import stamps" to be affixed to all packages of alcoholic products at the point of production overseas, before exportation to Viet Nam. Under the proposed new arrangements, a limited number of importers of alcoholic beverages would be given, and be responsible for, a registered quantity of import stamps for their import business. Importers and exporters would then need to ensure that the stamps were affixed to packaging units of alcoholic products intended for Viet Nam. While the decree had been under development for some time, and was now in its 14th draft, it was still not notified to the WTO. Australia recalled that the notification of proposed measures at an early appropriate stage, together with an indication of their objective and rationale, was essential so as to allow comments to be taken into account and amendments to be introduced, before the proposed measures entered into force. Australia therefore urged Vietnam to notify Decree 40 to the WTO so that concerns could be taken into account when finalizing the final version of the measure. In making this notification, Australia asked Viet Nam to clarify what objective Decree 40 was intended to achieve and how the proposed measures would fulfil such objective. Australia also asked what alternative measures Viet Nam had considered to achieve its objective.

37. Australia also asked Viet Nam to provide an official translation of the proposed Decree 40 in order to allow WTO Members to become acquainted with this technical regulation. On the substance of Decree 40, Australia asked how the proposed liquor product trading licenses would work and why Viet Nam considered it necessary to limit the number of available licenses for liquor trading. Australia also asked clarification on how the "import stamps" system would operate and whether the import stamp system would differ from the stamps for *domestically* produced products. Australia appreciated Viet Nam's willingness to discuss the issues bilaterally.

38. The representative of the European Union shared Australia's concerns with regard to the draft Decree, in particular its Article 15, which required the affixing of fiscal stamps in the country of exportation, or at the production site, starting on 1 July 2013. This new requirement of affixing such stamps in the country of origin would entail significant costs and logistical difficulties for EU producers. What were the reasons that prompted this proposed change of the current system, which allowed for the affixing of fiscal stamps at the point of import, particularly in bonded warehouses? Did Viet Nam consider that the current system posed any risks? If so, which were these risks? Furthermore, would Viet Nam allow under the proposed new rules affixing the fiscal stamps at any time before importation, including in hub ports? Could Viet Nam provide an update on the state of play of this revision (which was already modified numerous times), and a timeline for its adoption?

39. The representative of New Zealand urged Viet Nam to notify its proposed Decree to the TBT Committee as soon as possible so as to allow sufficient time for comments and consultations. New Zealand was particularly concerned about a draft Decree proposal to require foreign alcoholic beverage producers to affix import stamps to bottles at the point of production. This would place significant compliance burdens on foreign exporters given the time and effort needed to obtain and affix labels, especially when the final destination of product may not be clear at point of production. New Zealand urged Viet Nam to assess this proposed requirement against Article 2.2 of the TBT Agreement, which stipulated that technical regulations should not be more trade restrictive than necessary (given the alternative approach of affixing stamps in Viet Nam). New Zealand also requested Viet Nam to provide more information about its proposed approach to the labelling of alcoholic beverages for sale in Viet Nam so as to enable a full assessment against TBT principles.

40. The representative of the United States associate herself with the interventions of previous delegations in urging Viet Nam to notify the revision to Decree 40. The US also asked for a delay in the implementation of the measure until after the notification was made, the comment period passed and those comments were taken into account in the measure. The US also shared the view on the need to apply stamps in bonded warehouses, rather than at the country of origin of the product. The US also asked for more information on the measure and its application.

41. The representative of South Africa shared the same concerns voiced by previous delegations. He stated that the proposed measure would require import stamps be given in a pre-established quantity to importers. The importers should then ensure that theses stamps be affixed to all packaging of alcoholic products at a point where they were produced before being exported to Viet Nam. South Africa urged Viet Nam to notify this draft technical regulation as soon as possible so as to allow Members to comment on it before its final adoption. South Africa also requested Viet Nam to give Members an update on the status of this draft regulation.

42. The representatives of Canada and Chile shared the same concerns and questions expressed by the EU. Canada asked whether alternative ways for affixing stamps, other than in the country of production, were available. Chile asked Viet Nam to notify the regulation so as to allow Members to comment on it, and requested an update of the status of this regulation be provided.

43. The representative of Viet Nam said that all statements and concerns raised by Members would be forwarded to capital so an appropriate response could be prepared. He also asked these Members to provide it with more details on their concerns in written form. He informed that the revision of the Decree was undergoing a drafting process and Viet Nam was in the process of notifying it to the TBT Committee.

(vi) Indonesia – Draft modification to the technical regulation HK.00.05.52.4040 on food categories, published on 9 October 2006

44. The representative of Mexico expressed concern with the draft modification of the Indonesian technical regulation HK 00.05.52.4040 on alcoholic drinks, published on 9 October 2006. Mexico shared Indonesia's objective of protecting human health and lives. However, also concerned with the compatibility of this measure with the provisions of the TBT Agreement, on 22 May 2012 Mexico sent the following comment to Indonesia: that the measure might be more restrictive than necessary in order to comply with the stated legitimate objective because the proposed definition for Tequila did not have the necessary elements that guaranteed the respect of that designation of origin's integrity. In particular, the measure did not minimize possible risks of fraud to the consumer and actions of unfair competition with respect to Tequila, which should had also been recognized in Indonesia as designation of origin and as a distinctive product from Mexico. Likewise, Mexico pointed out that this regulation might violate Articles 2.2 and 2.9 of the TBT Agreement and that it might also have a negative impact on the productive sector. According to Mexico, Indonesia did not comply with the obligations under Article 2.9 because the measure was not notified to the TBT Committee. Mexico asked Indonesia for information with regard to the status of this draft modification and to inform if it would provide a formal reply to Mexico to the comments presented on 22 May 2012.

45. The representative of South Africa also noted that these draft regulations were not notified to the Committee and requested Indonesia for further information on it.

46. The representative of Indonesia first asked the title of the STC to be corrected to be on the "food category". He informed that this draft regulation was currently under a revision process and would be duly notified to the WTO. With respect to the Tequila definition, he explained that Indonesia took positive consideration with respect to the proposed definition by Mexico. Indonesia also recognised the context of the definition part of the disciplines of the TRIPS Agreement as well as

the WIPO IP Conventions. Indonesia noted the comments and was ready to engage in further bilateral consultations.

(vii) European Union – Amended limit values for soluble cadmium in toys (Directive 2012/7/EU)

47. The representative of China noted that the EU revised the content on toy safety of Part III, Annex II of Directive 2009/48/EC so as to modify the limit values for cadmium in toys. China recognized the efforts made by the UN, the WHO and other organizations in formulating regulations on tolerable cadmium intake for children, and appreciated the efforts of the EU to protect children from cadmium damage. However, China hoped that before implement this regulation the EU could consider the relationship between the "cadmium precipitation" and "cadmium content" of toys as well as the relationship between the daily intake and the source of cadmium. China conducted periodical research on toy safety and could cooperate with the EU on this issue, including by providing more scientific and rational assessment methods. China also believed that the expressions "dry", "brittle", "power-like" or "pliable and scrapped off" for toys caused difficulties for the implementation of the measure. China hoped the above expressions could be quantified via peeling strength and impact resistance in order to facilitate the enforcement of the production and inspection. While China appreciated the details on the measure explained by the EU during the bilateral meeting, China still needed written replies to the questions raised so they could be sent to its industries.

48. The representative of the European Union asked whether China's use of the term cadmium "precipitation" was, in fact, a reference to "migration". The EU then recalled that it had been the European legislator's choice to establish limit values for chemical substances expressed in terms of "migration". The use of "migration" instead of "content" was meant to focus on children's real exposure to the substance. "Content" referred to situations when "a substance [was] present in a toy". However, there were instances in which the substance would not "migrate", for instance if the relevant toy parts were not accessible to children when the toy was used as intended or in a foreseeable way (taking into account children's behaviour). In such cases, children would not be exposed and, consequently, it would not be necessary to establish limits. Migration limits for cadmium, as well as for other 18 elements, had been established in the new toy safety Directive 2009/48/EC, based on the best scientific evidence available at the time. This evidence originated from a study carried out by the Dutch National Institute for Public Health and the Environment (RIVM), details of which were provided in the preamble to Directive 2012/7/EC, at issue in this meeting. The Toy Safety Directive allowed the European Commission to amend such limits in order to take into account science evolution and assure alignment with the latest scientific evidence. The migration limits were set based on the assumption that exposure of children to chemicals in toys may not exceed a certain level, which was called "tolerable daily intake" (TDI). In this regard, since children were exposed to chemicals also via other sources than toys, only a percentage of the TDI should be allocated to toys.

49. As a general background leading to the amendment of the measure, the EU explained that cadmium and other chemical substances were particularly toxic and should not be intentionally used in those parts of toys that were accessible to children. Hence, the recommended allocation did not exceed 5 per cent of the TDI in order to ensure that only traces that were compatible with good manufacturing practice would be present. In January 2009, the European Food Safety Authority had issued an opinion recommending a lower TDI in view of new developments related to the toxicology of cadmium. As a result, the European Commission proceeded to an amendment of the limits for cadmium allowed under the Toy Safety Directive.

50. As to the relationship between the TDI and the source of cadmium, the EU explained that consideration was given to the amount of cadmium coming from toys compared to other sources of exposure, such as water and food. Thus, the legislation took into account the fact that children were more exposed to cadmium via water and food than via toys. On a conservative basis, it was therefore established that only 5 per cent of the TDI could come from toys and that 95 per cent of cadmium

exposure came from other sources. It was true that the contribution of toys to exposure to cadmium was insignificant as compared to the overall exposure of this substance. However, it was precisely because children were already overexposed via food and water that it was necessary to regulate toys and reduce exposure from other sources than food.

51. As to the final question on how to apply the migration limits to the different types of materials, the EU referred China to the guidance document on the application of the new Toy Safety Directive, which was also available in Chinese and was publicly accessible on the website.[3] In this guidance document, each type of material was described and explained in detail. By setting different limits for each type of materials, the aim of the legislator was to show as much as possible the reality of the exposure scenarios so as to simplify economic operators' situation. The strictest limit concerned toys containing liquid materials, like finger paints, where exposure was direct and immediate (as opposed to toys containing "scraped off" materials, in which the exposure was less probable). In fact, children would have to scratch or bite those "scrap materials" with their fingers or teeth for a long time to be exposed to significant risks. Pages 107 to 114 of the guidance documents contained the most relevant information on the matter. The EU concluded stating that it was available to continue discussions with China in the framework of their bilateral dialogue on toy safety, including exchanging views on relevant scientific evidence.

(viii) European Union – Air conditioners, liquid chilling packages and heat pumps, with electrically driven compressors, for space heating and cooling. Testing and rating at part load conditions and calculation of seasonal performance (EN 14825)

52. The representative of the China stated that his delegations had some concerns with the European Standard EN 14825:2012, approved by CEN on 14 January 2012. First, this EU standard required measuring "seasonal energy efficiency ratio" (SEER) and "active mode seasonal energy efficiency ratio" (SEERon). However, for "invariable air-conditioners", it was hardly possible to achieve the specified 74 per cent, 47 per cent and 21 per cent of part load ratio conditions though on-off mode. So the maximum uncertainty of 10 per cent for the heating and cooling capacity is impossible to be met. This standard was not therefore applicable to "invariable air conditioners". As most air conditioners that were exported from China to the EU were "invariable air conditioners", the EU standard would be greatly problematic for Chinese manufactures and exporters. China hoped the EU would make available the necessary documents to take into account of the situation of "invariable air conditioners". China concluded by asking the EU to explain whether under the standard the method of measuring SEER was the "air enthalpy method", the "room-type calorimeter method" or both.

53. The representative of the European Union stated that the Commission Regulation implementing Directive 2009/125/EC with regard to ecodesign requirements for air conditioners and comfort fans (document G/TBT/N/EEC/362) stipulated that measurement of the product parameters on energy efficiency and sound power should be measured through reliable, accurate and reproducible measurement methods. These measurement methods took into account the recognised state of the art including, where available, harmonised standards adopted by the European standardisation bodies. The European Commission mandated on 18 February 2011 the European standardization bodies (CEN, CENELEC and ETSI) for standards in the field of air conditioners and comfort fans. The standards currently developed under this mandate, in particular EN 14825, at issue in the present meeting, were intended to become harmonised standards for the EU Regulations on ecodesign and energy labelling for air conditioners and comfort fans.

54. Regarding the specific questions raised by China on EN 14825, the EU first clarified that it had not yet been accepted by the European Commission as a harmonized standard. The EU

[3] http://ec.europa.eu/enterprise/sectors/toys/documents/guidance/index_en.htm

confirmed that EN 14825 applied to both invariable (on-off, fixed capacity) and variable air-conditioners (variable capacity). Furthermore, with regard to China's question of whether the method of measuring the SEER and SEERon was the "air enthalpy method" or the "calorimetric room testing method" or both, the EU noted that this question was currently under discussion within the relevant CEN technical committee. Measuring Seasonal Energy Efficiency Ratio with the air enthalpy methodology showed higher uncertainties and might not meet the tolerance criterion of 8 per cent to be applied during the verification procedure for market surveillance purposes.

(ix) European Union – Lists of substances prohibited and restricted in cosmetic products (2008/0025 COD and other related regulations)

55. The representative of China asked the EU to explain the scientific rationale for the maximum concentration of certain restricted substances in cosmetic products, especially those that were accidentally incorporated due to technical limitations. Was there a monitoring mechanism for these restricted substances?

56. The representative of the European Union explained that according to the EU Cosmetics Directive 76/768/EEC the manufacturer was fully responsible for the safety of cosmetic products placed on the EU market. Manufacturers had to carry out the safety assessment of the product in conformity with the legal requirements set out in the Directive, and had to prepare a product information file (the "safety file"). In this file, information had to be provided on the qualitative and quantitative composition of the product, physicochemical and microbiological specifications of ingredients and the product, manufacturing methods, safety assessment for the whole product and undesirable health effects. In addition to the safety responsibility of the manufacturers, the Cosmetics Directive regulated certain ingredients of high concern. These ingredients were listed in several annexes to the Directive. Annex II (the "List of Prohibited Substances") contained over 1350 substances which were banned for use in cosmetics. Annex III listed over 250 substances that were subject to specific restrictions and conditions. Substances used as colouring agents, preservatives or UV-filters were allowed in cosmetics only if listed in relevant annexes to the Directive (i.e. Annexes IV, VI and VII) after a proper safety assessment was carried out by the Scientific Committee on Consumer Safety (SCCS).

57. The EU also said that the existing regulatory dialogue on cosmetics between the European Commission services (DG SANCO) and China's State Food and Drug Administration (SFDA) was a good way to gain a better mutual understanding of the EU and Chinese cosmetics legislation, in particular with regard to safety assessment of cosmetic ingredients. This dialogue allowed the two sides to clarify a number of issues and find solutions to concrete problems. This dialog helped ensure a smooth trade flow in cosmetic products between the two regions and was also beneficial for consumer safety.

(x) United States – Application of third party testing requirements; reducing third party testing burdens (G/TBT/N/USA/659)

58. The representative of China still had some remaining concerns left after the bilateral meetings his delegation held with the US before this meeting. The measure required that children's products be tested by the third-party testing bodies which were recognized by the US Consumer Product Safety Commission (CPSC). As this could result in duplicative test and increased burden to enterprises, China suggested CPSC accept the testing bodies accredited according to ISO/IEC 17025 as the appropriate third-party testing bodies without imposing additional requirements. Moreover, as certain international standards (e.g. ISO 8124 and IEC 62115) and Chinese standards (e.g. China National Toy Standard GB 6675-2003) were equivalent to the US toy safety standard in certain items, China suggested CPSC to recognize items which were equivalent to US standards.

59. The representative of the United States explained that in October 2011 the Consumer Product Safety Commission (CPSC) completed its rule-making pursuant to implementation of the Consumer Product Safety Improvement Act of 2008 (CPSIA) by adopting a final rule that established protocols and standards with respect to certification and continued testing for children's products. The final rule also established requirements for labelling of consumer products to show that the product complied with the certification requirements under section 14(a) of the Consumer Product Safety Act (CPSA). The final rule implemented several sections of the CPSA, as amended by section 102(b) of the CPSIA. In November 2011, the CPSC issued a Federal Register Notice inviting public comments on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any existing CPSC consumer product safety rules, bans, standards, or regulations. For CPSC, third party testing requirements apply to most children's products that were subject to a children's product safety rule. The comments period closed on 23 January 2012.

60. She noted that that CPSC was reviewing all of the comments submitted by China, including a suggestion that CPSC take the testing bodies accredited in accordance with ISO/IEC 17025 as the applicable third-party testing bodies accepted by CPSC. With respect to the latter suggestion, she explained that the law governing the CPSC's third-party testing program required the CPSC to either adopt or create an accreditation process for labs that test children's products. The CPSC chose to use the existing global ILAC system as the basis for ensuring fair and transparent accreditations. With the exception of governmental and firewalled laboratories, which had additional requirements under the law, any laboratory with the proper accreditation by an ILAC signatory could join the CPSC's program. However, to be recognized as valid, all testing must be conducted in a lab in the CPSC's program. However, the CPSIA did not permit government laboratories to participate in the CPSC's program if the laboratory was accorded more favourable treatment than other conformity assessment bodies in the same nation who was accredited for the programme. Accordingly, CIQ laboratories would not qualify because CIQ test results were required in order to obtain export permits for many consumer products and also because CIQ centres were the only entities in China authorized to issue product safety and quality export permits. CPSC officials spoke in depth with AQSIQ (General Administration of Quality Supervision, Inspection and Quarantine) Chinese counterparts about this bilaterally and there appeared to be no misunderstanding about this matter. Although CIQ labs did not qualify under the new law, other Chinese laboratories were well represented in the testing programme. The CPSC listed a total of 110 Chinese labs in its programme and of those 25 had Chinese Government affiliation.

61. Finally, she stated that CPSC was considering China's request for ideas on how to reduce third-party testing burdens. These alternatives were being considered bearing in mind the need to maintain a high level of safety for children's products.

(xi) United States – Energy conservation program: energy conservation standards for residential refrigerators, refrigerator-freezers, and freezers (G/TBT/N/USA/583; G/TBT/N/USA/583/Add.1; G/TBT/N/USA/583/Add.1/Corr.1)

62. The representative of China stated that in October 2010 the US notified its "Energy Conservation Program Energy Conservation Standards for Residential Refrigerators, Refrigerator Freezers, and Freezers" (G/TBT/N/USA/583). According to these standards, the annual energy consumption requirements for some refrigerators remained almost unchanged, while those for other refrigerators decreased by 25 per cent or more. This did not occur when standard edition 1993 was upgraded to edition 2001. There was a considerable quantity of refrigerators exported to the US from China falling into the categories with great annual energy consumption decline. Therefore, Chinese refrigerator manufacturers would have to develop new products and improve the production process, which, in turn, would increase the cost and lower the competitiveness of these products. Furthermore, it would be difficult to meet these requirements in such a short period of time.

63. China acknowledged that the introduction of these standards had positive effects on energy conservation and environmental protection. However, China noted that the US failed to explain the reason why the annual decline ratio in the value of energy consumption for different types of refrigerators differed so much. The adjustment coefficient was not changed so greatly as to cause such a big difference. This left open the question as to whether there were double standards in energy consumption for different types of refrigerators. China urged the US to clarify these questions, take them into consideration and take the necessary measures to minimize the impact of the revised standards on international trade.

64. The representative of the United States responded that the proposed rule was notified to the WTO in November 2010 and the final rule was notified in September 2011 (G/TBT/N/USA/583/Add.1). China provided comments on the proposed rule. With respect to the final rule, the Department of Energy (DOE) amended energy conservation standards for residential refrigerators, refrigerator-freezers and freezers. These revised standards in some cases were based on updated and more accurate test procedures, thus explaining the differences that China referred to in its intervention. The new DOE standards would take effect in September 2014, which was three years from the notification of the final rule. These new standards ranged from 10 per cent to 30 per cent more efficient than the current minimum base line depending on the product class. China was correct that DOE adopted amended energy conservation standards for residential refrigerator products that were in most cases more stringent than the existing standards as well as more stringent than the current energy star requirements.

65. She explained - by way of background and in order to reflect the importance of energy efficiency to the US' larger environmental energy security and other policy goals - that the US maintained two major energy efficiency programmes for electrical appliances. The DOE set minimum energy requirements for all appliances sold on the market, while the Environmental Protection Agency (EPA) maintained a voluntary labelling programme to identify for consumers the most energy efficient products. In effect, the DOE programme pushed up the energy efficiency by lifting the floor, while the EPA voluntary programme pulled up energy efficiency from the top. DOE set the floor for energy efficiency in appliances through a formula that incorporated factors that related to technical feasibility, economic expense, the impact on competition and other factors that were identified in statute. Although they were distinct programmes, DOE and EPA closely coordinated the revisions to their respective programmes and, as the floor moved up to reflect technological advances, economic feasibility and other market factors, the EPA would respond. The current EPA standards for these products dated to 2008 and a process was now underway in EPA to revise those standards. The effective date of DOE standards was in 2014 and the energy star level was expected to be in step with the DOE requirements by that date.

(xii) Viet Nam – Decree No 38 Detailing the Implementation of Some Articles of Food Safety Law (G/SPS/VNM/27)

66. The representative of the United States noted her delegation's interest in Viet Nam's decree No. 38, which was notified to the SPS Committee as document SPS/VNM/27. The US requested Viet Nam to respond to its most recent set of comments that were provided after the signing of decree No. 38 into law. The US also requested Viet Nam to immediately delay the 11 June 2012 implementation date of the Decree until these concerns were addressed. The US further requested that Viet Nam to enter into technical discussions with the US and take further action to ensure that there would not be trade disruptions as a result of this measure.

67. The representative of Australia said that while her delegation supported Viet Nam's right to implement measures to protect the health of its consumers, it was also important that such measures not be more trade restrictive than necessary to achieve their stated objectives. Australia understood that Decree 38 was scheduled to enter into force on 11 July 2012 but there were still some conflicting

information as to how this measure would be implemented. Australia encouraged Viet Nam to delay the implementation of Decree 38 until arrangements for such implementation were clearly communicated to trading partners and wanted to work constructively to ensure trade was not disrupted.

68. The representative of the European Union associated herself with the US' and Australia's concerns and stated that the EU was still waiting for responses to the questions it had posed bilaterally to Viet Nam. The EU was concerned with the complexity and unnecessary burden that this Decree would cause, in particular the multitude of declarations of conformity and related documentation that had to be submitted to Vietnamese authorities prior to importation. This complexity was compounded by the fact that several different Ministries apparently had competence over various aspects of these requirements. It was also unclear how coordination and timely processing of a dossier between these Ministries would be ensured, particularly when a product fell under the responsibility of more than one authority. Furthermore, as Decree 38 lacked clarity in many areas, its implementation would most likely require the issuance of further technical guidance and other implementing measures. This also contributed to the uncertainty felt by economic operators.

