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G/TBT/M/60

WORLD TRADE ORGANIZATION

Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 17, 19 AND 20 JUNE 2013

CHAIRPERSON: MR. JINGO KIKUKAWA

NOTE BY THE SECRETARIAT[1]

Contents

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

1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in WTO/AIR/4126.

2 ELECTION OF THE CHAIRPERSON

2.1. The Committee elected Mr. Jingo Kikukawa (Japan) as the Chairman of the Committee.

3 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

3.1 Statements from Members under Article 15.2

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

3.2 Specific Trade Concerns

3.2.1 New Concerns

3.2.1.1 Ireland - Proposal to introduce standardised/plain packaging of tobacco products in Ireland

3.2. The representatives of Malawi, Dominican Republic and Cuba expressed their concern with the measure's consistency with both the TRIPS and TBT Agreements. Their full statements are contained, respectively, in G/TBT/W/368; G/TBT/W/366 and G/TBT/W/364.

3.3. The representative of Australia commended Ireland for its proposal to introduce plain packaging of tobacco products. He stated that tobacco plain packaging was a legitimate measure designed to achieve a fundamental objective - the protection of human health. Australia appreciated the interest Ireland had shown in Australia's tobacco plain packaging measure and looked forward to supporting Ireland as it developed its own measure. Tobacco plain packaging was endorsed by leading public health experts as well as the World Health Organization and was supported by extensive research reports and studies. Tobacco plain packaging was recommended in the guidelines for the implementation of Articles 11 and 13 of the WHO FCTC to which Australia and Ireland were both parties. Australia was of the firm view that Members had the right to implement measures necessary to protect public health while complying with the relevant international treaty obligations, including the TBT Agreement.

3.4. The representative of New Zealand stated that his delegation supported Ireland's move to consider introducing controls on the packaging of tobacco products. The negative effects of

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

smoking could not be overstated. In New Zealand smoking was the single largest cause of preventable death and disease. WTO rules, including those in the TBT Agreement, contained appropriate flexibilities to enable WTO Members to regulate for health and other public policy purposes. New Zealand was determined to continue tackling the tobacco epidemic and takes a negative impact on public health of tobacco consumption very seriously. There was an extensive and compelling body of international research and scientific studies that established that plain packaging, as part of a comprehensive tobacco control programme, would contribute to the objective of improving public health.

3.5. The representative of Guatemala stated that while her delegation shared Ireland's policy objectives related to public health and tobacco control, it was nevertheless concerned with the proposed legislation and encouraged Ireland to consider less trade restrictive alternative measures that would effectively achieve its own legitimate objectives.

3.6. The representative of Honduras expressed concern with the fact that the proposed Irish tobacco plain packaging measure was similar to that of Australia, which was currently under four dispute settlement proceedings in the WTO - including one initiated by Honduras - and whose consistency with WTO rules has been challenged in this Committee by a large number of WTO Members. In its formal dispute against Australia's measure Honduras was not challenging Members' right to adopt measures to protect public health, provided they were WTO-compliant and had a solid scientific basis. In the case of Ireland, such requirements were not met for the following reasons. First, the Irish Government's press release stated that there was strong evidence pointing to the fact that plain packaging would increase the effectiveness of the graphic warnings, would reduce the misconceptions regarding the health of cigarettes and would also reduce the trademark attraction, particularly exercised on young people. Honduras invited Ireland to share the evidence used as a basis to make such assertions. In this respect, Honduras had already reviewed the studies used to adopt the Australian legislation and considered them to lack credibility because they had serious methodological shortcomings and did not show that plain packaging would effectively reduce the level of tobacco consumption. Second, the requirement for plain packaging was inconsistent with a number of obligations of the TBT Agreement. It was also inconsistent with the TRIPS Agreement (including certain provisions of the Paris convention) by affecting intellectual property rights, such as those concerning trademarks and geographical indications. Similarly to what Honduras indicated in the panel request in the Australian dispute, a possible similar Irish measure would cause serious effect of the main function of trademarks, which was to allow for producers to distinguish their products from those of their competitors. Such measure would also be more trade restrictive than necessary in attaining its objective. Apart from not achieving the reduction in tobacco consumption, plain packaging measures would also cause other negative consequences such as making impossible to communicate with the consumers through packaging that particular products were of premium quality. There would also be a price-based competition resulting in a drop in prices and, as a result, in an increase in tobacco consumption. Further, requiring tobacco products to be sold in plain packages would lead to an increase in illegal trade in tobacco products, facilitating the counterfeiting of packaging and making it more difficult to detect illicit products. In view of the foregoing, Honduras urged Ireland to reconsider its decision to start the adoption of plain packaging with respect to tobacco products and to, prior to taking such a decision, at least wait for the conclusion of the disputes lodged against Australia by Ukraine, Honduras, Dominican Republic and Cuba.

3.7. The representative of Nigeria stated that although her delegation recognized every country's right to take appropriate measures to protect its citizen’s health and welfare, it was also concerned with the compatibility of Ireland's proposed tobacco plain packaging measure with the obligations under the TBT and TRIPS Agreements. First, brand names needed to be attached to every product as a mark of identification for consumers. Second, these brand names also served as a defence against product imitation and faking, which could easily confuse consumers. Third, in case of any problem with respect to the product, such brand would make it easier to trace its origin. Lastly, like any other product, tobacco had some unique variations stemming from geographical and ecological differences.

3.8. The representative of Zimbabwe said that her delegation shared the concerns raised by the previous delegations regarding Ireland's proposal to introduce standardized plain packaging of tobacco products. While Zimbabwe appreciated efforts to protect the health of consumers, the proposed measure would be inconsistent with the TBT and TRIPS Agreements inter alia because there was no scientific evidence that it would meet the intended objectives. Developing countries,

such as Zimbabwe, rely on tobacco farming. The proposed measure would therefore negatively affect their employment creation efforts. Zimbabwe therefore urged Ireland to devise a less trade restrictive measure.

3.9. The representative of Norway recalled her delegation's usual stance that it was within the rights of each WTO Member to adopt measures necessary to protect public health as long as they would be consistent with the WTO Agreements. She recalled that plain packaging of tobacco products was a recommended measure under the WHO's Framework Convention on Tobacco Control (WHO FCTC). It was Norway's firm opinion that the WHO FCTC and the relevant WTO Agreements were mutually supportive, and that it was thus possible to implement measures intended to regulate the packaging of tobacco products in line with both sets of binding obligations. Norway therefore supported Ireland's intent to introduce this kind of measure.

3.10. The representative of Ukraine said that her delegation was closely monitoring the issue concerning plain packaging of tobacco products and asked whether Ireland intended to notify the issue to the WTO.

3.11. The representative of the European Union informed that on 28 May 2013 the Irish government decided to begin the process of developing legislation introducing plain packaging for tobacco products sold in Ireland. She took note of Members' concerns and explained that Ireland was still at a very early stage of the process. Her delegation considered that it was therefore premature to discuss this issue in the context of the TBT Committee. She further noted that a number of the points that were expressed during this meeting by some Members did not fall under the scope of the TBT Agreement and hence were not supposed to be discussed in this Committee.

3.2.1.2 European Union - Transformation of still wine into sparkling wine EC Regulation 479/2008 of 29 April 2008

3.12. The representative of Australia said that his delegation was concerned that EC Regulation 479/2008 of 29 April 2008 did not allow bulk still wine produced outside the EU to be transformed into sparkling wine in the EU. At the same time, the EU permitted still wine from one EU member state to be transformed into sparkling wine in another EU member state. The Regulation appeared to be inconsistent with the national treatment principle of the GATT as well as Art. 2.1 of the TBT Agreement. The issue was of genuine concern to the Australian wine industry, which would like to have some of their wine transformed into sparkling wine in the EU. He encouraged the EU to amend the Regulation as a matter of priority.

3.13. The representative of the European Union explained that the transformation from still into sparkling wine in the EU was subject to very strict regulations, regardless of the origin of the still wine. As a result, most sparkling wine sold in the EU could not be produced from still wine from another country, regardless of whether this was a third country or a European one. In the exceptional cases where this was allowed by EU legislation, specific labelling rules were in place in order to avoid consumer deception. She explained that her delegation was discussing this issue with Australia bilaterally in the framework of the EU-Australia Agreement on trade in wine.

3.2.1.3 European Union - Implementing Regulation (EU) No 481/2012 laying down rules for the management of a tariff quota for high-quality beef

3.14. The representative of Argentina noted that since 1 August 2009, when Council Regulation (EC) 617/2009, dealing with the opening an autonomous tariff quota for imports of high-quality beef, came into effect, Argentina began negotiations and exchanged information with the European officials so as to participate in this quota. As from that same date, technical work was undertaken in Argentina to rapidly submit the protocol of quality according to the requirements laid out in the regulation. Argentina's first application to participate in this new quota was submitted in 2009 and since then successive comments and clarification requests have been received from the DG Agriculture and Rural Development of the European Commission. In February 2012, the final version of the protocol of control and certification was submitted following the modifications made at the request of the European officials. However, four years after opening the bilateral negotiations and despite having complied with all the requirements requested by the EU, Argentina was still not authorised to send high-quality beef to Europe under this tariff quota opened in 2009. Argentina considered this to be an unjustified delay that created an unnecessary

obstacle to trade inconsistent with the TBT Agreement. Further, the fact that Argentina was not authorized to export beef under this new quota system was inconsistent with the TBT Agreement's MFN clause because other countries that had similar conditions as those of Argentina have already received authorization to access this quota for a long time. Due to the foregoing, Argentina requested the EU to clarify the reasons for the lack of progress since February 2012. He requested the EU to promptly take a favourable decision on Argentina's application, publish this decision without delay in the official bulletin of the EU with the name of the Argentine body issuing the certification of authenticity, as established in Art. 5 of Regulation 481/2012 concerning the management of the tariff rate quota so that Argentina could participate on equal terms with other Members that, for years, have enjoyed access to this tariff quota.

3.15. The representative of the European Union explained that Regulation 481/2012 related to the management of a tariff rate quota (TRQ) introduced by Council Regulation (EC) 617/2009. Her delegation had therefore doubts that this issue fell under the scope of the TBT Agreement. Regardless, she informed Argentina that the EU was currently in the process of examining the application it had submitted in order to benefit from this TRQ and was also discussing this issue with Argentina bilaterally.

3.2.1.4 Peru — Act to Promote Healthy Eating Among Children and Adolescents

3.16. The representative of Mexico expressed her delegation's concern with the fact that this law, which would have an impact on international trade, have not been notified to the WTO. Mexico considered that the use of expressions in the measures such as "high in" casted doubts as to whether this was the least burdensome measure possible. Mexico referred to other alternative measures, such as the "daily meal guides", used in other countries and based on the Codex, which showed the absolute amount of certain nutrients and their percentage in the daily food values. Mexico also noted that the measure did not mention any scientific basis proving that the use of expressions to inform consumers a product was "high in" a given nutrient - as well as the prohibition to sell such products in schools - would reduce the obesity of the population. Furthermore, it was difficult to know the impact that this law would have since the regulation has not been issued with the list of the foods that would be appropriate for each age as well as the technical parameters that allow for that such determination.

3.17. The representative of the United States associated herself with Mexico's concerns, including the fact that this measure has not been notified to WTO Members. She noted that the US shared Peru's concerns regarding nutrition and its impact on obesity and other non-communicable diseases. The US has been a key supporter of the work to implement the recommendations of the 2004 WHO Global Strategy on Diet, Physical Activity and Health through new Codex guidance on nutrition and labelling. However, the timeline for implementation included in Peru's approved legislation did not appear to consider a period between drafting of the implementing regulation and compliance with the regulation for notification of the draft regulation to the TBT Committee, for consideration of trading partners concerns and for outreach and consultation with stakeholders. She therefore asked Peru to consider a longer timeframe for development of the draft regulation in compliance with the TBT Agreement's notice and comment transparency obligations. She asked Peru extend the short timeframe of 120 days allotted for labelling compliance upon the completion of the final regulation. For example, when the US undertook major changes to its food-labelling regime, it allowed an 18-month period for compliance to reduce the costs associated with re-labelling of products, and an even longer period for labelling requirements related to trans-fat.

3.18. She also expressed her delegation's concerns with the legislation's lack of a full analysis of the costs to Peru and domestic and international food producers to implement the measure. In particular, the U.S. pre-packaged food industry has expressed concern over the economic impact of the inclusion of warning statements on a mandatory basis. She noted that alternative approaches could provide similar information to consumers, without the cost of mandatory product relabeling. Codex, for example, recommended mandatory nutritional labelling of products and recently expanded the list of nutrients for declaration to include saturated fat, sodium, sugars (and trans-fatty acids in countries where this nutrient was a public health concern). The *Codex Committee on Nutrition for Foods for Special Dietary Uses* has also proposed Nutrient Reference Values for labelling purposes for sodium and saturated fat, which provide another means for consumers to identify foods "low" and "high" in nutrients. In addition, Codex has defined voluntary "low" claims, "no added sugars" claims, and conditions for health claims.

3.19. Given the foregoing, she requested Peru to delay finalization and implementation of its regulation to allow for adequate dialogue and consideration of comments from stakeholders, as well as a discussion of the rationale, details and potential impact of this proposed regulatory approach and alternate approaches considered, and Peru's assessment of the costs and benefits associated with the proposed mandatory labelling requirements.

3.20. The representative of Argentina requested the measure to be reviewed in light of the obligation of Article 2.2 of the TBT Agreement that it should not be more trade restrictive than necessary for the achievement of a legitimate objective.

3.21. The representative of the European Union shared the concerns raised by Mexico, the US and Argentina, and urged Peru to notify the measure so as to give Members the opportunity to comment on it. She also stated that, while her delegation fully shared Peru's public health concerns regarding the provision of adequate nutritional information to consumers, it considered that the approach taken by the notified draft was not the best way and most proportional way to achieve the objectives of empowering consumers to make an informed choice in order to foster effective competition and consumer welfare. In this respect, and in relation to the warning labels and implementing provisions establishing limits for certain nutrients as foreseen in the transitional provisions, the EU call the attention to the Codex's *Guidelines on Nutrition Labelling* (CAC/GL 2-1985 CODEX), which stated that the information contained in the nutrient declaration "should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product". No nutrient thresholds have been established by the Codex for the nutrients targeted by the Peruvian legislation. The EU recognised that for certain nutrients there was evidence of a positive association between its intake and the risk of developing a disease or disorder, but there was no scientific evidence suggesting an identifiable threshold above which the risk existed. The risk increased rather continuously when the nutrient intake increased above the levels recommended by nutritionists.

3.22. She also requested Peru to provide information on the foreseen deadlines for the entry into force of this legislation. According to the second transitional provision, some of its provisions would come into force 120 days after the publication of the implementing regulation. The EU considered that the adaptation to the new labelling requirements would require significant investment for manufacturers and a redesign of the packaging for some categories of products which were not defined yet. In this regard, the EU asked Peru to postpone the entry into force of the measure and to provide a reasonable implementation period in accordance with Article 2.12 of the TBT Agreement. The EU noted that its own legislation on nutritional labelling was adopted in 2011 but would only come into force in 2014.

3.23. The representative of Switzerland said that while his delegation shared most of the concerns raised by previous Members, it also shared Peru's health concerns regarding obesity and other non-communicable diseases and recognised that they posed a threat to the economies of many countries. He informed that cognizant of the relationship between diet and health, the Swiss federal office of public health may issue recommendations on daily nutrient intake and may set nutrient thresholds for different food groups based on international standards. On a voluntary basis, producer would be able to reference on the product these thresholds identified by WHO or Codex. In this respect, Switzerland was pleased to note that Peru was considering Switzerland's voluntary approach. At this stage Switzerland asked Peru the following clarifications: (i) why were WTO Members not notified about this new law? (ii) what were the timelines for the implementing regulations and when would they be notified to the TBT Committee?; (iii) how did this law comply with Codex guidelines on nutritional labelling? With respect to the last question, he added that according to this Codex guideline, the information contained in nutrient declaration should not leave consumers to believe there were exact quantities of what individuals should eat in order to maintain health but rather to convey an understanding of the quantity of nutrient contained in the product.

3.24. The representative of Guatemala stated that her delegation shared the view that healthy eating should be promoted in order to prevent diseases among the population. Nevertheless, Guatemala was concerned that the Peruvian measure might be more trade restrictive than necessary to achieve the stated legitimate objective of reducing obesity in order to fight non-communicable diseases. In this context, it was absolutely essential to know the scientific basis of the measure.

3.25. The representative of Peru stated that the measure's objective was to reduce obesity and other risks to non-communicable diseases through: organizing educative campaigns in schools to promote healthy eating; increasing physical activity; promoting healthy cafeterias/kiosks; informing consumers about the content of processed food; and supervising advertisement and marketing of food and alcohol, especially when directed to children and adolescents. The technical regulation necessary to implement this law (which was approved on 10 May 2013) had to be in place in no more than 60 days after the entry into force of the law. At this moment, the Peruvian competent authorities were in the process of drafting this implementing measure. In conformity with Peru's obligations under the WTO Agreements and Andean Community rules, this draft would be notified to the WTO and a 90-day comment period would ensue. Peru would then be able to, based on these comments, re-evaluate the regulation. The final version of the regulation would then be published, entering into force 6 months after publication.

3.2.1.5 United States - Energy Conservation Program for Consumer Products: various products (G/TBT/N/USA/842 and G/TBT/N/USA/842/Corr.1, G/TBT/N/USA/848)

3.26. The representative of China first shared some background of his delegation's concerns with the US measure. Between January and March this year, the US Department of Energy (DOE) notified 19 TBT measures under the *U.S. Energy Policy and Conservation Act of the 1975*, as amended (as known as "EPCA"), 16 of which were about energy conservation programme. The product scope ranged from microwave ovens, set-up boxes to water heaters and lamps. While China supported the objective of the US of improving energy efficiency, it also hoped that these measures would not create unnecessary obstacles to trade due to the large number of the notifications and the wide coverage of products that China had special trade interests. China sent written comments on five of the notifications on 7 May 2013, namely: notifications G/TBT/N/USA/481/Add.6 and G/TBT/N/USA/739 (regarding testing procedures for residential furnaces and boilers); notifications G/TBT/N/USA/775 and Add.1 (regarding tests and procedures for residential clothes dryers); and notification G/TBT/N/USA/778 (regarding test procedures for set-up boxes). China asked the US to take its comments into account when finalizing the measures with a view to reducing unnecessary barriers to trade.

3.27. The representative of the United States stated that the critical importance of energy efficiency to the larger environmental, energy security and other policy goals, were well known. She recalled that Persistent Obama has repeatedly emphasized that these goals were a key priority for the US. The activities of the DOE to implement the EPCA were among the most important across the US government in its effort to achieve these priorities. Indeed, DOE maintained an extensive program to improve energy efficiency of consumer products, including electrical appliances, lighting and other consumer products. DOE's program to improve energy efficiency of consumer products under EPCA consisted of four integrated parts: (i) testing; (ii) labelling; (iii) energy conservation standards and (iv) certification, compliance, and enforcement. Under this program, DOE set minimum energy requirements for products to be sold in the US market. The setting of these requirements was done through rulemakings based on an extensive impact analysis to ensure its requirements were technologically feasible and economically justified. This impact analysis was extremely robust as it incorporated factors relating to performance, utility, estimated energy savings; economic expertise, impact on competition, as well as other relevant variables. These procedures ensured that DOE's proposed minimum energy requirements and the related testing procedures were based on the best technical and scientific evidence, were economically efficient, and would contribute significantly and efficiently to achieving US energy conservation goals. DOE's testing requirements consisted of test procedures that manufacturers of covered products must use as the basis for certifying to DOE that their equipment complied with applicable energy conservation standards and for making representations about the efficiency of this equipment on labels. Specifically, these test procedures also provided the protocols upon which the Federal Trade Commission based its energy guide label for these products. In implementing these programmes, DOE employed rule making procedures that were fully consistent with the US requirements under its administrative procedures act and associated body of law. These procedures also had implications for a robust public consultation, taking comments from a variety of stakeholders, incorporating these comments into the final rules. In this regard, she welcomed the comments from China on the five measures that it listed and assured China that these comments would be considered as the US Department of Energy moved forward on the particular rules to finalize them.

3.2.1.6 United States - Proposed Significant New Use Rules on Certain Chemical Substances

3.28. The representative of China said that his delegation appreciated the efforts of the US to strengthen the controls of chemicals and thanked it for bilaterally providing clarifications on the measure. China was nevertheless still concerned with the following issues: (i) the clarification of the CAS registered number; (ii) the explanation of the term "significant new use"; and (iii) the alignment of the OPPTS test method with those approved under the GSS.

