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Committee on Technical Barriers to Trade

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Chairperson: Ms Denise Pereira (Singapore)

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

I. ADOPTION OF THE AGENDA

1. The Committee adopted the agenda contained in WTO/AIR/3821.

II. IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

A. STATEMENTS FROM MEMBERS UNDER ARTICLE 15.2

2. The <u>Chairperson</u> said that the latest list of statements submitted under Article 15.2 of the TBT Agreement is contained in document G/TBT/GEN/1/Rev.10, issued on 22 February 2011. She noted that, since the last meeting, Zambia (G/TBT/2/Add.106) and Mozambique (G/TBT/2/Add.107) had submitted their statements under Article 15.2 and Georgia (G/TBT/2/Add.81/Rev.1) and Turkey (G/TBT/2/Add.33/Rev.1) had submitted revisions to their original statements. In total, since 1995, 124 Members had submitted at least one Statement on Implementation under Article 15.2. She recalled that this information was available, and regularly updated, on the TBT page of the WTO website and in the TBT Information Management System (<u>http://tbtims</u>). The latest list of enquiry point contact is contained in document G/TBT/ENQ/38/Rev.1, issued on 8 July 2011.

B. SPECIFIC TRADE CONCERNS

1. Specific Trade Concerns

(a) New Concerns

(i) Mexico - Draft Decree Amending Provisions for Drinks with Caffeine

3. The representative of the <u>European Union</u> expressed concerns regarding draft amendments to the Mexican General Health Law reinforcing the label provisions (health warnings) applicable to drinks with added caffeine. These warnings included that products should not be consumed in excess of 500 ml per day, that they should not be mixed with alcoholic drinks, that they are not suitable for persons under the age of 18, and that they may lead to intoxication, insomnia and cardiovascular and neurologic disorders. The EU Enquiry point, she said, had requested in October 2011 that this draft measure be notified to the WTO.

4. The representative of the <u>United States</u> said that his delegation shared Mexico's worries that energy drinks combined with alcohol could be harmful to young people. However, it also raised concerns that this proposal, if adopted, was going to ban or restrict the sale of energy drinks in the Mexican market, whether or not they were combined with alcohol. He urged Mexico not to proceed with this proposal until US and Mexican officials had a detailed technical discussion on the matter. He hoped that Mexico would discuss the US questions submitted in this regard.

5. The representative of <u>Mexico</u> clarified that this initiative was being discussed by the Mexican Congress and it was at an early stage. For this reason Mexico still had not notified this amendment to the WTO. On 27 September 2010, the Mexican Economy Ministry received a communication from the Mexican Embassy in Austria containing a number of comments concerning this draft amendment. These questions had already been transmitted to the competent authorities. Mexico continued to work on a set of technical regulations relating to this issue, namely the Official Mexican Standard PROY-NOM-218-SSA1-2009 *Products and services.* Non-alcoholic flavoured beverages, their frozen versions, concentrates to prepare these products and beverages with added caffeine. He clarified that this measure was published on 22 December 2010 and it was duly notified to the WTO for comments. The Mexican Health Ministry was still in the process of analysing the comments they received during the period of public consultations and responses to those comments would be duly published in the Mexican Official Gazette prior to the publication of the definitive measure.

(ii) Peru - Draft Supreme Decree Approving the Regulations Governing the Labelling of Genetically Modified Foods

6. The representative of <u>Mexico</u> voiced his delegation's concerns on this measure. The Mexican Government submitted a number of comments on this draft decree on 4 September 2011, including that this measure could potentially lead to discrimination. His delegation considered that this measure, in particular the requirement to label products containing genetically modified organisms (GMOs), lacked sufficient scientific basis. GMOs had been rigorously evaluated and authorized for marketing and consumption by more than 59 countries' authorities, including Mexico. Conventional products and GMOs were, in principle, equivalent in nature because there was no difference in their composition in terms of proteins, nutrition or toxicological or allergenic properties. In Mexico's view, labelling may only be justified where there were substantial significant differences in the nutritional makeup of a food, or in the properties that they contained, as opposed to conventional products.

7. Moreover, modern agricultural biotechnology was a process and a production method which did not bear any impact on the final characteristics of the products. Thus, in Mexico's view, an obligation to label products which were substantially equivalent to conventional products would constitute unjustified discrimination. The representative of Mexico called upon Peru, in line with the provisions of Article 2.5 of the TBT Agreement, to explain the technical and scientific justification of this measure in light of Article of 2.2 of the Agreement. He also requested, wherever possible, that Peru reply to these comments, in conformity with Article 2.9.4 of the TBT Agreement, to establish a dialogue between Peru, Mexico, and other interested parties, on these issues.