69. While it was commendable that Viet Nam had notified an earlier draft of this decree to the SPS Committee, the EU asked why Viet Nam did not notify this measure also to the TBT Committee as some of its elements - such as labelling requirements - were covered by the TBT Agreement. The EU considered that some of these obligations had the potential of being problematic, either because they were unclear (such as the ones related to the "best before" date), or were overly prescriptive (for instance, the requirement that the font of the name of the product be at least three times larger than the font of the other information on the label). The EU therefore requested Viet Nam to suspend application of the Decree pending a TBT notification, in order to enable interested trade partners to submit comments. The EU also noted that the implementation of the Decree already started on 11 June 2012, although its adoption only occurred at the end of April. In this context, the EU reminded Viet Nam of its obligations under WTO rules to provide a sufficient period between implementation and entry into force of mandatory requirements.

70. The representative of New Zealand endorsed the comments made by previous delegations that Decree 38 had to be also notified to the TBT Committee. Given its highly complicated nature, New Zealand urged Viet Nam to assess the content of this Decree against its obligations under Article 5 of the TBT Agreement, which obliged Members to ensure that conformity assessment procedures did not create unnecessary obstacles to trade. Given the significant uncertainty surrounding implementation of Decree 38 in practice, New Zealand also urged Viet Nam to establish an extended transition period so as to allow exporters and governments to seek clarification of various aspects of implementation without any disruption to trade in the meantime. Finally, New Zealand also requested that Viet Nam notify further draft circulars as well as other instruments guiding implementation of the Law on Food Safety that relate to food imports. This would allow Members sufficient time for submitting comments well before prior to their finalisation and entry into force.

71. The representative of Canada informed that his delegation was interested in any accurate information on any transitional or implementation measures enacted by Viet Nam. Canada already conveyed such interest directly to Viet Nam through its embassy in Hanoi and wished to continue discussing how this measure would be implemented so as to avoid disruption.

72. The representative of Chile shared the concerns voiced by previous delegations, in particular the lack of clarity of with respect to the implementation of Decree 38, in particular given that some circulars were already implemented, such as Circulars n. 13 and n. 25. Chile also considered that this measure should had been notified to the TBT Committee and asked for some delay in its implementation.

73. The representative of Viet Nam responded that because this trade concern was raised for the first time at the present TBT meeting it would like to simply take note on the comments and concerns made and send them to capital for adequate response. Viet Nam asked Members to send the details of their concerns in written form.

(xiii) Korea – Windows Energy Efficiency, Ministry of Knowledge Economy (MKE) Notification 2011-263, December 2011

74. The representative of the United States expressed her delegation's interest in this Korean measure setting requirements for testing the energy efficiency of windows. The US asked Korea to notify this measure and informed that the two countries had a constructive bilateral dialogue where particular concerns were taken into account.

75. The representative of Korea explained that this measure was not notified because it was harmonized with the relevant international standards in ISO 8990 and ISO 6613. Korea would however convey to capital the US' notification request.

(xiv) China – Draft Mobile Smart Terminal Administrative Measure, Ministry of Industry and Information Technology (MIIT), 10 April 2012

76. The representative of the United States noted that China's Ministry of Industry and Information Technology (MIIT) issued the *Mobile Smart Terminal Administrative Measure* on 10 April 2012 ("the Measure"). The Measure established a new regulatory framework for the mobile device market. The US's concerns with the Measure were first raised bilaterally with China in April and May 2012. The US considered that the Measure imposed numerous new obligations, technical mandates, and testing requirements on information technology and telecommunications hardware, operating systems, applications, app stores, and other related services. The scope and mandatory nature of these requirements were unprecedented among the major global markets for mobile smart devices. At the same time, the US noted that on 1 June 2012, MIIT published a draft of the Measure on its website, soliciting public comment for 30 days. The US appreciated this action, and acknowledged MIIT's positive response to the US' request for transparency on this measure. The US requested that China notify this technical regulation and any accompanying measures to the TBT Committee and fully consider the views of Members before finalizing them.

77. The representative of Japan shared the concerns expressed by the US. Japan considered that the measure imposed new technical requirements and obligations to conduct inspections on manufacturing and distribution of smart mobile terminals. Japan hoped that the new requirements would not constitute an excessive burden to manufacturers of smart mobile terminals or would not require excessive technological disclosures. The measure should take into consideration the fact that it would be difficult for terminal manufacturers to control all behaviours of applications. Japan hoped that the sufficient information would be provided through the TBT notification system or by other methods in the future.

78. The representative of the European Union shared the concerns raised by the previous delegations and noted that the measure established a rigid regulatory framework with a very prescriptive approach which regulated in detail every aspect of mobile smart phones. It also introduced burdensome testing requirements which resulted in voluntary industry standards becoming mandatory through conformity assessment. These were systemic concerns that the EU had already flagged at numerous occasions at the TBT Committee in respect of regulations developed by MIIT. On the other hand, the EU welcomed the website posting of the draft measures for public consultation, although it regretted that this was limited to 30 days. The EU therefore requested a longer period be allowed and that wider opportunities for input into this process be provided to

foreign industry. The EU also requested that the measures be notified to the TBT Committee when they reached maturity.

79. The representative of China stated that in order to protect user information security and personal privacy, MIIT drafted a notice on strengthening network access management on mobile smart terminals. The draft of the measure was put on MIIT's website on 1 June 2012 for public comment for one month. China understood the concerns from the foreign industry and welcomed any further comments, which would be taken into account within China's decision making process and in accordance to WTO rules.

(b) Previously Raised Concerns

(i) European Union – Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)[4]

80. The representative of Argentina said that REACH continued to present serious complexities that confirmed what Argentina had been stating since its entry into force in 2007: this Regulation constituted an unnecessary technical barrier to trade and was not in compliance with the environmental and health objectives for which it was, theoretically, established. The complexity of REACH was manifested by the incessant modifications of the Regulation as well as their guiding documents and, as a result, in the excessive and unpredictable compliance costs for SMEs exporting to the EU market. There were more than 20 modifications to the regulation and 25 guiding documents for its interpretation (that were also continually modified) – and this was only one example of the unpredictability and complexity of REACH. Since 2011, the regulation had already been modified eight times, and beginning in 2013, according to ECHA, more changes are foreseen including on the deadlines of some proceedings. Moreover, it could be assumed that additional modifications would be brought as a consequence of the general review undertaken by the European Commission.

81. In addition, there was cause for concern regarding the excessive costs (that ECHA appeared not to take into account) for SMEs exporting to the EU market generated by: a) Continual modifications to the regulation which forced SMEs to seek external advice, usually given by European consultants, to know their obligations; b) The designation of the only representative in the European market (a cost not to be faced by a local producer). Because this representative had to have residence in the EU, this service usually come from a European entity – the same as those providing consulting services; c) The cost of participating in the Substance Information Exchange Forum ("SIEF") was controlled by the major companies, mainly European. As SIEF was not subject to any control standards, the large companies that control them established prohibitive requisites and entry costs for SMEs; d) Bureaucratic steps required for registration of each substance were excessive because they did not take account of different cost structures between European and non-European SME. In relation to this last point, it was noteworthy that, in accordance with ECHA, almost 90 per cent of the registrations were carried out by major enterprises. As REACH provided that each substance had to be registered, it would be expected that, when the SME would comply with this proceeding, the SMEs would find out that the substance have already been registered and most probably by a large company. For this reason, SMEs had to face the unpredictable costs imposed

[4] 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, 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/52/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; G/TBT/W/208.

arbitrarily by major companies in the corresponding "SIEF" because of lack of regulation. In this context, the supposed flexibilities provided by REACH for the SMEs in the EC regulation 340/2008 become irrelevant. The registration process of REACH seemed to only favour big companies eliminating SMEs competition. SMEs could not compete when they had to comply with the last stage of registration in 2018 as they would find difficult to meet the direct registration costs or, most likely, the very high and arbitrary costs imposed by the major companies that had already registered the substances. His delegation urged the EU to make the process more transparent by avoiding continuous modifications to the regulation and by providing greater reduction to the registration costs for SMEs outside the EU, while establishing control mechanisms for the major companies which had already registered substances, so as to avoid prohibitive costs for SMEs. Without a solutions to these difficulties, he said, the majority of SMEs exporting chemical substances to the EU would progressively be displaced from the European market, resulting in job losses.

82. The representative of India shared Argentina's concerns. He reiterated his delegation's concern about the trade barriers for Indian SMEs. The definition of micro, small and medium sized enterprises (MSMEs) in the EU for the purposes of lower registration costs did not account for labour intensive industries in developing Members like India. The use of criteria like annual turnover, balance sheet ceiling and staff headcount rendered many of India’s micro enterprises large enterprises for REACH, despite meeting the first criteria. This resulted in their unfair treatment and was against the spirit of Article 12.3 of the TBT Agreement as it created unnecessary obstacles to exports from developing country Members.

83. The only representative (OR) is a burdensome proposition for many of our SMEs and adds on to their cost. Despite having raised this issue in earlier meetings, the problems associated with SIEFs and consortia persisted, including their opaque functioning, high joining fee, penalties for late joining with no clear timelines for joining, yearly maintenance fee, consultancy costs, non-uniform rules for every consortia. Data sharing under REACH remained a problem for Indian companies due to the prohibitive cost of data purchase. Most data sharing was commanded by the big companies. In addition, there was no provision for merchant exporters to undertake the registration process directly; his delegation had requested such a provision in the REACH legislation. The rationale for registration of the entire tonnage of the substance in an article, even if less than 100 per cent of the substance was intended for release in using the article, was not clear.

84. The representative of China supported Argentina and India. He had two questions for the EU from Chinese exporters. First, he asked the EU to check if there were sufficient human resources to deal with the complexity involved in complying with the REACH regulation. Understaffing would lead to different interpretations of the rules which would lead to inefficiency. Most customers of members did not supervise imports in line with REACH, and registration did not lead to different trade treatment. China hoped the EU could check these claims. Secondly, for some substances, registration involved millions of RMB, which often went beyond the capacity of exporters, especially for SMEs. The EU was asked to explain whether mechanisms existed to control costs.

85. The representative of Australia registered his delegation's on-going concern with REACH, referring to previous minutes of meetings. The representative of the Philippines supported the concerns raised by Argentina, India and China, particularly regarding the unpredictable costs for SMEs. The representative of Thailand shared the concerns raised by previous Members.

86. The representative of the European Union said that replies to most of these questions had been provided in previous meetings of the Committee and referred members to the minutes of those meetings. Attention should focus on the new registration deadline in 2013. ECHA and the European Commission had made huge efforts to inform companies about the REACH obligations and to take their concerns into account. To assist companies in their SIEF activities and in the preparation of the next registration deadline in 2013, ECHA was offering a series of support activities including

workshops in 2012, a series of webinars and other training opportunities, including a workshop on the functioning of SIEF and notably its data sharing.

87. To answer China's first question, the EU's position and interpretation on REACH had always been clear. Moreover, in order to enhance the efficiency of the system, the competent customs authorities of the member states meet regularly in the forum of the enforcement competent authorities of the EU member states to foster good practice and highlight any issues at the EU level. Regarding registration costs for some substances, the EU reiterate that the level of the fees and charges had been set taking into account the workload involved for each of the relevant processes managed by ECHA. The fees and charges applied equally to manufacturers and importers established inside the EU and to only representatives of non-EU manufacturers. Moreover the costs of testing were also included in the registration costs, and several approaches to avoid animal testing were described in Annex 11 of the REACH regulation. Finally, important reductions, of up to 90 per cent, applied to micro, small and medium enterprises.

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

88. The representative of the United States noted ongoing bilateral US and EU dialogue on wine trade. However, she asked again about current EU measures restricting U.S. wine exports to the EU. At the last meeting, the EU noted that it was still examining applications for recognition of certain terms submitted by the U.S. wine industry on 19 June 2010. U.S. suppliers using those terms were unable to export their products. The EU had granted approval to use the terms through its bilateral agreements with other countries, these terms did not have a common definition across all EU Member States, and there had been no effort to monitor or limit the use of these terms within the EU. She therefore asked how these measures could be preserving a general consumer perception regarding "terms traditionally associated with European wines". In addition to TBT-related aspects of the regulation, the US had concerns about the regulation regarding the protection of trademarks and intellectual property.

89. The representative of the European Union said that his delegation was still examining applications filed by the US industry for the use of traditional terms, and was providing information to the US on the status of these applications on a regular basis. He informed the Committee that a vote on the draft regulation recognizing the traditional term 'Classic' would take place at an upcoming Single Common Agricultural Market Management Committee; if the vote was positive, the Commission would proceed to formally adopt this regulation. Her delegation was open to continued discussion of this issue with the US, with a view to make progress on the US requests

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

90. The representative of Japan recalled that India had stated on two occasions that it would positively consider deletion of Clause 6.3, which prohibited export of the BIS marked tyres to countries other than India. However, this modification had not been carried out by the relevant companies. Presently, Japanese tyre manufacturers could not export BIS-marked tyres to countries other than India. This was an unreasonable restriction on trade. His delegation requested immediate deletion of Clause 6.3. Also, according to Japanese tyre manufacturers, India conducted certified factory audits every six months. Japan saw no other cases that required such frequent audits which were an unnecessary burden for tyre manufacturers. Japan requested a drastic reduction in the frequency of the audits.

91. The representative of Korea said his delegation continued to have concerns about Article 6.3, marking fees, time-consuming procedures, excessive paperwork, and the term of validity for ISI certification. Because Article 6.3 of the BIS Agreement prohibited exports of ISI-marked tyres to

other countries, the Korean industry had an undue cost burden. Korea also requested the repeal of Article 6.3. If India repealed Article 6.3, marking fees would also need to be reviewed. They were unfairly calculated (not on the basis of the total number of ISI-marked tyres imported to India, but on the basis of the total number of tyres produced and marked with the ISI symbol). Compared with similar marks issued by other countries, most of which did not charge marking fees, ISI fees were considerably higher.

92. Additionally, the process, from the application to the issuance of the certification, was rife with time-consuming administrative procedures and excessive paperwork which took almost one year. Other countries could process certification within 45 and 90 days. Considering the long time to obtain certification, Korean tyre manufacturers believed that one year validity was unreasonably short; manufacturers would have to apply to renew their certification as soon as they received it. Other countries granted 5 years or permanent terms of validity. Korea requested that India simplify its administrative procedures and extend the term of validity to at least five years, or indefinite.

93. Additionally, Korea asked India to accept test results carried out in in-house Korean laboratories, consistent with globally accepted practices. Common global common practice in the tyre industry was that, if the test laboratories of companies were verified according to international standards, the test results from these laboratories should be accepted by the tyre certification body. Lastly, Korea asked India to allow foreign laboratories located outside of India to be approved as test labs for the ISI mark.

94. The representative of the European Union recalled India's confirmation at the last Committee meeting that Article 6.3 of the BIS Agreement, which prevented ISI marked tyres from being sold outside India, would be removed. The EU would like to know whether further steps had been taken in this regard and when the modification of the BIS Agreement would be finally published. Furthermore, the EU remained concerned by the royalty fees to be paid on the total production of tyres produced and marked with ISI marking, not only on those which were actually imported to India. The EU urged India to remove the royalty fees, which were extremely burdensome and more restrictive than necessary, or at least to modify their calculation so that they would be limited to tyres which were de facto exported to India. Finally, the EU inquired whether tests, carried out by EU-accredited laboratories and showing compliance with the Indian requirements, could be accepted.

95. The representative of India said that his Government had decided to remove clause 6.3, and the revised agreement was being finalized. The marking fee charged and the overall fee was equitable in terms of unit cost of tyres for both domestic and foreign manufacturers. Moreover, the overall fee charged by India was comparable to those charged by other Members. He considered that it might actually be lower in India than in many countries charging an overall fee for these tyres. He added that the foreign lab recognition scheme of the BIS existed. He did not understand why this question was repeatedly asked when the scheme existed and none of the foreign labs from any of the three delegations that spoke had actually applied for recognition from the BIS.

96. Regarding the Korean question about the validity of the license being for one year, the internal Indian guideline was one year because that was what Indian authorities were comfortable with as a term of license both to domestic as well as to foreign manufacturers. There was also a provision for the renewal of the license for one or two years with payment of a requisite fee. Finally, he said that the norm for issuing the license was six months for normal applications, not one year.

(iv) Canada – Compositional requirements for Cheese (G/TBT/N/CAN/203, G/TBT/N/CAN/203/Add.1)

97. The representative of New Zealand referred to the minutes of the previous 16 Committee meetings where her delegation explained its continued concerns. The representative of Australia

supported New Zealand's intervention as his delegation continued to have concerns about Canada's regulation on compositional standards for cheese and the access for milk proteins. The representative of Canada took note of the two delegations' comments.

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

98. The representative of the United States continued to have concerns with India's proposed registration certificates and import licenses for foreign producers, particularly that they last for three years, while the certificates and licenses for domestic producers last for five years. She asked for an explanation regarding the difference. Following up on the November 2011 and March 2012 exchanges in the Committee, she also asked for clarification regarding the information required in the certificates and licenses for foreign and domestic producers. India had suggested at the November 2011 meeting that there were differences between those requirements. She also asked for an update on the state of play of the measure as India had said, at the March 2012 Committee meeting, that enforcement was postponed until April 2012.

99. The US industry also remained concerned with some details associated with implementation of the proposed regulation. In January 2011 they had asked to receive additional clarification from India on whether there would be an adequate transition period for suppliers to comply with the measure once it entered into force; whether the proposed registration fee of $250 "for each brand of cosmetic" referred to the trade name or the product line - and whether the latter could require additional filings for changes in manufacturing location, for example, which would result in increased expense as well as delays in registration approvals; and whether import registration numbers would only be required on the outer package, where they were visible to the consumer. Her delegation was pleased that India delayed implementation of the rules until October 1, 2012, and would like use the extra time to work through the remaining technical issues. Industry continued its dialogue with the relevant Indian authorities so that companies could understand how to comply with the regulation.

100. The representative of the European Union welcomed the postponement of the entry into force of India's registration procedure until October 2012, and the information provided at the last Committee meeting that labelling, specifically the name of the importer and import licence numbers, could be provided in an authorized place, such as a bonded warehouse, after import. The EU still wanted to know if the validity of import licences would be increased from 3 to 5 years, and if India was developing an arrangement for accepting reports of tests carried out in foreign laboratories attesting compliance with international standards or Indian standards, as an alternative to local testing.

101. The representative of India confirmed that the measure would come into force on 1 October 2012. He explained that the different time period was primarily because of the voluminous inspections of factories and even manufacturing practices carried out for domestic manufacturers compared to foreign suppliers. Thus, there was no intention at present to increase the period from 3 to 5 years. However, his Government was looking at temporary labelling requirement in customs designated warehouses. Permission for affixing self-adhesive/stickers or over printing of or stamping each pack of the imported cosmetics with registration number and the name of the importer at authorized places may be considered. His delegation would examine the technical questions posed by the US specifically on the labels on cosmetics. Finally, in terms of foreign lab recognition, there were currently no test reports required for inspection of cosmetics. If and when a regulation would come into force, his delegation would look at specific labs that would be recognized for testing.

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

102. The representative of the European Union still had concerns, as mentioned at the last Committee meeting and in written comments of 6 September 2011, with India's mandatory certification for steel products. He inquired about implementation of the third party certification,

which it considered inappropriate for intermediate steel products and too burdensome. He asked India to inform the Committee of the date of entry into force of the Steel and Steel Quality Products Order. Secondly, EU industry continued to report significant backlogs in the existing certification for galvanized steel. He asked how India would ensure that the plant verifications would be carried out for all products covered by the second addendum to G/TBT/N/IND/32 before it entered into force. In this context, the EU also invited India to recognize test results from foreign laboratories. Finally, the EU urged India to provide a more rapid procedure for the steel products that would now be submitted to third party certification, so as to ensure an equal treatment for domestic and foreign manufacturers.

103. The representative of Japan shared the EU view that India should postpone implementation of this order until the equal treatment principle of domestic and foreign manufacturers for obtaining IS certification was ensured, and that unnecessary barriers to trade were resolved. His delegation did not believe there was any functional purpose for imposing mandatory standards on intermediate goods, such as steel products. The protection of human health or safety could be attained only through safety regulations on final products, such as the Japanese regulations.

104. The representative of India informed the Committee that 9 steel products would be under mandatory BIS certification from 12 September 2012. Indian analysis carried out by technical authorities showed the significance of standards on intermediate products because they formed the bulwark for the performance of the finished product. For example, unless the steel plates that go into pressure vessels like boilers conformed to specific standards, there was a danger of explosion or other accidents in the plant. Similarly, electrical steel sheets (CRNO and CRGO) used in the production of transformers and power generation equipment were critical to the performance of both these end products, as were ingots/billets for the safety of the final building. As stated previously, the BIS had a scheme for recognition of third party labs, but neither the EU nor Japan had applied for recognition of their labs.

(vii) United States – Hazardous Materials: Transportation of Lithium Batteries (G/TBT/N/USA/518)

105. The representative of Korea asked the US to update the Committee on the current status and future prospects of the measure.

106. The representative of the European Union recalled the first addendum of G/TBT/N/USA/518 in which the US announced that it was considering whether to harmonise with the new Technical Instructions on the Safe Transport of Dangerous Goods of the International Civil Aviation Organization (ICAO). The EU asked for an up-date on the proposed requirements for the transport of lithium batteries. He asked the US to confirm that it would refrain from a unilateral approach and would bring its rules into alignment with the new Technical Instructions of the ICAO.

107. The representative of Japan supported Korea and the EU. While Japan shared the objective of ensuring air transportation safety, Japan had expressed concern about the negative impact on trade of the proposed US regulation on the transportation of lithium batteries which was inconsistent with the UN Recommendation on the Transport of Dangerous Goods and the ICAO Technical Instructions. In February 2012, the ICAO agreed to amend its Technical Instructions, effective January 2013. Though the US had not yet published a final regulation, Japan was looking at whether the final regulations were consistent with or more stringent than the ICAO Technical Instructions. He requested that the US provide an opportunity for comments on the final rules to the stakeholders.