3.29. The representative of the United States thanked China for its further questions on USAI814, EPA's Significant New Use Rule (referred to as a "SNUR") for eight chemical substances. She noted that in their bilateral discussions, the US relayed detailed information to China in response to its questions on technical elements of this programme. The US would be glad to respond bilaterally these further questions.

3.2.1.7 China – Innovative medical instruments and provisions for simplifying application materials for re-registration of medical instruments (G/TBT/N/CHN/965 and G/TBT/N/CHN/966)

3.30. The representative of the European Union expressed concerns with two separate yet related notifications from China, namely G/TBT/N/CHN/965 and G/TBT/N/CHN/966. The first concern related to an announcement by China's Food and Drug Administration (CFDA), issued on 20 March 2013 (CFDA Notice 98), notified to the TBT Committee as G/TBT/N/CHN/965. CFDA Notice 98 appeared to give preferential treatment to innovative medical devices manufactured in China, which contained Chinese indigenous innovation (intellectual property rights). While the EU appreciated China's efforts to put in place a streamlined approval procedure for innovative medical equipment, it saw no reason why this procedure would *only* be available for those Chinese devices. The EU reminded China that, in accordance with Article 5.1 of the TBT Agreement, "conformity assessment procedures should be prepared, adopted and applied so as to grant access for suppliers of like products originating in the territories of other Members under conditions no less favourable than those accorded to suppliers of like products of national origin or originating in any other country". The EU urged China to revise the CFDA Notice in order to also allow imported innovative medical devices to qualify for the expedited approval procedure.

3.31. The EU said that the second concern under this item of the agenda related to another CFDA Notice, on the re-registration of Medical Devices, notified to the TBT Committee as G/TBT/N/CHN/966. To recall, all medical devices sold in China needed to have their registration renewed every 4 years and any changes to these products would also trigger the need for re-registration. While the EU welcomed China's efforts to simplify the submission file for re-registration of medical devices, it was concerned with the re-registration procedure in China, which was only partly addressed by the notified draft. For instance, there was still no time limit foreseen for the completion of the registration process. In the European industry's view, it should be possible to foresee a deadline for completing the procedure at most 6 months following the submission of the re-registration file, at least for re-registrations of products that did not undergo any significant changes. Furthermore, it was not clear under what conditions products would qualify for this simplified re-registration procedure. The EU considered that this should be possible in all cases where the product was not subject to changes, or where the changes were minor as compared to the previous registration. In this respect, the EU asked whether the CFDA was planning to issue some guidance on the type of changes for which re-registration was required.

3.32. Finally, and in relation to both measures, the EU noted that China has submitted both notifications G/TBT/N/CHN/965 and G/TBT/N/CHN/966 under Article 5.7.1 of the TBT Agreement, providing a comment period of 30 days. The EU asked what urgent problems of health, safety, environmental protection of national security have arisen, or threaten to arise, which have led China to choose the urgency notification procedure for these two measures. In the absence of such an explanation, the EU invited China to provide the normal time period of 60 days for providing comments on these two notifications. The EU also asked information on the timeline foreseen for the entry into force of these measures.

3.33. The representative of the United States raised concerns with respect to the measures that were notified as G/TBT/N/CHN/965 and G/TBT/N/CHN/966. She stated that on 20 March 2013,

China's food and drug administration issued Circular No. 98 on the CFDA website for a 2-day comment period. Circular No. 98 included two draft regulations: Annex I, called "Procedures for Special Examination and Approval of Innovative Medical Instruments (For Trial Implementation)", and Annex 2, called "Provisions for Simplifying Application Materials for Reregistration of Medical Instruments". On 30 March 30, the US Enquiry Point requested that China notify these measures. China notified Annex I and Annex 2 as G/TBT/N/CHN/965 and G/TBT/N/CHN/966, respectively, on 4 June 2013 with a 30 day comment period. In addition, on 30 March 2013 the US submitted comments on CFDA Circular No. 98, noting that Article 2 of Annex 1 limited priority treatment only to products that were manufactured in China, and that used Chinese indigenous innovation, and urged CFDA to apply the procedures equally to all products sold in China regardless of where they were developed or manufactured, consistent with China's trade-related commitments. Transparency in medical devices issue has been a recurring concern of regulated community in China, in particularly the US industry. It put unnecessary burden on these industries, depriving them of the ability to provide full well-reasoned comments in China's regulatory system.

3.34. With respect to the measure that was notified in G/TBT/N/CHN/965, she noted that its text differed from that of the 20 March draft posted on the CFDA website. It seemed that China have revised certain problematic language contained in the earlier draft. The US was currently reviewing this revised draft. With respect to the measure that was notified as G/TBT/N/CHN/966, she said that this measure was a commendable effort to streamline CFDA's re-registration process by reducing the application material required for re-registration and by allowing for the re-use of information from the initial product registration. The measure also exempted devices with minimum changes from needing to submit test reports. However, certain burdensome requirements remained. For example, since the timeframe for registration was identical to that for the initial product registration, the US was still having difficulty with registration approval times where products were waiting in queue for approval.

3.35. The representative of Switzerland stated that, as an important exporter of medical devices, Switzerland strongly supported programmes intended to facilitate market access and was therefore in favour of a streamlined process for reregistration of medical devices. He asked China to inform the Committee about the foreseen date of entry into force of these regulations as well as to confirm that innovative products falling under this regulation were considered innovative independently of their country of origin.

3.36. The representative of China explained that the special approval procedures for the innovative medical devices (trial) included requirements for special approval process in order to promote the development of innovative medical devices at an operating level. Likewise, the provisions for simplifying the application materials for medical device re-registration were drafted to improve the re-registration process of medical devices. It distinguished different circumstances of application and simplified application documents. China started drafting these two documents in October 2012 and in March 2013 it published the Notice soliciting public comments on the special approval procedures for the Innovative medical devices and the provisions for simplifying the application materials for medical device re-registration (also known as Circular 98). During this period China received 527 comments, mostly positive, from 124 organizations, enterprises and individuals, (including foreign ones such as the EU Chamber of Commerce in China, the American Chamber of Commerce in China, the US Advanced Medical technology Association, the American Association of Medical Imaging and Technology Alliance, Johnson & Johnson medical company, Siemens AG). On 4 June 2013, China notified these two documents as G/TBT/N/CHN/965 and G/TBT/N/CHN/966.

3.2.1.8 China – China Food and Drug Administration (CFDA) EMC Enforcement Notice for medical devices of 19 December, 2012

3.37. The representative of the European Union explained that the measure enforced in-country testing on electro-magnetic compatibility (EMC) for Class III medical devices as of 1 January 2014, and Class II medical devices as of 1 January 2015. This EMC testing was mandated in the context of China's registration procedure for medical devices, and was carried out in order to ascertain compliance with Chinese mandatory standard YY0505:2012, which appeared to be equivalent to IEC standard 60601-1-2 (2nd edition, 2004). While the EU appreciated such equivalence, it asked China to accept test reports from foreign laboratories accredited by accreditation bodies who were members of ILAC, as an alternative to in-country testing by a Chinese laboratory. This would avoid unnecessary duplication of testing, as medical devices imported into China were already tested in

accordance with the IEC standard. It would also ensure that, beginning in 1 January 2014, there would not be disruption in the importation of medical devices into China due to a lack of necessary infrastructure to perform the EMC testing. In this regard, the EU noted that currently there were only around 10 laboratories accredited by the CFDA to perform the required EMC testing – this appeared insufficient to comply with the influx of heavy activity resulting from the enforcement of the CFDA notice as of 1 January 2014, and would likely lead to longer registration timelines and higher compliance costs for industry. In this context, the EU reminded China that, in accordance with Article 5.1.2 of the TBT Agreement, "conformity assessment procedures shall not be more strict, or be applied more strictly, than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create". EU also requested China to notify this Notice in accordance with its obligations under the TBT Agreement, in particular Article 5.6.2.

3.38. The representative of China said that on 19 December 2012 it issued a notice of the issuance of work a plan for the implementation of medical devices standard YY0505:2012, which was an identical transposition of the IEC international medical electrical equipment electromagnetic compatibility test standard IEC 60601-1-2, set to ensure a safe environment for medical devices so as to protect public health. As IEC standard 60601-1-2 was the recognized international standard in this area and has been widely used in WTO Members, the promulgation of this Chinese measure at issue would not have significant impact on international trade.

3.2.1.9 Indonesia - Ministry of Trade Regulation 82/M-DAG/PER/12/2012 on imported cell phones, handheld and tablet computers

3.39. The representative of the European Union expressed concern that this regulation was not notified under the TBT Agreement in its draft stage and other WTO Members did not have a possibility to comments on it. This Regulation provided for stricter controls on imported cell phones, handheld and tablet computers. The EU industry reported that following the entry into force of the Regulation, considerably more time was needed to put the products concerned on the Indonesian market. The Regulation required three types of labels to be attached to the products: conformity of International Mobile Equipment number (IMEI), type label (SKPLBI) and type approval number label (POSTEL). The EU considered these labelling requirements excessive and was also concerned with burdensome pre-shipment inspections for every import taking place at the port of loading by an appointed representative of the Indonesian government. In addition, the SKPLBI and POSTEL must be available already at the pre-shipment inspection stage, while the usual practice was *after* custom clearance. The EU asked Indonesia to consider less time-consuming and burdensome procedures on imports of cell phones, handheld and tablet computers.

3.40. The representative of the United States associated herself with the concerns raised by the EU and noted that the Indonesia measure, which went into effect on 1 January 2013, was notified to the Import Licensing Committee. She also noted that the labelling provisions of this measure were related to G/TBT/N/IDN/47, which was notified to this Committee in December 2010. However, in May 2013, Indonesia's Ministry of Communication and Information Technology, KOMINFO, published additional technical guidance for registering product information, which was not notified. The US asked Indonesia to clarify the legitimate objective for the measure and whether these requirements were the least trade restrictive approach that could be taken to address its stated objective. In particular, US asked Indonesia to state the objective for requiring product identification numbers up to a year in advance as this seemed unnecessarily burdensome. She also noted that the Indonesian Ministry of Communication and Information Technology has issued additional technical guidance related to the regulation at issue in Postel Notification 5/2013 on 14 May 2013. The US asked Indonesia to notify this additional measure and expressed concern about the lack of transparency with such technical requirements. It also noted that the measure at issue was published at a later point than the entry into force of new wireless certification requirements which were due to start on 1 March 2013. Finally, the US asked Indonesia to delay implementation of this technical guidance and to provide a sufficient implementation period for companies to comply.

3.41. The representative of Indonesia explained that the measures have been notified to the Committee on Import License under G/LIC/N/2/IDN/13, dated on 8 February 2013. This notification containing two regulations namely: (i) Regulation of Minister of Trade of Indonesia No. 82/M-DAG/PER/12/2012, dated 27 December 2012, on Provision of the Import of Cellular Phones, Handheld Computer and Computer Tablet, and (ii) Regulation of Minister of Industry Regulation of

Minister of Industry of Indonesia No. 108/M-IND/PER/11/2012, dated 12 November 2012, on Registration of Cellular Phones, Handheld Computer and Tablet. Therefore, these measures did not fall under the scope of the TBT Agreement. With regard to labelling requirements, he noted that both of these regulations referred to "Obligatory Label Affixing on any Goods", which was notified under G/TBT/N/IDN/47. Concerning the certification for telecommunication equipment, his delegation would inform and encourage the Ministry of Communication and Information (KOMINFO) to notify the regulation under the relevant provisions of the TBT Agreement.

3.2.1.10 Indonesia – Ministry of Health Regulation 30/2013 on the inclusion of sugar, salt and fat content information, as well as health messages on the label of processed foods

3.42. The representative of the European Union requested Indonesia to suspend the application this technical regulation until a TBT notification has been submitted to the Committee and Members have been provided sufficient time to comment on it. She also recalled the need to provide a sufficient implementation period for industry to be able to adapt to the new requirements. She also stated that while the EU shared and supported Indonesia's goals of providing nutritional information to consumers, and preventing diet-related chronic diseases, it also wondered whether these objectives could not be achieved with less trade restrictive means, such as, for example, awareness raising campaigns, or a general message promoting healthy lifestyle and eating habits, rather than through a warning message applicable to all pre-packaged products.

3.43. She also expressed her delegation's uncertainty as to how these requirements would apply. First, Article 3.2 of the measure indicated that the labelling requirements would be "implemented gradually" for different processed foods depending on the risk of non-communicable diseases that a certain food presented. How, and under which timeline, would this "gradual implementation" be achieved? Second, Article 3.3 of the measure indicated that further details as to the type of processed foods covered by the Regulation would be specified in a subsequent Ministerial Regulation. When would this Regulation be issued and notified to the TBT Committee? Third, the Regulation stated, in its Article 3.4, that the inclusion of the nutrition information and health warnings shall be made in accordance with the legislation. Which legislation was Indonesia referring to? Would Indonesia issue additional implementing measures or guidelines on compliance with the Regulation, and notify them to this Committee? Finally, would Indonesia allow stickers placed after importation, and before being placed on the market in Indonesia (for instance, in customs warehouses) as a means to show compliance with the Regulation?

3.44. The representative of the United States associated herself with the comments of the United Sates. While the US shared Indonesia's concerns regarding nutrition and its impact on obesity and other non-communicable disease, it was also concerned over the adverse impact of mandatory health warning on processed foods containing sugar, sodium and fat. She call Indonesia's attention to important alternative regulatory approaches (including those consistent with the Codex Alimentarius) that provided similar information to consumers without the misleading effect of mandatory health messages that may unfairly position certain foods in the eyes of consumers. The health message required by the measure at issue may be particularly misleading since this seemed to be required by the mere presence of certain nutrients, namely sugar, sodium and fat, which were also necessary components of a healthy diet. In this respect, she sought clarification of the testing provisions set forth in Article 6 of the measure, which seemed to establish a strict testing procedure that would not allow minimum normal variations between batches and would possibly include unnecessary shipment by shipment inspections. She concluded by reminding Indonesia of its obligation to notify new labelling requirements to the TBT Committee and take WTO Members comments into account.

3.45. The representative of Brazil stated that his delegation shared the concerns expressed by the EU and the US and encouraged Indonesia to notify promptly the measure at issue so that other Members would be able to evaluate its scope and impact.

3.46. The representative of Indonesia informed that the regulation at issue was issued by the Minister of Health on 11 April 2013 and would be gradually implemented 3 years after promulgation. The measure's objectives were consumer protection and the reduction of certain diseases such as stroke, heart disease and diabetes. Furthermore, the regulation was also designed to educate the public through health messages. With regard to the obligation of

notification, Indonesia said that it would inform and encourage the relevant Ministries, in particular the Ministry of Health, to notify the regulation under the applicable provisions of TBT Agreements.

3.2.1.11 Russia – Safety of light industry products

3.47. The representative of the European Union expressed concern with this measure, aimed at the protection of human life and health, which subjected all textile and clothing, footwear and leather products to detailed mandatory conformity certification procedures. The EU considered that subjecting these relatively low risk products to compulsory certification of compliance created an unnecessary barrier to trade. While the EU shared Russia's legitimate objective of consumer health protection, it believed that this objective could be ensured by less strict means, for example random inspections. Moreover, the EU posed various questions with respect to how this legislation would be implemented: when would the conformity certificate need to be provided by testing? Should a self-declaration of the manufacturer be sufficient for all the products covered by the measure? Which standards would be applicable? Furthermore, the EU noted that the measure also provided for extensive labelling and marking requirements, some of them of limited use for the customer. The EU considered that mandatory labelling requirements should be limited to essential elements, leaving the remaining information at the discretion of the producer or distributor. The EU concluded by asking Russia to take into account, and provide a written reply to, the written comments on this notification that her delegation sent to them on 8 May 2013.

3.48. The representative of the Russian Federation explained that this technical regulation, developed in accordance with Article 2.2 of the TBT Agreement, was introduced in December 2011 and entered into force in July 2012, prior to the Russian Federation's accession to the WTO. This technical regulation of the Customs Union actually replaced the national legislation and substantially facilitated regulation in this field in the market of all the member states of the customs Union. Under paragraph 4 of Article 11 of this measure, mandatory certification was only required for three kinds of textile products that had direct contact with the skin, for example underwear. All other textile products were only subject to self-declaration of conformity. Furthermore, during the implementation of this technical regulation, in practice, it was decided that certain provisions therein had to be amended. Accordingly, under the new draft amendments, imports of raw materials for manufacturing of final products would not be subject to confirmation of conformity. Instead, only final products would be subject to conformity assessment. The draft amendments were notified by the Russian Federation in document G/TBT/N/RUS/14.

3.2.1.12 European Union - Proposal for a Regulation on Fluorinated Greenhouse Gases

3.49. The representative of the United States said that while her delegation supported the global efforts to phase down the consumption and reduction of climate damaging HFCs, it was also concerned with the development process and implementation difficulties of this regulation, as currently proposed. US appliance manufactures were particularly concerned with the proposed changed to ban the use of Hydro fluorocarbons (HFCs) with a global warming potential of 150 or more in residential refrigerators by January 2015. On process, she first noted that some US stakeholders have been eager to participate and offer input on the development of this proposed regulation but were not given the access given to other stakeholders. She wished to understand the EU Commission's policy on such discussions, and whether there was guidance to regulatory agencies on access by stakeholders from the US and other countries.

3.50. She also asked the EU to clarify the role of the impact assessment study in formulating DG Climate's proposed legislation. In the development of its proposal, DG Climate commissioned an impact assessment by a consultancy to evaluate alternative options for the regulation. In fact, this report considered a ban for refrigerators/freezers and concluded that a ban on domestic (residential) refrigeration was not recommended because of its low effectiveness and "a strict regulatory instrument such as a ban would need to be justified with a substantial contribution to the EU's emission reduction targets." It concluded that this was therefore "unlikely, given the limited potential of these options." She considered that the ban on refrigerators/freezers did not meet the minimum effectiveness criterion in the consultant's report, and would contribute to a very limited extent to the overall necessary emissions reduction while adding costs. Furthermore, despite this recommendation in DG Climate's impact assessment, its proposal contained a ban with an aggressive timetable that would unduly impact exports of US refrigerators to the EU and would involve extensive product redesign and considerable expense to retrofit factories in order to safely handle flammable products. She asked the EU to reconsider this ban and its aggressive timetable.

3.51. The representative of Japan associated himself with the comments made by the US and stated that Japan was also concerned with the measure's prohibition of pre-charging (Article 12) and the allocation mechanism for produced/imported HFCs amounts (Article 14). Firstly, the prohibition of pre-charging air conditioning equipment with HFCs and the requirement to charge the equipment with HFCs at the place of installation would increase HFCs emissions due to leakage from the equipment rather than pre-charge in a factory, as not only Japan industry but also European industry pointed out. This implied that this environmental regulation lacked rationality. Secondly, Article 14 allocated quotas of HFCs to HFCs producers and importers in the EU based on the amounts from 2008 to 2011. However, with regard to the controlled equipment which was produced and charged outside the EU, the quota allocation of HFCs was not taken into account in this mechanism. Given the foregoing, Japan considered that, as a consequence of Article 12 (Prohibition of pre-charging) and Article 14 (Quota allocation) of the measure, the EU would practically stop importing air-conditioners. Japan therefore requested the EU to withdraw these provisions of the measure.

3.52. The representative of Korea stated that while his delegation respected the efforts of the EU to protect the environment, like other delegations, it also had some concerns with this measure, which required that HFC gas should not be charged into refrigeration, air-conditioning and heat pump before it was place on the market or before it was made available to the end-user for its final installation. To comply with these requirements, manufacturers had to remove HFC gas which had already been inserted in the product during tests. These kinds of additional processes might be significant burdensome to manufacturers, requiring huge amount of investment and might also lead to lowering performance of equipment. Moreover, the precise level of refrigerant was a critical factor for the performance and energy efficiency. The regulation required only a certified person to charge HFCs after its installation, so manufacturers might not guarantee the performance of the products because it was not clear who was responsible for degradation in some cases. Korea also wondered if the prohibition of pre-charge was the only best way for achieving the objective of the regulation of monitoring and managing the amount of HFC gas usage in the EU. For instance, allowing manufacturers and importers to report the level of HFC gases charged and the total volume of exported products could be a less trade restrictive alternative.