8. The representative of <u>Brazil</u> echoed Mexico's concerns. Comments had been submitted and they looked forward to receiving Peru's responses.

9. The representative of <u>Canada</u> said that his delegation appreciated information provided by Peru so far, in particular in relation to how the measure was to be applied, provisions on testing and how imports were going to be monitored. He requested confirmation on the status of the draft regulation, and whether their comments would be taken into account.

10. The representative of <u>Colombia</u> indicated that his Government supported labelling to provide information to the consumer where this information was verified, based on technical facts and did not induce error. However, in his view there was no evidence that there was any difference in properties between genetically modified foods and conventional food products. Thus, a differentiated label for food products containing GMOs would constitute a technical barrier to trade under the TBT Agreement offering no benefits in terms of additional information to the consumer.

11. The representative of <u>Chile</u> noted that this proposal did not set forth a threshold to determine whether a product contained genetically modified substances. Chile wished to learn whether there was a list of Peruvian laboratories accredited by Peru's National Institute for the Defence of Competition and the Protection of Intellectual Property (INDECOPI) to carry out the tests mentioned in the draft and whether foreign laboratories could be accredited or recognized for the same purpose. Also, Chile did not consider that the 180-day adaptation period for the phasing in of the new requirements established by the measure to be sufficiently long.

12. The representative of <u>Argentina</u> said that his delegation also considered that this draft measure discriminated against products derived from modern genetically modified food. This measure was not proportional to the risks involved and would only apply to certain types of products such as colza, soya, corn, cotton, etc. without providing an explanation about the exclusion of other products also containing transgenic substances from the application of this measure. Argentina was concerned that this measure would be followed by other initiatives regulating matters beyond labelling requirements which could have serious negative effects for the development and

commercialization of certain genetically modified foods. According to the Food and Agriculture Organization (FAO), world food production need to increase by 50% to meet global food demands and these new technologies would therefore be necessary.

13. The representative of <u>Peru</u> clarified that Peru was presently evaluating and reviewing the draft regulations on the basis of the comments received. In line with its international obligations, Peru would publish comments in due time, before the final version of the measure was adopted.

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

14. The representative of <u>China</u>, while thanking the EU for formally replying to China's comments, said there were still two points that had not yet been solved. First, China suggested the adoption of different evaluation methods and energy efficiency requirements for air conditioners with inverters and air conditioners without inverters. His delegation considered that this was a reasonable distinction since there were substantial differences between the operation principles and characteristics of these two types of air conditioners. Second, he invited the European Union to provide the scientific justification for the noise limits established by this draft regulation according to which noise produced by air conditioners with a rated capacity of equal to or less than 12KW would harm humans and the environment. If there was no scientific basis for this requirement, it should be removed from the draft regulation.

15. The representative of the <u>European Union</u> explained that the Draft Commission Regulation implemented the ecodesign Directive 2009/125/EC and had, as the latter, the objective of environmental protection and fighting climate change through reduced energy consumption and emissions. She informed that the Regulation was not yet adopted, but that adoption was imminent. As soon as the adopted text was published, it would be sent as an addendum to the WTO notification.

16. The draft measure established eco-design requirements for certain air conditioners and comfort fans without distinguishing between those with or without inverters. Inverters allowed the appliance to receive information on the varying air temperature outside/inside of a building in order to adjust its performance to these temperatures. Thus, inverters allowed for savings in energy consumption emissions, but air conditioners with and without inverters had exactly the same function. Since the objective of the legislation was the reduction of energy consumption in the fight against climate change, the requirements for power consumption could not be set on the basis of a given technology or component used in an appliance. In her delegation's view, China was asking for less stringent requirements for a generally less efficient technology. The EU believed that such differentiation would jeopardize the fulfilment of the legislation's objective.

17. Moreover, the EU's regulations did not prohibit the marketing of air-conditioners without inverters; they could be sold in the European Union if the efficiency requirements were met. Regarding the proposed noise limits in the draft measure, noise was one of the environmental aspects that had to be assessed in the framework of eco-design requirements and these limits were based on the stakeholder consultation and on limits identified by the World Health Organization. Further information on this could be found in the impact assessment that would be available once the measure was adopted. The respective website on which the impact assessment would become available had already been sent to China.