108. The representative of the United States, in its recent notification, G/TBT/USA/N/518/Add.l, informed its trading partners that the Department of Transportation (DOT) would be requesting public comments on the impact of changes to the requirements for the air transport of lithium cells and batteries that had been adopted in the 2013-2014 ICAO Technical Instructions on the Transport of

Dangerous Goods by Air. Experts from Korea, Japan, several EU States and the US participated in the ICAO Dangerous Goods Panel for the development of the ICAO Technical Instructions. The revised ICAO standards had the support of the entire Panel. In its request for comments, DOT said that it was considering whether to harmonise with these requirements. During the comment period, DOT received several comments similar to the concerns raised by members here. DOT was reviewing the comments and considering how to proceed. All comments could be read online. Regarding the timeline, she replied that DOT was aware of the January 2013 effective date.

(viii) Turkey – New conformity assessment procedures for pharmaceuticals

109. The representative of the United States continued to find certain aspects of Turkey's decree on conformity assessment procedures 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, in principle, to inspection requirements for pharmaceutical manufacturing facilities, it remained concerned about several aspects of Turkey's requirements which were neither published in the official gazette nor notified to the WTO. She urged the Turkish Government to consider processing registration forms submitted prior to March 2010 as filed; to not apply retro-actively the GMP requirement; and to give priority to innovative drug applications that provide new medicinal therapies to Turkish patients, all to alleviate the current blockage of pharmaceutical imports. She understood that Turkey was considering allowing the integration of the GMP inspection into the marketing authorization process. She requested an update on this as it would be a positive step. Finally, her delegation was pleased with the positive discussions held on GMP over the year including in bilateral trade talks and during regulators' dialogues in workshops. However, the number of pharmaceuticals awaiting marketing authorization was still high. This was an urgent market access issue for US exporters and Turkish patients and her delegation urged Turkey to take steps to restore market access.

110. The representative of Turkey explained that the GMP certificate was a document required for the licensing of pharmaceutical products. The aim of the regulation was the protection of human health and life by providing that pharmaceutical products meet the required effectiveness and safety conditions. The Turkish Ministry of Health had been conducting GMP inspections since 1995 in accordance with "GMP Guidelines for Pharmaceutical Products", which were in compliance with the relevant guidelines of the World Health Organization (WHO). Prior to March 2010, GMP certificates of other countries along with those provided by the Ministry of Health were accepted when applying for licensing. However, the Ministry of Health was concerned that automatic recognition of GMP certificates of other countries without having access to the relevant background documentation, posed serious risks to human health. Therefore, the Ministry exercised its legitimate right to conduct GMP inspections for the protection of public health and human life.

111. To further improve enforcement, the Ministry developed its capacity to accept and process applications for GMP certificates. All applications were immediately processed as long as the related application files were complete. Turkey reiterated that the GMP was applied to all countries and all products equally, as well as to national products. Hence, GMP inspections aimed not to restrict trade but to secure public health. Furthermore, in line with public health concerns, the Ministry of Health applied a classification system based on the therapeutic priorities of pharmaceuticals. Turkey informed members that there would not be any policy change regarding the GMP implementations, such as unilateral acceptance of GMP certificates. Lastly, he re-emphasized Turkey's willingness to communicate and work constructively with interested members upon their request.

(ix) Brazil - Health Products (G/TBT/BRA/328)

112. The representative of the European Union reiterated concerns about the 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 of health products in Brazil. A

GMP certificate was issued only after ANVISA had inspected the manufacturing premises. The EU was aware that Brazil was taking some steps to accelerate GMP inspections. However, there was still a number of manufacturing sites for which an inspection request had been submitted but no inspection had taken place, and 20 months appeared to be the average waiting time. The EU asked for an update on the current situation.

113. The EU stressed that ANVISA needed to carry out inspections to foreign manufactures within 3 months after the request had been filed. In case reasonable inspection deadlines could not be met, the EU invited ANVISA to rely on and take into account Quality Management System audits conducted by accredited auditing bodies such as EU Notified Bodies, which guaranteed that the products were safe, and consider accepting, on the Brazilian market, products authorized in the EU or in other major markets, pending the completion of ANVISA inspections. As an alternative, ANVISA was invited to consider subcontracting overseas inspections to accredited auditing bodies such as the EU Notified Bodies that would inspect EU facilities on behalf of ANVISA. This procedure would allow for a reduction of the current backlog.

114. The representative of Brazil recalled a bilateral meeting with the EU on this issue and that Brazilian authorities were aware of the current situation. ANVISA continued to work to improve the efficiency of the GMP inspections. His delegation had provided considerable detail at the last meeting about the measures adopted or are under consideration by ANVISA; he invited Members to refer to the minutes of that meeting. He highlighted some of the main actions envisaged by ANVISA to better organize the international GMP inspections: ANVISA was considering new criteria to prioritize inspections taking into account, for example, the proximity between companies in the same region or the risk of lack of supply of certain products in the Brazilian market; ANVISA had sought to make the best use of its human resources to avoid capacity deficiencies in inspection teams; and Brazil was considering changes in its legislation so that experts from other federal or local bodies could be incorporated in the inspection teams. He informed the Committee that up to May 2012, ANVISA conducted 104 inspections which pointed to an increase in the pace of inspections. Brazil reiterated its interest in pursuing bilateral arrangements with Members like the EU in health surveillance, and that some arrangements such as confidentiality agreements, for example, could speed up the process of GMP certification since they would allow information exchange between the authorities of both parties. Finally, Brazil joined the International Medical Device Regulators Forum (IMDRF) and was committed to the objectives of regulatory convergence in this area.

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

115. The representative of India noted that the EU Directive 2001/83/EC relating to medicinal products for human use and the subsequent Directive 2004/24/EC on traditional herbal medicinal products were not notified to the WTO. His delegation was concerned that there was no simplified, specific alternative application dossier for registration of traditional Ayurveda products. The EU should therefore consider Ayurvedic Pharmacopoeia as India's specifications and quality parameters for registration of traditional Ayurvedic Medicines. The definition of herbal, medicinal products in the EU directive did not include products that had minerals and other non-herbal substances which provided a synergistic effect to the herbs in the formulation. India requested the EU to consider expanding the definition of herbal medicinal products to include non-herbal biological and non-biological ingredients. He concluded that the Common Technical Document ('CTD') format under the THMP Directive was inappropriate for multi-component, traditional, medicinal formulations given that it was almost impossible to provide information with respect to multi-component, traditional medicinal formulations.

116. The representative of China supported India's concerns. It hoped that the EU would review this directive because it was causing problems for the traditional herbal medicine users in the EU.

117. The representative of the European Union recalled that extensive technical clarifications had already been provided in previous meetings of the Committee. The EU reiterated that the 2004/24/EC Directive introduced a simpler and less costly registration procedure for traditional herbal medicinal products as compared with medicinal products falling under the full market authorization procedure foreseen by Directive 2001/83/EC. In addition, herbal products that did not fulfill the definition of medicinal product do not fall under the scope of the registration. On India's request for the EU to accept Indian Pharmacopeia as sufficient proof of quality parameters of herbal medicinal products, the EU highlighted that quality, together with safety and efficacy, was one of the essential pillars of the EU code for medicinal products for human use that guaranteed that products were adequate for human health. Therefore, the quality requirements defined under Directive 2001/83/EC had to be fully met.

118. The EU noted that the eligibility criterion of 15 years of use in the EU allowed sufficient monitoring of the side effects and increased confidence in the safety of the products in the absence of tests and clinical trials. For medicinal products for which 15 years use in the EU could not be demonstrated but were otherwise eligible for the simplified procedure, the Directive 2004/24/EC allowed manufacturers to prove the safety of the product by other means, which were to be assessed by the Committee for Herbal Medicinal Products of the European Medicines Agency. Finally, the Common Technical Document (CTD) was an internationally agreed consistent format, widely known by market operators. Specific guidelines for multi-ingredient components were also available.

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

119. The representative of the United States said that her delegation had continued to seek a solution for these issues raised since June 2010. She requested an update on when Korea's study on the environmental impact of thin film solar panels would be released. She expected this study to show that other types of solar panels did not have an adverse impact on the environment, and that, therefore, they would be expeditiously incorporated into Korean standards and certification programs to enable equal access to the Korean markets to domestic and foreign producers. She also requested that Korea give stakeholders the opportunity to comment and seek clarification on the results of this study.

120. The representative of the European Union supported the US concerns and recalled that, in the past, Korea expressed its intention to complete a feasibility study on the inclusion of non-amorphous silicon types of thin film solar panels - Cadmium Telluride (CdTe) and Copper Indium Gallium Selenide (CIGS) in standard KS IEC 61646 by 30 May 2012. She asked Korea to provide an update on this study and share its conclusions with the Committee. She also asked what the next steps envisaged by the Korean Ministry of Environment were, in particular whether the Korean standard would be amended as requested by the EU and the US.

121. The representative of Korea indicated that under the current standard KS IEC 61646, all types of thin film solar panels could enter the Korean market without certification. Thus, certification of solar panels was not mandatory in Korea. In May 2012, his Government had completed a two-year comprehensive feasibility study to evaluate the environmental risks involved in the use and end-of-life disposal of cadmium telluride and CIGS photovoltaic modules. The purpose was to determine the convenience of introducing certification systems for these products in Korea. To ensure the highest degree of reliability, the study involved Korean test methods for domestic waste as well as US Environmental Protection Agency (EPA) method 1311 and the EU EN 12457 method.

122. The study found that when cadmium telluride modules were damaged or discarded, a significant amount of cadmium was leached into the surrounding environment. The concentration of cadmium leached from these modules was much higher than the allowable levels specified in various national environmental standards. When Korean test methods for domestic waste were used, the average concentration of cadmium was 1.65 milligrams per liter. The average concentration was

17.75 milligrams per liter with the EPA Method 1311, and 0.84 milligrams per liter with the EN 12457 test. The maximum allowable concentration of cadmium in Korean drinking water was 0.005 milligrams per liter. For bodies of water, the maximum was 0.01 milligrams per liter. And for industrial wastewater, it ranged between 0.02 and 0.1 milligrams per liter. In addition, it found that higher concentrations of cadmium were leached into the environment when cadmium telluride was exposed to acid. Thus, there was great potential harm to the environment from just a tiny amount of powder from a damaged module, if the powder came into contact with acid rain. An agency in Japan (SIMAZU), reached the same conclusions. Therefore, Korea concluded that the social and economic costs of allowing cadmium telluride modules on the Korean market would outweigh the benefits. The competent authorities would provide Members with the results of this feasibility study upon request. Since CIGS modules contained little cadmium, Korea was considering setting up a certification system for this type of module. This process would take approximately two years.

(xii) India – New Telecommunications related Rules

123. The representative of the European Union reiterated its concern regarding the revised telecom network security regulations and their accompanying template agreement on security and business continuity between telecom network operators and equipment suppliers. He believed that the regulations adopted on 31 May 2011 constituted the final version. Considering that 1 April 2013 was the deadline for the implementation of the requirement for in-country testing of network elements, he requested the Indian authorities to reconsider discontinuing the acceptance of foreign test results of network elements as of 1 April 2013, and moving to a system based solely on in-country testing. He inquired whether the certificates issued under the Common Criteria Recognition Agreement (CCRA) would be accepted as before, and whether such certificates would be sufficient to meet all the security testing requirements under the new rules. He requested that only those elements that were essential for ensuring the security and integrity of the telecom network system be covered by the test, in order to avoid the disclosure of sensitive propriety information.

124. In addition, he mentioned that the Indian authorities had held a public consultation process from 18 April to 18 May 2012 on draft guidelines for certification of telecom equipment. He requested clarification on the relationship between these new draft guidelines and the revised telecommunication network security regulations. In his view, the scopes of these two documents partly overlapped, and the EU was concerned that these draft guidelines could establish an additional layer of testing and certification for telecom equipment. According to the draft guidelines, suppliers could choose from among three different approval schemes. The Telecommunication Engineering Center based in New Delhi, along with its regional offices, were in any event the only laboratories entitled to carry out the corresponding testing. It was not clear to the EU whether foreign testing outside India by internationally accredited laboratories would be accepted. He welcomed the public consultation process and expected the Indian authorities to properly take the comments submitted into consideration, and to eventually notify these measures in accordance with the TBT Agreement.

125. The representative of the United States supported the EU comments. Her delegation appreciated India's reassurance that it remained committed to complying with the CCRA. However, the US did not understand the reasons for requiring in-country testing for telecommunication networks, and requested clarification on the relationship between this requirement and India's assurance that it would continue to accept CCRA certifications. India had not explained the security reasons for requiring all telecommunication equipment to be tested in-country, especially considering that the testing could be conducted by foreign telecom firms as well. Thus, she requested an explanation of the concerns underlining the in-country testing requirement, and the reasons why testing in common criteria labs could not address India's concerns.

126. The representative of Japan echoed the EU and US concerns. Japan was concerned about the compatibility between the new regulations and the CCRA. Japan believed that, as it mentioned at the

previous TBT meeting, according to the new rules, only network elements approved by Indian certification agencies would be allowed. He sought reassurance that India's telecom regulations would not impede market access for foreign companies.

127. The representative of India restated India's intention to continue to recognize the process-based conformity tests conducted by international labs for general IT products covered under the CCRA. However, for national security considerations, India had issued regulations for the testing of telecom equipment against security standards. For such security testing, India intended to establish test standards, procedures, tools and accreditation of test labs in India. Addressing the US concern for the protection of property rights under the new regime, he stressed that the new regulations contained adequate safeguards for protecting intellectual property rights. He would revert to the comments on the relationship between the new testing guidelines and the security guidelines; and requested that the three delegations provide their informed comments to India's regulatory agency concerning the draft guidelines for certification of telecom equipment.

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

128. The representative of India requested an update on the status of these provisions which could severely impact India's exports of textiles and clothing to Italy. The representative of the European Union reiterated that Italian authorities had postponed application of this law until the adoption of the implementing measures. Adoption was not foreseen at present.

(xiv) 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)

129. The representative of Mexico said that, despite answers provided by Brazil, her delegation remained concerned that some aspects of the draft resolution could be inconsistent with Articles 2.2 and 2.8 of the TBT Agreement, and requested further information on the resolution's implementation.

130. The representative of Guatemala reiterated her delegation's concern that this draft resolution could have negative impacts on the marketing of cigarette products of American tobacco mixture because it prohibited the use of certain types of additives necessary for its preparation. She requested Brazil to clarify how each of the ingredients of the American mix would be covered by Article 7 of the draft resolution, and whether the American mix could be marketed in Brazil.

131. The representative of the Dominican Republic supported Mexico and Guatemala. He asked that Brazil take proper account of these observations and provide information on this measure.

132. The representative of Colombia recalled previous concerns expressed regarding this measure, and noted that no response had yet been provided by Brazil to their comments and questions.

133. The representative of Chile, while appreciative of the recent notification of the addendum, restated her delegation's concerns and requested more information on the measure's implementation.

134. The representative of Turkey expressed regret that the draft resolution entered into force on 15 March 2012 without taking Turkey's and other countries' comments into consideration. Banning additives in tobacco products should be based on scientific evidence that proved that the additives posed increased risk to human health. A ban on all additives constituted, in Turkey's view, a disproportionate measure. As a result of comments, however, Brazil had removed sugar from the list of banned additives. However, this modification was insufficient to address their concerns.

135. He reiterated that some of the prohibited additives were essential components of blended cigarettes, in which both Oriental and Burley tobaccos were used. Since blended and non-blended tobacco products were "like products", a measure resulting in a prohibition of blended tobacco products would be discriminatory. Further, these additives did not give characterizing flavor to tobacco products. Thus, Brazil failed to consider the effects of such ingredients on final products, and Turkey expected it to reconsider adoption of this resolution and to amend it to avoid discrimination.

136. The representative of Australia welcomed Brazil's decision to implement tobacco control policies and preventative measures aimed at reducing the attractiveness, in particular to children and youth, of certain tobacco products. Each Member had the right to implement measures necessary to protect public health, while complying with relevant international treaty obligations. Australia remained prepared to continue to defend this right.

137. The representative of Brazil recalled bilateral discussions with Mexico where some concerns were addressed. He informed Members that the definitive regulation on the control of additives in tobacco products was published as Resolution RDC14 2012 from ANVISA in March 2012; and notified to the TBT Committee in April 2012. Brazil had also prepared a compilation of the answers to comments submitted during the consultation period; they were willing to transmit them to interested Members. In relation to the concern regarding the American blend of tobacco products in Brazil, the production of tobacco products known as "American blend" was not affected by this regulation, since the use of sugar - a key ingredient for this product - as an additive in tobacco products was permitted under the Brazilian measure.

138. He invited Members to consult the minutes of the previous meeting, where they could find extensive answers and explanations on some of the points raised. He recalled that two hundred thousand people died every year in Brazil due to tobacco consumption-related diseases. This measure was intended to protect public health by reducing the attractiveness of tobacco products, especially among children and young people. He assured Members that this resolution would not discriminate between domestic and foreign producers. Finally, Brazilian authorities had circulated a compilation of the international and scientific references used as the basis for this measure.

(xv) 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)

139. The representative of the European Union reiterated concerns on these measures and asked for an update on the status of the revision of the 1999 Regulation on commercial encryption products managed by the Office of State Commercial Cryptography Administration. The EU requested confirmation that this revision was still formally on the agenda of the State Council Legislative Office for 2012, and that the draft regulation was going to be published before its promulgation and notified to the TBT Committee in due time, to allow adequate opportunity for comments from all interested parties.

140. Secondly, he restated the EU's concern about the "Multi-Level Protection Scheme (MLPS)", which required the classification of IT systems according to their importance for national security. The EU requested that the classification of IT systems be carried out in a more transparent and predictable manner. He inquired as to how many IT systems had been assessed according to the MLPS criteria, in what sectors, and how many had been considered as critical infrastructure. The EU's concern was that sectors such as banking, insurance, transport and energy, which were not, strictly speaking, sensitive for national security, would be classified as critical infrastructure, significantly affecting the ability of products incorporating foreign technology to be used in those sectors.

141. Thirdly, the EU also requested an update on the six information security standards that had been submitted for consultation in July 2011 by the Information Security Standardization Technical Committee (TC 260) managed by the China Electronics Standardization Institute (CESI). He asked to what extent the comments received had been taken into account in the final drafts, and whether these drafts had been published.

142. Fourthly, the EU recalled that, in the previous TBT Committee meeting, it had also mentioned a new concern, on radio-frequency based mobile payments, i.e. payments that could be made with a mobile phone. In May 2012, European industry had held meetings with the China National Information Technology Standardization (NITS) on the new standard on radio frequency-based mobile payments, where it had been confirmed that the new standard required users to implement n algorithm which would not be defined in the standard itself (and thus generically referred as "Algorithm E"), but one of the existing national algorithms whose intellectual property rights belonged to Chinese holders. In the absence of clear information in the standard about the content of the algorithm and the conditions under which the algorithm could be accessed, the EU had serious concerns about the workability of the standard in practice. He therefore requested that the algorithm, its content, its use, and its accessibility be clearly defined in the standard itself.

143. Finally, considering the global nature of the relevant market, the EU strongly believed that it would be beneficial to all participants -including Chinese manufacturers - to develop these standards in the most inclusive way, allowing the participation of all interested actors, including foreign stakeholders, from the start.

144. The representative of the United States supported the EU comments which they had raised in bilateral meetings with China. The US was concerned about the requirement to use only Chinese intellectual property in the core components of IT security products, and urged China to implement the MLPS regime in the least trade restrictive possible way. Regarding China's 1999 Regulation, the US requested China to notify any revisions of this measure to the TBT Committee to allow interested parties to comments on them. Any expansion of the scope of the 1999 Regulation to cover more IT products would create trade disruptions across a broader swath of the global IT sector, similar to those created when China issued the first version of these regulations, before their scope was limited to products whose core function was encryption. Such an expansion could call into question whether this measure was the least trade restrictive means to assure China's objective.

145. The representative of Japan supported the EU and US comments, adding that China's regulations on information security were not in line with global norms and approaches and, thus, posed difficulties for the future of international trade on information security products. Japan was closely monitoring the potentially negative effects of these measures on international trade.

146. The representative of China recalled bilateral talks with the EU and the US. The 1999 Regulation was still being redrafted, therefore, he had no update to provide on it. As to the MLPS, China encouraged the EU, US and Japan to explain how their products were affected by this measure. He asked Japan to explain why it did not consider that this measure conformed to global norms on information security. He added that it had been made clear during bilateral talks with the EU that the six information security standards submitted for consultation by the TC 260 managed by the CESI, were voluntary.

147. Five new standards on radio frequency-based mobile payments, issued by China National Information Technology Standardization (NITS), had been open for public comment from January 19 to March 2, 2012. The European Chamber of Commerce had submitted comments which were discussed with the Chinese authorities on 13 April 2012. He explained that these standards did not set up a patent pool and, thus, did not prevent the use of foreign technology in radio frequency-based

mobile payments. However, the use of any patented technology in radio frequency-based mobile payments would require the authorization of the patent holder.

148. He clarified that the reference to "Algorithm E" in the standard served simply as a symbol for text description; it did not specify any particular algorithm.

(xvi) China – Administration on the Control of Pollution Caused by Electrical and Electronic Products (G/TBT/N/CHN/140, G/TBT/N/CHN/140/Add.1, G/TBT/N/CHN/140/Rev.1)

149. The representative of Korea reiterated her delegation's request for China to indicate the date on which these revised regulations were scheduled to enter into force; to provide detailed information on the management catalogue of standards; and to reduce the number of items in this catalogue. She also inquired if the certification procedures established in these regulations were mandatory; whether the Chinese authorities had identified certain certification bodies and laboratories eligible for State Recommendation Voluntary Certification on Electric Information Products; and whether China provided any incentives, such as tax relief, in exchange for complying with certification requirements. Korea believed that the use of such incentives could in practice, turn a voluntary standard into a mandatory measure. Lastly, she requested China to include in its State Recommendation Voluntary Certification System, the possibility of submitting conditional suppliers' declarations of conformity (SDoCs). For example, China could allow companies with good quality records or with no problems detected at market surveillance to do SDoCs for a certain period of time.

150. The representative of the European Union supported Korea's comments and requested an update on the measure notified in G/TBT/N/CHN/140 Rev. 1 and on the discussions on the type of conformity assessment to determine compliance with the requirements of this measure. The EU also recalled its previously raised concerns on the use of mandatory third-party certification in this field.

151. The representative of China recalled the 2010 revision of this measure, and its notification of 21 October 2010 in G/TBT/N/CHN/140 Rev.1. The measure was under revision and the Management Catalogue and corresponding conformity assessment procedure would be determined after the measure was promulgated. In April 2012, the Certification and Accreditation Administration (CNCA) and China's Ministry of Industry and Information Technology (MIIT) jointly launched the Confirmation on Certification Bodies and Laboratories Engaged in the State-Recommended Voluntary Certification on Electronic Information Products. The corresponding certification procedures would be launched soon, with the aim of allowing enterprises to choose freely qualified certification bodies.