3.53. The representative of the European Union recalled the US request to exclude household refrigerators and freezers from the proposal’s ban on products containing HFC. The EU confirmed that the preparatory study carried out by the external contractor concluded that banning these products would only result in low additional emission reductions. However, this was due to the fact that the vast majority of manufacturers which supplied the EU market have already converted to the use of non-HFC technologies. Therefore, in view of the low additional costs of this conversion, a ban on HFCs in these appliances was deemed appropriate to safeguard the emission reductions achieved in the past by avoiding a shift back to HFCs. Regarding the US concerns on transparency, the EU explained that it has extensively consulted stakeholders throughout the review process, starting with an expert committee assisting the preparatory study and including an internet consultation open to all entities registered in the European Commission's transparency register and a subsequent stakeholder meeting, which US stakeholders also attended. Due to the great number of sectors concerned, it was not always possible to accommodate all meeting requests and priority had to be given to meetings with associations representing a larger range of stakeholder interests, for example the American Chamber of Commerce in the EU. However, individual companies, including US domestic refrigeration equipment manufacturers, had the opportunity to put forward their specific concerns, which were taken into account.

3.54. Concerning the Japanese and Korean concerns on the prohibition to charge refrigeration, air conditioning and heat pump equipment with HFCs before it was placed on the market and installed, the EU clarified that this ban applied without discrimination to all equipment, whether produced in the EU or imported, and also covered equipment with capped valves. This measure ensured that equipment would be installed and filled with HFCs by certified persons, as only those were allowed to access bulk HFCs. This reduced the risk of accidental release of HFCs during installation by using unqualified persons; a risk which was in particular high in the case of split air-conditioners, which represented a large share of HFC in pre-charged equipment and were sold in large quantities in retail shops. In line with this objective, equipment that was hermetically sealed during manufacturing and did not allow for opening of the refrigerant circuits was exempted from this requirement. In addition, the ban on pre-charging reduced the risk of leakage during packaging and transportation. After intensive consultation with various stakeholders, the EU came to the conclusion that CO_2 emission savings would out-weight potentially higher emissions

occurring during filling on the installation site compared to filling in a controlled environment in the factory, all the more so since, in many cases an adaptation or topping up of the charge size after installation was necessary. Furthermore, the ban on pre-charging ensured that also the quantities for the first fill of imported equipment were covered by the HFC phase-down mechanism. Without this measure, alternative options would be needed to avoid a circumvention of the phase-down by imports of HFCs inside equipment. The share of around 11% of the total EU HFC supply today could increase dramatically due to the scarcity of bulk HFCs on the EU-market under the phase-down mechanism, if the first fill of imported equipment was not accounted for under this mechanism. In sum, the EU has concluded that the ban on pre-charging would be the least restrictive option for non-EU manufacturers, after also considering alternatives such as product bans or an inclusion of HFC-containing equipment in the phase-down mechanism. A reporting obligation for importers of HFC containing equipment was already foreseen in the proposal but would not prevent an increase of the imported quantities. With regard to the Japanese concerns related to the allocation of quotas for those importers who have not imported HFCs between the reference period of 2008 to 2011, the EU explained that, according to the draft regulation, 5% of the overall quantitative limits should be reserved for importers and producers who have not imported or produced more than 1 tonne of fluorinated greenhouse gases in the reference period.

3.2.1.13 Peru — Implementing Regulations of 14 November 2012 for Moratorium on Planting Genetically Engineered Crops

3.55. The representative of the United States considered that these implementing regulations included unclear conformity assessment procedures that needed to be streamlined in order to avoid further trade disruptions. She therefore urged Peru to notify the measure to this Committee and take WTO Members' comments into consideration. She recalled Peru's position that such notification was unnecessary due to an exception under GATT Article XX. The US however considered that this GATT provision did not relieve Peru of its independent notification obligations under the TBT Agreement. Peru's prior practice appeared to be consistent with this point. For example, Peru notified its labelling rules for genetically-engineered foods in June 2011 using the TBT template form and allowed until 15 September 2011 for comments to be submitted (G/TBT/N/PER/37).

3.56. The representative of Peru stressed that in his delegation's view the moratorium on planting genetically engineered crops for ten years was not a technical regulation within the meaning of the TBT Agreement and, consequently, it did not have to be notified to this Committee. Instead, this moratorium was an environmental measure meant to protect biodiversity. Peru was considered as one of the ten countries with the highest level of biodiversity in the world for its multiple ecosystems, genetic resources and aboriginal and indigenous cultures. The measure's objective was to strengthen the national structures and ensure the sustainability of the national lines of production. This law established a 10-year moratorium to the entry in Peru of *live* GMOs, including live animals and live plants, thus avoiding their release into the environment. The following activities were however *excluded* from the moratorium, under certain conditions: GMOs used for research purposes; GMOs used for medical or veterinary purposes; and GMOs and other GMO-based imported products, used for direct animal or human consumption or for their processing. Peru also had separate, specific legislation dealing with the risks of the use of biotechnology, such as Law n. 27.104 of 1999 ("*Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología*"), and Supreme Decree n. 108-2002-PCM ("*Reglamento de la Ley de Prevención de Riesgos Derivados del uso de la Biotecnología*"). Finally, Peru noted that the measure at issue was in line with international agreements signed by Peru and has not resulted in any trade impacts given that the seeds traded or transported to Peru were for animal consumption.

3.2.1.14 European Union — Revised Proposal for the Categorization of Compounds as Endocrine Disruptors of 19 February 2013 by DG Environment

3.57. The representative of the United States stated that under existing EU legislation on chemicals, pesticides and other products, the Commission was due to develop measures related to endocrine disruptors by the end of 2013. The outcome of this work, led by DG Environment, would form the basis of amendments to EU REACH, the EU Biocides Directive, the Plant Protection legislation, the Cosmetics Directive and other EU legislation. The DG Environment's work as of February 2013 has resulted in an approach that would categorize substances into two categories: (i) known endocrine disruptors; and (ii) suspected endocrine disruptors. The EU has noted its view that the categorization was similar to its approach to carcinogenic, mutagenic and reprotoxic

substances. We see substantial differences, and believe this approach to endocrine disruptors raises several concerns. Endocrine disruption was a mode of action rather than an adverse event like cancer or birth defects. The EU was embarking on a course that diverged significantly from approaches to endocrine disruptors, such as that of the US Environmental Protection Agency (EPA). EPA screened and tested substances before determining if the weight of evidence indicated that they produced adverse effect. It then based regulatory decisions, such as to register or re-register a substance, on a risk analysis that took into account both the hazard and the likely exposure. In the approach under discussion in the EU, however, a substance could be de-registered if it was assigned to a category that met the cut-off, without a risk assessment or the weight of evidence indicating that an adverse event was likely. US industry was concerned about this work because categorization and the development of lists of substance according to those categories (such as suspected EDs) would likely precipitate decisions to stop using those substances, or switch to alternatives, that would maybe be less well understood without any scientific justification. In turn these decisions could result in significant and unwarranted dislocations in trade.

3.58. Given the foregoing, the US asked the EU the following: (i) please clarify the relation of the work streams under way in the Commission related to endocrine disrupting substances, and the relation of these to potential changes to EU REACH, and other EU legislation, such as Cosmetics; (ii) please identify the specific inconsistencies and errors that DG Environment identified in the recent report by EFSA (European Food Safety Authority); (iii) please explain how DG Environment's ED hazard identification approach differed and concurred with EFSA's recommendations; (iv) please indicate when other WTO Members would have the opportunity to formally comment on the EU's new approach to endocrine disruptors and whether these comments would be taken into account; (v) please confirm that notification and comment would happen only *after* the new approach would be agreed and actually adopted in its specific EU legislation (such as plant protection, biocides or REACH).

3.59. The representative of South Africa associated himself with the comments made by the US and requested the EU to notify the proposed amendments to the criteria for identification of endocrine disruptors and the proposed residue threshold for food and feed treated with possible or potential endocrine disruptive compounds as soon as possible so as to allow trading partners, especially developing countries, at least a period of 90 days to provide comments, before any new regulations in this regard were adopted by the European Commission.

3.60. The representative of the European Union explained that several pieces of EU legislation contained specific provisions as regards endocrine disruptors. This was the case for the plant protection products Regulation, the biocidal products Regulation, the REACH Regulation, the water framework Directive, and the cosmetics Regulation. It was therefore judged essential to determine horizontal scientific criteria for the identification of endocrine disruptors applicable across all relevant pieces of legislation. The objective was to ensure a harmonised and coherent approach when dealing with endocrine disruptors, as well as coherence and predictability to all players. In this context, the European Commission has been working for a number of years to collect and develop scientific information on this matter. For instance, a study with a scientific review and an overview of the assessment methods for endocrine disruptors was published in early 2012. In June 2012, an EU conference gathering the world's experts on endocrine disruptors and around 300 stakeholders was organised. In March 2013, a report outlining experts' opinions on key scientific issues relevant to the identification of endocrine disruptors was published by the EU Joint Research Centre. Finally, in March 2013 the European Food Safety Authority published its scientific opinion as regards endocrine disruptors.

3.61. She further explained that the European Commission would probably adopt by September 2013 a Recommendation with the criteria for identifying endocrine disruptors. This Recommendation would use the World Health Organization definition of endocrine disruptors and was likely to establish a system with several categories – comparable to what has been done in the UN Global Harmonised System for Classification and Labelling for the classification of substances identified as carcinogens, mutagenic or toxic to reproduction (CMRs). Substances would be allocated to one of these categories based on strength of evidence in a weight-of-evidence approach. The Recommendation would also define the criteria for placing substances in the categories. Once the Recommendation with the horizontal criteria was adopted, the plant protection products Regulation and the biocidal products Regulation would have to be amended to render the criteria legally binding in the context of those Regulations. As a consequence,

substances identified as endocrine disruptors would not be approved as active substances for use in plant protection products, nor for biocidal products. As regards REACH and other legislation, a direct implementation of the criteria into REACH was not envisaged. However, the horizontal criteria would be taken into account when identifying substances as endocrine disruptors for inclusion into the so-called candidate list of Substances of Very High Concern, which may fall under the authorisation regime. As regards the consultation process, it has been conducted in full transparency and the scientific community and WTO Members have had several opportunities to comment on the methodology for the identification of endocrine disruptors. The EU has made a presentation on the development of criteria for identification of endocrine disruptors at the meeting of the OECD Endocrine Disruptors Testing and Assessment Advisory Group already in 2009 and then again in 2010 and 2011. Members of the Committee, notably the US, were represented at the EU Conference on Endocrine Disruptors held in June 2012. In February 2013, the Commission shared with the EPA a paper with possible elements as a basis for the criteria for identifying endocrine disruptors. The EPA comments were considered by the European Commission. There have been also several bilateral discussions with the EPA on this matter.

3.2.2 Previously Raised Specific Trade Concerns

3.2.2.1 European Union - Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)[3] (IMS ID 88)

3.62. The representatives of India, China, the United States, Argentina, Australia, the Philippines and Brazil reiterated concerns expressed at past meetings with respect to REACH. In addition, the representative of India referred to a number of outstanding issues: the opaque and arbitrary functioning of the Substance Information Exchange Fora (SIEF), including the prohibitive costs associated with them; definitions of a micro, small and medium size enterprise (SME); the cost associated with hiring an Only Representative (OR); and the request for merchant importers to directly undertake registration. He also raised a new issue: Commission Regulation 836/2012, which prescribed a threshold concentration of 0.05% for the use of lead in jewellery. In this respect, he asked whether the EU had issued guidance to parents for avoiding mouthing of jewellery and inquired on the rationale for exempting crystal glass and vitreous enamel from the scope of the regulation.

3.63. Concerning the notification G/TBT/N/EU/73, the representative of China was concerned about the restriction of polycyclic aromatic hydrocarbons (PAHs), in particular with respect to the stringent and uniform limit of 1 ppm established for PAHs, which could result in over protection for a large number of products that did not pose a risk. He also requested clarification regarding the testing methodology associated with the measure.

3.64. The representative of the United States also raised four new issues under this trade concern: the proliferation of redundant national registries of nanomaterials within the EU; the proliferation of inconsistent interpretations of the term "article" within the EU; the uncertainty of whether ORs would be able to submit an application for a REACH authorisation; and the lack of transparency in the processes of the Community Rolling Action Plan (CORAP). She also inquired on the role of the national registries of nanomaterials, on whether the EU intended to establish an EU-wide registry of nano-products, on the view of the European Commission regarding programmes that singled out a single class of chemicals without articulating the benefits of doing so, and on the steps that the EU was taking to address the numerous concerns regarding the measure.

3.65. The representative of Australia was interested in hearing about practical steps the EU was taking to try to mitigate the impact of REACH on SMEs, given the findings of the Commission's recent review of REACH. Like the United States, the representative of Brazil was also concerned with the proliferation of inconsistent interpretations of the term "article" within the EU.

3.66. The representative of Argentina stated that REACH created competitive distortions when substances were produced by a reduced group of competitors, as registration costs within SIEF

[3] The relevant notifications and documents are: G/TBT/N/EEC/52 and Adds.1-7; Add.3/Rev.1, G/TBT/N/EEC/295, G/TBT/N/EEC/295/Add.1; G/TBT/N/EEC/297, GG/TBT/N/EEC/297/Rev.1, G/TBT/N/EEC/297/Rev.1/Add.1; G/TBT/N/EEC/333, G/TBT/N/EEC/333/Add.1, G/TBT/N/EEC/334, G/TBT/N/EEC/334/Add.1; G/TBT/N/EEC/335, G/TBT/N/EEC/335/Add.1; G/TBT/N/EEC/336, G/TBT/N/EEC/336/Add.1; G/TBT/N/EU/73; and, G/TBT/W/208.

were distributed among competitors on equal parts, regardless of their market share. Moreover, the larger companies were usually the owners of the information within the SIEF. Thus, the incidence of the registration cost per tonne and the information access cost would leave outside of competition those firms with lesser volume. The need to register a product through a legal European entity (OR) also put foreign companies at a disadvantage – indeed this requirement posed a number of risks, including: that the OR could legally cease to exist or could change, and, there were also risks pertaining to confidential information about clients and trade volumes. According to REACH, these issues could be resolved through negotiations. However, these negotiations would cause a legal cost that probably would not be justified when the volume market share was reduced.

3.67. The representative of the European Union said that information on the estimation of exposure to PAHs arising from the use of consumer articles as well as conditions of use of these articles was available in the 2010 report by the German competent authority for REACH. She also said that there were currently no standard analytical methods to test PAHs but that some EU member states had their own analytical methods, and that a two year transitional period from the adoption of the measure was foreseen. With respect to Commission Regulation 836/2012, she explained that the 0.05% limit was based on the opinion delivered by the risk assessment committee, and that the social economic committee exempted crystal glass and vitreous enamel after examining the evidence presented on the comparative effect in relation to lead. As to the national registries of nanomaterials, she informed that the European Commission had not found incompatibilities with the internal market rules, but was preparing an impact assessment for a possible future harmonising measure, one of the options being a harmonised registry. Regarding the interpretation of term "article", she said that the European Commission sustained that the 0.1% threshold for substance of very high concern applied to articles as produced or imported, and not to components or homogenous parts of articles. Further, the European Court of Justice was the only authority that could decide on the correct interpretation of the term. On the CORAP processes, she clarified that since 2013 most of the background documents were published. Finally, regarding ORs, she said that, as was clarified by the European Chemicals Agency (ECHA) guidance documents, an OR could submit an application for a REACH authorisation.

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

3.68. The representative of Japan requested India to correct the discrimination in article 10.2 of the revised "Agreement for the Grant of BIS Licence" under which only foreign tyre manufacturers were required to provide a bank guarantee of USD10,000. He also requested a revision of the ISI Marking Fee calculation method which was based on the total number of ISI marked tyres, including tyres destined for export outside the Indian market.

3.69. The representative of the European Union reiterated the longstanding concerns about the Indian Quality Order on Pneumatic Tyres and Tubes for Automotive Vehicles, which included a certification procedure with mandatory marking for tyres, and the requirement regarding the bank guarantee of USD10,000 for the payment of royalty fees. Of particular concern were the royalty fees to be paid on the total production of tyres marked and produced with ISI marking, and not only those which were actually imported to India. She urged India to remove the royalty fees, or to modify their calculation to limit them to tyres which were *de facto* exported to India.

3.70. The representative of Korea also reiterated previous concerns regarding marking fees and performance bank guarantees. He said that the manner in which marking fees were calculated – on the basis of the total number of tyres produced and marked with the ISI symbol – was unfair and needed to be reviewed; it needed to reflect the total number of ISI-marked tyres imported to India. Compared with similar marks issued by other countries, fees were considerably higher for the ISI system, and in general most countries did not charge marking fees for tyres. He also requested India to repeal the USD10,000 performance bank guarantee required for foreign manufacturers outside India.

3.71. The representative of India answered that the performance bank guarantee was intended to protect the Bureau of Indian Standards (BIS) from breach on behalf of the licensee during the tenure of the licence, and that such guarantees were customary in the international sphere. He also said that the marking and overall fees were comparable or even lower than those charged by other Members for similar schemes.

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

3.72. The representatives of the European Union, Brazil and the United States recalled their previous concerns about the on-going revision of China's Order 276 on Medical Devices and requested China to notify any revision to the TBT Committee. In particular, the representative of the European Union noted that on 23 April 2013 Chinese authorities announced the revocation of China Compulsory Certification (CCC) requirements for eight categories of medical devices, which had been a longstanding concern of EU industry in China, and hoped that this was the first step to ensure that medical devices imported into China were not subject to duplicative regulatory controls due to the overlapping responsibilities of the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and the State Food and Drug Administration (SFDA). She asked China for an update on the status of the revision, and recalled the specific EU industry concerns: registration procedures, differences between China's and international standards, insufficient acceptance of foreign clinical trial data and test results, and the need for approval of the products in the country of origin or manufacture. She stressed the need for China to: notify this legislation to the TBT Committee; allow Members a reasonable time to provide comments; take Members' comments into account; and provide for an adequate implementation period of at least one year between the publication of the Order and its entry into force. The representative of Brazil recalled the need for greater convergence of China's applicable mandatory standards to international ones, as well as the need for more flexibility in accepting medical devices on the Chinese market which had been made in compliance with international standards.

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

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

3.74. The representative of the European Union thanked India for suspending the application of the mandatory third party certification for certain steel products until 1 October 2013. Her delegation considered third party certification to be inappropriate and too burdensome for intermediate steel producers. She inquired about the implementation of this mandatory third party certification, given that the European industry continued to report significant difficulties during the certification procedure, including long delays for issuing certificates, extensive and detailed information to be provided, mandatory factory inspections, the lack of feedback on reasons for refusal of applications, and the lack of recognition of test results carried out by foreign laboratories. Finally, she asked India to take measures to ensure equal treatment for domestic and foreign manufacturers, and invited India to institute a more expeditious procedure for the steel products subject to third party certification with clear deadlines and possibility to challenge the refusal of the application.

3.75. The representative of Japan reiterated three concerns with regard to the technical regulation. First, he considered that technical regulations were not needed for intermediate products such as steel products because the objective of securing consumer's health safety should be achieved by safety regulations for final products. Second, the scope of the regulation was unclear and India needed to clarify which products were covered. His delegation considered that the measure, if put into effect as scheduled, would create unnecessary obstacles for customs procedures, disrupt Japanese high-quality steel supply. Finally, he asked India to postpone the commencement of operation and implementation of the regulation until its scope of application was clarified.

3.76. The representative of India reiterated that product coverage, HS codes, titles and Indian standard numbers had been provided, and that the regulation applied to intermediate products because this affected the performance of the final product.

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

3.77. The representative of the European Union recalled Brazil's information at the last TBT Committee meeting that it had adopted several measures to improve the National Health Surveillance Agency's (ANVISA) inspection capacity. Such measures included the augmentation in the number of Good Manufacturing Practices (GMP) inspectors, and the publication of a draft resolution aimed at, *inter alia*, optimising conditions for the concession of GMP certificates. The EU understood that several hundred medical devices were still awaiting GMP inspections, thus pending authorization to be placed on the Brazilian market. The EU welcomed efforts taken by Brazilian authorities to accelerate inspections, but stressed that it would take a long time before the situation was regularized. Therefore, the EU called on Brazil to consider interim steps, such as temporary authorization of foreign GMP certificates. She suggested that ANVISA could continue issuing GMP certificates, however on the basis of inspection reports carried out by bodies established outside the Brazilian territory and shared on a confidentiality basis. This would allow Brazil to safeguard consumer health and safety, optimise resources, and guarantee inspections being carried out within three months after filing of a request. The EU enquired if Brazil was considering these suggestions and asked for an update on the situation and steps to be taken.