(xvii) 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)

152. The representative of Korea requested an update on the status of this un-adopted draft decree. He restated Korea's view that Indonesia should regulate final, and not intermediate, products.

153. The representative of Japan supported Korea, adding that finished products, not intermediate materials, were relevant for the protection of human health or safety. Japan was concerned that further expansion of mandatory standards for steel imports from Japan, which were produced under strict quality management systems at steel mills, would increase the time and resources required to receive and maintain certifications, thereby increasing distribution costs and delaying deliveries in specific Indonesian industries. These negative impacts could even make Indonesian industries less competitive in global markets.

154. The representative of Indonesia said that the national standard SNI for electrolysis tin coated steel sheets was still under revision. On the ISO 9001 standard, product certification was not similar

to the management system of certification. Therefore, manufacturers certified under ISO 9001 had to comply with product certification or SPPP SNI. Indonesia welcomed continued bilateral discussions.

(xviii) China – Provisions for the Administration of Cosmetics Application Acceptance (G/TBT/N/CHN/821)

155. The representative of Japan recognized China's efforts to address Members' concerns regarding these provisions, noting that China's State Food and Drug Administration (SFDA) preferred bilateral technical exchanges between competent authorities which were responsible for safety examinations. Japan recognized the importance of such dialogues. However, Japan was concerned that most Japanese applications of new plant extracts and ferments were rejected because the safety evaluation was not carried out as a single substance, but as a mixture or complex. These new ingredients, having passed safety evaluations, were used in finished products already on the Japanese market and had not caused any consumer safety problems. Only 2 applications in the two years after the publication of these provisions have been approved for new ingredients. Thus, exports of many cosmetics containing other new ingredients were blocked.

156. Japan believed that this was a trade-restrictive requirement unnecessary to ensure the safety of cosmetics containing new ingredients. It considered that the best way to evaluate the safety of cosmetic ingredients was to conduct tests with the same substance that was used in the finished product, as accepted by international safety management practices and other countries such as Japan, the EU and the US. Japan requested China to approve applications of plant extracts from a single substance or of plant ferments without requiring the exclusion of solvents or other substances. Alternatively, Japan invited China to provide scientific grounds for the exclusion of solvents from other substances or risks that were derived from the evaluation without exclusion of solvents by taking specific examples supporting China's claims. He recalled China's announcement during the last Committee meeting that solvents from plant extracts would be handled on a case-by-case basis. To ensure fairness, he asked for clear guidance on the kind of solvents to be isolated.

157. The representative of the European Union restated EU concerns about the significant trade disruptions from these requirements since April 2010. The approval of products with new ingredients continued to be blocked, despite the 2011 publication of the Guidelines for the registration of new ingredients. She requested an update on China's measures to address this problem. She hoped that further dialogue at the expert level between the SFDA and the European Commission's Directorate General for Health and Consumers would lead to a satisfactory solution.

158. The representative of the United States supported the EU and Japanese comments. It was her understanding that the SFDA's reclassification proposal would impact more than 70 per cent of cosmetic products being marketed in China. US industry reported that registration of ordinary cosmetics could typically take many months. Moreover, the additional requirements imposed on "new ingredients" in April 2010 resulted in a virtual standstill in approvals for cosmetics containing new ingredients, evidenced by the fact that only two new ingredients had been approved for use in China, despite their acceptance in the US and European markets. The US was concerned that the criteria used by SFDA to create a new category of "special function" cosmetics was not transparent and appeared to differ significantly from those applied in other countries; this created unnecessary delays and significantly disrupted trade.

159. She welcomed a recent SFDA call for comments on non-special use cosmetics category management, recalling that, on 1 May 2012, the US submitted comments through its Enquiry Point. She urged China to continue dialogue with all interested parties regarding these measures and to take into account the comments received. China should also consider alternative measures that were more commensurate with the risks involved, such as post-market surveillance and reliance on

internationally-recognized good manufacturing practices (GMPs). These alternatives would meet China's legitimate regulatory objectives with less disruptive effects on international trade.

160. The representative of China recalled bilateral talks with Japan the day before where they learned of Japan's comments submitted through its Enquiry Point on 6 June 2012. The SFDA would reply to these comments in written form. Although China had already provided sufficient information, it remained open to future bilateral, technical exchanges, and hoped to be able to provide more detailed answers to Japan's questions at the next TBT Committee meeting. Concerning the classification and management of non-special cosmetics, the SFDA requested comments on-line from the public from February to March 2012. On 28 March 2012, China notified the corresponding revision in G/TBT/N/CHN/887. Moreover, the SFDA called again for public comments on-line from 29 May to 15 June 2012. He welcomed all the comments and concerns from interested parties.

(xix) Colombia – Alcoholic beverages (G/TBT/N/COL/121, 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)

161. The representative of the European Union recognized Colombia's efforts to address some EU concerns. However, on 23 March 2012, the EU submitted a new set of comments to which Colombia had not yet responded. The EU was still concerned about the definition of Gin, particularly the definition of London Gin, and considered that the requirement to fix labels at the origin could be problematic, particularly for imports of low volume. Labeling in warehouses should be accepted for imported products since the information to consumers would be provided anyway. She also asked if the requirement that issuance of a sanitary inspection certification be based upon the presentation of a quality certificate issued by the manufacturer and complemented by physical sanitary checks was also applicable to locally produced goods. For imported alcoholic beverages, this requirement could be substituted by the quality certificate and random physical sanitary checks, when deemed necessary.

162. The representative of Colombia said that the measure would enter into force in July 2012. All comments had been taken into account, including the EU's concerns on labeling products at origin.

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

163. The representative of the European Union asked for an update on Korea's indication in the previous Committee meeting that the Cosmetics Act would be amended to allow foreign manufacturers to apply for KCGMP certification. She also reiterated the EU's request for the Korean Food and Drug Administration (KFDA) to accept certificates issued by independent third parties proving compliance with ISO 22716, or self-certification by cosmetic manufacturers.

164. The representative of Korea announced that the Cosmetics Act would be amended to revoke the Cosmetics Standards and Test Methods. The Enforcement Regulations of the Cosmetics Act had also been amended to allow manufacturers to self-select testing items during quality inspection of final products. Furthermore, the KCGMP would be amended, and re-notified during the second half of 2012. However, in compliance with Article 2.1 of the TBT Agreement, equal treatment under the KCGMP meant that both domestic and foreign manufacturers must receive an independent KFDA certification even if they had third party certification from an overseas certification body attesting compliance with international standard ISO 22716.

(xxi) 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)

165. The representative of the United States said that both notices, the Ministry of Finance Document Number 4629 on the import of spirits and cosmetics and the Ministry of Industry and Trade Notice Number 197 on the import of alcohol, cosmetics and mobile phones, appeared to be legally binding as of June 2011, and involved new conformity assessments procedures. In addition, they seemed to require specific quality control procedures, such as the submission of quality control certificates and the designation of specific ports in charge of control. Answers provided by Viet Nam to comments raised were not satisfactory. For instance, Viet Nam denied that the measures were legally binding or created any new requirements, while acknowledging the US interpretation. She urged Viet Nam to notify these measures to the TBT Committee, to suspend their implementation until comments were received and taken into account, to modify the measure as appropriate, and to provide a reasonable period of time for suppliers to comply.

166. The representative of New Zealand continued to monitor these measures and requested an update as to whether Viet Nam intended to establish a new certificate of quality achievement process for alcoholic beverages and cosmetics as proposed in the MOF Official Letter 4629/BTC-TCHQ of 7 April to MOIT. If yes, did Viet Nam intend to notify this new process to the WTO?

167. The representative of the European Union supported the US and New Zealand comments. She appreciated the additional information provided by Viet Nam. However, she sought further clarification as to whether quality checks applied to all consignments of alcoholic beverages, cosmetics and mobile phones; whether a Quality Control Certificate should accompany these consignments; if so, what entity was in charge of issuing it; and what the timeline for issuing was. She also requested further details about this certificate. For instance, was there a template to be used; what quality standards were to be certified; and what other information should accompany this certificate?

168. The EU also inquired as to whether these measures had resulted in reducing counterfeiting or smuggling of these products. Finally, she requested a clarification on whether these measures were intended to be temporary, and, if so, how long would they last.

169. The representative of Australia supported the US, New Zealand and EU concerns, adding that his delegation was concerned with the conformity assessment procedures in Ministry of Finance Document Number 4629 and the measures' consistency with the TBT Agreement. The Ministry of Industry and Trade Notice Number 197 was an administrative burden on exports, especially for small and medium enterprises, thereby having unintended negative trade consequences.

170. The representative of Viet Nam confirmed that responses to questions raised by some Members had been sent by email to the respective TBT enquiry points. He also offered hard copies of those answers to interested Members. He took note of the additional comments and questions made during this session which would be sent to the Capital for analysis and future responses.

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

171. The representative of the United States informed the Committee about productive bilateral discussions in February 2012. The US still had concerns, including on the requirement that production facilities be dedicated exclusively to halal production, which raised consistency issues with the Codex guidelines. She asked for continued discussions for a mutually acceptable resolution.

172. The representative of Brazil shared the US concerns on the halal facilities. He encouraged Malaysia to align with the relevant international standard as required by Article 2.4 of the Agreement.

173. The representative of the European Union shared the concerns of the US and Brazil, and requested full transparency of Malaysia's import conditions. Clear and comprehensive guidelines for importers were necessary prior to the implementation of such measures, including the public availability of draft requirements at an early stage, sufficient opportunities for economic operators to comment on drafts, and a sufficient interval between publication and entry into force. The EU was concerned that Malaysia's import conditions were not aligned to the relevant international standard, and urged Malaysian efforts to alleviate the impact of its requirements on foreign producers.

174. The representative of Argentina reiterated concerns on the guidelines of the Draft Protocol which provided, *inter alia*, that the facilities to which a country could export be exclusively devoted to halal production. This created unnecessary barriers to trade and was more trade-restrictive than necessary to reach the legitimate objective of guaranteeing that halal meat complied with relevant prerequisites and was genuinely halal. The Codex relied on general guidelines for use of the term halal in labelling products. The Malaysia's Protocol did not take the Codex guidelines into due account. Seven Argentinian facilities that were authorized to export to Malaysia had been suspended by the Malaysian Department of Veterinary Services (DVS) since November 2010 without any official communication or warning.

175. The representative of Turkey said that the Malaysian Draft Protocol envisaged special requirements for production facilities, the handling of products, as well as limitations on conformity assessment bodies. The Protocol was inconsistent with international rules and practices of Muslim countries. The "Standards and Metrology Institute of Islamic Countries" (SMIIC), established under the Organization of Islamic Cooperation (OIC), had adopted guidelines for standardization, certification, and accreditation of halal food. While it fully supported attempts towards setting common halal standards and conformity assessment procedures, such rules and procedures should be determined collectively and in close cooperation with other Muslim countries. Turkey invited Malaysia to participate in the development of common standards, conformity assessment, and accreditation procedures on halal food, and to reconsider the Draft Protocol.

176. The representative of Malaysia indicated that bilateral discussions were on-going; Malaysia would continue working with its trade partners to find a mutually acceptable solution.

(xxiii) Korea – Regulation on Registration and Evaluation of Chemical Material

177. The representative of the United States said the US Government and industry appreciated the objective of safeguarding public health and the environment, and hoped that consultations would continue to develop a regulation able to achieve these goals with minimum adverse effects on US and Korean firms. Korea's proposed "Act on Registration, Evaluation, Authorization and Restriction of Chemical Substances" (Public Notice 2011-74) had broad implications not only for US industry, but for producers and importers of chemicals in Korea as it created significant changes to Korea's chemical regulatory regime. US industry had expressed concerns with the proposed regulation, submitting comments directly to the Ministry of Environment and meeting with the Ministry of Knowledge Economy. She asked Korea to update the Committee on key issues previously raised regarding the proposed annual reporting requirement and the 0.5 minimum ton threshold for preregistration and registration. She requested confirmation on whether this would increase to 1 ton.

178. The representative of Korea explained that the Ministry of Environment taking into account all Members' comments and no date had been determined for the finalization of the legislation. If it passed in the National Assembly, subordinate regulations would be proposed that would take effect one to two years after the proclamation date. The Ministry would notify WTO Members and invite

comments from stakeholders once a draft of the subordinate regulations was published. On the minimum tonnage threshold of 0.5 ton and the annual reporting requirement, the Ministry of Environment was considering whether to amend these provisions following consultations with industry. It would increase the threshold to 1 ton and extend the mandatory reporting period to every two years. The points raised in the Committee would be conveyed to the competent authorities.

(xxiv) Kenya – Alcohol Labelling: The Alcoholic Drinks Control (Licensing) Regulations, 2010: Legal Notice No. 206: 2010 (G/TBT/N/KEN/282)

179. The representative of the European Union said the EU had provided written comments to Kenya in April 2011. This measure had not been notified to the TBT Committee, and her delegation was still waiting for a written response from Kenya. Had Kenya considered less burdensome alternatives than mandatory health warning labelling to modify drinking behaviour? She also requested confirmation on whether the requirement that health warnings comprise at least 30 per cent of the total area of the package had been amended to 30 per cent of the label surface, as stated at the November 2011 TBT Committee meeting.

180. The representative of Mexico said her delegation had asked Kenya to provide information on the implementation of the regulation published on 17 December 2010. Her delegation was concerned that this bill was in violation of Articles 2.1, 2.2 and 2.9 of the Agreement. She requested information on the implementation of this legislation and a formal reply from the Government of Kenya to observations made on 12 May 2011.

181. The representative of Kenya took note of the concerns raised. Written responses would be provided to interested delegations. The regulation notified as document G/TBT/N/KEN/282 had been adopted as an emergency measure in response to public concern and adverse effects of alcohol consumption, as well as to safeguard against continued loss of life and to protect public health. Kenya took note of the views expressed by the EU regarding public education on responsible drinking and behaviour change. Public campaigns to nurture responsible citizenry had been on-going long before the legislation was drafted, and had yet to show effect. The bill was unlikely to make meaningful progress anytime soon. Most of the current court cases came from manufacturers of PET bottles that were challenging the requirement that alcohol drinks being bottled only in glass bottles. Most of these cases had been dismissed; and no conservatory orders or injunctions had been issued on any of the Act's provisions. The regulation remained in force and Kenya remained open to further consultations.

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

182. The representative of Argentina reiterated his delegation's concerns about the lack of transparency and predictability of the Grenelle 2 Law. In particular, there was concern about any labelling requirement, either mandatory or voluntary, which implied unnecessary or disproportionate costs and certification burdens - because these prevent small and medium enterprises (SMEs) and as well as larger companies in developing countries from getting market access to developed countries. To begin with, there was a lack of transparency as the law was never notified to the WTO. For that reason, Members had never been able to put questions and requests for clarifications and express their opinions. In addition, no information had been provided by the EU regarding the consistency of this law with the EU regulations. Moreover, scarce and confusing information had resulted in the absence of predictability. The law had been implemented as a pilot project from July 2011 to July 2012 but its status after this period was unclear.

183. The representative of Argentina stressed that the law would be an unnecessary obstacle to trade due to its formulation, eventual implementation and impact, particularly on developing countries. The law implied unfair treatment of like imported products, particularly from developing

countries, as: (i) discrimination was based on processes and production methods not directly related to the products themselves, like their environmental impact or the emissions from production of a good; (ii) the accounting of carbon emissions, as a result of distribution and transport, would be negligible for EU goods compared to geographically distant countries and (iii) the costs of certifying products would be more significant for a company from a developing country than from a developed one.

184. The representative of India supported Argentina's statement. He urged the EU to notify the measure, and requested clarifications on the methodology and period used to compute the carbon footprint of products, i.e. whether it was computed over the entire product lifecycle or were there any assumptions made in the computation; and whether regulatory impact assessments had been carried out by the EU, specifically with regard to effects on developing country Members. Had consultations been carried out with WTO Members, and were the special and differential treatment provisions in line with Article 12 of the Agreement? Did the measures cover both agricultural and NAMA products; was it based on the relevant international standard? Lastly, he asked for a clarification of the standards on which was based the provision in the law, requiring members to provide a certificate that fish and fish products on sale in the French market had been raised in a sustainable manner.

185. The representative of South Africa shared Argentina's and India's concerns and requested further information. The regulation would particularly impact exports from developing countries to the EU, particularly because of the geographical distance of developing countries, and historic trade links as former colonies of EU Member States.

186. The representative of Uruguay expressed his delegation's concerns on possible adverse effects of carbon footprint labelling on SMEs in developing countries.

187. The representative of Cuba recalled previous discussions, as well as the Spanish legislation on biofuels discussed during the morning session. Cuba shared concerns and doubts on the extent to which the legislation would mitigate adverse effects on climate change. The measure would have adverse effects on developing country companies, and the lack of a scientific basis for the legislation was discriminatory towards developing countries. Cuba requested clarification and additional information and asked whether the effect on developing countries had been taken into account.

188. The representative of the European Union recalled that the provision of the Grenelle 2 Law on carbon labelling was an experiment without long-term measures. He referred to the minutes of previous meetings for information on the objective and scope of this legislation. The pilot project was under way until the end of 2012. For transparency and cooperation, and to ensure that trading partners fully understood, the EU could share the results of this French experiment once these were known.

(xxvi) Korea – Proposed Cosmetics Labelling and Advertisement Guidelines: KFDA draft Guidelines for Management of Nanomaterials in Cosmetics (G/TBT/N/KOR/308, G/TBT/N/KOR/362)

189. The representative of the European Union reiterated her delegation's concerns, particularly on those related to the control of claims in foreign languages. The EU also asked for clarification on the link between these Guidelines, notified under G/TBT/N/KOR/308, and the draft Notice on the Substantiation of Cosmetics Labelling and Advertisement notified under G/TBT/N/KOR/362. Did Korea intend to revise the Guidelines to bring them in line with the new Notice and, if so, would Korea notify the revised Guidelines? Finally, she thanked Korea for its openness to discuss these issues bilaterally.

190. The representative of the United States clarified that her delegation was commenting on G/TBT/N/KOR/308. She appreciated Korea's accepting the comments of US industry on the timeline

for implementation, and requested Korea to consider additional changes. The requirement to list the address of a manufacturer and marketing authorization holder, a manufacturer's name, and the location of imported cosmetics on the primary or secondary packaging was difficult and could confuse the consumer. She suggested only requiring the marketing authorization holder on the label.

191. US industry had expressed concern that the positive and negative claims list in KFDA's "Guideline for Cosmetics Labelling and Advertising" applied to claims printed in Hangul as well as English. This would restrict companies' ability to market English-marked products in multiple markets. The US understood Korea's possible concerns regarding consumer deception through false labelling, but considered that the objective would be better addressed through consumer protection laws. She requested an exemption for claims printed in English to enable all industry participants to market the same product in multiple countries.

192. The representative of Korea explained that specific standards for the Cosmetic Advertising/Labelling scheme came into effect on 5 February 2012 following the Amendment in the Cosmetic Act. KFDA had specified the standards under the Cosmetic Act and had notified the draft 'Regulation on Substantiation of Cosmetics Labelling and Advertisement' in April 2012. Overlaps with regard to specifications on the substantiation of the cosmetics labelling and advertisement in the two laws would be deleted after the latter's final notification. KFDA could not exempt foreign languages from labelling items that required regulation. Product names, written in foreign languages on imported cosmetics which could deceive consumers, were to be regulated under the revised as well as the previous Cosmetic Act. The Guidelines specified the methods of modification for importers with regard to correction, deletion and over-labelling for advertisements or labels written in foreign languages. The draft Guideline for cosmetics containing nanomaterial was provided in December 2011 as uploaded on KFDA's website. This guideline contained information on labelling safety document verification in the submission of cosmetics containing nanomaterials.

(xxvii) Colombia – Commercial Truck Diesel Emissions Regulation

193. The representative of Mexico appreciated the meetings held between the Mexican private sector and Colombian ministries. She asked for information on the status of the planned amendment and a formal reply to Mexico's communication of 5 September 2011, 30 January and 11 April 2012.

194. The representative of the United States appreciated the regulator dialogues between environmental experts in Colombia and the US. The trade impediment cited at the Committee's last meeting would not be an issue if Colombia was to make 15 parts per million sulphur fuel available. This would permit Colombia to achieve higher emission reductions, while yielding greater environmental and health benefits. Many countries had made or were making this transition, including in Latin America. The US would monitor developments and looked forward to working with Colombia on this issue.

195. The representative of Colombia clarified that the texts were preliminary, and not yet official drafts. As soon as the content was defined, they would be notified for comments, and Colombia would provide formal replies to questions raised.

(xxviii) Peru – Draft Supreme Decree approving the regulations governing the labeling of genetically modified foods (G/TBT/N/PER/37)

196. The representative of Mexico said that, on 14 September 2011, his delegation had presented comments on the draft notified under G/TBT/N/PER/37 of 27 June 2011. It requested a formal reply to its questions regarding the status of implementation of the draft decree.

197. The representative of Canada hoped that his delegation's previously sent comments were reflected in subsequent changes to the regulation, and asked for information on the status of the measures and their application.

198. The representative of Chile requested an update on the status of Peru's Draft Supreme Decree on which Chile had presented comments at past Committee meetings. She hoped Peru would take into account her delegation's suggestion to extend the timeframe beyond 180 days so that industry would have sufficient time to adapt to the new obligations.

199. The representative of Colombia had expressed his delegation's concerns at the past two Committee meetings and asked for a reply and an update on the status of the draft measures.

200. The representative of Peru said that the preparation and adoption of the Draft Supreme Decree was under way; Peruvian authorities were assessing comments received. The multi-sectoral working group in charge of this draft regulation would continue its work and did not specify a publication date for the final regulation. Peru would announce the changes to the draft before final adoption. The draft regulation never put into question the safety of genetically modified foods as some comments suggested; it sought to guarantee clear and precise information for consumers on various products, to avoid any type of potentially misleading practices and to ensure the security of consumers.

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

201. The representative of the United States reiterated concerns about India's measure developed by the Ministry of Consumer Affairs Bureau of Indian Standards (BSI) that would impose additional conformity assessment on foreign toy manufacturers. Appreciative of information provided by India at the last meeting, her delegation considered that early engagement with stakeholders on draft measures meant gathering of information from a wide range of perspectives, to assist regulators in crafting measures that achieved legitimate goals in the most efficient and effective manner. The notification and comment provisions of the TBT Agreement were aimed at enabling regulatory officials to find trade facilitative solutions and avoid unnecessary obstacles to trade. In light of the extensive trade concerns, the US urged India to work with the BIS, the Ministry of Commerce and Industry's Director General of Foreign Trade (DGFT) to ensure transparency, adherence to WTO obligations, and trade-facilitative solutions.

202. The representative of the European Union supported the US statement. Associating all interested parties, including foreign stakeholders, in the development of new conformity assessment procedures was important if significant changes to the current regime, reflecting the intention of moving towards a system of mandatory testing by domestic laboratories coupled with onerous registration procedures, were being contemplated. The EU also requested an update on the timeline and a transparent and open process leading to eventual notification of the measure.

203. The representative of India recalled that the issue had germinated from informal consultations held by the Department of Industrial Policy and Promotion (DIPP) on specific guidelines for registration of toys. He assumed that the US, EU and other Members' industry were aware that the Government was having preliminary discussions on formulating a registration order. The DIPP had not produced a draft guideline yet. If it did, India would notify it to the WTO and provide a draft on the website.

(xxx) 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.

204. The representative of the United States had highlighted concerns at Committee meetings in November 2011 and March 2012 over this draft voluntary standard. It inquired about the purpose of the new national voluntary standard, an office equipment information security standard designed as an alternative to IEEE 2600, which was an international information security standard. Her delegation understood that the draft had been released for public comment for 30 days by a standardization institute under China's Ministry of Industry and Information Technology (MIIT), the China Electronics Standardization Institute (CESI), and the China National Information Security Technical (NITS) Standards Committee (TC260, Working Group 5).

205. In the interim, US industry had noted several improvements and positive developments in the most recent revisions, such as the removal of consumables from the product scope and the narrowing of applicable encryption requirements to exclude non-sensitive data. The US understood that China might be developing conformity assessment procedures related to this standard. With a view to harmonising conformity assessment procedures on as wide a basis as possible, her delegation encouraged China to base these on relevant guides and recommendations of international standardizing bodies, and, where appropriate, to play a full part in their preparation of guides and recommendations for conformity assessment procedures. The US remained concerned about China's plan to implement a national voluntary standard for wireless Local Area Network (LAN) devices, which seemed to diverge from an existing international standard, IEEE 802.11n.

206. On 13 February 2012, China's MIIT had announced the finalization of the standard on its website. The US was concerned that the standard might be incorporated into type approval, CCC mark registration or other certification processes. She encouraged China to include all relevant and interested parties in the development of these central government standards and conformity assessment procedures, and to notify drafts of the new conformity assessment procedures, when available, so that all Members could comment and have their comments taken into account.

207. 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 standards to alleviate trade concerns in security-related products. Japan appreciated the admission of foreign, including Japanese, manufacturers in the drafting process, and hoped that their comments would be reflected in the final drafts. He asked China to provide information on implementation of recent drafts, including on the office device standards, which applied to each Member's demands.

208. The representative of the European Union supported the US and Japanese statements. The development of standards would have benefited from greater involvement of foreign stakeholders and all interested parties. His delegation welcomed the publication of draft standards by the TC260 Working Group 5 for consultation, but would have appreciated greater transparency throughout the process. He hoped that comments from foreign stakeholders would be reflected in the final draft and recommended transparency and involvement of affected parties in case any conformity assessment procedures were developed in relation to these standards, and that any standards made mandatory through conformity assessment procedures be notified.

209. The representative of China informed that the standard was voluntary, currently in the process of approval, with no plan for certification considered yet. Regarding high spectrum efficiency and high throughput WLAN technical requirements, he referred to the minutes of the last Committee meeting. China would continue to monitor development of the relevant international standards in this regard.

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

210. The representative of the European Union requested an update on the timeline for the finalization of the draft conformity assessment procedures, supporting the application of Indonesia's mandatory toy safety standard that had been adopted by the Indonesian Minister of Industry in May 2010. He requested that the process be conducted in a transparent and open manner, allowing all stakeholders to provide input, and to finalize measures only after all parties had had an opportunity to comment. He sought reassurance that the measure would be notified in due time to the Committee.

211. European industry had concerns on the latest draft of the conformity assessment procedures which appeared quite burdensome and were based on mandatory product testing. This implied, on the one hand, mandatory testing of every shipment of toys imported into Indonesia (compared to every six months for domestic products), and on the other hand, certification of the product management system of the manufacturer through on-site verification of production facilities and process and quality control of production. His delegation understood that the approach was to reserve testing for domestic laboratories appointed by the Minister of Industry or accredited by the Indonesian national accreditation body (KAN). Foreign labs would be allowed to perform this testing provided they were covered by a mutual recognition agreement (MRA) to which KAN or the Indonesian Government were a party. Since KAN was a signatory to ILAC, the EU sought confirmation that the test results of laboratories accredited by signatories of the ILAC MRA would be accepted under the new rules. Likewise, the EU considered that the certification of the quality management system of the manufacturer should rest on a certification of compliance with the ISO 9001 standard. He requested that certificates of compliance with ISO 9001, issued by bodies accredited by signatories of the IAF MLA, also be accepted under the new rules. The EU confirmed the EU toy industry's desire to co-operate with Indonesian authorities on this issue and welcomed further dialogue.

212. The representative of the United States supported the EU's comments and asked for an update. The US had raised concerns over these conformity assessment procedures at November 2011 and the 2012 meetings. She encouraged Indonesia to engage in bilateral discussions on these issues, including with regard to the acceptance of testing done by bodies accredited by ILAC and IAF MLAs.

213. The representative of Indonesia informed that this measure was currently being notified to the WTO and said his delegation welcomed further bilateral discussions with both countries.

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

214. The representative of the United States asked for a reply to comments sent on 27 February 2012. She requested more details on Korea's indication at the March 2012 Committee meeting that it would make available tax reductions to domestic and foreign manufacturers to help with costs associated with the equipment necessary for radio frequency id tags. The US understood that Korea was implementing the Notice to enable consumers to ensure brand authenticity and to provide information to authorities on tax payments. Her delegation supported the legitimate goals associated with preventing counterfeiting and collecting tax payment information, but considered that this could be met through less burdensome methods. She requested an extension to 1 October 2012 of the implementation date to provide companies with sufficient time to prepare.

215. The representative of the European Union expressed some concerns that the measure could cause financial and logistical burdens to small European whisky producers that exported to, or that sought to enter the Korean market. She asked for more details, including on the application procedure for the tax reductions granted to companies that had to comply with these requirements that Korea had mentioned at the March 2012 meeting. Korea had informed that the National Tax Service that it

would allow exemptions subject to prior approval in individual cases, such as those that malfunction or where there is difficulty tagging small bottles. The EU asked for more information on granting these exemptions, for instance whether they would be provided on a case by case basis upon request by the economic operator concerned. Furthermore, what were the conditions economic operators had to comply with and how could they apply to benefit from these exemptions? Finally, the EU enquired whether Korean authorities were considering issuing additional technical guidelines to clarify questions related to the implementation of Notice 2011-17. She asked for a reply to the EU's follow-up questions.

216. The representative of Korea noted that the competent authority, NTS, had replied to the US and the EU this week. An RFID tag included all information on importers and wholesalers so that producers could be protected from counterfeits by tracing transactions of each whiskey. This measure enabled consumers to drink whiskey with greater safety, and might benefit whiskey exporters by curbing trade in counterfeit whiskeys. Attaching an RFID tag was necessary to prevent counterfeiting; it was impossible to determine whether an individual product was counterfeited by just scanning the bar code. An RFID tag proved the product's authenticity, and enabled a user to track all previous transactions involving that product. The tag was designed to break when a bottle was opened to prevent an individual from acquiring an empty or refilled bottle of whisky. For this reason, the lot code, as requested by the EU, could not be considered as a less expensive alternative.

217. She hoped that producers would use certificates of origin in conjunction with RFID tagging. However, according to Article 236 of the Customs Law Enforcement Ordinance and to avoid unnecessary costs for importers, a certificate of origin issued by the competent authorities in the country of origin was currently only required for the first shipment of whiskey from each importer. If Korea was to require a certificate of origin for every individual product, costs would inevitably increase. She considered that such a requirement was not sufficient to deter counterfeiting. Since 2008, the Korean Government had invested a significant portion of the national budget in the RFID business and was making every effort to minimize inconveniences to whisky importers by subsidizing the purchase of RFID scanners. As the RFID technology was gradually developing, the NTS was consulting with experts to find solutions that would allow data to be readable if the RFID chip was placed in the cap seal or in the packaging. As for issues such as malfunction or the difficulty of tagging a very small bottle, the Korean authority would allow attaching the tags to individual cases or cartons with prior approval. If such an exemption was granted, producers and importers were responsible for any issues that could arise as a result of the distribution of counterfeit whiskey.

218. Her delegation considered that there had been plenty of time since the measures had been announced in July 2011 and the October implementation was expected to proceed smoothly. Importers were currently preparing to adopt the RFID tag system. Since a civic organization had recently complained that the system constituted unfair discrimination against Korean domestic whiskey manufacturers, an extension of the implementation date could strengthen their case. However, she stressed that RFID tags would not have to be attached to whiskey bottles sold to liquor retailers before 1 October 2012. Regarding the EU's request for an exemption for companies that exported small amounts of whiskey (i.e. less than 5 per cent of the whiskey market), Korea explained that domestic whiskey manufacturers accounted for only around 1 per cent of Korea's whiskey market, but were required to attach RFID tags to their products since 2010. Thus, such an exemption could not be granted. The other points raised would be conveyed to the competent authority.

(xxxiii) 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 (G/TBT/N/ARG/166/Add.7)

219. The representative of the European Union thanked Argentina for information on this measure and for its reply to the EU's comments. However, they did not address the EU's concerns. First, the

measure had been adopted and published at the time of notification, and it had not been notified in draft stage. Second, the EU welcomed that a sworn declaration would be allowed for a transition period for inks, lacquers and varnishes. However, her delegation understood that this was only a transitional provision until the entry into force of the administrative act establishing the definitive conformity assessment regime. For graphic products, the EU noted that mandatory third party certification would apply progressively and only above certain amounts of production. In light of Article 5.1.2 of the TBT Agreement, and in view of the future administrative act, while the EU shared the objective of protecting health and environment through maximum levels for lead, a mandatory third party certification did not seem proportionate to the risk involved. The EU asked Argentina to consider removing the certification procedures or to simplify them by accepting a permanent sworn declaration for all products covered by the order. If Argentina insisted on a compulsory third party certification procedure, could tests carried out in internationally accredited laboratories within the EU be accepted for certification? If not, what were the reasons for obliging operators to test in Argentina?

220. The representative of Argentina pointed out that the EU's concern about the possibility to submit a foreign sworn declaration of conformity was already contemplated in the provision of the national trade office 26/2012 for all products included in Article 1 of Resolution N° 453/2010 (i.e. inks, lacquers, and varnishes used in the graphic industry). As to products in Article 2 of this Resolution (i.e. printed graphic products), the same provision 26/2012 established a chronogram of deferred dates for the entry into force of the mandatory certification requirement for commercialization, as well as a quantity of cases they would be able to sell through presentation of a sworn declaration. Argentina considered that the EU and the US comments had been taken account of through the regime's flexibility and extension of the deadlines for adaptation.

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

221. The representative of the United States reiterated its concerns, in particular with the specification requiring the disclosure of formulas for imported food additives sold in China, which entered into force on 1 July 2011. The transparency issues raised during previous Committee meetings had still not been addressed. In a letter to China of 31 May 2012, the US detailed their questions and concerns regarding the serious impact on legitimate commercial interests from the required disclosure of formulas on labels; the reasons for China's labelling measures diverging from those of the Codex; and from these requirements appearing not to apply equally to imported and domestic products. She asked for written responses and for a technical dialogue, and urged China to suspend implementation until a solution, satisfactory to the US and China, could be found.

222. The representative of China reiterated that the objective of the specification was to ensure the quality and safety of both imported and exported food additives to protect human health. The mandatory labelling applied equally to both imported and domestically produced food additives, and his delegation did not agree with the US that there were substantive inconsistencies with this measure and other food additive labelling measures in China, or that it was inconsistent with Codex standards. The law did not require the exact percentages of ingredients to be specified on the label. The labelling provisions in the specification and in the Food Safety Law were based on the relevant international standard, the Codex Standard for the Labelling of Food Additives When Sold as Such - Codex STAN 107-1981 (GSLFA). Both Article 4 "Mandatory Labelling of Prepackaged Food Additives Sold by Retail" and Article 5 "Mandatory Labelling of Prepackaged Food Additives Sold by Other Than Retail" set out requirements for the labelling of "net contents" of food additives and provided general recommendations for food additive labelling. Finally, he explained that the standard referred to by the United States - Codex STAN 1-1985 (GSLPF) - set out labelling requirements for pre-packaged foods in language very similar to that used in Codex STAN 107-1981 (GSLFA).

(xxxv) 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)

223. The representative of the United States said that, despite efforts, Mexico's National Water Commission (CONAQUA) was still not certifying pipes from US companies consistent with Mexican law and with international trade agreements. Efforts by the Mexican Department of Economy to convey the concerns to the relevant agencies were appreciated. The US Government and industry would continue to use appropriate formal processes to obtain certification to ensure equal competition in the Mexican market. She looked forward to continued coordination with Mexico on this.

224. The representative of Mexico said that the US concerns were being followed closely. The CONAQUA authorities had never refused to certify HDPE but Mexico did insist on the application of ISO 21138, in conformity with the TBT Agreement. A number of options had been proposed so that products could meet ISO 21138, such as the US standard ASTM F894, or the standard ASTM F2762 and F2764. As notified to the Committee in G/TBT/N/MEX/206/Add.2, paragraph 5 of NOM-001-CONAGUA-2011 established that, in order to meet specifications enshrined in Mexican and international standards, for product certification and the construction of portable water systems, domestic consumption and sanitary systems, and in keeping with those free trade agreements to which Mexico was a party, specific standards could be applied if they met the requirements for safety and quality, as laid out in Mexican and International standards. Mexico was willing to consider US and other trading partners' standards as long as they met with what was set out above. Those that met quality requirements and the relevant standards in the country of origin would be allowed to enter the Mexican market; Mexico was awaiting formal requests from interested parties.

(xxxvi) Russia – Draft on Technical Regulation of Alcohol Drinks Safety published last October 24th by the Russian Federation

225. The representative of Mexico requested an official reply from Russia to concerns submitted on 14 December 2011. In the proposed definitions of tequila and mescal, there was no guarantee of denomination of origin which could lead to deceptive practices and misleading consumers. She also raised concern with respect to the maximum levels in beer.

226. The representative of New Zealand raised concerns on the definition that excluded wine produced with Concentrated Must (CM) or Rectified Concentrated Must (RCM) to be labelled as wine. There was no relevant international standard which distinguished wine produced from CM or RCM from wine produced without CM or RCM as these were considered 'like products'. This distinction served no purpose from a consumer protection or safety point of view. Labelling wine produced with CM or RCM as a 'wine drink' would render it to be considered of lesser quality and value by consumers, and was therefore an unnecessary obstacle to trade under Article 2.2 of the Agreement.

227. The representative of the Russian Federation (Observer) informed the Committee that the Customs Union members had completed internal negotiations on the draft and an updated version would be published, with comments and replies received during the public discussion period, on the official website of the Customs Union when the official internal procedure of final confirmation began. The recognition of conformity assessment results was not part of this technical regulation and therefore each case would be examined in accordance with Article 6 of the TBT Agreement.

(xxxvii) 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)

228. The representative of India asked that the implementing act of the directive also be notified. Many Members, including India, could not certify compliance with EU Good Manufacturing Practices and this was clearly in breach of Article 12.3 of the Agreement. India considered that the ICH GMP guidelines were not based on the relevant international standard - WHO GMP guidelines on Active Pharmaceutical Ingredients (API), whereby equivalence must be accepted for exports from other countries. He asked for clarification of the definition of a "falsified medicinal product" as he did not see how "history" and "source" were related to "falsified medicinal products", while quality, safety and efficacy were not included in the definition. Did EU producers of APIs also have to submit certificates of compliance with EU GMP guidelines? Finally he requested that the EU provide a sufficient time period before mandatory enforcement to allow industry time to adjust.

229. The representative of China shared India's concerns. While appreciative of the open and cooperative way the EU was addressing this issue, he urged a response to the questions raised at the last Committee meeting and to the issues raised since. The eradication of falsified medicines was being undertaken globally, and while China welcomed EU GMP inspections on Chinese API exporters, they were concerned that authentic products regulated by China could suffer. He urged the EU to use means other than HS codes to distinguish API products at EU customs. He also was concerned that under the directive, EU holders of manufacturing authorizations of medicinal products could verify GMP equivalence of API producers only by conducting audits, while imported APIs had to also provide a written confirmation to guarantee the GMP equivalence of the exported APIs with the EU standards. This had national treatment issues in violation of Article 5.1.1 of the Agreement. Also, in the new directive, active substances could only be imported if, *inter alia*, they were accompanied by a written confirmation from the competent authority of the exporting third country. This did not match the common international practice whereby competent authorities, including the EU, only regulated domestic enterprises by their respective GMP standards. The obligation to fulfill GMP requirements fell upon importers rather than competent authorities of the exporting third countries. China believed that both China and the EU should assume equal responsibility whereby the EU would issue written confirmation according to Chinese standards and report any non-compliance.

230. Despite EU assurance that the draft template for public consultation released on 16 April 2012 was based on, and in conformity with, the WHO Model Certificate of GMP, Chinese authorities did not find this to be the case. He urged the EU to either follow the WHO model certificate completely or accept the Chinese GMP certificate as equivalent. He also urged the EU to provide a transitional period so as to guarantee a stable supply into the EU, given that imported APIs accounted for 80 per cent of the EU market share; and that for EU/GMP-certified companies and for Chinese companies certified by "white list countries", the written confirmation requirement could be waived as for EU MRA partner countries or PIC/S members.

231. The representative of Brazil associated his delegation with the Chinese and Indian concerns. While appreciative of the bilateral discussions, concerns remained on the requirement that the exporting countries' regulatory authority should confirm that the APIs exported to the EU comply with GMP standards at least equivalent to those of the EU. Brazil's regulatory authorities faced legal and administrative obstacles to issue such a confirmation. He asked that the questions posed during the previous Committee meeting on this be addressed. In particular, would EU authorities be willing to certify that the European medicinal products complied with Brazilian requirements for GMP certification? Finally, he asked for further clarification on comments sent during the public consultation held in March on the criteria to assess the equivalence between GMP requirements related to APIs. The EU reply did not address some technical issues. Also, there seemed to be a

misunderstanding as the EU replies wrongly assumed that the Brazilian comments addressed final products instead of GMP requirements on APIs.

232. The representative of the European Union informed the Committee that Directive 2011/62/EU had been notified to the Committee in 2009 (G/TBT/N/EEC/246) and would be applicable from July 2013. It meant that manufacturers of active substances in the EU had to comply with good manufacturing practices. Therefore, imported active substances also had to be manufactured in accordance with standards of good manufacturing practice 'at least equivalent' to those applied in the EU. The Directive provided that competent authorities of the exporting countries issue a written confirmation establishing that the standards of good manufacturing practice applicable to the plant manufacturing the active substance are at least equivalent to those in the EU ; this written confirmation had to accompany API consignments imported into the EU. This confirmation constituted a simple system built on trust between competent authorities worldwide. In response to a question raised at the previous TBT Committee meeting, the EU confirmed that EU/ICH guidelines for active substances were considered equivalent to World Health Organization GMP guidelines for active substances. Concerning implementation rules, a draft template for the written confirmation, fully in line with the WHO-formatted API GMP certificate, had been shared with main trading partners. The EU had discussed this issue repeatedly, organised awareness-raising sessions with third countries and remained open to discussing any further issue bilaterally.

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

233. The representative of the European Union reiterated concerns raised previously on measures for the administration of certification bodies issued by China's General Administration of Quality Supervision and Inspection and Quarantine (AQSIQ), and Certification and Accreditation Administration (CNCA). These measures took effect on 1 September 2011. The EU concerns centered on the extra-territorial application of the new requirements which forced foreign conformity assessment bodies acting in the framework of mandatory conformity assessment procedures set out in foreign regulations to either open a subsidiary in China or to subcontract their activities to Conformity Assessment Bodies (CABs) in China to carry out their tasks. This approach could impact the ability of foreign CABs who were already approved by foreign regulators to fulfill their obligations regarding certification of Chinese products intended for export. China's approach was unique, and without precedent in any WTO Member. He asked China to explain why it considered necessary to regulate the activities of CABs performing activities required by the regulations of another country and already approved by the competent authorities of that country. He sought China's assurances that activities of foreign conformity assessment bodies, when acting in the framework of foreign regulations and not established in China, would not be covered by the new rules. Finally, he invited China to consider that the requirements set out in the measures at issue could potentially diverge from those in force in third countries. If foreign CABs were required to comply with the requirements laid down in the Chinese measures as well, that might cause problems with the continued acceptance by foreign regulators of certificates issued by such CABs. He looked forward to continued bilateral discussions.

234. The representative of the United States shared the concerns of the EU and appreciated the bilateral discussions. Work was on-going to gain a full understanding of the measure and its relation to the provisions of the Agreement and international standards, as well as to laws and norms of other WTO Members. She asked for clarification on the relevance of the international standard cited by China at the March meeting (ISO IEC 17021, ISO IEC Guide 65, ISO 19011) as it dealt with guidelines for auditing management and not product certification. The application of this measure to certification bodies providing certification of products for export to the laws or requirements of the destination country meant that the CABs had to comply with two, potentially conflicting, sets of legal requirements in the certification procedures for a particular product. Her delegation believed that

there was no CASCO standard that provided for the measure to be applied in such a manner and that, therefore, China was going beyond acceptable practice. CASCO standards in general did not deal with or contravene national laws. She requested China to continue to engage in dialogue with interested foreign parties on the implementation of this measure.

235. 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 on 1 September 2011. Comments had been received from the EU and China had duly replied. The US had submitted comments on 5 August 2011, over two months after the comment deadline. Replies to those comments were provided in November 2011. Article 9 of the Regulations on Certification and Accreditation of China provided for the control and approval of certification activities within China. As far as provisions on the legality of certification bodies and certification activities are concerned, the measure under discussion imposed no new requirements. Besides, it applied equally to domestic and foreign certification bodies. It was based on relevant international standards and was fully WTO compliant. He assured the Committee that China was willing to continue technical discussions on the measure in all appropriate arenas.