3.78. The representative of the United States supported the EU's intervention and recalled previously raised concerns on this issue.

3.79. The representative of Brazil referred to the minutes of previous meetings containing explanations on this subject. With regard to the Brazilian authorities' work to improve ANVISA's inspection capacities, he informed that improvements had been taken in the certification process due to the relocation of experts from other areas. Further measures under consideration included an increase in the number of GMP inspectors by opening a new public selection process, and a new regulation allowing for the mutual recognition and acceptance of GMP certificates issued by foreign authorities. He said that Brazil remained open to alternative approaches, such as confidentiality agreements between health agencies in Brazil and other Members to exchange inspection reports, and recalled that Brazil had joined the International Medical Device Regulators Forum (IMDRF).

3.2.2.6 Korea – KS C IEC61646:2007 Standard for Thin-film Solar Panels

3.80. The representative of the United States recalled their intervention on this issue at the March 2013 Committee meeting that detailed concerns regarding methodologies and scientific flaws employed in Korea's environmental study, which had led to the continued exclusion of a certain type of solar panel from its certification programme manufactured in the US. She said this would enable eligibility for certain voluntary government programs and *de facto* determine access to the Korean market. While the US appreciated engagement with Korea on this issue, the results thereof had rather been disappointing. She requested anew to incorporate the specification for this type of solar panel in relevant Korean IEC standard as well as in its certification programme.

3.81. The representative of the European Union recalled their past statements on this issue and welcomed Korea's replies and updates.

3.82. The representative of Korea referred to a bilateral meeting held between Korea and the US in Seoul on 11 June 2013. As to the US concern regarding test methods on thin film solar panels, Korea welcomed the US positive response to its suggestion of holding an expert-level dialogue. Moreover, Korea underlined that the related certification system for thin film solar panels was not mandatory but voluntary, thus not leading to any restrictions in entering the Korean market. The Korean government had conducted a two-year, comprehensive feasibility study to review the possibility of including CdTe and CIGS modules in the scope of KS C IEC61646:2007. This study was conducted to assess the effect to the environment of solar panels being damaged and discarded during and after their use. As no relevant international standards existed on the assessment of the degree of hazardous waste from thin film solar panels, Korea conducted tests based on the US EPA method and the EU method. Results of the feasibility study were discussed at the International Symposium held in March 2012. Korea informed that it was reviewing the necessity of conducting a feasibility study, as well as setting usage restrictions and recovering waste from thin film solar panels with regard to silicon-based solar panels. He informed that Korea has decided to adopt a certification system for CIGS modules that satisfied national environmental

standards, and was working on setting out criteria as well as installing necessary facilities for certification. Korea planned to complete these procedures by January 2014.

3.2.2.7 India – Telecommunications Related Rules (IMS ID 274)

3.83. The representative of the European Union asked India to confirm the postponement of the entry into force of the new security clearance requirements from 1 April to 1 October 2013. The EU was concerned with the absence of final guidelines on applicable standards and the actual scope of testing. He also suggested limiting mandatory testing to critical elements only. Moreover, the EU remained concerned with the requirement for in-country testing, and reiterated its request that India maintain the current level of acceptance of test results and certificates issued by foreign laboratories and approved under the Common Criteria Recognition Arrangement (CCRA). Finally, with regard to testing methods, he reiterated the EU's request that relevant international standards for information security be referenced in the final guidelines, and asked for an update on the availability of the final guidelines.

3.84. The representative of the United States also requested confirmation of the postponement of the security clearance requirements' entry into force to October 2013. The US expressed continued disappointment with the lack of progress in addressing serious concerns with the licensing amendment, including (i) the requirement for telecommunications equipment vendors to test all imported information and communications technology (ICT) equipment and labs domiciled in India; (ii) the requirement to allow the telecommunications service providers and government agencies to inspect a vendor's manufacturing facilities and supply chain, and to perform security checks at any time during the supply of the equipment; and (iii) the imposition of strict liability and possible blacklisting of a vendor for taking inadequate precautionary security measures. She echoed the comments made by the EU on the need to make use of international standards and arrangements for conformity assessment. As an in-country testing requirement would impose costs and burdens on economic operators outside as well as inside India, the US was concerned about capacity, competence and independence of some of the labs established in India. Criteria and systems to assure the competence and independence of testing laboratories were well established in international standards and systems of conformity assessment. She pointed out that India's legitimate security concerns could be addressed in a less costly and trade restrictive approach, and welcomed the opportunity to further discuss this issue on a bilateral basis.

3.85. The representative of Japan supported the concerns expressed by the EU and the US. Japan understood that the implementation of the Unified Access Service License Agreement had been postponed to 1 October 2013. Japan asked India to ensure that its telecommunications regulations would not impede market access for foreign companies.

3.86. The representative of India clarified that security, certification and testing by Indian labs would be mandatory as of 1 October 2013. With regards to the accreditation process and related security concerns, he stressed that the decision on in-house testing had been made with a view to taking into account security concerns on telecom equipment. He pointed out that the CCRA system was not very conducive in terms of security aspects of telecom equipment testing.

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

3.87. The European Union recalled that this was an issue that it had raised on multiple occasions. The European Union was grateful to China for the bilateral dialogue so far; however, it wished to take the opportunity of this meeting to reiterate some systemic concerns about the Chinese regulatory landscape on ICT security and request for a specific update on a number of items. The systemic concerns were principally on the regulatory framework - including the standards to support it, which were being developed in an opaque way, with no opportunity to provide input into the standard-setting process. Despite the repeated assurance given by Chinese authorities that all enterprises in China would be treated equally, the fact remained that this principle had numerous exceptions in the way in which this regulatory framework and standardisation process unfolded. The relevant technical committees remained largely foreclosed to inputs from foreign companies, even if established in China; the implementation of the Multi-Level Protection Scheme

was equally not very transparent, and this created a rather unpredictable business environment posing a lot of difficulties to EU companies wishing to plan their business in China in this sector.

3.88. The representative of the European Union also requested China for specific updates on several issues. First, on the on-going revision of the regulation on commercial encryption products managed by the Office of State Commercial Cryptography Administration (OSCCA), he reiterated the European Union's expectation that the process would be finalized in a transparent way, that the text would be notified and that the revision would restore a level playing field among domestic and foreign operators and eliminate discriminatory elements that characterize the current version, such as the prohibition on the use of foreign technology. On the MLPS, he indicated that the EU would welcome more transparency and predictability regarding its implementation (particularly since this scheme concerned sectors beyond those covered traditionally by national security exceptions) , as well as further clarification on the criteria and rationale for the classification of IT systems as critical infrastructure. He encouraged Chinese authorities to review the requirements that only home-grown Chinese technology could be used in such systems. The EU further requested an update regarding the standards on radio frequency based mobile phone payments developed by the China Electronic Standardisation Institute (CESI) technical committee. The EU expressed concern with the fact that the standards in question made reference to algorithms, but did not contain the algorithms as such; these would be later determined by OSCCA. This raised questions as to the accessibility and licensing conditions on which these algorithms would be made available. Finally, he requested an update regarding the announcement by the People's Bank of China that all banking financial payment systems would need to integrate Chinese algorithms, and he asked for clarification on the relationship between the announcement by the Bank of China and the parallel publication by OSCCA of a series of 14 standards related to the implementation of this policy.

3.89. The representative of Japan reiterated support for the EU's position. Japan paid particular attention to the various schemes and regulations within China with regard to how these could negatively affect trade of information security products.

3.90. The representative of the United States recalled his delegation's previous statements in the Committee since March 2011 and shared the concerns outlined by the EU on the lack of transparency and potential trade impact of China's development of standards, technical regulations and conformity assessment procedures on encryption requirements for commercial products. She requested China to provide an update on its development of technical regulations in this area. The US welcomed China's statement at the March meeting that OSCCA would ensure openness and public consultation in the formulation of these requirements. She said that information security measures aimed at banking, education, healthcare, transportation and other public utilities would have a significant impact on trade. She noted the obligations of the Code of Good Practice on the activities of central government standardizing bodies, and particularly the requirement for public comment. The US was concerned with the short comment period of 10 days in standards' development and the lack of limited ability of US companies to participate in this process. She recalled that the TBT Agreement applied to products of enterprises produced in the territories of other WTO Members, not simply to enterprises within China.

3.91. The representative of China replied that no update did yet exist on the OSCCA Regulation on commercial encryption products and MLPS. She referred Members to the minutes of the last meeting and welcomed their continued interest in monitoring these measures. As for the five standards for radio frequency-based mobile payment, she clarified that they were voluntary. Further, algorithm E was only a symbol for text description which has not specified any specific algorithm and the technical content of this algorithm was not covered by this standard.

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

3.92. The representative of Japan asked for confirmation on the latest situation concerning the postponement of the implementation of this labeling regulation for cosmetics. He expressed two concerns on the application and evaluation of the new cosmetic ingredients system. First, Japan requested China to accelerate the examination of new ingredients as only three new ingredients have been approved since the implementation of this system. Second, as regards safety assessment of compound materials, Japan considered that the requirement of each constituent being isolated and assessed separately was unnecessarily trade-restrictive. Japan requested China

to review the current regulations, taking into account the practices of safety evaluation of cosmetic ingredients currently taken in many countries, including Japan, the US and EU.

3.93. The representative of the European Union expressed appreciation for the constructive regulatory dialogue between the European Commission and China's State Food and Drug Administration (CFDA). This cooperation contributed to progress on a number of issues of bilateral interest; however, there was still a lack of sufficient progress in the approval of new ingredients and of cosmetic products with new ingredients. Only three new ingredients (and one product containing a new ingredient) have been approved during the last three years, although 120 applications have been made and several hundred new ingredients have been introduced safely outside China during this time. The EU believed that further efforts were necessary to ensure that the registration of ingredients and of products with new ingredients increased to levels comparable with those prior to the introduction of these requirements, and welcomed an update from China on steps being taken to solve the situation. Secondly, on the new draft requirements on the labelling of cosmetics (notified under G/TBT/N/CHN/937), the EU recalled its concerns that they might introduce duplication of, or even conflict between, requirements of the CFDA and the Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). At the last TBT Committee meeting, China had indicated that the CFDA was still in the process of analysing all comments received and that, given the large amount of input from stakeholders, the implementation of this measure could be postponed. She therefore asked for an update from China on the state of play of this notification.

3.94. The representative of the United States associated herself with the points made by Japan and the EU, particularly on the issue of the virtual standstill in approvals for cosmetics containing new ingredients. She supported the comments from the EU on the issue of a potential overlap of the requirements outlined in notification G/TBT/N/CHN/937 with AQSIQ regulations. With respect to G/TBT/N/CHN/821, the US expressed concern about the CFDA's creation of a "positive list" of ingredients and requested China to instead allow companies to demonstrate that ingredients were "existing" by means other than appearance on a positive list. She asked for clarification of CFDA's stated intention to devolve responsibility for managing imported "normal cosmetic" registrations to provincial-level authorities, and inquired whether these would have adequate training and resources. She thanked China for their bilateral engagement on this issue, and particularly for their assurance of treating imported normal cosmetics in the same manner as locally manufactured products. She also requested that CFDA address existing concerns on the failure to provide alternative means of labelling small packages that lacked enough surface area to carry all the information as required.

3.95. The representative of China said that her delegation has been cooperating closely with their trading partners in the implementation of the regulation. China believed that specific technical issues could be solved by means of bilateral communications between technical experts and, in this respect, it has formed a working group on this issue with the EU, Japan and Korea. She reiterated that the cosmetic label instruction regulation and guidance had been notified on 21 December 2012 as G/TBT/N/CHN/937. China has received comments from, *inter alia*, the EU, the US, and Japan. She clarified that the former SFDA was reformed into a new department known as CFDA that was still under the procedure of adjustment. China was processing and analysing comments at this stage, and would postpone the proposed date of adoption and entry into force due to the great amount of comments received.

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

3.96. The representative of the United States stated that the requirement under the measure for all new materials to be registered could have far reaching impacts and particularly seriously disrupt product development for semi-conductors, phones, LED TV's and many other household and industrial products. The US was also concerned with the sharing of proprietary information within the supply chain as well as with the onerous and burdensome reporting requirements under the measure, which would be expensive and disproportional to the benefits it could bring. The US requested an update from Korea on the status of the Act and implementing deadline, and asked Korea whether industries would have the opportunity to provide comments.

3.97. The representative of Korea informed that the Act on Registration and Evaluation of Chemical Materials has been implemented taking in to account examples from other countries,

such as the EU's REACH. Korea would provide multilateral support to smooth the implementation of the Act, including an advance notice regarding substances subject to registration, establishment and operation of a chemical substance data processing system, training, and public relations. On the registration requirement, he said that the purpose of the Act was to protect public health and the environment from the potential risk that new chemicals might have, and to prevent manufacturers and importers from avoiding meeting the requirements. Therefore, all new chemical substances, regardless of volume, were subject to registration. Only a small volume of chemical materials were exempted, or excluded, from registration, such as substances contained in machines or in solid form and substances used for tests and research. He noted that Article 38 of the Act specified that if a foreign seller felt difficulties to share confidential business information with domestic importers, the foreign seller was allowed to appoint a proxy to fulfill its obligations. Moreover, the purpose of the mandatory annual report was to obtain data from manufactures, sellers and importers, and to designate chemicals subject to be registered. Korea was of the opinion that the burden was not as heavy on manufactures, sellers, and importers, because the annual report was an extension of business. Korea would operate integrated electronic systems with regard to information overlapping with other laws. He informed that the competent authorities would notify WTO Members when publishing a draft of the subordinate regulations, and would invite comments from stakeholders. The Presidential and Ministerial decrees as well as the Act were to be enacted on 1 January 2015. Subordinate regulations would be drafted by December 2013 at the latest and would be followed by the legislative process, including internal consultations, notice and promulgation by the first half of 2014. Various foreign and domestic stakeholders would be consulted, including the industries concerned and private organizations.

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

3.98. The representative of India asked France to provide more details about the scope of the measure, including whether the measure was to be based on an international standard, and whether any impact assessment had been carried out on this measure.

3.99. The representative of Argentina reiterated his delegations' previously raised concerns and recalled that at the March 2012 Committee meeting the EU delegation stated that the results of the experiment would be made available at the beginning of 2013. He asked for an update on this aspect and also whether the results had already been submitted to the French Parliament, and how they could be accessed. The representative of Cuba echoed the statement of Argentina.

3.100. The representative of the European Union reiterated the view that the Grenelle 2 Law did not contain technical regulations and provided only for an experiment concerning environmental labelling. She invited Members to refer to minutes of past meetings with respect to the objective and scope of the experiment. The results of the experimental phase were currently being evaluated. As noted in the March 2013 Committee meeting, a report on the results would be submitted to the French Parliament in the summer of 2013. Once the evaluation was completed, her delegation was prepared to share information about the results of the experiment.

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

3.101. Indonesia The representative of Indonesia requested that the European Union delegation provide information on the calculation method for determining sustainability criteria under Article 17 of the amendment of Directive 2009/28/EC. He also asked for further detail about "environmental protection" in relation to Article 17(2) of the Directive. Finally, with respect to the notified amendment, he asked for clarification about the Articles which included technical regulations. He reiterated the request that the EU reply in writing to all his delegation's questions.

3.102. The representative of Argentina reiterated concerns previously expressed by his delegation at the June 2012 and March 2013 meetings, including with regard to the proposal for amendments to Directive 2009/28/EC and 98/78/EC on the quality of fuel, which was put forward by the European Commission to the European Parliament and the European Council on 17 October 2012. Argentina shared Indonesia and other biofuel producers' concerns regarding Directive 2009/28/CE for its impact on biofuel trade, as the European market was its main destination. He said that the importance his delegation attached to this topic and product was evidenced by Argentina's

repeated recourse to the DSB, a path that it was obliged to take in light of the lack of a satisfactory response from the EU to Argentina's concerns. While his delegation shared the EU's objectives of sustainability and conservation, the implementation of these measures must be in line with multilateral trade agreements, and must not impose unnecessary trade obstacles on the products of other Members.

3.103. The representative of Malaysia expressed her delegation's concern with the discriminatory treatment of palm-based biofuel under the EU - RED. Palm-based biofuel was given a lower default greenhouse gas emission saving value compared to biodiesel from other competing raw materials, such as rapeseed oil. She explained that this disadvantaged palm based biodiesel in terms of access to the EU market. Malaysia has conducted research on the greenhouse gas emissions saving of palm based biodiesel, and the results indicated high emissions savings compared to the EU assessment under the EU - RED. She urged the EU to consider the technical data Malaysia submitted to the Joint Research Centre of the European Commission and the European Commission. A revision of default values for palm-based biodiesel using the data offered by Malaysia would provide further market opportunities for Malaysian biodiesel producers.

3.104. The representative of the European Union explained that they notified the draft Renewable Energy Directive to the TBT Committee in July 2008[4] due to the existence of TBT elements in the original proposal's Articles 18(2) and 18(3). These elements were, however, not retained in the final Directive. Moreover, the recent proposal for the amendment of the Directive did not fall within the scope of the TBT Agreement, and had therefore not been notified. She stated that Indonesia's concerns about sustainability criteria for biofuels fell outside the scope of the TBT Agreement. Her delegation therefore considered that the TBT Committee was not an appropriate forum for discussing this issue, or providing a reply to these queries. The EU remained open to further bilateral exchange in this regard.

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

3.105. The representative of Mexico said that these proposed measure would violate fundamental principles established in the TBT Agreement, in particular with regard to: proportionality; being more restrictive than necessary to achieve the legitimate objective sought; lack of scientific evidence; lack of transparency; and not being based on international standards. She requested that Colombian authorities provide an official response to the comments submitted by Mexico during the public consultation period. Further, she asked Colombia to present the scientific and technical evidence upon which the measure was based, including evidence of how it would comply with their legitimate objective. Should the proposed measure not be amended, Mexico requested that Colombia provide a sufficient transition period between publication and entry into force.

3.106. The representative of Canada expressed its support for the concerns outlined by Mexico, and hoped that Colombia's regulations would be developed in a transparent manner consistent with the TBT Agreement.

3.107. The representative of Colombia noted that a formal response had already been provided to comment submitted by Mexico, Japan and the United States. He requested that Canada formally present comments and explain their concerns about transparency. He noted that the Minister of the Environment was currently reviewing the measures in question, and hoped that revisions would be made available soon.

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

3.108. The representative of the United States requested an update from Peru on the status of its proposed labelling requirements, and recalled concerns about potential impacts on trade. She suggested that mandatory labelling requirements for genetically engineered foods that were substantially equivalent to conventional foods could give the false impression that the labelled food

[4] G/TBT/N/EEC/200.

or feed was substantively different from, or less safe than, the conventional equivalent. Her delegation believed that a voluntary labelling would allow for consumer choice at a lower cost and with less trade disruption. She sought clarification as to how Peru was taking the comments of other Members into consideration when finalizing the measure. Should Peru decide to move forward with the implementation of the regulation, she requested further clarity on the scope of the requirements as well as the implementing mechanism for monitoring, supervision, verification and compliance. Additionally, she asked for an extension to implementation period beyond the currently envisaged 180 days, in order to provide sufficient time for industry to adapt to the new requirements.

3.109. The representatives of Chile and Colombia recalled their respective previously expressed concerns on this measure, and specific questions regarding the public consultation to which their delegations awaited a response. They also asked for an update of the measure at issue.

3.110. The representative of Peru said the measure continued to evolve. The expected date of entry into force was not yet clear. The final measure would reflect comments received from other Members.