(xxxix) Egypt – Two Decrees of the Minister of Industry and Foreign Trade (626/2011 and 660/2011) Related to the Import Requirements for Leather, Footwear and Textile Products (G/TBT/N/EGY/29; G/TBT/N/EGY/30)

236. The representative of the European Union welcomed the notification and postponement of the implementation of two decrees of the Minister of Industry and Foreign Trade of Egypt related to the import requirements for leather, footwear and textile products. She asked that the Egyptian standards mentioned in the notification form, which contained the requirements the products have to comply with, be made available to WTO Members so as to allow for analysis and comment. With regard to the requirement for an inspection certificate from an authorized authority, the EU felt that a conformity assessment procedure was inappropriate and too burdensome for textile, clothing and footwear products. Within the EU these were considered low risk products, and therefore no conformity assessment procedure was required. Rather than a compulsory certificate of compliance, protecting human health and safety could be met by other means such as random inspection. She inquired whether domestic products were also subject to the same certification procedure. She urged Egypt to consider allowing the import of textile, clothing and footwear products without systemic compliance certificate and test reports.

237. The representative of Turkey expressed thanks for the postponement and said that, while his delegation accepted the legitimate objective pursued by the measures, further clarification was necessary. He asked if the Egyptian standards, as specified in the notification, were in conformity with international standards, and if so, why did the Egyptian authorities not refer to the international standard. He also asked for information on how these decrees affected domestic products. As Turkey had significant investment in the Egyptian textile and clothing market, he urged Egypt to reconsider implementation of these decrees to avoid discrimination between imported and domestic products.

238. The representative of Egypt confirmed the postponement of implementation of both decrees. The new certification requirement applied to both domestic and imported products on the Egyptian market. He requested the EU and Turkey to provide their concerns in writing for a prompt reply.

(xl) European Union – Safety evaluation of childcare cosmetic products (G/TBT/N/EEC/246, G/TBT/N/EEC/246/Add.1)

239. The representative of China asked the EU to provide information on the "Guidelines on Safety Management of Cosmetics" to be published by July 2013. In particular, he asked in what context, and when would these guidelines be published, and about their relationship with those issued

by the *Agence Française de Sécurité Sanitaire des Produits de Santé* (AFSSAPS) and related regulations already published and to be published at the EU level.

240. The representative of the European Union confirmed that the regulation on safety evaluation of childcare cosmetic products would enter into force in July 2013. Work on the guidelines on product safety management was still on-going and would be ready in advance of that date. Concerning the safety evaluation of childcare cosmetic products, there were no harmonized specific childcare cosmetics safety management guidelines at the EU level. The guidelines on safety management on cosmetics, which were also under development, would have some parts dedicated to products for children under three years old. These guidelines would be published before July 2013. She flagged the EU's on-going concern that no approvals on the registration of baby care cosmetics in China had been granted to EU products since April 2010. Her delegation hoped that the bilateral exchanges that had taken place between the European Commission (DG SANCO) and SFDA in March would help solve this longstanding trade concern.

(xli) European Union – Alternatives to animal testing and new cosmetic regulations (G/TBT/N/EEC/246, G/TBT/N/EEC/246/Add.1)

241. The representative of China, referring to information provided by the EU at the last Committee meeting, asked the EU if a solution had been found on the marketing ban which would come into force on 11 March 2013, given that validated alternative methods for the three endpoints would not be available by 2013. He asked for confirmation that the regulation on alternatives to animal testing and new cosmetics applied only to EU member states.

242. The representative of the European Union confirmed that this regulation provided a robust internationally recognized regime, reinforcing product safety while taking into account latest technological developments, including the use of nanomaterials. With regard to the marketing ban which would come into force on 11 March 2013, the European Commission was looking at three options, including letting the 2013 deadline come into effect, postponing the deadline or, a case-by-case derogation mechanism. She confirmed that the marketing ban applied to all cosmetic products placed on the EU market, both within the EU and those imported from third countries. The European Commission was aware of the need to clarify the practical effects of the marketing ban in more detail. The new cosmetic regulation had been discussed at length between the European Commission, China's State Food and Drug Administration (SFDA) and the China's Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) in Beijing in March 2012.

(xlii) 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)

243. The representative of Korea respected Colombia's efforts to improve services for people with reduced mobility and communication difficulties. However, the measure should be harmonized with the relevant international standard, in this case UNECE regulation No.107 which excluded vehicles used for school transportation purposes. By applying the international standard, Colombia ensured compliance with its obligations under Article 2.4 of the Agreement. He asked Colombia to modify the regulation prior to adoption and to provide an update on the current situation. He also asked that Colombia provide an official reply to Korean comments submitted on 15 January 2012.

244. The representative of Colombia informed the Committee that the Ministry of Transport was reviewing the content of the regulation. An official reply to Korea would be provided once the final draft was ready.

(xliii) European Union – issue with respect of honey containing pollen from genetically modified maize MON810, Ruling from ECJ

245. The representative of Argentina reiterated the concern expressed before this Committee on November 2011 as well as in other WTO fora regarding the ruling of the European Court of Justice of 6 September 2011 (Case C-442/09) on honey containing pollen with traces of DNA from genetically modified maize MON 810. According to the ruling, the honey containing pollen derived from Genetically Modified Organisms (GMOs) authorized by the EU was a food product produced from GMO, and therefore came under Article 3, paragraph 1C of the Regulation (EC) 1829/2003.

246. This ruling adopted a new interpretation regarding the scope of Regulation 1829/2003 without appropiate scientific justification. At the same time, the ruling interpreted that pollen was an ingredient of honey, not a natural component, conflicting with the standard for honey in Codex and the European Regulations (Annex II of Directive 2001/110/CE and Article 6, paragraph 2C of the Directive 2000/13). According to said EU Regulations, honey was legally declared in its label as a single ingredient in and of itself; and therefore there was no need to specify pollen as a separate ingredient in the label of that product. The legal uncertainty arising from the ECJ ruling, together with the fact that the implementation of said ruling at EU level was still pending, affected the exportation of argentine honey to the EU, having an impact on regional economies and small producers. Given that more than 9 months had passed since the ECJ ruling, Argentina reiterated its request for the EU to promptly dispel all uncertainties raised by the ruling as well as to eliminate their impact on honey exports to the EU from third countries. Argentina also requested that the implementation of the ruling not result in export restrictions.

247. The representative of Brazil supported Argentina noting the trade disruptions from the uncertainty surrounding implementation of the ECJ ruling. His delegation sought clarification on the measures taken to implement the ECJ decision, requesting that such measures not create unnecessary obstacles to trade in the sense of Article 2.2 and 5.1.2 of the TBT Agreement.

248. The representative of Mexico supported the Argentinian and Brazilian statements and requests.

249. The representative of the United States supported the other speakers. Her delegation believed this ruling was a barrier to trade, and encouraged the EU to take expeditious action to resolve this trade disruption. She asked what progress the EU had made on addressing the impact of this ruling on imports.

250. The representative of Uruguay said that honey was an important commodity in Uruguay, and a significant proportion was exported. Until 2011, the EU was Uruguay's main market; it exported more than 85 per cent to the EU. Following the ECJ ruling, it had been difficult to export to the EU; less than 3 per cent of honey exports went to the EU. This had affected the more than 2000 workers. Her delegation asked the EU to consider these adverse effects of the ruling.

251. The representative of the European Union recalled that a detailed explanation on the background and implications of this ruling had been provided at the November 2011 Committee meeting. According to the European Court of Justice ruling, genetically modified pollen in honey fell under the scope of the relevant EU legislation on genetically modified food and feed (Regulation 1829/2003). Therefore, GM pollen in honey must be subject to an authorization for such honey to be placed on the EU market, and honey containing authorized GM pollen would have to be labelled according to the provisions of the same Regulation (1829/2003).

252. In this case, MON810 was a GM crop that had been authorized in the EU for more than 10 years, but not uses in pollen. In October 2011, the EU's risk assessment body, the European Food

Safety Authority (EFSA) had delivered the opinion that MON810 in pollen was as safe as non GM maize pollen. Meanwhile, in March 2012, the company in question, Monsanto, had submitted an authorization application to cover MON810 pollen in or as food, as required in procedure provided by Regulation 1829/2003. The EU was actively working to ensure the proper implementation of the ruling without causing unnecessary disruptions to the supply of honey to EU consumers, be it from domestic or imported production. Harmonized methods are under development by the Joint Research Centre of the Commission on sampling and detection methods of GM pollen in honey to help EU Member States apply the Court's ruling. In parallel, the Commission is shaping its position on the need to clarify Directive 2001/110/EC relating to honey.

(xliv) European Union – Directive 2009/28/CE, Renewable Energy Directive (EU - RED) (G/TBT/N/EEC/200; G/TBT/N/EEC/200/Add.1)

253. The representative of Argentina noted that the Directive was an unnecessary obstacle to trade due to its unjustified restrictions on imports of biofuels, in particular to the main suppliers of the EU, like Argentina. This directive restricted biofuel imports by requiring, on one side, the compliance and certification of sustainability criteria and, on the other side, the fulfilment of emissions reduction requirements. Regarding the sustainability criteria, they were unnecessarily excessive, cumbersome, arbitrary and unjustified, without any scientific evidence, demanding as well the certification of said criteria as an access requirement to the EU market. Moreover, the directive specified that the reduction of GHG emissions, derived from the use of biofuel had to be a minimum of 35 per cent. This Directive assigned to each biofuel a determined level of GHG reduction. If this level is under the minimum required, as in the case of soya biodiesel, the EU compelled the demonstration the accomplishment of the minimum level of reduction. In this regard, Argentina considered that the minimum level of reductions, and the values assigned to each biofuel had been arbitrarily established without any scientific basis. It is remarkable that soya-derived biodiesel, being the type of biofuel exported by Argentina -as a main supplier- to the EU, was one of the few to which was assigned an emission reduction level under the minimum required of 35 per cent. Due to the sustainability criteria, exports from outside the EU faced problems, including adverse effects on soya derived biodiesel. This Directive indirectly obliged the European user to avoid the soya biodiesel and to opt for biofuels that supposedly comply with the sustainability criteria. Argentina asked the EU to ensure the transparency of this Directive and that its requirements had a clear, scientific basis and did not adversely affect suppliers of biofuels to the EU.

254. Argentina further requested the EU to ensure that exporters did not have to meet high costs and cumbersome procedures as a result of certification, which would unfairly exclude them from the European market. The EU had set a GHG reduction for Argentinian biodiesel of 31 per cent, while the National Institute of Agricultural Technology (INTA) had provided documentation demonstrating that the biodiesel produced in Argentina, through direct seeding, represented more than a 75 per cent saving in GHG. This saving value, owing to the production of soya with the most advanced technology of direct seeding, had manifest advantages for the environment with regard to sustainability, facilitating carbon sequestration in the soil, saving water supplies as well as a sound management of pesticides and less use of fuel. As the EU had not approved the certification system of the Argentinian private sector since December 2010, Argentinian exporters faced difficulties. Since the EU sustainability requirements of biofuel production had to be certified, in December 2010 the argentine private sector grouped around the Biofuel Argentine Chamber (CARBIO) had provided to the EU authorities a voluntary certification scheme. This procedure was still under consideration, even though seven different voluntary certification schemes had been approved, including one for wheat based bioethanol. Argentina asked for information about the current status of the certification procedure submitted by CARBIO.

255. The representative of the United States supported the EU's objective of promoting sustainable sources of renewable energy, but expressed concern that the RED was creating considerable

uncertainty in global biofuel and biofuel feedstock markets and trade. Implementation had already negatively affected imports of US soybeans into the EU. Exports of US soybeans had decreased by 70 per cent from September 2011 to February 2012, compared to the same period the year before when the RED had not been implemented yet. Implementation of sustainability measures with significant economic impact, such as the RED, had to be done in a flexible manner to avoid unintended consequences. The US, in its bilateral dialogue with the EU, had presented creative, flexible proposals that would enable sustainably produced US soybean exports to be recognized as equivalent to the sustainability criteria in the RED. The US had laws and policies to produce soybeans sustainably under the RED criteria, as well as considerable empirical evidence supporting their success. Her delegation requested a response to the US proposals tabled during bilateral talks, and recognition of the sustainability of US soybean exports. The US believed that the TBT Committee was the proper forum for discussing the RED and disagreed with the EU's contention that it fell outside the scope of the TBT Agreement. The US urged the EU to put the issue in the larger economic context, to ensure that sustainability goals were met in a manner that did not present unnecessary barriers to trade or reduce the potential for growth and jobs in a "green" industry.

256. The representative of the European Union informed that the EU had notified the draft Renewable Energy Directive to the Committee in July 2008 (G/TBT/N/EEC/200) due to the TBT elements in the original proposal's Articles 18(2) and 18(3). These, however, were not retained in the final Directive. Concerns expressed by Argentina and the US related to the sustainability criteria for biofuels outlined in the Directive that fell outside the scope of the TBT Agreement, and, therefore, her delegation considered that the TBT Committee was not the appropriate forum for discussing this issue or providing replies to queries. The EU remained open to further bilateral exchange.

(xlv) European Union – Production and Labelling of Organic Products (G/TBT/N/EEC/101; G/TBT/N/EEC/101/Add.1)

257. The representative of Argentina said that the requirements for organic product labelling in Regulation (EC) 834/07 went beyond the objectives established in the text and did not have any basis in relevant international agreements. For these reasons, this Regulation 834/2007 was an unnecessary obstacle to trade. Since the Regulation's objective was to promote fair competition, consumer confidence, and a market for organic products, the requirement set out in Article 24 by which labels had to indicate whether raw materials or final products were obtained in the EU was irrelevant. The TBT Agreement clearly established that technical regulations were not to restrict trade more than necessary to meet a legitimate objective. The imposition of an indication as to the origin of the raw materials on the label did not determine the organic nature of the product and could confuse the consumer, as a product's organic character was the result of its processing rather than of the material's origin. He asked the EU whether similar requirements for organic products had been in place before the introduction of this labelling requirement, and if so, whether there was an obligation to indicate the origin of raw materials. If not, it requested that the EU explain the reason of the changes and clarify on which international convention or standard were based since the Codex Alimentarius guidelines related to production, processing, labelling and marketing of organic products did not contain any obligation to indicate the origin of raw materials on the labelling of an organic product. In addition, and as a result of higher certifications costs, the system was unfavourable to exporters from developing countries. Argentina requested the EU to eliminate this unnecessary requirement that distorted the objectives of Regulation (EC) 834/07 by restricting the importation of organic products from non EU Members.

258. The representative of the European Union recalled that the issues mentioned by Argentina had already been discussed in the Committee several times, most recently in 2009. There was no evidence that the new labelling rules would negatively impact sales of Argentinian products or those from other countries. A new logo had been introduced by Regulation (EC) 271/2010, following Article 24 of Council Regulation (EC) 834/2007 since 1 July 2010. Its use would be compulsory on all European

originating pre-packaged goods from 1 July 2012 onwards but optional on organic products originating in third countries and marketed in the EU. If the logo was used, the obligation to indicate the place of farming under Article 24 would apply.

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

259. The representative of the Dominican Republic recalled that, as from 1 December 2012, Australia would require that all tobacco products (such as cigars and cigarettes) presented for retail sale be in plain packaging. Other restrictions and requirements regarding the appearance of these products would also apply. These requirements would be mandated through the *Tobacco Plain Packaging Act 2011*[5] and its implementing regulations, which were the *Tobacco Plain Packaging Regulations 2011*, as amended by the *Tobacco Plain Packaging Amendment Regulation 2012* (No. 1).[6] The Dominican Republic and other Members had repeatedly expressed concerns with these measures, both in the TBT Committee and the Council for TRIPS.[7] Two Members, Ukraine and Honduras, formally requested consultations with Australia regarding the measures.[8] The Dominican Republic considered that these plain packaging measures restricted international trade in a manner that was inconsistent with Australia's obligations under the TBT Agreement. The measures ran counter to the protection of intellectual property rights, including trademarks and geographical indications, as provided by the TRIPS Agreement and the Paris Convention (as incorporated into the TRIPS Agreement). Australia failed to identify credible evidence that its measures would achieve their objective of reducing tobacco prevalence. In fact, the measures would undermine Australia's objective because they would trigger price competition as a result of the "commoditization" of tobacco products, also leading to increased levels of illicit trade. In view of these concerns, the Dominican Republic informed the Committee that it was compelled to request, in the coming days, formal consultations with Australia regarding these measures, pursuant to Article 4 of the DSU and Article 14 of the TBT Agreement.

260. The representative of Nicaragua supported the Dominican Republic and voiced her delegation's concerns with respect to Australia's measures; they would have adverse economic and social consequences for Nicaragua. As the measure would prevent the use of trademarks on any tobacco product (only allowing the name of the brand in standard print on a plain package), Nicaragua claimed violations of both the TBT and TRIPS Agreements. In particular, the measure violated Articles 2.2 and 11.3 of the TBT Agreement as it created unnecessary restrictions to trade without meeting the Australian Government's goals of limiting adverse health effects. The measure would also make it difficult for foreign firms to export to Australia, thus creating unnecessary barriers to imports. Nicaragua urged Australia to review its measure so that domestic health protection would not adversely affect other countries' rights under the TBT and TRIPS Agreements.

261. The representative of Guatemala said her delegation was still unclear how Australia's plain packaging measure would be compatible with its obligations under the TBT and TRIPS Agreements. She cautioned that international, WHO measures on tobacco and health must be implemented in a way that would not result in violation of these two WTO Agreements.

---

[5] *Tobacco Plain Packaging Act 2011, No. 148, 2011, An Act to discourage the use of tobacco products, and for related purposes* (date of assent: 1 December 2011).

[6] *Tobacco Plain Packaging Regulations 2011, Select Legislative Instrument 2011, No. 263,* as amended by the *Tobacco Plain Packaging Amendment Regulation 2012 (No. 1), Select Legislative Instrument 2012 No. 29*.

[7] G/TBT/W/339; G/TBT/W/346; IP/C/W/565; IP/C/M/66.

[8] Ukraine filed a consultations request on 13 March 2012 (WT/DS434/1; circulated 15 March 2012) and Honduras filed a consultations request on 4 April 2012 (WT/DS435/1, circulated 10 April 2012).

262. The representative of Uruguay said that Members were entitled to protect lives and health of their citizens, including by implementing the WHO FCTC. This was, thus, a matter of national sovereignty. On the other hand, Members must not take measures that adversely affect their obligations under the TBT Agreement. Australia had properly justified its tobacco plain packaging measure as it was in keeping with its WHO obligations.

263. The representative of Norway supported Australia's policies on tobacco control, including its plain packaging measures. Public health in general - and tobacco control regulation in particular - were of particular interest to Norway. It was within the right, indeed within the obligation, of each WTO Member to adopt measures necessary to protect public health. Clearly tobacco control policies and preventative measures, such as those implemented by Australia, had the legitimate objective of protecting public health by reducing the use of tobacco products. Norway trusted that Australia's legislation would be implemented in compliance with Australia's international treaty obligations.

264. The representative of New Zealand welcomed Australia's decision to legislate for the plain packaging of tobacco products. The negative effects of smoking could not be overstated; in New Zealand, smoking was the leading preventable cause of early death. Past discussions made clear that Australia respected its WTO obligations in developing its plain packaging proposal. On 19 April 2012, New Zealand's Associate Minister of Health announced that its Government had agreed, in principle, to introduce plain packaging of tobacco products, subject to the outcome of a public consultation process. Final decisions on whether to introduce such legislation would be made only after the results of the public consultation process had been taken into account. This process was a transparent way to review the evidence and test the case for plain packaging, while giving the public, the health sector and business interests a chance to have their say. New Zealand would notify the details of this consultation to the TBT Committee later this year to allow all interested trading partners to have their say.

265. The representative of Canada said that his delegation continued to follow the on-going international developments on plain packaging of tobacco products, in particular the Australian measure, and how they might interact with international trade and public health. Canada understood that Australia conducted serious research to support the introduction of its measure.

266. The representative of the Philippines said her delegation was following these discussions both in the TBT Committee and in the TRIPS Council. It had a substantial trade interest, having initiated cigarette exports to Australia in 2010 and experiencing significant export growth in 2011. As a relatively new entrant in the Australian market, the Philippines was keen to further understand the potential impact of the plain packaging law on Philippine cigarette exports. On the other hand, the Philippines was also a party to the FCTC and, as such, was interested in knowing more about the relevance of the measure to the effective implementation of this WHO convention.

267. The representative of Brazil said his delegation supported the legitimate objectives of public health protection that the Australian measure sought to achieve. It recognized the right of Members to regulate the tobacco sector in conformity with the WTO Agreements to protect public health. Brazil would continue to follow the international developments and Members' experiences in this area.

268. The representative of Australia was disappointed by Dominican Republic's announcement to this Committee of its intention to request dispute settlement consultations with regard to Australia's plain packaging measures. His delegation had not yet received any official request for consultations from the Dominican Republic. It was, therefore, surprising that the Dominican Republic chose to announce its intention in this manner, especially given the bilateral nature of dispute settlement consultations. As explained in previous meetings, Australia was implementing the measures in the interest of promoting public health. Australia was confident that, as part of a comprehensive package of tobacco reforms, the measures would make an effective contribution to efforts to reduce smoking

rates, thereby reducing the health impacts of smoking on Australian individuals and the community at large. Australia had consistently engaged with WTO Members on these measures, including those Members that had raised concerns in this Committee. Australia expected any requests for consultations to be made in accordance with Article 4 of the DSU and would vigorously defend any challenge that might result from any such consultations.

269. Australia also acknowledged the support it received for the important measures. Australia said that there was no significant change in the status of the measure since the last meeting. The *Tobacco Plain Packaging Act 2011* and the *Trademarks Amendment Tobacco Plain Packaging Act 2011* were passed by the Australian parliament in November 2011 and received royal assent on 1 December 2011. The final Tobacco Plain Packaging Regulations relating to cigarette products, which contained additional, specific detail on how the plain packaging requirements had to be implemented, were approved on 7 December 2011. The final Tobacco Plain Packaging Amendment Regulation 2012, which incorporated the specifications of non-cigarette tobacco products into the regulations, was approved by the Executive Council on 8 March 2012. The Government undertook two consultation processes on the approach to plain packaging of non-cigarette products and the details of the Amendment Regulation. Submissions made in those processes were taken into account. All retail tobacco products manufactured or packaged in Australia for domestic consumption would be required to be in plain packaging by 1 October 2012. All tobacco products sold in Australia would be required to be in plain packaging by 1 December 2012. Australia received two requests for formal consultations under the DSU from Ukraine (on 13 March 2012) and Honduras (on 4 April 2012). These Members claimed that Australia's plain packaging measures were inconsistent with certain WTO obligations. Australia held consultations with Ukraine and Honduras on 12 April and 1 May 2012, respectively. Australia had been responsive to comments from trading partners and other stakeholders and these comments were taken into account and led to changes in the Bill and draft regulations where the changes were in line with the Government's policy objectives. Australia recalled that the objectives of the measures were: (i) to reduce the attractiveness and appeal of tobacco products to consumers, particularly young people; (ii) to increase the noticeability and effectiveness of mandated health warnings; (iii) to reduce the ability of retail packaging of tobacco products to mislead consumers about the harms of smoking; and (iv) through the achievement of the above aims in the longer term (and as part of a comprehensive suite of tobacco control measures) contribute to efforts to reduce smoking rates.

270. The Committee took note of the statements made under this agenda item.

C. EXCHANGE OF EXPERIENCES

1. Good Regulatory Practice

271. The Chairman recalled previous recommendations made under the Fifth Triennial Review.[9] The following submissions had been made: New Zealand (JOB/TBT/5) and the United States, on behalf of APEC member economies (G/TBT/W/350).

272. The representative of New Zealand recalled her delegation's submission (JOB/TBT/5) which proposed a draft outline of Guidelines on Choice and Design of Trade Facilitation Mechanisms, and which was developed in response to one of the Fifth Triennial Review decisions.[10] She said that work remained to implement this Fifth Triennial Review decision. She therefore suggested that the Secretariat could begin the drafting process outlined in her delegation's submission, populating the framework with examples that have been shared in Committee context, including: the joint International Laboratory Accreditation Cooperation (ILAC)/ International Accreditation Forum (IAF)

[9] G/TBT/26, paras. 11 and 16.
[10] G/TBT/26, para. 19.

presentation delivered during the June 2011 Committee meeting[11]; the presentations and discussions at the November 2011 Regulatory Cooperation Workshop[12]; and, the submission from the United States on the use of the ILAC MRA and IAF MLA by central government bodies.[13]

273. The representative of Mexico found New Zealand's submission to be useful, and said that her delegation was willing to share information with Members as proposed therein. She expected to make further comments on the submission after analysis by responsible agencies.

274. The representative of Australia expressed willingness to further explore the ideas in New Zealand's submission in the context of the Sixth Triennial Review.

275. The representative of the European Union observed that the work on the guidelines for GRP and on the illustrative list of good implementation practices would necessarily extend beyond the time horizon of the Sixth Triennial Review since it was a comprehensive exercise requiring significant work, also on finding a suitable balance among various Members' positions. He believed that the Committee had already made good progress towards fulfilling the recommendations of the Fifth Triennial Review in respect of Good Regulatory Practice (GRP)[14] through useful dialogue in the Committee, the Workshop on Regulatory Cooperation, and contributions from the Secretariat.[15] He said the Committee should now consider how to further advance work on GRP in those areas that were most relevant for the implementation of the TBT Agreement, in the context of the Sixth Triennial Review, and beyond.

276. While this process should in the first rely on submissions from Members, he suggested that it may be better facilitated through discussions in an ad hoc Working Group, or in some other informal context, organized on specific themes of GRP and held back to back with regular Committee meetings. He explained that this would provide opportunity for interested Members to make progress on GRP in a less formal setting, without the need to record the discussion in Committee minutes. The outcome of such work could subsequently be shared with the Committee. He suggested, as a realistic deliverable on GRP for the Sixth Triennial Review Report, that the Report could identify areas where Members believed there was potential for undertaking this kind of analytical and in-depth work. This need not include an agreed list of list of illustrative principles and practices of GRP, but rather it would identify the broad headings upon which work would be undertaken towards formulating such a list.

277. The representative of the United States said her delegation had expressed interest in furthering work on GRP in the TBT Committee, including in respect of development of an illustrative list of practices and ideas. While she believed that this work should be driven by submissions from Members, her delegation was open, subject to views of other Members, to the EU suggestion of a Working Group or other informal setting to advance work. From the United States' perspective, simply discussing the importance of the relationship between trade and GRP was valuable for Members. She specified that any work in this regard should be explicitly non-binding. With respect to the New Zealand submission, she was of the understanding that it related to conformity assessment.

278. The representative of the Secretariat recalled the substantial information exchange on GRP that had been undertaken by the Committee, including at workshops on Regulatory Cooperation between Members and on Good Regulatory Practice, he also noted the Secretariat background papers. He said that more work could be done based on Members' suggestions and input.

[11] G/TBT/GEN/17.
[12] G/TBT/W/348.
[13] G/TBT/W/349.
[14] G/TBT/26, paras. 11 and 16.
[15] G/TBT/W/340.

279. In concluding, the Chairman stressed the importance of GRP to the effective implementation of the TBT Agreement. With regard to the deliverables in the Sixth Triennial Review on GRP, Members contributions would be important for continued progress on GRP, and for setting a good course for future work. He noted suggestions from Members about the process for advancing this work after the Review, including in a Working Group format.

2. Standards

280. The Chairman recalled previous recommendations made under the Fifth Triennial Review and drew the Committee's attention to the following relevant submissions: Colombia (G/TBT/W/351), India (G/TBT/W/345) and Korea (G/TBT/W/353).

281. The representative of Korea introduced his delegation's submission (G/TBT/W/353), stressing, in particular, the importance of developing country participation in the development of international standards.

282. The representative of India, recalling earlier discussions, noted that some Members appeared to be striving for a less ambitious approach on international standards. He sensed that since the existing *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")[16] offered a certain amount of flexibility (to regulate) that Members were comfortable with, there was hesitation to tamper with the existing text. Thus the Committee, India proposed, could consider a work programme on standards – one that encapsulated all Members' participation and considered specific areas or themes, such as: best practices by standard setting bodies; definitions of international standards (as suggested in the Colombian paper and supported by Mexico); and, practical aspects of the implementation of the Committee Decision's six principles on standard setting by international standardizing bodies including exploring any new principles. Another topic could be to explore specific provisions on transparency related to standards (as opposed to technical regulations and conformity assessment procedures), such as comment periods on draft standards, access to full text of the standard, providing on a voluntary basis the impact assessments along with the notification format. Other possible points for discussion could be electronic working methods and reasonable fee for access to standards. As some standard setting bodies had an Action Plan for developing country Members, this could be tailored to ensure participation of developing country Members.

283. The representative of Cuba stressed the importance of the effective participation of developing countries in standard-setting activities. She also agreed with the points India had made on transparency in standard-setting and proposed a closer co-operation between the WTO and different international standards bodies.

284. The representative of China proposed that a special mechanism be established to ensure that more developing country Members could participate in international standardization. With respect to the development of international standards, China suggested that mechanisms or remedies should be established to enable any Member to appeal unreasonable decisions made by technical standardizing committees. For technical regulations based on international standards, China supported the proposal that standardizing bodies involved should allow Members who adopt those technical regulations to publish those technical regulations for free.

285. The representative of Malaysia said, with respect to the Indian submission, that the principles for international standards were adequately captured in the existing TBT Committee Decision and posed no difficulties for competent bodies to comply with. She emphasized that standards

[16] The full text of this Decision is contained in Annex B of G/TBT/1/Rev.10, dated 9 June 2011.

development was a diverse activity and an overly prescriptive or limited set of principles could be counterproductive. In particular, she argued, in a world of fast changing and new emerging technologies, it would be futile to limit international standards to any particular organization. Clear principles to guide the development of international standards were needed, not restrictions on *which* organizations could develop them. With respect to India's paper, paragraph 3 (in G/TBT/W/345) seemed to imply that *regulators* developed international standards. This was not the case: as was set out in Annex 1 of the TBT Agreement, standards were defined as documents prepared by the standardization community, not regulators.

286. With respect to India's specific proposals (in paragraph 4) Malaysia had a number of comments. On openness, Malaysia asked for clarification on the operationalization of the mechanism and action plan for the participation of LDCs in the development of international standards. On impartiality and consensus, Malaysia was of the view that the consequence of the procedures as proposed would slow down the development process and result in fewer standards. On the issue of coherence, Malaysia did not see the need to create a database of existing standards; instead, the existing system for the sharing of information on relevant international bodies needed to be improved through better coordination. With respect to the additional principles as proposed by India (paragraph 5) Malaysia noted that there existed appeals mechanisms in the ISO context (ISO IEC Guide 59). Finally, on guidelines for transposition to national standards, Malaysia sought some further clarifications India. The representative of Malaysia also acknowledged the proposal from Korea and said that her delegation might have comments at the following meeting.

287. The representative of Colombia expressed support for the programme of work suggested by India: this could indeed lead to an in-depth discussion which would engage developing countries on the subject of international standards, and help address some of the underlying uncertainties. There was a need for a clear definition of international standards that would enable the Committee to address the ambiguity in the TBT Agreement. For Colombia, such clarification would mean that Members would be able to make better use of international standards. Currently it was difficult to know whether a standard was or was not international, unlike, for instance, in the SPS context.

288. The representative of Mexico supported the Korean proposal, particularly on the importance of harmonization.

289. The representative of Canada asked for some clarification on Korea's proposal in particular with respect to the reference to the "pace of harmonization".

290. The representative of Brazil noted that India's proposal regarding a work programme on international standards seemed to be a useful approach to addressing some of the most important aspects in the area of international standards before the Committee. Regarding possible topics for the agenda, the Committee could consider: "best practices" in international standardizing activities; the definition of relevant international standards; and, the principles of the TBT Committee Decision.

291. The representative of Japan recalled the recommendation contained in the Committee's Fifth Triennial Review to share experiences on the application and use of the Committee Decision.[17] He also recalled that the OECD had shared a publication entitled "The Use of International Standards in Technical Regulations," which had examined to what extent technical regulation had been introduced in line with international standards by Members. This type of input was important in considering the nature of international standards. It was better, in the view of Japan, to continue to share these experiences rather than to rush to the development of new principles.

[17] G/TBT/26, para. 25(c).

292. The representative of the United States supported the proposal to share experiences on the application of the Committee Decision's principles. However, the United States did not agree that defining particular international standards would help the Committee promote harmonization of product requirements across export markets. This could instead pose a risk to the wide range of standardizing activities undertaken in the private sector that were essential to supporting global trade. As had been said by the delegation of Malaysia, the United States stressed that standards development occurred in many different contexts and bodies; achieving the objectives of all of these activities was essential to underpinning the modern global economy. These objectives ranged across a wide array of areas, including: quality and efficiency of domestic production; consolidating internal markets and enabling access to foreign markets; supporting the operation of complex supply chains; creating new markets through interoperability, which was critical in the modern economy; and, supporting regulatory quality and coherence in addition to providing commercial platforms that enabled all to benefit from innovation. The work of the Committee needed to promote principles and practices that embodied the validity of all of these objectives, even if they were weighed differently by different Members. In this regards, a good balance had been struck in the Committee Decision.

293. Regarding the issue of the impact of "private standards" raised in Colombia's submission, the representative of the United States recalled that the Committee had had an informative exchange at the Committee's workshop on international standards in 2009.[18] Valuable insights had been provided by several Members on the on the role of collaboration among producer groups, industry associations, exporters and national standards bodies in developing strategies and building technical conformance infrastructure to enable local producers to meet those challenges. There had also been a constructive exchange of views on this topic in the Fifth Triennial Review, including with respect to the lack of applicability of provisions of the TBT Agreement to what were essentially the terms of private contracts between buyers and sellers. She recalled that the Report of the Fifth Triennial Review fairly represented the balance between Members' views in the Committee on this issue. The United States would have concerns with proposals that move beyond the consensus reached.[19]

294. Regarding the programme of work suggested by India, the United States recalled the ambitious mandate set out in the last triennial review, including on standards. The Committee needed, in practical terms, to now consider next steps. The work of the Committee could perhaps be usefully focused, under the agenda item on standards – by agreeing ahead of time on particular themes for individual Committee meetings. This would help the membership to be better prepared and could facilitate progress on existing recommendations.

295. Finally, the representative of the United States wished to stress one particular point that India had raised and on which they were in complete agreement: the need for transparency in the development of standards by national standards bodies, and in particular central governmental bodies. She noted that in TBT Code of Good Practice there was reference to a mechanism for transparency on standards – the ISO NET. Yet this had, according to the US understanding, ceased to exist many years ago. This only accentuated the challenge before the Committee.

296. The representative of Chinese Taipei recalled three of the principles set out in the TBT Committee Decision: (i) transparency, (ii) openness and (iii) impartiality and consensus. In her view, these principles underscored the importance of participation by – and inclusiveness of – all WTO Members in international standardizing bodies. In terms of inclusiveness there were a number of important questions to pose: would an international standardizing body invite comments from specified stakeholders, or, rather, from the general public? If only from specified stakeholders, what would the criteria be for selection of such stakeholders? If from the general public, how would consultations be conducted? Moreover, would an international standard setting body consider

[18] G/TBT/W/310.
[19] G/TBT/26, para 26.

stakeholder comments from unsolicited sources? Would, for instance, an international standardizing body consult entities of a WTO Member that was *not* a member of the standardizing body, particularly if and when the entity of such (a WTO Member) was a leader or otherwise highly relevant in the field? In terms of impartiality and consensus, the representative of Chinese Taipei preferred to retain the WTO definition of consensus. Chinese Taipei emphasized that her delegation stood ready to engage in discussions about how to implement the principles on the basis of all Members' meaningful and effective participation in international standardizing activities.

297. The representative of Switzerland referred to the alleged "ambiguity" of the term "international standard" in the TBT Agreement. He noted that, as mentioned in the Colombian proposal, the Committee Decision could serve as a first checklist in order to frame the development of international standards. He did not see any urgency to re-open the Committee Decision. While it was not necessarily possible to define what an "international standard" was, the Committee could perhaps usefully clarify the phrase. The representative of Switzerland also considered the idea of setting up a database of standards as worthy of exploring.

298. The representative of the European Union referred to Korea's paper and expressed his delegation's support for work aimed at enhancing the participation of developing countries in international standard-setting activities. On India's proposal for a work program on standards, which the EU understood as applying to "standards" in general, whether national or international in nature, the EU would look with interest at any proposal submitted in time to be considered in the framework of the Sixth Triennial Review. In general, however, he stressed the need to focus on topics that were realistically feasible. The European Union wished to focus, as a matter of priority, on exchanging experiences and collecting information on the application of existing principles for standard setting as they were currently embodied in the Code of Good Practice (Annex 3) of the TBT Agreement, and in the 2000 Committee Decision (the six principles). He also stressed the importance of focusing on the transparency aspects of standard-setting, in particular with respect to how the public enquiry stage was handled at a national and regional standard-setting level, as well as how stakeholder input and the principles of inclusiveness were implemented in international standard-setting. He supported the Colombian point that when standards were made mandatory through technical regulations or through references in conformity assessment procedures; they needed not only to be notified to the TBT Committee, but associated texts also needed to be made fully available. Regarding the definition of an "international standards", the European Union referred to previous comments.

299. The European Union supported the idea that the Committee could hold dedicated thematic sessions to allow Members to delve deeper into certain topics - without necessarily dealing with all of them in one and the same meeting. This approach would allow delegations to better prepare, and, if necessary, bring relevant experts to address specific topics. This approach could be developed for much of the Committee's work as a means of having a more fruitful exchange of views in several of its areas of work (i.e., not limited to standards).

300. The representative of Japan referred to the points made by Colombia on private standards. Japan was of the view that it was not clear whether Colombia, in its submission, was referring to standards developed by a standardization body or a private entity. Japan echoed the position of the United States on private standards. In the context of Article 4.1 of the TBT Agreement, the Committee had discussed standards developed by non-governmental standardization bodies for years in connection with Members' obligation to take *reasonable measures* to ensure that non-governmental standardization bodies adopted and applied the Code of Good Practice. Thus, if Colombia's proposal was relevant to such bodies, the Committee could discuss them in that context (Article 4.1). However, if Colombia was referring to standards developed by other private entities, this was outside of the scope of the TBT Agreement.

301. The representative of the ISO wished to follow-up on the Committee's March discussion on standards. In general, the ISO fully supported the idea that international standardizing bodies who claimed to observe the Committee Decision's six principles needed to be able to demonstrate that claim; nevertheless, there would be difficulties associated with an independent verification of compliance with the six principles. On participation in ISO technical committees, the representative of ISO stressed that all WTO Members could become Members of ISO and participate in technical committees dealing with standards development. Even ISO Members not participating in technical committees had a voice, since they could vote on draft standards.

302. The representative of the OIML said that his organization mainly developed model technical regulations in the field of legal metrology. He stressed that the OIML, as an international standardizing body, supported the principles of good practice as set out in the TBT Agreement. He agreed with the concerns expressed by the ISO representative, as well as the United States, concerning the appropriateness or need to restrict the list of international standard setting organizations or attempt to define it any further. He informed Members that the OIML was in the process of finalizing a revision of its working procedures for its technical work; these procedures were intended to embody the principles of the TBT Agreement as far as possible, and to ensure that the work of the OIML was conducted in compliance with those principles, where possible. On the issue of consensus, although the OIML tried in its work to ensure that the views and needs of as many of its members as possible were taken into account, it was constrained by certain voting requirements which were enshrined in the OIML treaty. Nevertheless, all information on the OIML technical work – from the very initial drafts through to final publications – was publically available and free of charge through its website. This process provided adequate opportunity for all interested stakeholders to participate and to provide comments.

303. The representative of India said that his delegation did not envisage verifying the principles that the OIML or the ISO followed, rather his delegation was proposing an exchange of information (among WTO Members) on how exactly standards were set. For example, with respect to the ISO process, although all ISO members participated, for those that were not part of the technical committee, it was only the negative vote that counted, not the positive vote. The positive vote could only be made by the members of that technical committee. These nuances were difficult to follow and could benefit from a closer look in the context of a Committee work programme. There was no intention of harmonizing the practices across different bodies but rather to have a better understanding of how the organizations worked.

304. The representative of India further noted that Malaysia had addressed the issue of how to ensure that LDCs participated in standard-setting. In this regards, his delegation's paper had suggested that standardizing bodies look at having an action plan for developing countries (this already existed in some organizations), whereby a single representative of an LDC group – or some other developing country group – could participate in, for example, the ISO process representing a larger group. While perhaps not the best solution, it would be a step in the right direction. On the voting process, India understood that this was contentious: methods varied from body to body. Again, India was not proposing to change this; nevertheless, there needed to be some way to ensure that there was a sufficiently large number of positive votes before a standard was adopted.

305. The representative of India thanked both Brazil and Colombia for support on the idea of a work programme and agreed with the United States on the importance of transparency in standard-setting. On the modalities, in India's view the best forum for this work was the Committee itself with an agreed agenda item for each Committee meeting.

306. The representative of the United States referred to the point made by India on "action plans" for financing the participation of developing countries in standardizing activities. She stressed that most standardizing bodies were private sector bodies – not public sector bodies. Therefore, as WTO

Members, governments only exerted influenced through their participation in these bodies or their technical committees. A number of the (private) bodies were doing considerable work trying to enlarge participation by developing countries – however, she noted, participation in technical committees was done largely by volunteers – and this was in large part driven by an interest in using the outcome, which was essential for the quality of the standards thereby developed. She noted that voting processes varied widely across bodies, depending on the type of standard in the pipeline; this process was also closely linked to what the members and participants of the particular body felt was appropriate for the standard in order to develop it in a timely and effective manner.

307. In concluding the Chairman stressed the importance that the Membership had given to participation in international standardizing activities – in this regard he stressed the principles of transparency, inclusiveness and consensus. He also noted that the proposal to develop a work programme, or otherwise find ways and means of focusing the Committee's work, appeared to have gained traction.

3. Conformity Assessment

308. The representative of the United States reiterated that conformity assessment was key to regulators' ability to assure confidence that requirements set out in technical regulations were being met. Moreover, conformity assessment was increasingly being used in voluntary programmes, including voluntary standards. She recalled that the United States had presented its paper on ILAC and IAF at the previous meeting of the Committee.[20] In this regard, she said that the United States saw the work of regional networks of accreditation bodies as essential in building competence, proficiency and avoiding conflicts of interest. In addition to strengthening ideas on the implementation of Aarticle 9 of the TBT Agreement, the United States was interested in finding ways to improve the implementation of Article 5 of the TBT Agreement, and in particular Article 5.4 – which, she recalled, required central government bodies to base their conformity assessment procedures on international standards, except where they would be inappropriate in meeting their objective. It was particularly important to ensure the competence and independence of conformity assessment bodies; a closer inspection by the Ccommittee of the provisions of Article 5 could yield important returns in terms of strengthening implementation. In terms of the themes for discussion in a dedicated work programme, the United States proposed that the Committee could have an information session where, for instance, ISO CASCO experts and other experts from conformity assessment bodies or accreditation bodies would provide information in this respect.

309. On New Zealand's submission on trade facilitation[21], the United States supported efforts by Members to provide information and perspectives to the Ccommittee to promoted shared understandings - particularly regarding complex issues such as the choice of conformity assessment procedure in different situations. The United States was somewhat concerned that the suggested content was too detailed for a Ccommittee document and that the level of analysis and complexity in the paper was perhaps greater than what was ppracticable in terms of gaining agreement on the language. The United States would support a more simplified and flexible approach; for instance, the Committee could discuss or compile a set of options for reference for Members to inform internal decision making with respect to trade facilitative mechanisms on conformity assessment. Such options would need to include a reference to the use of international standards and international systems of conformity assessment.

310. The Secretariat recalled that some of the recommendations contained in the 6th Triennial Review Report were specific in nature.

[20] G/TBT/W/349, dated 13 March 2012.
[21] JOB/TBT/5, dated 17 September 2010.

311. The representative of the United States noted that, in her delegation's view, conformity assessment was a particularly complex area and that therefore continued information exchange on the implementation of Articles 5.2 and 5.4 of the TBT Agreement would be useful. This need was further underlined by the many trade concerns discussed in the Committee that were fundamentally about conformity assessment procedures. She reiterated that there was existing guidance in international standards that could be shared and discussed. It could be useful to begin by considering existing work on this subject, and the meaning of various guides and recommendations put out by different bodies. It was also important to consider these along-side efforts to increase transparency in standard-setting as more and more Members regulated on the basis of voluntary standards which addressed critical, societal, public health and/or environmental objectives.