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

3.111. The representative of the European Union expressed appreciation for recent bilateral discussions with Indonesia on this issue. He noted that on 12 April 2013 the Indonesia Ministry of Industry adopted Decree No. 24, concerning the mandatory application of the Indonesian national standard for toys. The text of the final Decree was almost identical to the text that had been notified in draft form[5], and therefore, the concerns the EU had expressed with regard to the draft text as notified remained. He noted that the testing requirements provided for in Decree No. 24 appeared to lay down different and more burdensome procedures for imported products as compared to domestic products. For domestic products, mandatory testing had to be carried out on samples taken every six months from the same production line. For imported products, samples are taken from each imported shipment, which would lead to more frequent testing if a company imported more frequently than every six months. He stressed that this constituted less favourable treatment for imported products versus domestic products. He asked about the rationale for this differentiation in testing. Regarding the laboratories approved for conducting testing required under Decree No. 24, he noted that Article 5 of that Decree provided that such laboratories were to be accredited by the National Accreditation Body of Indonesia (KAN) and appointed by the Minister of Industry. He enquired whether applications for accreditation from foreign laboratories would be accepted. Further, he asked whether foreign laboratories that were accredited by an accreditation body that was a signatory to the ILAC MRA would be accepted, without having to be separately accredited by KAN. With respect to the factory audit, he submitted that the conformity assessment procedures provided by Decree No. 24 foresaw not only mandatory testing, but also a factory audit of the quality management systems of the companies and manufacturers. These audits would be conducted at least once per year, and Article 11 of Decree No. 24 established that these audits could only be carried out by Indonesian government officials. He reiterated the request that companies holding ISO 9001 certification delivered by an accreditation body signatory to the IAF MRA should be exempted from such audits. He also said that it was unclear how the restrictions on the use of Phthalates and Azo dyes should be interpreted. He therefore welcomed the imminent adoption of technical guidelines to clarify how the Indonesian standards for toy safety should be applied. Finally, he noted that Decree No. 24 set the entry into force for the new requirements on 12 October 2013, which was 6 months from adoption. However, given that technical guidelines supporting the decree and application of the standard were not yet available, he invited Indonesia to consider further postponement of the entry into force of these measures.

3.112. The representative of the United States stressed that the areas of concern raised by the EU were equally shared by US industry and the US government, and requested a response from the Indonesian delegation on these questions. Furthermore, she also requested a delay in the implementation of the measure, given the level of uncertainty and lack of clarity with respect to

[5] G/TBT/N/IDN/64.

technical aspects of the measure. Finally, she expressed appreciation for on-going bilateral engagement with Indonesia on this issue.

3.113. The representative of Indonesia informed that the draft regulation on Mandatory Implementation of Indonesia National Standard (SNI) for Toys was stipulated through Decree of Minister of Industry No. 24/M-IND/PER/4/2013 dated 12 April 2013, entering into force six months thereafter. With respect to the procedures for sampling, testing and marking, he explained that requirements would be set out in technical guidelines on the implementation of Indonesia National Standard (SNI) for Toys. The Government of Indonesia, and in particular the Ministry of Industry (responsible for the regulation), was still in the process of discussing the guidelines with relevant stakeholders. He said that Indonesia had based its conformity assessment procedures on international standards ISO/IEC Guide 67:2004, Conformity assessment – Fundamentals of product certification. Indonesia was also a signatory of ILAC/APLAC mutual recognition arrangement (MRA) for testing and calibration laboratories. Therefore, an MRA could be envisaged with other APLAC/ILAC signatory countries. However, he explained that establishment of a government (or regulator) to government (or regulator) MoU was a necessary element of an MRA, since not all Members' accreditation bodies were government entities. He also stated that questions with regard to chemical phylates and axo-dyes would be clarified in technical guidance. His delegation would respond to EU concerns in writing, and encouraged both the US and the EU to continue to engage with Indonesia bilaterally.

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

3.114. The representative of the European Union reiterated previous concerns expressed with this measure, including a detailed written comments sent to Russia in March 2013. Her delegation continued to await a response to those comments, including information on whether and how they have been taken into account. She also inquired about the current status of the draft text and timeline for its adoption. Regarding the information requested under the notification procedure for alcoholic products, given that it was already provided under other administrative procedures, it was duplicative and did not provide any health and safety-related added value. She therefore requested confirmation that the notification system would be withdrawn from the draft technical regulation and not be introduced in any Russian specific national legislation. She asked why a notification procedure that has been considered by the members of the Customs Union as inappropriate was still being considered by Russia alone under Russian Resolution No. 474 of June 2013. Finally, should this procedure constitute a conformity assessment procedure, she requested that it be notified by Russia to the TBT Committee, and that sufficient time be provided for comments.

3.115. She also sought confirmation that the production control and conformity assessment procedures would not be applicable to production sites that had been already controlled by EU national authorities. Regarding wines, she sought confirmation that enrichment with "concentrated must", "rectified concentrated must" or "sucrose" would be allowed under the measure for all types of wines, since these were oenological practices used in quality wines and widely accepted internationally level. Regarding beers, while the decrease of compulsory malt content from 80% to 50% was welcomed, the limit on sugar content should be eliminated and the use of fruits and additives should be allowed in beer production. She asked that definitions for some products, such as "Cognac", "Calvados" and "Champagne", which were currently absent from the regulation, be added to the final version along with measures to adequately protect EU geographical indications. Finally, she sought confirmation that the ban on PET packaging would be withdrawn from the draft technical regulation, and would not be introduced in any Russian specific national legislation. On this point, she informed that a Russian proposal to ban PET packaging on drinks sold in quantities over one-half litre was foreseen to be adopted before mid-July. She asked Russia to explain which health and safety risks this ban would address. She suggested that Russia reconsider this measure and notify it to the TBT Committee. The representative hoped that EU concerns and suggestions be duly taken into account before the final technical regulation on alcoholic drinks was adopted.

3.116. The representative of the United States echoed that concerns expressed by the EU, and noted that the most recent draft of Eurasian Customs Union Technical Regulation on Alcoholic Beverage Product Safety included a notification procedure for alcoholic beverages. She requested a response to US comments sent in December 2011 and also on 5 March 2013 and asked for an update on the status of the technical regulation, in particular its provisions to establish a

notification procedure. She asked Russia to clarify its national notification procedure, created by amending Federal Law SF 171 in December 2012, which duplicated the notification procedure in the draft Eurasian Customs Union Technical Regulation. She asked Russia to confirm whether it has adopted a resolution on 5 June 2013 that would render this notification procedure mandatory, with an entry into force of 1 October 2013. If this were the case, it would be regrettable that the decision to finalize this requirement was taken without taking into account concerns expressed by trading partners. Her delegation believed that the notification procedure would be burdensome and duplicative since it would add to the already complex scheme of documentation required to assess conformity, such as state registration and declaration of conformity. She expressed was further concerned that entry into force was foreseen for 1 October 2013. This short transparent transition period would not provide enough time for US exporters to adapt without trade disruption. She also asked Russia to clarify the scope of the measure that was adopted on 5 June 2013, and in particular, if any additional requirements have been added beyond what was originally proposed in the draft. She stated that the US had several concerns with this technical regulation, and requested in particular that Russia consider different practices for the aging of whiskies, which depended on different factors including climate. Under the current system, several US whiskies could not be shipped to Russia because of the three-year aging requirement. In addition, the measure did not include several processing aids and additives commonly used in winemaking countries. The United States also referred to Eurasian Customs Union's list and requested that it be expanded to include all processing aid and additives commonly used internationally.

3.117. The representative of Australia said his delegation had submitted comments on Russia's notification in February 2013, which included concerns on restrictions or bans on commonly used additives and processing aids, identified by the OIV, which did not affect the safety of alcoholic products. Australia considered that restricting the use of, or banning, these oenological practices would limit Australia's ability to continue to provide quality wine to the Eurasian Customs Union. He recalled his delegation's suggestion that Russia consider adopting the OIV list of approved additives and processing aids, as set out in the International Oenological Codex and the International Code of Oenological Practices. He continued to seek clarification about the legal status of wines which conformed to the health warning statement under the previous legislation, and were in circulation at the time the draft regulation entered into force. If such wines were to be affected, he suggested that Russia introduce a six-month transition period for those products so as to enable industry sufficient time to implement the new labelling requirements. He asked Russia to confirm whether wines labelled with an Australian GI would be considered as a protected GI under the new technical regulations, and whether the relevant exemptions from the regulations for protect GIs would apply to them. He also requested clarification about requirements relating to the bottling location of wines that include a GI in their description and presentation. He asked whether the Eurasian Customs Union regulations required such wines to be bottled within the boundary of the GI stated in the description and presentation of the wine. Finally, his delegation asked for an update on Russia’s consideration of the comments it had received to date on the issue.

3.118. The representative of Argentina expressed concerns with this measure, and asked Russia to bring it into conformity with the provisions of the TBT Agreement, without creating unnecessary trade obstacles.

3.119. The representatives of New Zealand and Mexico supported the statements of other Members, and recalled comments and concerns previously submitted to Russia. New Zealand, in particular, stated that the notification procedure duplicated requirements that were found elsewhere and were unnecessarily burdensome. His delegation understood that the notification procedure was adopted on 5 June 2013 without sufficient changes to address the duplication with other requirements. He reiterated that this was more trade restrictive than necessary to achieve Russia’s objectives, and asked that Russia streamline this process and to remove the duplicative requirements. He also noted that the notification procedure would enter into force in October 2013, and requested that Russia provide a full six months before entry into force to allow exporters to comply with this regulation without disruption to trade. Mexico requested a response to its comments that were submitted in 2011.

3.120. The representative of Russia said the draft technical regulation was being developed in order to establish unified requirements for turnover of alcoholic products - both imported and domestically produced in the single market. A public hearing on the draft technical regulation was completed in December 2011, prior to Russia's accession to the WTO. In accordance with the TBT Agreement, all interested parties were given opportunity to provide their comments during a

60-day comment period and even comments received thereafter were being carefully examined. Moreover, a number of issues were solved and questions answered bilaterally with other Members. With regard to the definitions of various alcoholic products, he noted that the minimum malt content under the definition of beer was decreased from 80% to 50%. In addition, the ban on use of PET bottles was eliminated from the text of the draft, except with regard to the strong spirits. The draft provisions on the notification procedure were also excluded from the text. In this respect, he asked that questions on Russia's notification procedure be submitted in writing. He mentioned that in accordance with Resolution No. 474, as of 5 June 2013 a legal entity would have to provide information on the product to the Federal Service of Alcohol Market Regulation in electronic form, including an electronic signature on the notification by the legal entity. Information provided in such notifications would be publicly available at the website of the Federal Service of Alcohol Market Regulation. The objectives of the notifications procedure were exclusively related to information and greater transparency of the market. Given that at all stages of the procedure information would have to be provided by electronic means, his delegation believed that it would not be burdensome for economic operators. His delegation would continue to engage in bilateral consultations with interested WTO Members, making an effort to take into account their different positions, even if these positions often contradicted each other, as was the case with definitions of certain alcoholic products.

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

3.121. The representative of India reiterated his delegation's previous comment that Indian authorities were having problems in certifying compliance with third-party Good Manufacturing Practices (GMP), like those of the EU, as required under this Directive. While he noted that there was a clause in the Directive stating that the GMP were equivalent to the WHO GMP, nevertheless third party certification by Indian authorities needed to clearly indicate compliance with EU GMP, which was a problematic issue for Indian regulators. He also expressed concern with the definition of falsified medicinal products, which did not include parameters of quality, safety and efficacy. It was still unclear to Indian industry whether generics that were in transit through the EU market could be subject to seizure. Finally, he requested a sufficient time period for compliance with the Directive.

3.122. The representative of the European Union said that the Directive was notified to the TBT Committee in 2009, and had been extensively discussed at previous meetings of the Committee and also bilaterally. Starting in early 2012, a number of meetings with third countries and information sessions were organised in order to ensure that all public authorities were aware of the Directive's provisions and in particular the written confirmation. A template for the written confirmation, as well as a "questions and answers" document, has been made available to market operators and competent authorities. She stressed that the template for the written confirmation clearly stated that EU GMP rules for active substances were equivalent to WHO GMP rules for active substances. She reported that several countries have confirmed readiness to issue the written confirmation, while other countries have requested that the European Commission (EC) include them on the list of countries for which the written confirmation was waived. She said all relevant information on this was available on the EC website. The EC expected a smooth implementation of the rules by July 2013, and a postponement of the deadline was not possible.

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

3.123. The representative of Argentina reiterated his delegation's concern that these measures were not consistent with the EU's obligations under the TBT Agreement. Nevertheless, Argentina had engaged in discussions with the European authorities to overcome the obstacles and avoid the halting of shipments to the EU. At the EU's invitation, Argentina submitted in July 2009 its dossier on the terms "Reserva" and "Gran Reserva". Although this dossier has been approved by the European Commission's Management Committee for Wine in March 2012, has still not been adopted within the Commission and published in the official gazette. Despite several requests, the

EU has still not provided a satisfactory response as to the cause of the unjustified delay to conclude this process, that have already amounted to 15 months since the approval. High quality Argentine wines continued to suffer a significant price disadvantage, as compared with competitor countries that could accede the European market with their wines clearly identified and labelled as being of high quality for whom better prices were obtained. He said that Argentina has worked in good faith, both bilaterally and multilaterally, to obtain a positive response, or valid explanation for the delay. However, to date it has only received copies of the statements delivered by the EU at the previous two TBT Committee meetings, where they stated that the draft regulation with regard to the expression "Reserva" and "Gran Reserva" has been subject to a vote within the Management Committee for Wine and its formal adoption by the Commission was pending. Finally he noted that the number of times and Members raising this STC clearly indicated that the EU was protecting this sector.

3.124. The representative of the United States requested the EU to provide an update on the status of applications submitted by US wine industry in June 2010. These wine suppliers were still unable to ship their products to the EU market. She informed that the World Wine Trade Group[6] has sent a letter to the EU's Directorate General of Agriculture on 4 June 2013, to which no response was received to date, expressing their joint concern with the lack of progress on this issue and their discontent with the process of unilateral recognition of terms. She reiterated the view that this application process was more trade restrictive than necessary.

3.125. The representative of the European Union thanked the delegations of Argentina and the United States for their continued interest in the EU's regulation on wine products and said that discussions on the applications submitted by the US and Argentine industries were continuing and she had no further updates on the issue.

3.2.2.19 Viet Nam – Decree No 38 Detailing the Implementation of Some Articles of Food Safety Law (G/TBT/N/VNM/22, G/TBT/N/VNM/22/Suppl.1) (IMS ID 356)

3.126. The representative of the European Union recalled concerns on the complexity and unnecessary burden that this measure would cause due to the multiple declarations of conformity and related documents that had to be submitted to Vietnamese authorities prior to Importation, and the number of different ministries involved. This Decree would have an impact on imports into Viet Nam due to the lack of clarity on the applicable requirements, scope of products covered, and authorities responsible for implementation. She also highlighted the lack of an inter-ministerial circular clarifying the responsibilities of the authorities involved and list the products covered. She requested Viet Nam to suspend the application of the Decree until this circular, and any other implementing acts, have been notified to the WTO, giving Members sufficient time to comment. She also requested that a sufficient transition period be provided when all details regarding implementation have been adopted and published. She also requested that Viet Nam provide a reply to the comments submitted by the EU on 25 February 2013 and also engage with the EU industry to ensure equally treatment between domestic and imported products.

3.127. The representative of Australia reiterated concerns raised at the previous Committee meeting. While his delegation supported Viet Nam's right to implement measures to protect the health of its consumers, it was important such measures were no more trade restrictive than necessary to achieve the objective. Given that it was still unclear how Decree 38 would be implemented, he encouraged Viet Nam to delay its full implementation until arrangements for implementation had been fully considered and clearly communicated to trade partners. He encouraged Viet Nam to continue to notify the WTO of any technical circulars guiding the operation of the Law on Food Safety.

3.128. The representative of New Zealand endorsed the statements made by other delegations and reiterated his delegation's request that all regulatory changes brought about by the implementation of Decree 38 by clear notification as early as possible. His delegation encouraged Viet Nam to ensure adequate time for industry to prepare for, and adjust to, such regulations prior to their entry into force.

3.129. The representative of the United States supported the concerns raised by the EU, Australia and New Zealand and said that her delegation continued to have significant concerns with both the

[6] Argentina, Australia, Canada, Chile, Georgia, New Zealand, South Africa and the United States.

technical components and implementing circulars of Decree 38. She urged Viet Nam to conduct the implementation, in particular when made across the three corresponding ministries, in a transparent and efficient manner so as to avoid trade disruption.

3.130. The representative of Viet Nam said, with respect to the issue of responsibilities in food management, which were already regulated for in the Food Safety Law that, her delegation understood the need for transparency in drafting technical regulations and had already notified some technical regulations and requirements to both the SPS and TBT Committees. She informed Viet Nam has received comments from many delegations and has also contacted the US Embassy in Viet Nam and other Members to arrange meetings with their concerned ministries, although no response has been received so far with respect to this invitation.

3.2.2.20 Brazil - Draft ANVISA Resolution on Used, Refurbished, Rented or Lent Medical Devices (G/TBT/N/BRA/440) (IMS ID 362)

3.131. The representative of the European Union reiterated concerns regarding ANVISA's draft resolution. The EU requested that equipment reconditioned overseas should be allowed for importation to Brazil as long as it complied with the health and safety performance requirements. She recalled that Brazil had informed the Committee at the March meeting that a final draft was not yet available and that a public hearing would be organised. She asked if the EU's suggestions would be taken into account, and for an update on the timeline for adoption of the Resolution.

3.132. The representative of Switzerland shared the concerns raised by the EU. As an important exporter of new and refurbish medical devices, Switzerland was of the opinion that any refurbished equipment, independent of its place of first installation, should be allowed for importation to Brazil so long as it complied with national health, safety and environmental requirements. While his delegation shared Brazil's objective of avoiding medical devices being exported to Brazil for final disposal, he requested Brazil to inform the Committee on which less trade restrictive alternatives the authorities were considering to assure Brazil's legitimate objective.

3.133. The representative of Brazil noted the continued interest in this issue and referred the Committee to previous minutes where information had already been provided. He emphasized that one of the main objectives of the draft regulation was to avoid used medical equipment being exported to Brazil as a means of final disposal of those products. Another important objective was to make producers of new medical equipment take responsibility for their appropriate disposal. The draft measure, he said, was open for public consultation for two months in 2011, and a significant number of comments were received. ANVISA was organizing a public hearing on the issue where stakeholders could exchange views in an open and transparent manner with Brazilian regulators and developments on this issue would be communicated to Members.

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

3.134. The representative of the European Union requested that Israel provide a written reply to their comments submitted on 17 September 2012, and also an update on the adoption procedure. The EU was concerned that the draft regulation introduced two different types of warnings addressing the alcohol content of liquor. This was contrary to scientific studies, where excessive consumption was harmful to health, and not the alcoholic beverage itself. Therefore differentiation between strong intoxicating liquors and intoxicating liquors as regards the warning message, as laid down in the notified draft regulations, could mislead consumers who might conclude that some alcoholic beverages were more harmful than others. She also asked for clarification on where the warning message was to be affixed, and whether an additional label or sticker being added in the distribution phase might be acceptable to the Israeli authorities. If warnings and information had to appear on the front label, EU producers would have to make front labels for the Israeli market only, which would have a burdensome and costly impact on imports. Finally, her delegation considered the strict provisions of the warning concerning size, colour of text, and the black frame to be unjustified. This information, she said, could be provided to the consumer in a less restrictive manner

3.135. The representative of the United States recalled previous interventions on this issue and noted that her delegation remained watchful regarding the outcome of Section 2 of the draft

amendment, which created two distinct warning labels for alcoholic beverages. She requested that Israel share the scientific rationale behind the split warning statements where those products containing more than 15.5% alcohol by volume were obliged to carry a distinct and stronger warning statement. She asked that an update be provided when this issue would be discussed in the new Knesset and looked forward to working with Israel to resolve concerns on this issue.

3.136. The representative of Israel thanked the US and EU for their comments, and informed the Committee that all concerns had been forwarded to the Minister of Health and to the Economics Committee of the Israeli Parliament. She said that the provisions on the size and design of the warning labels were still being examined by the Committee. As to the timeline of the legislative process, she explained that since the Committee had only reconvened two months earlier, after the election, this measure has not yet been discussed.

3.2.2.22 India – Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order, 2012 (IMS 367)

3.137. The representative of Canada stated that her delegation had submitted comments on India's proposed measure on 18 December 2012. She noted that Canada was concerned that India's new regulations, and the short timeframe provided to comply with them, could hinder or shut Canadian exporters out of the Indian market. She said that there were well-established international standards for evaluating the competencies of conformity assessment bodies, particularly ISO IEC 17025 and ISO IEC 10765. ILAC and IAF provided mutual recognition arrangements for a peer review system to ensure the contents of signatory accreditation bodies. She said that recognition by India of foreign conformity assessment bodies accredited by signatories to the ILAC and IAF MLAs would minimize the negative impact on companies wishing to export to India while at the same time providing assurance to India that these recognized bodies were competent. Allowing accredited foreign conformity assessment bodies to test and certify to India's regulatory requirements would also reduce testing costs and allow exporters to bring their products to the Indian market more quickly.

3.138. The representative of the European Union associated his delegation with Canada's comments and thanked India for bilateral discussions. He welcomed the fact that the entry into force of the measure was postponed from 3 April to 3 July 2013 and that, subject to certain conditions, an additional three-month delay could be obtained by individual manufactures. He also referred to a circular issued by the Department of Electronics and Information Technology of the Indian government on 29 May 2013. This circular provided that safety critical components would be accepted if they were either certified or tested by a certification body that was a signatory to the IECEE CB scheme, or were accredited according to the relevant international standard IEC17025 by an accreditation body that was a signatory to the ILAC MRA. He asked India to clarify the meaning of the phrase "until further orders". Did it mean that it was a temporary measure or would these arrangements be permanently available to foreign manufacturers wishing to export to India? He also reiterated the EU's general concern about the necessity and proportionality of India's compulsory registration system. In this respect, he urged India to consider whether a less burdensome conformity assessment procedure could not be equally effective in achieving the legitimate objective of protecting health and safety since the products concerned were office equipment and goods which would rarely give rise to safety problems and accidents. Further, he underlined that the EU was still not comfortable with the mandatory frequency of testing, which must occur every two years pursuant to the Indian measure. The EU instead believed that testing should only be repeated if products were substantially changed in such a way that their safety properties were affected.

3.139. The representative of the United States associated her delegation with the comments made by Canada and the EU and thanked India for their bilateral discussions. She asked India to: (i) confirm 3 October 2013 as the measure's implementation date; and (ii) clarify the meaning of the phrase "until further orders" in the measure; and (iii) explain the use of the IECEE CB scheme in the circular that was issued on 29 May 2013. She expressed concern with the product coverage of the measure since it covered highly specialized industrial equipment where consumer product safety issues would rarely arise. She also expressed concerns with: (i) the in-country testing requirements and lack of testing capacity; (ii) the inconsistency with IECEE CB scheme requirements; and (iii) the propensity to regulate via FAQs and notices of a general manner, rather than through proposed regulation and comment. Finally, she welcomed India's indication of

additional flexibilities with respect to the extension for implementation and the use of the IECEE CB scheme.

3.140. The representative of Korea acknowledged India's consumer safety efforts and appreciated the postponement of the entry into force of the measure from 3 April 2013 to 3 July 2013, although, depending on the status of product tests and registration, some manufacturing units would still be provided an additional grace period of three months. In particular, this grace period would be granted to products for which tests have been completed and registration forms have been submitted to the BIS before 3 July 2013. However, in the case of products submitted to BIS-recognized labs *before* that date, but for which test reports were not available, manufacturers would have to pay $1,000 - 2,000 a month for each model until they submitted a request for registration to the BIS with complete test reports. She explained that the reason why manufacturers could not register before the effective date – even in cases in which they submitted products for testing before the date – was that laboratories did not complete the tests in time. She noted that Korea did not think that it was fair that manufactures should be held responsible for such delays. She therefore asked the Indian authorities not to impose any charges in these situations.

3.141. The representative of Switzerland echoed the comments made by the EU, the US and Korea and asked India for further clarifications regarding the matters raised by these delegations.

3.142. The representative of India clarified that although the order technically entered into force on 3 July 2013, it would de facto enter into force only on 3 October 2013 as some manufacturers have been provided a grace period of three months. He said that that although India believed adequate time has been given for companies to comply with this order, it would nevertheless take into account the specific comments made by delegations in this respect. On the issue of compliance with the IEC standards, he explained that because the relevant Indian standards were mostly based on ISO IEC standards, there should not be any specific problems for Members to comply with them. He also underlined that India had an adequate number of testing labs which could manage any backlog that may occur in terms of testing. Regarding the circular issued on 29 May 2013, he reiterated that the circular primarily pertained to the safety critical components. He clarified that the phrase "further orders" was a terminology used to express that the government was deliberating upon the issue and that the order stood as it was unless changes would be made in the drafting process by the BIS. Finally, with respect to Korea's concern regarding an imposed fine of $1,000 - 2,000, he explained that test reports would be provided at an early stage.

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

3.143. The representative of Brazil stated that, given the growing problem of childhood obesity, his delegation considered the combat of diseases caused by the consumption of certain foods to be a legitimate objective. However, it was not clear to Brazil what the scientific basis for the Chilean measure was and how it could be reconciled with the Codex guidelines. Brazil also believed that the measure's objective could be addressed by more effective and less trade-restrictive public policies so as to stop it from conflicting with Article 2.2 of the TBT Agreement. Brazil acknowledged that it may be justified to introduce labelling on certain types of food with a view of indicating the presence of ingredients or substances that caused, for example, allergies or that were related to food intolerance, as those components may harm human health per se. Brazil was concerned, however, with the introduction of warning signs to indicate that certain foods contained a given amount of calories, fat or salt. The WHO's dietary guidelines considered the daily intake of nutrients that a balanced diet should contain whereas the proposed measure seemed to isolate food from the context of daily intake, which, as a result, could mislead consumers. His delegation hoped that the implementation of the measure could be delayed in order for it to be further clarified.

3.144. The representative of Mexico voiced her delegation's concerns with the proposed amendment. These are contained in full in document G/TBT/W/372.

3.145. The representative of Guatemala reiterated comments made at the previous TBT meeting. While Guatemala shared Chile's legitimate objectives of providing consumers with sufficient information about the food which they consume and reducing non-communicable diseases, it also

recalled that technical regulations should not be more trade restrictive than necessary to fulfil a legitimate objective. He asked Chile to respond to Guatemala's comments which were made in February 2013 and called upon Chile to consider alternative less trade-restrictive measures.

3.146. The representative of the European Union thanked Chile for their bilateral dialogue and asked it to provide a written reply to the EU's comments to the notification which were submitted on 7 March 2013, explaining how these comments would be taken into account. She also reminded Chile to notify any follow-up rules relevant to this measure. She stated that the law itself was never notified to the WTO and Members did therefore not have the opportunity to comment on it. She further noted that Article 5 of Law 20.606 established that the Ministry of Health would determine categories of foods to be labelled as "high in calories", "high in salt" or an equivalent designation. The Ministry would also determine the content, form, size, messages, signs or pictures used for the labels. However, "high in"-warnings, such as those proposed by the Chilean legislation, were not foreseen by the applicable CODEX guidelines on nutritional labelling and risked stigmatising some foods whose moderate consumption could be part of a healthy diet. The EU was concerned with the measure's proportionality to the aim pursued, which was to empower consumers to make an informed choice in order to foster effective competition and consumer welfare. Furthermore, this approach would have a discriminatory effect on foreign manufacturers that needed to adapt their packaging for the Chilean market. Given the foregoing, the EU was not convinced that the Chilean approach was the best way to achieve such legitimate objectives. She therefore invited Chile to consider less trade-restrictive measures.

3.147. She made four specific points regarding the Chilean measure. First, she asked Chile to explain the rationale behind imposing additional warnings and its compatibility with Article 2.2 of the TBT Agreement. Second, she recalled that the "Guidelines on Nutrition Labelling" (CAC/GL 2-1985 CODEX) stated that information contained in a nutrient declaration "should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product". She noted that no nutrient thresholds have been established by the CODEX for the nutrients targeted by the Chilean legislation. Although, there was evidence of a positive association between the intake of certain nutrients and the risk of developing a disease or disorder, there was no scientific evidence suggesting an identifiable threshold above which the risk existed. Third, according to the draft notified under G/TBT/N/CHL/219, the warnings would need to be placed in the middle of an octagonal icon, - a STOP sign - which must occupy not less than 20% of the main face of the packaging, must be located in the upper right corner, and must have a size of at least 4 square centimetres. These burdensome and prescriptive requirements raised concerns regarding the labelling of small packages. Further, it was not clear if stickers would be accepted in order to comply with the regulation. Should the additional warnings be eventually imposed, she asked Chile to consider less trade-restrictive size and placement requirements. In this respect, she drew Chile's attention to the EU's legislation, which provided less burdensome nutrition labelling requirements for packages whose largest surface had an area of less than 80cm², and an exemption from labelling for packages whose largest surface area was less than 25cm². Four and last, she asked Chile to provide information on the foreseen deadlines for the entry into force of these modifications, an important matter since the adaptation to the new requirements would require significant investment for manufacturers and a redesign of the packaging for some categories of products. She also asked Chile to postpone the entry into force of the modifications and provide a reasonable implementation period in accordance with Article 2.12 of the TBT Agreement. In this regard, she drew attention to the fact that the EU's legislation on nutritional labelling was adopted in 2011 but would only come into force in 2014.

3.148. The representative of the United States associated her delegation with the comments made by Brazil, Mexico, Guatemala and the EU. She asked that Chile, in conjunction with mandatory nutrition labelling, to consider a voluntary claims approach in line with international standards such as the Codex Guidelines for Use of Nutrition and Health Claims. She noted that the Codex contained guidance for establishing conditions for voluntary "low", "free" and "no added" claims in tandem with mandatory nutrition labelling. Another option for Chile would be to express nutrition content of a food as a percentage of the daily intake reference values. She explained that it was the US understanding that Chile has established a special committee with members from the Ministries of Economy and Health, and a representative from the office of the president, to develop a draft regulation that would take into account the trade concerns raised by stakeholders at previous TBT Committee meetings. It was moreover the US understanding that the Chilean Ministry of Economy has put forward an alternative approach that would be preferable to that

proposed by the Ministry of Health. Under this alternative approach the information displayed would indicate how many calories and how much saturated fat, sodium and sugar was contained in each serving of a particular food based on daily intake reference values. Such alternative approach would be consistent with Chile's legislation and provided more useful information on foods to the consumer, minimizing the chance that they would be misled. This alternative proposal would also decrease the number of foods that must be labelled with "high in" claims. She asked Chile to confirm that the Ministry of Health's final regulation would not include "STOP signs" as the primary means to communicate nutritional information to consumers, and that nutritional thresholds would be based on portion sizes by food category. The US encouraged Chile to delay finalization and implementation of this regulation to allow for adequate dialogue and consideration of comments from stakeholders. Further, the current timetable to implement the regulation by July 2013 did not leave sufficient time for industry compliance or discussion of trading partners' concerns.

3.149. The representative of Switzerland said that while sharing Chile's views regarding obesity related to non-communicable diseases, his delegation also had some concerns with the draft measure, which have been sent to Chile in writing after their bilateral consultations. His delegation looked forward to hearing how these concerns would be reflected in the draft regulation and also invited Chile to consider Switzerland's voluntary approach regarding the referencing of nutrition thresholds on products.

3.150. The representative of Australia said that while his delegation supported Chile's right to implement measures to provide consumers with information in order for them to make appropriate dietary choices and reduce the risk of non-communicable diseases, it was important that such measures were no more trade-restrictive than necessary to achieve the objective. He noted that Law No. 20.606 was published in the official gazette on 7 June 2012 with a one year implementation date. Since the overarching law was not notified to the WTO, Members did not have the opportunity to submit comments until the implementation phase. Australia was concerned with the mandatory nature of the front-of-pack nutritional labelling requirements and with the lack of clarity around many issues related to the law's implementation. He underlined that there were less trade-restrictive measures available that were being considered by other countries, including Australia. He encouraged Chile to delay implementation of the law until the arrangements for implementation have been fully considered and clearly communicated to trading partners. He also encouraged Chile to continue notifying the WTO of any further amendments, as well as guides, on the operation of the Food Health Regulations.

3.151. The representative of Argentina said that his delegation shared the concerns of other delegations with the negative trade effects of the provisions of both the law 20.606 and its regulation on the nutritional composition of foods and their advertising. He reiterated his delegation's previously expressed view that the Chilean measures did not meet the provisions of Article 2.2 of the TBT Agreement as they were excessive in relation to the legitimate objective they sought to achieve, and asked the Chilean authorities to provide responses to Argentina's comments.

3.152. The representative of Canada said that her delegation supported Chile's policy objective of promoting healthy dietary choices and reducing obesity and related non-communicable diseases. However, Canada was concerned that the regulatory proposals would deviate from international standards, may not have a scientific basis and would likely be more trade-restrictive than necessary. Canada therefore encouraged Chile to consider less trade-restrictive alternatives. She noted that Canada has raised this issue with Chile in several fora, including the TBT Committee and on the margins of APEC in Indonesia, as well as bilaterally, via the Canadian embassy in Chile. Canada has been assured that Chile was reconsidering its regulations with a view to making them WTO compliant. She asked Chile to provide an update regarding this regulatory review and timelines for the measure's implementation.

3.153. The representatives of Colombia and Costa Rica echoed the comments made by Brazil, Mexico, Guatemala, the EU, the US, Switzerland, Australia, Argentina and Canada. They also thanked Chile for its replies concerning some of the concerns which they have has previously raised.

3.154. The representative of Chile stated that obesity was becoming epidemic in Chile, particularly among those aged under 14. This law was one of the first measures which Chile has adopted to address this problem and was based on the understanding that the public needed to be

able to make informed decisions about their food consumption and avoid excessive consumption of substances which lead to obesity. She said that the Chilean government was currently working on the final version of this regulation. She also explained that during the preparation of the final draft, Chile welcomed a number of experts from other countries, including the EU and US, and integrated their contributions as well as developments in the TBT Committee. It was precisely due to the large number of comments and developments being taken into account that the implementation process would take longer than expected and the deadlines for implementation would be modified accordingly. She also clarified that Chile was no longer envisaging an octagonal shaped warning "STOP sign" but instead a smaller one, different from that originally proposal. Finally, she ensured that Chile would continue to keep Members informed of developments.

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

3.155. The representative of the European Union reiterated her delegation's concerns with the measure and noted that, despite several reminders, the EU has not received any replies to its comments sent to Korea on 1 March 2012. The Korean draft introduced a system of self-certification of certain car parts. Manufacturers or importers of these parts would have to be registered with the relevant Korean authority (the Ministry of Land, Infrastructure and Transport, or MoLIT), and apply the self-certification mark (the KC mark) on the product before placing it on the Korean market. She also noted that in accordance with Article 2.4 of the TBT Agreement, where international standards existed or their completion was imminent, Members shall use them as a basis for their technical regulations, unless such standards were inappropriate or ineffective to achieve the legitimate objective pursued. She said that Korea has not provided any explanation, scientific evidence or any other relevant information as to why the relevant UN Regulations and e-mark would be inappropriate or ineffective in attaining Korea's objective. She reiterated the EU's request that car parts certified as complying with UN Regulations, and marked with the international "e-mark", be accepted on the Korean market. She further asked Korea to in the meantime accept stickers to affix the KC mark for the indefinite future, or until any eventual acceptance of the e-mark. She said that her delegation also remained concerned with the fact that the implementing legislation to the amended Ordinance and Regulation – MLTM Notice no. 2013-70 on "Guidelines for Motor Vehicle & Vehicle Parts Self-Certification" - was published by the MoLIT on 22 February and entered into force on 22 May, without ever having been notified to the WTO. She requested the suspension of the requirements until these TBT Agreement obligations were complied with, or, at a minimum, to ensure a flexible implementation with a view to minimizing trade distortions.

3.156. The representative of Korea noted that the Korean authorities have been in contact with the EU regarding this issue many times and in its last official response of 26 March 2013 Korea has fully addressed the concerns raised by the EU. Korea said that its regulation was harmonized with relevant international standards and many countries, including the US and the EU, operated similar certification schemes for automotive parts under which they required the use of their own marks. While Korea did not see any reason why parts with an e-mark instead of a KC-mark would be admitted, it would however allow stickers to be used for small parts. Korea noted that the regulation entered into force on 22 February 2013 and that it was thus not possible to grant an additional grace period. The regulation, which was notified to the WTO in December 2011, granted a three-month grace period to ensure that manufacturers would have time to get acquainted with it.

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

3.157. The representatives of Cuba, Dominican Republic, Malawi, and Zimbabwe expressed their concern on the consistency of the proposed EU measure with the TRIPS Agreement and/or the TBT Agreement. Their full statements are contained, respectively, in G/TBT/W/365, G/TBT/W/367, G/TBT/W/369 and G/TBT/W/370.

3.158. The representative of Nicaragua expressed concerns regarding the most recent developments of the EU's proposed measure. He noted, in particular, that the presentation of the draft report on 10 April 2013, made by the rapporteur of the European Parliamentary Committee on the Environment, Public Health and Food Safety, Linda McAvan, suggested a series of

amendments which, in Nicaragua's point of view, increased the trade-restrictive nature of the measure. Of particular concern for his delegation were the proposals to adopt plain packaging for cigarettes and roll-your-own tobacco, the requirement for authorization of new products and the restriction of distribution and sales of tobacco products. Nicaragua considered that because the draft directive was more trade-restrictive than necessary and lacked scientific basis, it was not in accordance with Article 2.2 of the TBT Agreement. He encouraged the EU to consider less trade-restrictive alternatives. Nicaragua also believed that the proposal of introducing plain packaging can, in particular, could not be justified under the WHO's Framework Convention on Tobacco Control (FCTC), as the EU's proposed measure extended beyond the requirements of this Convention. He explained that Nicaragua has about 23 tobacco producers which together generated 35,000 direct jobs and 45,000 indirect jobs. Nicaragua's tobacco exports were valued up to 185 million dollars. He also underlined that the tobacco industry helped to stimulate Nicaragua's tourist sector as the tobacco production sites attracted many visitors. The EU's proposed directive could therefore cause serious economic and social adverse effects to his country.

3.159. The representative of Guatemala explained that while her delegation shared the policy objective of the EU to improve public health by discouraging the use of tobacco products, it was nonetheless unclear how the proposed regulation would achieve such legitimate objective. Furthermore, as the EU's measure appeared to be more trade-restrictive than necessary to achieve that legitimate objective, Guatemala asked the EU to consider less trade-restrictive alternatives.

3.160. The representative of Honduras stated that her delegation shared the concerns expressed by other delegations, in particular those related to the compatibility of the proposed measure with WTO Agreements, particularly the TRIPS and TBT Agreements. While Honduras understood the need to protect human health, it considered that the measure was more trade-restrictive than necessary.

3.161. The representative of Mozambique said that while his delegation recognised EU's right to protect its citizens, it also associate itself with the concerns expressed by Malawi, Nicaragua, Cuba and other Members, which would hopefully be taken into consideration by the EU.

3.162. The representative of Australia reiterated his delegation's previous support of the EU's proposal to revise the Tobacco Products Directive. Like Australia, the EU was a strong supporter of effective tobacco control and as parties to the WHO FCTC both Members shared common goals. He noted that one of the objectives of the EU proposal was to implement the WHO FCTC. He also underlined that the significant public health challenge resulting from tobacco use was a global issue which all WTO Members must face. He commended the EU and its member states for the tobacco control measures it had implemented to date. He noted that under the proposal EU member states would be allowed to implement plain packaging of tobacco products as far as it was compatible with the Directive and EU law. He said that Australia particularly welcomed the announcement by the current EU presidency, Ireland, that it would be taking the lead by introducing legislation to mandate plain packaging of tobacco products. Australia was of the firm view that Members had the right to implement measures necessary to protect public health while complying with relevant treaty obligations, including the TBT Agreement. He viewed the proposed EU Directive as a legitimate measure designed to achieve the fundamental objective of protecting human health, in particular protecting young people against smoking initiation and uptake.

3.163. The representative of Norway stressed that public health and tobacco control were topics of particular interest to her delegation and thanked the EU for notifying the proposal at such an early stage in the process. In Norway's view, it was within the rights of each WTO Member to adopt measures which were necessary to protect public health as long as they would be consistent with WTO obligations. Norway considered the FCTC and the relevant WTO Agreements to be mutually supportive, and that it was possible to implement measures intended to regulate the use of tobacco products in line with both sets of binding obligations. Norway strongly supported the EU in its efforts to combat the tobacco epidemic.

3.164. The representative of New Zealand underlined his delegation's support for the EU's consideration of introducing controls on the packaging of tobacco products as part of their comprehensive tobacco control regime. In New Zealand, smoking was the single largest cause of preventable death and disease. He noted that WTO rules included appropriate flexibilities to enable

WTO Members to regulate for health and other public policy purposes. This right was explicitly expressed in the ability to issue legitimate regulatory objectives under the TBT Agreement. New Zealand also welcomed the ability of individual EU member states to introduce plain packaging under this draft directive as well as Ireland's efforts to do so. New Zealand expected the EU to regulate in a manner that would be consistent both with its obligations under the WTO Agreements and the FCTC.

3.165. The representative of the European Union explained that the proposal had been put forward by the Commission on 19 December 2012, and was now going through the EU's legislative process, in which both the European Council and the Parliament would have to give their approval in order for the proposal to be adopted. Once adopted, the Directive would become applicable 18 months later, and products not in compliance with the Directive would be able to be placed on the market for an additional 6 months. The proposal was notified to the WTO on 18 January 2013, and Members were provided with 90 days to comment on the draft. Three Members had submitted comments: Malawi, Malaysia and Chinese Taipei. The European Union would reply to these comments in writing in the next few weeks.