312. The representative of the European Union noted that the Committee had progressed less on conformity assessment as compared to GRP. Nevertheless, he noted that the recommendations from the Fifth Triennial Review still held and provided a roadmap to follow. Indeed, Members were aware during the last Review that the work to be done would not be accomplished in the timeframe of one triennial review. Hence, the exchange of information needed to continue. This would enable the Committee to extract some principles, guidelines or illustrative examples to base its work on. And while on GRP the exchange of information has progressed well, and the Committee had gathered enough of a critical mass of information from which to extract principles, on conformity assessment there was clearly still scope for more exchange of information before going a step further. It made sense, in the view of the European Union, to identify areas where there was sufficient interest to continue work through thematic sessions. For instance, one issue that had not been explored in the TBT Committee was the issue of risk assessment vs. risk management in the TBT area. While all Members very much supported a risk based approach to conformity assessment, views differed widely on the notion of risk assessment and how to manage risks through conformity assessment. These discussions could usefully be explored in further depth. Indeed, this was also relevant to GRP: to date, GRP had mainly been looked at with regard to technical regulations but discussions on GRP were equally relevant to conformity assessment.

313. The Chairman concluded that the emphasis in the area of conformity assessment appeared to continue to be on information exchange.

314. On a separate matter, the representative of Canada drew the Committee's attention to the fact that the governments of Canada and Mexico had agreed on an MRA on conformity assessment for telecommunications equipment. The agreement was subsequently notified to the Committee.[22] The MRA was aimed at streamlining conformity assessment for a wide range of products.

4. Transparency

315. The Chairman recalled previous recommendations made under the Fifth Triennial Review[23] and drew the Committee's attention to the following recent submissions: Japan (G/TBT/W/352), Korea (G/TBT/W/353) and European Union (G/TBT/W/354).

316. In introducing his delegation's submission, the representative of Japan stressed the importance of improving and strengthening the implementation of the transparency provisions of the TBT Agreement. With regard to the first element of the submission – response to inquiries and comments on TBT notifications – he said that responses to all reasonable inquiries should be provided in a timely manner, and that a standard time period could be set from receipt of comments to response in the context of the Sixth Triennial Review. Allowing Members to share experiences regarding difficulties in responding to comments could be beneficial in this regard.

[22] G/TBT/10.7/N/110, dated 12 June 2012.
[23] G/TBT/26, paras. 29-54.

317. On the second element – ensuring opportunities for comments to TBT notifications – the representative noted cases when Japan's written comments in English were not accepted by the notifying country, because only written comments in Spanish were accepted. In this context, his delegation faced difficulties in providing translated comments within the comment period. In response to such situations, he suggested the Committee recommend that if a comment were written in one of three WTO official languages and reached a notifying country within the comment period, Members should accept a translated version of the comment (if that Member only accepted comments in one language) even after the end of the comment period, provided that the translated comments are delivered within a reasonable period of time.

318. Regarding the third element of the submission – reply to enquiries through the TBT enquiry point – he suggested that the Committee include in the Sixth Triennial Review a recommendation to encourage Members to reply to enquiries, and for Members to share experiences about cases where it was difficult to respond to enquiries.

319. With respect to the fourth element – Code of Good Practice – he recalled that Paragraph L of Annex 3 of the TBT Agreement states "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." He proposed the Committee consider initiating in the Sixth Triennial Review a sharing of Members' experiences and best practices on implementation of this paragraph.

320. The representative of Korea noted three issues from her delegation's submission. First, she highlighted the ambiguity of the criteria used to determine "significant" trade effects in Articles 2.9 and 5.6 of the TBT Agreement, and that notifications ultimately relied on the subjective judgement of the competent authorities concerned. Her delegation believed that the abstract criteria to assess the significance of a regulation’s effects on trade were partly to blame for the failure of some Members to notify important technical regulations, and she stressed that more precise criteria in this regard were necessary. As a first step, she suggested the WTO Secretariat investigate specific trade concerns that had not been the subject of TBT Committee notifications, and analyse the rationale behind the failure to notify.

321. Second, she proposed that Members submit, whenever possible and on a voluntary basis, an electronic version of the regulatory impact assessment in the Members' national language along with notifications to the WTO Secretariat. The regulatory impact assessment could be made available through a hyperlink on the Members website, marked on the notification. The representative said the new procedures could be phased in gradually; Members could initially share impact assessments for Acts, and later for subordinate statues and regulations.

322. Third, her delegation suggested that in the context of the Sixth Triennial Review, Members reaffirm the importance of mechanisms to ensure intra-governmental coordination under Articles 3.2 and 7.2 of the TBT Agreement, including encouragement that Members notify the TBT Committee of local government regulations. She said that Committee was still not being notified of many such local government regulations, and that her delegation had noticed disharmony between technical regulations proposed by central and local governments. She suggested the Sixth Triennial Review encourage Members to share experience and difficulties regarding these issues.

323. The representative emphasized the importance of progress in this respect to build Members’ confidence in the implementation of the TBT Agreement. Her delegation intended to further develop this submission, and was open to any comments or guidance from other Members.

324. The representative of the European Union explained their submission addressed existing obligations under the TBT Agreement and recommendations developed over time by the Committee

on transparency, as well as proposals to improve the TBT Information Management System (TBT IMS). He noted Section 2 of the submission covered similar themes as Japan's submission, namely that there remained some serious short comings in Members complying with certain basic obligations in the field of transparency, such as a lack of notifications or lack of response from the enquiry points, as well as Members not following Committee recommendations.[24] The representative stressed the need to reaffirm the importance of Members fully complying with their transparency obligations, and implementing the recommendations of the Committee.

325. He expressed concerns about uncertainty as to the actual duration of the comment period, and the actual deadline for comments. More specifically, he said there was a margin of ambiguity as to whether the 60 day period began from the moment of sending a notification to the Secretariat, or if it began from the moment of circulation of the notification by the Secretariat. Given that there was no uniform time period between sending a notification to the Secretariat and its circulation, this increased uncertainty about the comment period, and often reduced the effective length of the comment period to significantly less than 60 days.

326. The representative said his delegation, despite being a large Member with significant capacity in principle, had faced challenges in managing the growing number of TBT notifications over recent years, which raised the question about ways to help facilitate Members efforts to access and manage this substantial flow of information. He said this was important for maximizing the chances that Members take full advantage of their opportunities and rights under the notification procedure, in other words: becoming aware of notifications; reacting to those that are of interest; and, keeping track of regulatory developments in other members.

327. He believed one way to address this information management challenge was improvements to the existing TBT IMS. Given that the Secretariat was engaged in on-going work to enhance the TBT IMS, he believed this was an opportune time to engage in such a discussion in the Committee. His delegation's submission covered three broad objectives in this respect: promoting efficiency; keeping track of information relating to a single notification; and awareness raising.

328. In terms of making the system more efficient to promote time savings, his delegation proposed that the forthcoming online TBT notification submission system enable direct uploading of TBT notifications. He insisted on direct uploading to avoid repetitive copy and paste steps by TBT enquiry points, as was the case with the new online SPS notification submission system (NSS). This was technically feasible; his delegation successfully implemented a similar database for managing internal notifications of draft technical regulations by EU member states, and was willing to share experience in this regard. A further advantage of direct uploading would be to minimize the need for processing by the Secretariat, reducing uncertainty about the length of the comment period. The comment period could begin immediately from the uploading of the document to the database, or in any event, would provide for a standard time period between the uploading of the document and it being made available to WTO members. He noted that online submission should remain voluntary, and that Members could continue to use other means of notification if they found them more suitable for their needs. However, in this case, he suggested that the starting date for the comment period be the date of the circulation of the notification by the Secretariat.

329. Further on efficiency, with respect to definition of the scope of draft measures, he said that reliance on the Harmonized System (HS) codes or International Classification of Standards (ICS) was cumbersome and did not reflect the reality in which technical regulations and conformity assessment procedures were developed. He explained the difficulty of capturing in an exhaustive way all the products that are covered by a technical regulation or conformity assessment procedure under an HS codes. As a user it was very challenging to search for technical regulations that apply to particular

[24] See: G/TBT/1/Rev.10

products, if one was not very well versed in a particular product sector, and was familiar with the HS customs nomenclature. Therefore, his delegation proposed a new categorization of products, defining by a number of product categories which correspond to the main industry product sectors subject to TBT notifications. When uploading a notification, he explained the notifying authority would choose from those predefined categories the one which best matches the scope of the notifying text. His delegation was open to ideas about the length of the list of categories and their description. This approach would create a repository of technical regulations and conformity assessment procedures that apply to a given product sector in all Members, since a user could search by product sector and have immediately have access to all notifications from all Members pertaining to that sector.

330. With respect to keeping track of information relating to a single notification, he suggested that all information concerning a notification be accessible on one single page. In other words, the original notification, the final adopted texts, and any amendment thereto, any corrigendum, and any revision should all be accessible on one and the same page. He noted that this was implemented in the European Union database, to the appreciation of by users who were thereafter better equipped to follow developments related to a given measure. Along these lines, the representative proposed that the Committee agree to a uniform coding system for the use of addenda and revisions, since there was currently some irregularity in the use of addenda and revisions by Members which caused confusion and complicated following developments on a measure.

331. Lastly, on awareness raising, he said that IT tools helped build and raise awareness about TBT notifications, the content of technical regulations, regulatory developments, and about the TBT Agreement in general. In this regard, he proposed that a facility be created so that Members could, on a voluntary basis, upload comments received from other members and also responses given to comments. He explained that this would allow Members to become aware of concerns raised by each other, and since specific trade concerns were largely a repetition of concerns already communicated in written comments, he said this shouldn't create confidentiality issues. However, he submitted Members should be entitled to bring confidentiality issues to the attention of the Secretariat, and therefore refrain from posting comments in that case. Nevertheless, his delegation believed there was great potential for learning from one another, since the written exchange that takes places in the framework of the TBT notification was a powerful learning tool.

332. The representative noted a second aspect concerning awareness raising: the use of IT tools to develop an email alert system whereby subscribers could choose to be informed about notifications in one or more product sectors. In this regard, he proposed that synergies be explored with existing national or regional databases for TBT notifications, with a view towards an interactive system that could link with existing or future national or regional databases, facilitating dissemination of information to national authorities as well as stakeholders.

333. His delegation recognized this was an ambitious proposal, and welcomed any comments from Members. He suggested that the next Special Meetings on Procedures for Information Exchange consider these issues in greater detail, and noted that timing was linked to the on-going work of the Secretariat towards upgrading the TBT IMS.

334. The representative of Ukraine highlighted key elements in respect of transparency, including, Members providing for opportunities for comment, responding to comments, and ensuring well-functioning TBT Enquiry Points. She noted the Ukrainian TBT Enquiry Point rarely received responses to its enquiries. Yet, it received many enquiries and comments from other Members and, in this context, there were challenges in providing prompt and clear responses. Her delegation supported Japan's submission, in particular regarding encouragement of written responses to comments and Members replying to enquiries. Her delegation was willing to share national experiences concerning difficulties in responding to comments.

335. The representative of Malaysia supported the submission of Japan, and agreed that better implementation of the transparency provision of the TBT Agreement could result from sharing of experiences amongst stakeholders and Members. She made a number of specific comments on the submission. Regarding responses to enquiries and comments to TBT notifications elaborated in paragraph 6, her delegation supported the proposal for a standard time period for response to comments, so as to encourage timely responses and establish an understanding on what constitutes a timely response.

336. The representative welcomed the proposals outlined in paragraphs 7 and 9, on ensuring opportunities for comments on TBT notifications in any of the official languages of the WTO, and on ensuring a 60 day comment period under the Code of Good Practice. She said the proposal in paragraph 4 for sharing Members' experiences on implementation of Paragraph L of the Code of Good Practice was worthy of further consideration, and she requested clarification from Japan on the precise nature of this experience sharing.

337. The representative of Cuba expressed support for Japan's submission, in particular on the need for enquiry points to reply in writing to requests, in good time and within a standard time period.

338. The representative of India agreed with Japan's submission on the need for standardizing bodies to provide for a 60 day comment period on draft standards. However, he was cautious about setting a standard time period for responses by enquiry points, since this could pose difficulties for developing countries; in this regard, he favoured sharing of Members' experience on the response time periods.

339. Turning to Korea's proposal, he submitted that sharing of regulatory impact assessments in the context of notification could be useful, provided it was on a purely voluntary basis. On the proposal for the Secretariat to review specific trade concerns that were not related to notified measures, he said this would be burdensome for the Secretariat and may create controversy, citing experience in the Trade Policy Review Mechanism context.

340. The representative shared the objective of the European Union proposal to improve TBT information technology systems. From his perspective, the future TBT online notification submission system could follow the model of the SPS NSS, provided that some mechanism was included to allow the Secretariat to continue to work with Members to correct discrepancies in their notifications. He was however concerned that development of new product categorization approach would be a disincentive for Members to provide HS codes on notifications; regulators may stop sharing data on product coverage which they already have on hand, or may not take the time to assess affected products. After all, HS codes remained at the essence of trade and tariffs data, and he cited related problems that had arisen in the context of the Information Technology Agreement.

341. The representative of Hong Kong, China supported the proposals outlined in Japan's submission, regarding timely responses from enquiry points on receipt of comments on TBT notifications or other enquiries, and experience sharing on this aspect.

342. The representative of the United States said her delegation shared the general concerns identified in the three submissions regarding the lack of notifications and the inability of some enquiry points to respond to basic requests for information. She believed that helping Members to meet existing obligations on transparency was an important goal for the Committee. She noted that many Members faced significant institutional, legal, resource, and other governmental coordination challenges in establishing an enquiry point and notification processes, and any support the Committee could provide, including experience sharing, was valuable. On strengthening notification processes and enquiry point operations, she noted that Members had established various mechanisms – for example, the United States notification process was supported by a strong inter-agency committee

structure as well as a single official journal – and she suggested that Members share best practice for these mechanisms.

343. Regarding Korea's submission, she supported publication of regulatory impact assessment on a voluntary basis, and echoed the importance of notification of sub central government measures. On Korea's suggestion that the Committee develop more detailed criteria for "significant effects on trade", she noted the challenging analytical and methodological issues in assessing impacts of regulations on trade. In order to minimize the reasons and opportunities for Members to avoid notifying important measures, her delegation believed that Members should adopt a liberal interpretation of significant effects, with a bias towards notification.

344. With respect to Japan's submission, she reported that the United States provided responses to comments once the final rule was published by regulators, and she viewed the TBT Committee and the interaction amongst trade officials as an important means to provide interim feedback and clarifications. Her delegation would continue to take time to interact with Members in order to clarify concerns on proposed technical regulations. Finally, her delegation supported the intent of the European Union proposal of promoting efficiency in information technology systems and expanding the uptake of good practices on notification.

345. The representative of Brazil agreed with the objective of the European Union submission of using technology as a tool to improve transparency practices. He noted useful ideas, including the direct upload of notifications. However, in terms of initiating the 60 day comment period from the upload of a notification, he said there were occasions when it was not possible for Members to provide this amount of time for comments. Nevertheless, he did recognize that Members should do their utmost to fulfil this recommendation of the Committee. Lastly, on the proposal for storing comments and responses given during public consultation processes, he said this should be done on a voluntary basis.

346. The representative of New Zealand was supportive of increasing the efficiency and effectiveness of national enquiry points, and making further improvements to transparency practices among Members. Her delegation believed there was value in further encouraging Members to take practical steps to improve their current practices.

347. Turning to Japan's submission, she noted that the role of national enquiry points in receipt of and response to comments and enquires was often that of a conduit; regulators were usually responsible for considering and responding to comments and enquiries. In order to address Japan's concerns, she first suggested the Committee encourage national enquiry points to acknowledge the receipt of a query and to provide a contact point in the organization or ministry responsible for the measure, to facilitate direct and fruitful dialogue between parties. Second, she suggested incorporating a discussion on this topic in next Special Meeting on Information Exchange, with a view to identifying practical ways to address these challenges.

348. Her delegation was supportive of Japan’s suggestion of sharing information among Members on how the transparency provisions of the Code of Good Practice were currently being implemented, and any challenges encountered. However, she questioned whether this should be a focus of the Committee’s work; should Members wish to discuss issues around the operation of national standards bodies, including transparency issues, a separate forum could be created such as an ad hoc meeting or a dedicated workshop.

349. With regard to the transparency aspects of Korea's submission on "significant effects on trade", she suggested that as a starting point Members exchange information as to how they are currently applying Articles 2.9 and 5.6 of the TBT Agreement and the TBT Committee recommendations on this point. Further, her delegation supported Members supplying more

information to the WTO as part of the overall notification process, including regulatory impact assessments, so long as it remained voluntary and flexible enough to be appropriate for all Members. Finally, she expressed support for promoting intra governmental coordination mechanisms as a means to enhancing implementation of the TBT Agreement. She noted that her delegation would further consider the European Union submission, but was generally supportive of issues raised therein.

350. The representative of Switzerland said that the Fifth Triennial Review recommendation on responding to comments in writing should be reaffirmed and made more precise in the Sixth Review. Responses should be encouraged for comments made in any official language of the WTO, within an indicative deadline. If for some reason this deadline cannot be respected, he said enquiry points should be encouraged to at least acknowledge receipt of the comment. Regarding the role of enquiry points, he suggested the Committee come up with guidance that would better enable them to respond to comments.

351. The representative welcomed any efficient and user-friendly information technology solutions that reduced the burden on the WTO Secretariat, reduced the delay between receipt of notifications and circulation, and facilitated access to notifications for interested stakeholders (such as regulators or companies). His delegation favored an automatized system, which was lean, simple, and available in the near future.

352. In terms of the European Union submission, he welcomed the proposal on general categorization of goods subject to measures. However, he questioned the feasibility of publishing comments online, and said that discussions in the TBT Committee currently provided information in this regard.

353. He expressed interest in Korea's submission with regard to "significant effects on trade", and supported the United States' remarks related to that matter. The existence of specific trade concerns on measures that had not been notified suggested a need to clarify this ambiguous wording. He asked Members to share the criteria they used to decide whether legislation projects were notified.

354. Speaking of Korea's submission, the representative of Canada noted that challenges arose in providing guidance to Canadian authorities developing regulatory measures on the meaning of "significant effects on trade". His delegation believed it was best to understand the phrase from the point of view of any other Member which may perceive the measure to be significant, and therefore it was best to err on the side of caution and notify measures when in doubt. The representative suggested the Committee develop some guidance on this point, which Members could provide to their regulatory authorities.

355. He stressed the importance of using information management tools and technology to provide information more quickly and efficiently to Members, and noted the interesting concepts contained in the European Union submission. The representative called for simplified access to notification information, and support to stakeholders in identifying only those measures that are important to them (e.g. measures in key export markets), particularly given the year on year growth in the number of notifications.

356. On the European Union proposal for developing a new categorization for measures, he observed that although identifying HS codes for a measure was valuable, it was often very challenging or even impossible. He explained that regulators did not develop measures with particular HS codes in mind, rather measures applied to an open scope of products relevant to the policy objective of the measure. Being precise in identifying HS codes could undermine the objectives of a regulation, for example, if certain products were missed which were relevant, or if new products were developed. The representative saw some value in providing information to stakeholders in terms of broad categories, and would consider the EU proposal further.

357. He noted there were few significant delays in circulation of notifications by the Secretariat. Nonetheless, there remained a risk of certain delays (e.g. time for translation, human error) reducing the 60 day comment period, and he said improved technology should be used to avoid this risk.

358. The representative of Japan said his delegation was open to comments and discussion on the proposed standard time period from receipt of comments to response. He noted that, on average, Japan replied within 60 days of receipt of comments. The representative stressed the importance of Members acknowledging comments received on TBT notifications, and welcomed the suggestion of New Zealand on this matter.

359. The representatives of the Secretariat presented recent enhancements to the TBT Information Management System (TBT IMS)[25], including new layout and search functions, and the forthcoming WTO Integrated Trade Intelligence Portal (I-TIP)[26], which provided a birds-eye view of trade policy information notified by WTO Members, including TBT information.

360. The representative of India asked a number of questions about I-TIP: how information displayed in I-TIP for measures which lacked HS codes was being managed; were measures that lacked an entry into force date assumed to enter into force 8 months after date of circulation (i.e. 60 days for comment period and 6 month "reasonable interval"); and, how this database interfaced with UNCTAD, World Bank and ITC databases?

361. The representative of the European Union asked whether a more user friendly approach to product categorization of measures had been considered. Finally, he asked about the timeline for development of the TBT on-line notification submission system, and whether it would be constrained to follow the SPS NSS model.

362. The representative of the Secretariat said that the focus was on improving the TBT IMS and access to its data. The TBT IMS was directed to officials and stakeholders working directly on TBT issues, while I-TIP was directed to a broader group of users. He explained that I-TIP drew on the data contained in the TBT IMS, and relied on the completeness and accuracy of the TBT IMS data. He noted that the recent enhancements to the TBT IMS addressed some of the issues mentioned in the European Union submission, although work remained to be done. For example, there was a time lag between the receipt of notifications and circulation of between three and five days. This time lag was due to the Secretariat performing quality checks on notifications, and the need to follow WTO formatting and documentation rules. He noted that the forthcoming on-line notification submission system for the TBT IMS would improve this situation. On the question from the European Union, he explained that HS codes were one of the common features that linked the different databases and types of measures (e.g. TBT IMS, SPS IMS, anti-dumping) integrated by I-TIP. The intention was to make the on-line notification system operational during 2013. The system would be based on the SPS NSS as the initial prototype, but would be customized for TBT and any required functionalities.

D. OTHER MATTERS

363. The Chairman informed the Committee that a room document[27] was made available with provisional dates for Informal meetings. These dates were 4 October, 6 November and 26 November.

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

[26] A prototype of the I-TIP system can be accessed by WTO Members at: https://I-TIP.wto.org (username: tntanyuser and password: RWUs3r@10). Comments should be directed to: I-TIP@wto.org.

[27] RD/TBT/9

IV. UPDATING BY OBSERVERS

364. The representatives of the ITC and IEC updated the Committee on their on-going activities in developing countries and work related to TBT.[28]

365. The representative of the UNECE informed the Committee that WP6 (Working Party on Regulatory Co-operation and Standardization Policies) was now focusing on education in standards-related issues. A revision of a recommendation from 1970 was necessary as there was a lack of awareness by students of the basic standards related issues. This revised recommendation, which it was hoped would be adopted at the November meeting, would then lead to a model programme on standardization which would be included in the UNECE university programme. The first draft of this programme included contributions from European and CIS universities and from intergovernmental organizations. She invited Members to share any experiences they had in educational programmes in this field. A workshop would be held on 8 November 2012 on this subject and all Members were warmly invited to attend.

366. The representative of the OIML informed the Committee that the Organization had undergone a complete revision of its working procedures for all technical work. A room document would be provided at the November meeting of the Committee explaining in detail the voting procedures in the OIML.

V. DATE OF NEXT MEETING

367. The next regular meeting of the Committee is scheduled for 27-29 November 2012.

[28] G/TBT/GEN/133, G/TBT/GEN/134.