3.166. She also responded to some of the points raised by Members during this meeting and the March 2013 TBT Committee meeting. Firstly, with regard to the draft Directive's requirements on ingredients, she explained that the prohibition of tobacco products with characterising flavours, contained in Article 6 of the proposal, did not prohibit the use of individual additives provided that they did not result in a characterizing flavour. She said that the use of additives which were essential for manufactures' tobacco products and did not result in a characterizing flavour shall not be prohibited. A ban on tobacco products with characterising flavours was deemed necessary and proportionate in relation to the legitimate objectives of the measure. It was also in line with the guidelines on the implementation of Articles 9 and 10 of the FCTC. She also explained that scientific studies and market data demonstrated that flavours influenced and enhanced smoking initiation. For instance, a Eurobarometer survey from 2012 confirmed that flavours played a bigger role in smoking initiation in young people than in other age groups. In particular, the growing trend of using fruit and other flavourings, such as vanilla and chocolate in tobacco products has been shown to serve as an inducement to young people to start smoking. Products with characterising aromas or tastes could also easily influence consumers' perception of harm. For the particular case of menthol, evidence suggested that the availability of menthol cigarettes increased the likelihood of experimentation and regular smoking. She further explained that, in addition to the ban of tobacco products with characterising flavours, the proposal included a ban of a limited number of individual additives (Article 6, para. 4) which gave the impression that a tobacco product had health benefits, presented reduced health hazards or increased mental alertness and physical performance. Secondly, with regard to the packaging and labelling, she said that the proposal foresaw a mandatory combined health warning (which included a picture and a text message) on 75% of the two main surfaces of cigarettes and roll-your-own products. It also foresaw a ban on promotional and misleading elements. She noted that, in the EU's view, these requirements were proportionate and non-discriminatory. The proposed size of the health warnings balanced the legitimate objective of informing consumers and discouraging smoking initiation with the economic interests at stake. She highlighted that the Guidelines for implementing Article 11 of the FCTC concluded that the effectiveness of health warnings increased with size, and recommended FCTC Parties to cover as much of the principal display areas as possible. As certain packet shapes could mislead consumers to believe that a product was less harmful than others, a certain standardisation of package appearance and a minimum number of cigarettes per package was also required. She further noted that, while the draft Directive did not mandate cigarettes to be sold in plain packaging, EU Member States maintained the right to regulate autonomously aspects not covered by the prescriptions of the Directive or other Union legislation. Any such national rules concerning aspects not covered by Union legislation should be adequately justified and compatible with the Treaty on the Functioning of the European Union and with international agreements binding on the Union.

3.167. The European Union concluded by underlining once again that the draft Directive was the result of thorough consultations with all stakeholders involved, and provided for a broad range of measures which were non-discriminatory and proportionate to the legitimate health objectives pursued. It joined a broad array of legislative and non-legislative initiatives (such as excise duties, public awareness campaigns, bans on smoking in public places, prohibition of advertising), at both EU and Member State level, to increase awareness of tobacco risks, reduce the appeal and attractiveness of tobacco products, and therefore contribute to a decrease in smoking rates and

smoking initiation, particularly among youngsters. This draft was therefore fully consistent with the EU's international commitments, including its obligations under the WTO TBT Agreement, and throughout the legislative process WTO aspects would duly be taken into account.

3.3 Exchange of Experiences

3.3.1 Good Regulatory Practice

3.168. The Committee held a second thematic discussion on Good Regulatory Practices (GRP) on 17 June 2013. The Chairman's oral summary report is contained in G/TBT/GEN/143/Add.1.

3.169. Referring to the report, the representative of China asked the Chairman to clarify what he had meant with "TBT-plus" outcomes. He specifically asked whether the inclusion of Regulatory Impact Assessments (RIA) in the non-exhaustive list of voluntary mechanisms, designed to guide Members in the efficient and effective implementation of the TBT Agreement, constituted a "TBT-plus" outcome.

3.170. The representative of Cuba associated herself with the concerns expressed by China. She said that it remained important to share best practices in the area of GRP and that the situation of implementation has been unsatisfactory.

3.171. The Chairman emphasized that the Committee was, as per its mandate from the Sixth Triennial Review, in the process of identifying a non-exhaustive list of voluntary mechanisms to implement the TBT Agreement in a more efficient and effective way. This work was not intended to add or detract from the disciplines of the TBT Agreement.

3.3.2 Transparency

3.3.2.1 Seventh Special Meeting on Procedures for Information Exchange

3.172. Pursuant to its 1995 decision to convene, on a biennial basis, "regular meetings of persons responsible for information exchange, including persons responsible for Enquiry Points and notifications"[7], the TBT Committee held its Seventh Special Meeting on Procedures for Information Exchange on 18 June 2013. The Chairman delivered an oral summary report of that Meeting (G/TBT/GEN/151). A more detailed summary of the meeting is contained in Annex 1, below.

3.3.2.2 Coherent Use of Notification Formats

3.173. A representative of the Secretariat (SPS Committee) made a presentation on the SPS Committee's experiences with notifications. She said that the SPS Committee has periodically reviewed its transparency obligations and its recommended procedures and formats.[8] Recommended formats had last been revised in 2008 when the SPS Committee adopted a format for addenda that gave clear checkmark options for Members to indicate the purpose of their addenda. She explained that a "revision" was defined by the SPS Committee as a document that had replaced a previous notification. "Corrigenda" were defined as corrections of errors that stemmed from the submission itself, or from the Secretariat's handling of the notification. She underlined that since the SPS Committee last revised its recommendations and adopted new formats for addenda, revisions and corrigenda, 25% of the notifications were addenda. Very few revisions and corrigenda have been submitted. She explained that the system for on-line submissions of SPS notifications had been active for more than 18 months and that close to 50% of all notifications had been received through this system. She said that, from the Secretariat's perspective, notifications had been processed and published much faster when submitted on-line. Members had also indicated that the submission of notifications online had saved substantial amounts of time.

3.174. The representative of the United States underlined that in arriving at a common understanding of the meaning of notification formats, due regard had to be paid to the efficiency of the notification process as well as institutional differences in Members' regulatory systems.

[7] G/TBT/1/Rev.10, page 35.
[8] G/SPS/7/Rev.3.

3.175. The representative of the European Union highlighted that the EU's paper on the use of notification formats[9], referred to the SPS Committee's document setting out recommendations on the use of notification formats. The representative suggested that it would be useful to mirror the good practices of the SPS Committee when providing guidance to Members on the uniform use of notification formats.

3.176. The representative of India asked for clarification regarding what the EU wanted as an outcome of their proposal for a coherent use of notification formats.

3.177. The representative of the European Union replied that his delegation hoped that the outcome would constitute recommendations giving clear and practical guidance as well as examples of when new notifications, addenda, revisions and corrigenda should be used. He suggested that the EU proposal could form the base of a Committee recommendation if Members so wished.

3.178. The representative of the Philippines asked whether it was the ambition of the Committee to follow the practices stated in the EU's proposal or rather to imitate the guidance of the SPS Committee.

3.179. The representative of the United States suggested that a way forward to standardize practices for notification formats could be to develop a basis for commonality in Members' notification practices. She hoped that criteria for formats could be structured to encapsulate both the diversity of notification practices and provide a common basis.

3.180. The Chairman noted that although the EU proposal constituted a good foundation, it was not necessary to adhere to a single proposal. He encouraged Members to make use of this opportunity to think about their current notification practices and make additional proposals. He said that the deadline for submitting comments should be on 6 September 2013.

3.3.3 Special and Differential Treatment and Technical Assistance (preliminary discussion on the thematic session)

3.181. At the request of the representative of Ecuador, a communication[10] regarding the preparation of the thematic session on Special and Differential Treatment (SDT) and technical assistance in October 2013 was circulated.

3.182. The representative of China expressed his delegation's support of Ecuador's proposals for the upcoming thematic session. His delegation believed that more concrete work needed to be carried out by the TBT Committee in order to enhance the effective implementation of Article 12 of the TBT Agreement. He noted that the principle contained in Article 12 of the TBT Agreement was as important as the principles of transparency, non-discrimination and the use of international standards, and should thus be applied throughout the entire regulatory lifecycle. He noted that there was no specific guidance document regarding best practices in the field of SDT and that China considered it important to work towards the development of such guidelines. The representative invited Members, particularly developed Members, to share experiences on how Article 12 had been implemented in the preparation, adoption and application of technical regulations, standards and conformity assessment procedures. These could include, as required by Article 12, what active and meaningful consideration had been given to the special development, financial and trade needs of developing Members in the regulatory life cycle, and what measures had been taken by Members to facilitate active and effective participation of developing Members in the work of international standardizing bodies and international systems for conformity assessment.

3.183. The representative of Argentina expressed his delegation's support of Ecuador's proposal and China's statement. He drew attention to the work of the CTDSS on the implementation of the relevant provisions of the SPS Agreement, and noted that similar work could be carried out by the TBT Committee.

[9] JOB/TBT/48.
[10] JOB/TBT/49.

3.184. The representative of India supported the previous delegations' statements. He noted that in the context of discussion on specific trade concerns, developing countries had pointed out that their SMEs were facing difficulties when attempting to conform to the regulations of other Members. He stated that his delegation wished to enhance the Committee's work in this field by sharing experiences and developing guidance documents. India also asked the Secretariat to prepare a background paper highlighting the various aspects of Article 12 of the Agreement.

3.185. The representatives of the Dominican Republic, Cuba and Indonesia supported Ecuador's proposal.

3.186. The representative of the Philippines expressed her delegation's support of Ecuador's proposal and suggested holding an informal meeting to discuss how Members can move forward in this regard.

3.187. The representative of Brazil expressed his delegation's readiness to participate in the structuring of the thematic discussion on Article 12 of the TBT Agreement.

3.188. The representative of South Africa supported Ecuador's proposal and the statements made by other delegates. He also said that South Africa would appreciate if the Secretariat would develop a background paper outlining how developed country Members were implementing Article 12 of the Agreement.

3.189. The representative of Mexico supported the suggestion made by the Philippines to hold an informal meeting to lay out the foundations of the thematic session.

3.190. The representative of the United States encouraged Members to consider the topic of best practices on technical assistance developed in the Fifth Triennial Review with respect to demand driven technical assistance which she underlined had been a long standing element of the Committee's work.

3.191. The representative of the European Union welcomed Ecuador's proposal. He asked if the Secretariat could provide a background note on the Committee's work, but also developments taking place elsewhere in within the WTO, on the topic of SDT and technical assistance.

3.192. The representative of the WTO Secretariat noted the request by Members for a background note on the topic of SDT. He explained that a first note on the topic could be found in document JOB(05)/269.

3.193. The representative of Ecuador expressed his delegation's appreciation of the EU's comments and welcomed the incorporation of these in the preparation of a background note on SDT by the Secretariat.

3.194. The representative of China asked whether informal consultations would be held regarding the session on SDT and technical assistance.

3.195. The Chairman underlined that a programme based on Members' comments would be developed and circulated in due course before informal consultations would take place.

3.3.4 Conformity Assessment (preliminary discussion on the thematic session)

3.196. The representative of the United States proposed that, regarding the thematic session on Conformity Assessment Procedures, three main elements were of particular interest: the results of conformity assessment procedures, the international system of accreditation and the development of technical infrastructure.

3.197. The representative of South Africa supported the ideas underlined by the US and added that the topic of Mutual Recognition Agreements (MRAs) was also important.

4 TECHNICAL COOPERATION ACTIVITIES

4.1. The representative of UNECE updated the Committee on activities in the Working Party on Regulatory Cooperation (WP6).[11] He said that at the annual meeting in November 2013, a recommendation on a reference to standards (Recommendation D) would be revised.[12] He invited all organizations and interested parties to take part in this revision. A workshop would also take place at the November meeting, covering topics such as education on standard related issues.

4.2. The representative of Codex Alimentarius informed the Committee that the FAO/WHO Project and Fund for Enhanced Participation in Codex would meet from 1-5 July 2013.[13]

4.3. The representative of Senegal suggested to the Committee that there would be more training activities on the TBT Agreement, for example regional workshops covering subjects such as market access difficulties.

4.4. The Chairman informed the Committee that an Advanced Course on the TBT Agreement had taken place from 10-21 June. This intensive course was carried out as part of the WTO Trade Related Technical Assistance plan 2012/2013. Twenty-four participants from developing countries took part in this activity, which included presentations, interactive discussions, simulation exercise and visits to international standard setting bodies.

4.5. The representative of South Africa thanked the Secretariat for organizing this activity and said the knowledge their participant gained would help South Africa to further improve their implementation of the TBT Agreement.

5 UPDATING BY OBSERVERS

5.1. The representatives of IEC and Codex Alimentarius[14] updated the Committee on their activities. The representative of Codex Alimentarius highlighted the work of its Committee on Food Labelling. Given the number of STCs raised on this subject, she considered that the work of this Codex Committee could be of interest to the TBT Committee.

5.2. The representative of OIML informed that Rwanda, Uganda and Yemen became corresponding members. OIML was also working with UNIDO and the ITC on a number of programmes to reinforce legal metrology as part of quality infrastructure in developing countries. With UNIDO, a metrology school for all African countries - AFRIMETS[15] would be organized in 2014, concentrating entirely on legal metrology. With ITC there were some on-going programmes concerning control of pre-packages.

5.3. The representative of South Africa proposed that the Committee grant *ad hoc* observership status to ILAC and IAF. As a signatory to both IAF and ILAC Mutual Recognition Arrangements, he said South African goods were accepted in 61 economies, represented by 73 accreditation bodies. The purpose of ILAC and IAF was to establish multilateral arrangements between their member accreditation bodies, which enhanced the acceptance of products and services across national borders by removing the need for additional testing, inspections or certification, thereby helping to reduce bureaucracy and costs for businesses. Multilateral arrangements also provided governments and regulators with an internationally recognized stamp of approval.

5.4. The representative of the United States thanked South Africa for supporting ILAC and IAF's request for observer status in the Committee. As this issue was still under discussion internally, she was not able to lend her support at the time, but would bring it back to capital for further discussion.

5.5. The representative of the European Union thanked South Africa for supporting the application of ILAC and IAF. However, he reminded the Committee that there was a formal impediment to granting this request as the guidelines for observer status clearly stated that observer status was

[11] http://www.unece.org/trade/wp6/welcome.html
[12] http://www.unece.org/index.php?id=32879
[13] ftp://ftp.fao.org/Codex/Meetings/cac/cac36/cac36_14e.pdf
[14] G/TBT/GEN/152 and G/TBT/GEN/153
[15] http://www.afrimets.org/SitePages/Home.aspx

only granted to inter-governmental organizations. In the EU's view, ILAC and IAF should be invited to events where their presence could add a valuable contribution but this did not qualify them for permanent observer status. He requested that the WTO Secretariat provide a legal clarification on how the guidelines for observer status should be interpreted.

5.6. The Chairman proposed that all Members seek advice from their relevant authorities on pending requests for observer status, including the proposal from South Africa and said he would revert to pending requests at the next meeting of the Committee.

6 DATE OF NEXT MEETING

6.1. The next meetings of the TBT Committee will take place on 30-31 October 2013. It will be preceded by a thematic sessions on Special and Differential Treatment and Technical Assistance, and Conformity Assessment Procedures on 29 October.

ANNEX 1
SUMMARY REPORT OF SEVENTH SPECIAL MEETING ON PROCEDURES FOR INFORMATION EXCHANGE

1.1. Pursuant to its decision to hold, on a biennial basis, "regular meetings of persons responsible for information exchange, including persons responsible for enquiry points and notifications"[1], the TBT Committee held its Seventh Special Meeting on Procedures for Information Exchange on 18 June 2013.[2] The Special Meetings are organized to provide Members with an opportunity to discuss issues relating to information exchange and to review periodically the functioning of notification procedures and the operation of enquiry points. The meetings are also used to follow-up on decisions and recommendations agreed by the TBT Committee during its triennial reviews. The Seventh Special Meeting was organized in three panel sessions dealing with (i) online notification; (ii) use of notification formats; and (iii) functioning of enquiry points.[3]

1 ONLINE NOTIFICATION: TBT NOTIFICATION SUBMISSION SYSTEM (TBT NSS)

1.2. The representative of the Secretariat presented the TBT Notification Submission System (TBT NSS), which had been developed in response to the mandate of the Sixth Triennial Review.[4] He explained that the TBT NSS allowed Members to submit notifications online, and was aimed at facilitating the submission and processing of notifications by Members and the Secretariat. At the time of the meeting, the TBT NSS was functional but remained in a state of live testing. Three Members had taken part in the testing phase (United States, European Union, Canada) and were submitting notification through the TBT NSS. The Secretariat reported that in the testing phase, Members had identified a number of issues and bugs in the TBT NSS.[5] In light of this, a number of fixes and upgrades were planned. For instance: the implementation of a new homepage to provide Members' with an overview of the status of notifications; a template function to reduce repetitive data entry; improved navigation and more prominent buttons; and, implementation of an email alert system. The Secretariat would continue to work with Members to develop and enhance the TBT NSS towards an official launch before the end of 2013. He stressed that the objective of the TBT NSS was to improve efficiency in the work of the Secretariat and Members, which was especially important given the growing number of notifications submitted. Other Members were encouraged to participate in the live testing phase.

1.3. The representatives of Switzerland and South Africa indicated their interest in beginning to use the TBT NSS. The representative of South Africa also noted that identifying products and assigning product codes (i.e. HS and ICS codes) covered by notified measures was challenging, and wondered to what extent the TBT NSS would enable precise identification of relevant products.

1.4. The representative of Uganda asked about the level of resources needed to use the system.

1.5. The representative of Japan enquired whether notifications submitted through the old approach would continue to be accepted once the TBT NSS was officially launched and enquired how Members could obtain their user names and passwords for the TBT NSS.

1.6. The representative of Ecuador asked if use of the TBT NSS would become mandatory in the future, and if there was a deadline envisaged in this respect.

1.7. The representative of Brazil requested confirmation that online submission of a notification would replace the old approach of notification (e.g. by email).

1.8. The representative of Cuba emphasized the importance of the development angle, and hoped that the TBT NSS could improve transparency and implementation of other provisions of the TBT Agreement across the regulatory lifecycle.

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[1] G/TBT/1/Rev.10, page 35.
[2] The programme for the Special Meeting is contained in G/TBT/GEN/150.
[3] Presentations made during all three sessions can be downloaded at: http://www.wto.org/english/tratop_e/tbt_e/special_meeting_june13_e.zip.
[4] G/TBT/32, para. 18.
[5] For instance, in a few cases, some information had been lost in the issued notification (e.g. HS codes). Also, it was noted that in the testing phase, submission of notifications through the TBT NSS was more time and resource intensive as compared to the old approach for submitting notifications (i.e. by email, fax or post).

1.9. The representative of Korea supported the introduction of the TBT NSS, which he believed would improve transparency of the notification process.

1.10. The representative of the Secretariat explained that use of the TBT NSS was voluntary, and would remain so even after the official launch. In other words, Members would continue to be able to submit notifications through the old approach (e.g. by email). For new users, Members were invited to contact the WTO Secretariat for instructions.[6] However, he reminded Members that the system remained in a state of live testing, and, therefore, additional time and resources could be needed to submit notifications through the TBT NSS. Once the TBT NSS was officially launched, it would be less time and resource intensive than the old approach for submitting notifications. On the issue of product codes (the question raised by South Africa) the system could assist Members in identifying product codes through integration of the searchable list of the HS and ICS codes into Box 4 of the online notification form.

1.1 European Union: A journey to the TBT NSS

1.11. The representative of the European Union[7] presented his delegation's experience with the TBT NSS.[8] He first stated that the TBT NSS was intuitive to use and had accelerated the processing of notifications by the Secretariat. His delegation had already submitted over ten notifications online. However, submitting notifications through the TBT NSS in the current testing phase was time consuming, due to the need to follow up on notifications and double check for errors. He stressed the need for improvements before the official launch of the system, namely, the removal of all bugs, the publication of a help manual, and an email alert system. In terms of future developments, his delegation sought ways to further automatize submission of notifications to the WTO, and suggested a solution whereby Members could submit a PDF form directly to the TBT NSS. Finally, he encouraged other Members to begin using the TBT NSS, and take part in the live testing phase.

1.2 United States: Using the TBT NSS

1.12. The representative of the United States[9] shared the experiences of her delegation with the TBT NSS. She said that while the United States had submitted seven notifications without incident through the TBT NSS, three notifications had encountered issues and delays in submission, and another two were eventually submitted using the old approach to avoid delays. She said that it currently took longer to use this system than to submit notifications via the old approach, and that in order for the TBT NSS to become a long-term viable option for submitting notifications, additional improvements were necessary. Nevertheless, she appreciated the collaboration with the WTO Secretariat and noted that feedback and the concerns of the United States – as well as other Members – were being taken into account.

1.3 Canada: Reflections on the proposed TBT NSS

1.13. The representative of Canada[10] welcomed the introduction of new technologies such as the TBT NSS, which helped to increase efficiencies, streamline processes and strengthen ties between Members. However, she believed that there was scope for further improvements to the usability as well as the efficiency of the TBT NSS, in order to ensure widest possible uptake across the WTO Membership. In particular, she highlighted the need for: more intuitive navigation and layout (e.g. larger boxes and more prominent buttons), making the TBT NSS faster and less burdensome to use, and new ways of storing information in the system (e.g. the implementation of a template function, and allowing Members to assign an internal identification number to notifications under preparation in the TBT NSS).

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[6] Please contact Ms Una Flanagan, una.flanagan@wto.org.

[7] Mr Cyril Hanquez, Application Architect, DG Enterprise and Industry.

[8] Presentations can be downloaded at: http://www.wto.org/english/tratop_e/tbt_e/special_meeting_june13_e.zip.

[9] Ms MaryAnn Hogan, USA WTO TBT Enquiry Point, National Center for Standards and Certification Information (NCSCI).

[10] Ms Andrea Spencer, Manager Information and Research Services, Standards Council of Canada.

1.4 Discussion

1.14. The representative of South Africa asked how long it took to complete a notification through the TBT NSS, in light of the fact that many developing countries struggled with inconsistent and slow internet connections.

1.15. The representative of the European Union explained that submitting a notification online through the TBT NSS was just like using a regular electronic form, and that anybody with experience using these types of forms should not face any particular challenges. For instance, the EU team was able to prepare their first notification on the TBT NSS in less than two minutes. Rather, he stressed the impact of the TBT NSS on Members' internal workflows for preparing notifications. He noted that the TBT NSS was designed with two accounts per Member, which enabled officials of Ministries to log on to the system and prepare a notification, before final validation and submission by the notification authority (through the TBT NSS).

1.16. The representative of the United States noted that the TBT NSS allowed Members to easily save a notification in progress. Therefore, if a Member were to lose internet connection, so long as the notification was being saved periodically, they could simply log back into the TBT NSS later and continue to edit the notification. She suggested that Members take this precaution as a way to insure against losing work.

1.17. The Chairman concluded the session by encouraging other Members to participate in the live testing phase of the TBT NSS. He understood that the Secretariat would continue to work on developing the TBT NSS, and the Committee would look forward to further updates on its status in the near future.

2 GOOD PRACTICES IN NOTIFICATION: USE OF NOTIFICATION FORMATS[11]

2.1. In the Fifth Triennial Review[12], the Committee recommended establishing common procedures for notification formats. This recommendation was recalled in the Sixth Triennial Review[13], in which additionally the Committee agreed to exchange experiences on Members' use of notification formats.

2.1 European Union: EU proposal for a coherent use of notification formats

2.2. The representative of the European Union[14] presented on EU's proposal for a coherent use of notification formats.[15] She underlined that the EU had in its submission under the Sixth Triennial Review[16], pointed out several difficulties associated with Members' notification practices. She said that it was particularly problematic when Members notified modifications to an already adopted text as an addendum. Since an addendum also served to communicate other kinds of information, notifying modifications as addenda could result in other Members failing to identify important new measures, and thus not being able to comment on the measure. She noted that the EU notified amendments to already adopted measures as new notifications with new periods for Members to comment on the relevant measures. The EU considered that the following information should be notified using addenda: amendments made to a draft measure during the legislative process, the final adopted text and other non-compulsory but useful information related to the status of the original notification.

2.3. She stated that the EU used revisions to notify replacements of previously notified measures that had not yet been adopted. Revisions typically included cases where substantial re-drafting of the previously notified draft measure had taken place. She underlined that a new comment period was always given to Members when a revision was notified. The representative further explained that the EU used corrigenda when obvious clerical errors had occurred in original notifications. She underlined that the EU's practices in notification were consistent with the recommendations issued

[11] G/TBT/32, para. 15.
[12] G/TBT/26, para. 43.
[13] G/TBT/32, para. 15.
[14] Mrs. Jana Krestynova, European Commission, DG Enterprise and Industry, Unit C.3.
[15] Circulated as JOB/TBT/48.
[16] G/TBT/W/54, paras. 33-38.

by the SPS Committee[17] and that these could constitute a good basis for work in the TBT Committee. Clear guidance from the TBT Committee on the use of notification formats was needed.

2.2 South Africa: Use of new notification formats

2.4. The representative of South Africa[18] presented on her delegation's experience with the use of notification formats. She explained that the South African Bureau of Standards managed and ran the national Enquiry Point and was responsible for the decisions taken by the WTO TBT Committee. She said that South Africa introduced a general template in 2012 for notifying any amendments or corrigenda. She underlined that one of the biggest challenges that South Africa had met in notifying measures was indicating the rationale for measures. Although Article 2.2 of the TBT Agreement had provided some guidance, she said that South Africa would appreciate if a guidance list could be produced by the WTO Secretariat. Another challenge for South Africa when notifying a measure had been the indication of the correct HS-codes and the usage of hyperlinks. She said that HS-codes were sometimes not indicated by other Members and instead only ICS-codes were used. Hyperlinks would often open up in foreign languages and it was difficult to navigate to the original page and find appropriate translations. She concluded by highlighting that South Africa strived to make their national Enquiry Point and their notifications as user-friendly as possible.

2.3 Discussion

2.5. The representative of the Russian Federation asked how the EU notified errors that were more substantial than clerical errors. He asked whether these would be notified as revisions or corrigenda.

2.6. The representative of the European Union replied that corrigenda would not be used in such cases. She said that such errors could either be notified as revisions or addenda. She explained that revisions were used for substantial changes where main provisions had changed and when the original notification could not be considered to be the same. A new comment period was therefore necessary in such cases. In the EU's opinion, addenda were rather used to notify minor changes which did not necessitate a new comment period for Members.

2.7. The representative of the United States asked the representative of the European Union to clarify the EU's practices when notifying new measures. Did the EU notify amendments to adopted measures as new notifications?

2.8. The representative of the European Union replied that the EU notified amendments as new notifications if these included technical regulations or conformity assessment procedures that fell under the TBT Agreement. The EU regarded these amendments as new pieces of legislations, thus deserving a new comment period. She also said that the EU's approach in this matter was consistent with the recommendations of the SPS Committee.

2.9. The representative of the United States noted that the US and the EU had diverging approaches regarding this matter and suggested this could be tied to the institutions and procedures used to develop the relevant measures. She noted that an addendum could be used effectively to track the progression of a measure, but also agreed with the EU that more consistency across the use of notification formats would be useful.

3 FUNCTIONING OF ENQUIRY POINTS[19]

3.1. In the Sixth Triennial Review, the Committee reiterated the importance of well-functioning enquiry points to the implementation of the TBT Agreement. In this regard, the Committee recommended that Members share experiences on challenges faced by enquiry points in responding to comments and requests, with a view to improving their functioning; and, agreed to discuss the functioning of enquiry points, including with respect to building support among interested stakeholders in the private sector for the services of the enquiry points.

[17] These recommendations are outlined in document G/SPS/7/Rev.3, paras. 35-42.
[18] Mrs. Ronel Greyvenstein, WTO/TBT Enquiry Officer at the South African Bureau of Standards.
[19] G/TBT/32, paragraph 16.

3.1 Information Services Provided by the Brazilian WTO/TBT Enquiry Point to SMEs

3.2. The representative of Brazil[20] indicated that the National Institute of Metrology, Quality and Technology (INMETRO)[21] acted as the Brazilian TBT Enquiry Point. He said that INMETRO was under the responsibility of the International Affairs coordination within the Brazilian Ministry of Development, Industry and Foreign Trade. The representative explained that besides functioning as Brazil's Enquiry Point, INMETRO provided Brazilian Small and Medium sized Enterprises (SMEs) with information on matters related to the TBT Agreement. INMETRO also assisted the Brazilian Ministry of Foreign Affairs on TBT matters in relevant negotiations, managed the export alert system and provided training activities to interested parties. The representative highlighted that INMETRO produced competitiveness studies and technical documents in an attempt to enhance exporter awareness of technical barriers to trade. The representative finally underlined that INMETRO had hosted the First Meeting of the Enquiry Points of Americas in order to strengthen the working relationships amongst TBT Enquiry Points.

3.3. The representative of the United States asked the Brazilian representative to elaborate on the level of engagement of Brazilian SMEs in terms of requesting information or providing comments to INMETRO.

3.4. The representative of Brazil replied that unfortunately to date very few comments had been communicated to INMETRO. Raising awareness amongst SMEs remained a priority for Brazil's Enquiry Point.

3.2 Adding Value to the National Economy: USA WTO TBT Enquiry Point

3.5. The representative of the United States[22] explained that the US TBT Enquiry Point was responsible for identifying and notifying proposed measures at federal and state level and to provide associated texts of standards, technical regulations and conformity assessment procedures to the WTO Secretariat. Its responsibilities also included distributing US TBT notifications and other Members' notifications to interested parties via the on-line registration service "Notify US"[23]. She explained that many different stakeholders used "Notify US", and that the business sector represented the majority of its customers. She underlined that companies and WTO Member economies can benefit greatly from TBT Enquiry Points, for example, by directly lowering costs of trade, reducing the information asymmetries, and increasing exports and access to new markets. She finally said that the cooperation and exchange of experiences with other TBT Enquiry Points was very important and that the US Enquiry Point has participated in several events in this respect.

3.3 Experience and Operation of the Japan TBT Enquiry Point

3.6. The representative of Japan[24] explained that the work of the Japanese TBT Enquiry Point was divided between the International Trade Division in the Ministry of Foreign Affairs and the Business Service Department of Japan's External Trade Organization (JETRO), depending upon the nature of the TBT enquiry or notification. He said that the Japanese TBT Enquiry point was small, yet effective and active through extensive cooperation with relevant Ministries and the Japanese Mission in Geneva. The main responsibilities of the Japanese Enquiry Point were to respond to enquiries from other WTO Members, submit notifications to the WTO Secretariat, comment on notifications made by other Members and to provide advice on TBT matters to relevant stakeholders. He underlined that some of the challenges were to maintain an effective and active TBT Enquiry Point with limited resources, improve its internal coordination, as well as raise awareness of TBT matters and about the Enquiry Point.

3.7. The representative of Norway asked how Japan dealt with incoming notifications with such limited resources and what system Japan used to distribute notifications to relevant authorities.

[20] Mr. Rogerio Corrêa, Head of the Division of overcoming Technical Barriers to Trade – INMETRO, Brazilian WTO/TBT Enquiry point.
[21] www.inmetro.gov.br.
[22] Ms. MaryAnn Hogan, United States WTO Enquiry Point.
[23] www.nist.gov/notifyus.
[24] Dr. Daisuke Tanaka, Deputy Director, International Trade Division, Economic Affairs Bureau, Ministry of Foreign Affairs, Japan.

Given that Japan had multiple Enquiry Points, the representative of Korea asked if certain priority enquiries were handled by one Enquiry Point, or if all enquiries were gathered together in one single place. The representative of Zambia asked whether the Ministry of Foreign Affairs was responsible for notifying the WTO Secretariat of new measures, and the representative of Senegal asked Japan to clarify if there was one single national authority that was responsible for TBT notifications. The representative of Cuba asked for clarification regarding in which cases the Japanese Enquiry Point would operate via email. The representative of the United States asked how Japan liaised with regulatory agencies to ensure notification of a proposed regulation.

3.8. The representative of Japan replied to Norway that Japan's TBT Enquiry Point did not distribute incoming notifications to the relevant Ministries. He clarified that the WTO had a mailing list system that informed each Ministry (if they were users of the mailing list system) of incoming notifications from every Member country. Regarding Korea's query, the representative replied that Japan had two enquiry points that have the same status and position and that neither had priority over the other. The representative answered to Zambia and Senegal that a notification to the WTO was firstly prepared in the relevant Ministry that had proposed the measure but that the Ministry of Foreign Affairs and the TBT Enquiry Point finalised and sent the notification to the WTO Secretariat. The representative replied to Cuba that when it was important to respond to enquiries quickly, emails were used. When it was important to get in touch directly with relevant Ministries of another Member country, diplomatic channels were used. Regarding the question from the United States, the representative replied that the Japanese TBT Enquiry Point adapted its methods of liaising depending on the TBT matter in question, and that it frequently contacted officials of relevant Ministries directly.

3.4 The functioning of China's TBT Enquiry Point

3.9. The representative of China[25] clarified that the Enquiry Point was situated within the General Administration of Quality, Supervision, Inspection and Quarantine (AQSIQ). He explained that the Enquiry Point was responsible for preparing, checking and submitting China's TBT notifications. The Enquiry Point's also provided information on the TBT Agreement to stakeholders, provided training, responded to reasonable enquiries of other Members, received comments on China's notified measures and transferred these comments to the relevant government bodies. An additional important task of the Enquiry Point was to translate other WTO Members' TBT notifications into Chinese, and that much effort was put into preparing translations within three days. Many of China's SMEs faced serious language obstacles when complying with other Members' measures and the Enquiry Point thus provided translations online for interested stakeholders.[26]

3.10. The representative of the United States asked if China translated the notifications as well as the relevant full texts, and how the Chinese Enquiry Point determined which notifications to translate. The representative also asked if the AQSIQ provided guidance to Chinese agencies on what constituted TBT/SPS measures. Lastly, the representative asked about the number of comments received from Chinese enterprises regarding other WTO Members' notifications. The representative of Trinidad and Tobago enquired as to the languages of translations provided by the Chinese Enquiry Point. The representative of Cote d'Ivoire asked if the Chinese Enquiry Point provided any assistance to SMEs to ensure compliance with the requirements of other Members' markets. The representative of Viet Nam asked if the Chinese Enquiry Point translated all relevant texts upon the request of Chinese enterprises. The representative of Brazil asked if the full texts of translated and notified technical regulations and conformity assessment procedures could be made available on-line for all WTO Members. The representative also suggested that China make full texts of their own regulations available online in file formats which were easier to translate.

3.11. The representative of China replied, first, that the Chinese Enquiry Point did not translate the full texts and other attachments to notifications into Chinese. Rather, it was the TBT notifications themselves which were translated into Chinese, and distributed to relevant ministries or trade unions. Second, he noted that guides did exist regarding how relevant Ministries must notify measures in order to comply with the TBT Agreement. Third, he stated that information in the form of brochures had been distributed to raise awareness of other Members' measures and that the Enquiry Point was in contact with leading enterprises and trade unions that provided comments on other Members' measures. Fourth, he said that the Enquiry Point had many

[25] Professor Lizhou Wang, Deputy Director General of China's TBT Enquiry Point.
[26] http://www.tbt-sps.gov.cn/Pages/home.aspx.

branches throughout China with experts in different fields who were able to provide assistance regarding compliance with TBT requirements. He noted that the Enquiry Point translated notifications and comments with the help of technical experts. Lastly, he explained that it remained beyond China's responsibility to provide full texts in a WTO working language, but submitted that Members may request extracts of the text translated into English from the responsible agency indicated in the notification. He noted that Brazil's suggestion of an appropriate file-format would be communicated to the responsible regulatory bodies.

3.5 EU TBT Notification and Enquiry Point: Better communication with stakeholders and recent technical assistance activities

3.12. The representative of the European Union[27] showed a promotional awareness raising video on the work of the EU TBT Enquiry Point and the benefits of private sector participation in the TBT notification procedure. She then recalled that the EU TBT Notification and Enquiry Point was located within the European Commission's DG Enterprise and Industry, and was responsible for the TBT notification procedure information provision in respect of technical regulations and conformity assessment procedures. Standards, in this respect, were handled by European standardisation bodies, and all EU Member States operated their own national TBT Enquiry Point. Her delegation believed that active communication with relevant stakeholders was crucial to ensure effective implementation of TBT obligations, and noted that the 2012 Commission report on the functioning of the TBT Agreement notification procedure had concluded that further awareness-raising could trigger enhanced comments from EU economic operators. She informed the Committee that the EU TBT website[28] could be accessed publically, and included an alert system for economic operators and other parties. Finally she reported that the EU TBT Enquiry Point had hosted study visits from two WTO Members, Ukraine and Malaysia, which had enabled experience sharing on the functioning of TBT Enquiry Points.

3.13. The representative of Mexico asked whether each EU Member State could notify independently, or whether the EU TBT Enquiry Point carried out all notifications. The representative of South Africa asked Brazil, the United States and the EU how awareness was raised regarding their national Enquiry Points, especially amongst SMEs. The representative of Cote d'Ivoire asked the presenters whether the activities of the different Enquiry Points had a budget designated for them. The representative also asked whether subscriptions to Enquiry Points were subject to a charge.

3.14. The representative of the European Union replied to Mexico that there were two ways a TBT measure could be notified: either by the European Commission or by the individual Member State. She however underlined that EU legislation covered the majority of technical regulations and conformity assessment procedures in question, and that these would be notified by the Commission. Member States were responsible for notifying their own legislation. She clarified that when Member States received comments from other WTO Members, it was the Commission that replied. Regarding South Africa's question, awareness raising took the form of the video presented at the Meeting, maintaining regular contact with professional associations, and by working on improving the user-friendliness of the EU TBT database. The representative replied to Cote D'Ivoire that there was no budget allocated for the TBT Enquiry Point's activities but that it was a public service and that subscription to the database was free of charge.

3.15. The representative of the United States replied to South Africa that in the past, the US had drawn up marketing plans which detailed the industries to target and how to target them. However, this approach had proven time consuming and difficult. The US had therefore instead used promotional materials and brochures and distributed these to international visitors and industry. She explained that the US also had a news-feed which regulatory provided around 4000 subscribers with brief details on new notifications. She noted that the US Enquiry Point also took part in export training events organized by the US commercial service and would sometimes present through webinars on such occasions. Finally, she highlighted that the Enquiry Point attempted to make contact with individuals in government offices who they knew could reach out to relevant manufacturers and industry sectors.

[27] Mrs. Jana Krestynova, European Commission, DG Enterprise and Industry, Unit C.3.
[28] http://ec.europa.eu/enterprise/tbt.

3.6 WTO/TBT Enquiry Point – Malaysia's Approach

3.16. The representative of Malaysia[29] stated that the Malaysian Enquiry Point, SIRIM, was handled by the Standards Research and Management Centre, SIRIM Berhad, under the Malaysian Ministry of Finance. Its primary responsibilities included the handling notifications, providing technical advice to the Malaysian National Mirror Committee for TBT (NMC TBT), and arranging programmes to enhance awareness amongst regulatory agencies on TBT notification obligations. She also said that the Enquiry Point produced a WTO/TBT newsletter[30], informing up to 400 different stakeholders on TBT matters. The Malaysian Enquiry Point moreover provided an export alert system to stakeholders, which sent email warnings whenever foreign regulations in relevant sectors were subject to change.

3.17. The representative of Uganda underlined that Uganda had faced challenges in fulfilling notification requirements as regulators sometimes did not inform the Enquiry Point of the enactment of new regulations. He asked the representative of Malaysia if Malaysia had a mechanism in place to inform its Enquiry Point of new regulations that must be notified to the WTO Secretariat. The representative of the United States also asked how Malaysia ensured that that the notification authority was aware of draft regulations. She also asked if Malaysia had any legislation or institutional framework in place for the development of regulations and for enabling public comment.

3.18. The representative of Malaysia replied that Malaysia had indeed missed out on certain regulations that should have been notified and that it was up to relevant regulatory bodies to inform the Enquiry Point. The representative explained that there was no mechanism in place to ensure notification but that it was something Malaysia and the NMC TBT was working on. The representative underlined that as soon as a regulatory body had produced a draft regulation, a public comment session, albeit in-house, was held where relevant stakeholders could participate. The representative nonetheless explained that it remained a challenge to inform all relevant stakeholders of such occasions.

[29] Mrs. Anuja Balachabdran, WTO/TBT Enquiry Point, SIRIM Berhad.
[30] Available on www.sirim.my/web/srmc/wto/tbt-notification-newsletter.