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

The representative of Argentina expressed his Government's concerns about the European 18. Court of Justice 7 September 2011 ruling that pollen was a natural component and an ingredient of honey. His delegation believed that this decision contradicted the standard for honey established by Codex Alimentarius 81/2001. Thus, this particular court ruling gave rise to legal uncertainty causing honey importers in the EU to interrupt virtually all purchases of honey produced in Argentina. This had an impact on the traditional trade flows in this sector, causing major social consequences, in particular, for small-scale producers, family businesses and regional economies in Argentina. Argentina had more than 30,000 beekeepers with a longstanding tradition of producing honey for over 50 years and exporting to more than 40 different countries. The EU market was the main destination for the export of Argentinian honey, accounting for 30 per cent of its total production. For this reason, Argentina called on the EU to promptly take all necessary measures to remove any legal uncertainties arising from this ruling and to eliminate the impact that it had on the import of honey into the EU from other Members. In addition, he requested the EU to comment on the opinion of the IPSAS regarding the innocuous nature of honey containing pollen and to ensure that implementation of this ruling did not, in any way, prevent exports of Argentinian honey into the EU.

19. The representatives of <u>Brazil</u>, <u>El Salvador</u>, <u>Mexico</u> and <u>Uruguay</u>, shared Argentina's concerns regarding the decision of the European Court of Justice and respectfully invited the European Union to remove what they perceived as legal uncertainty arising from this court ruling as well as the negative trade impacts arising for imports of honey into the European Union. The representative of <u>Canada</u> echoed the concerns regarding uncertainty and potential for trade disruption. The representative of <u>Mexico</u> also mentioned that the same concerns had been voiced in a recent meeting of the WTO SPS Committee. This ruling affected developing-country Members in particular, and failing to grant special and differential treatment in this case would negate the meaning of the relevant provisions in the TBT Agreement.

20. The representative of the <u>European Union</u> explained that, in 2008, a German beekeeper challenged the regulations concerning pollen that contained traces of genetically modified organisms (GMOs) after he detected GM maize MONSANTO 810 pollen in his honey. The contamination originated from GM plants grown for research purposes near the beekeeper's hives. The "GM honey" case was brought to the European Court of Justice. In its 6 September 2011 ruling, the Court said that GM pollen in honey fell under the scope of the relevant EU legislation on GM food and feed (Regulation 1829/2003). Therefore, the marketing in the EU's territory of honey with traces of GM pollen became subject to an authorization. Moreover, according to this ruling, honey containing authorized GM pollen had to be labelled according to the provisions of Regulation 1829/2003.

21. This issue had not arisen in the past since pollen was regarded only as a constituent in accordance with Directive 2001/110/EC relating to honey thus falling out of the scope of the corresponding labelling directive and honey containing GM pollen was considered to be out of the scope of Regulation 1829/2003. She acknowledged that the ruling's effects were numerous and related not only to imports, but to honey produced within the European Union as well. The development of harmonized methods for the sampling and detection of GM pollen had yet to be assessed in order to help EU Member States apply the Court's ruling, in terms of controls and labelling at a national level, of both imports and of national production. Regarding imports into the EU, since some GMOs were authorized in third countries but not in the EU, imported honey products from these countries containing GMOs that were not authorized for use in pollen in the EU, would not be allowed in the EU market.

22. The specific case examined by the European Court of Justice, involved MON810, a GM crop that had been authorized in the EU for more than 10 years. However, it was authorized for food uses

which did not include pollen, on the basis of an assessment prepared by the European Food Safety Authority (EFSA) in 2009. In addition to these food uses, MON810 was also authorized for feed uses and for cultivation. EFSA prepared an opinion on the safety of MON810 pollen in honey, delivered on 20 October 2011, concluding that MON810 in pollen was as safe as non-GM maize pollen. In the meantime, the company in question, Monsanto, intended to submit an application to cover MON810 pollen in or as food, according to the authorization procedure provided by Regulation 1829/2003.

23. Finally, she added that the EU was actively reflecting on the best possible approach to ensure the proper implementation of the ruling without causing unnecessary disruptions to the supply of honey to EU consumers, be it from domestic or imported production. To this end, the European Commission held several meetings with third countries concerned about this issue, including Argentina, as well as a stakeholder meeting on 29 September 2011. The EU's intended to continue discussing this issue bilaterally over the following weeks.

(v) United States - ENERGYSTAR 6.0 Draft 2 Program Requirements for Displays-Draft Partner Commitments

24. The representative of <u>Korea</u> expressed concerns regarding the scope and range of this draft measure. Korea was particularly concerned about the feasibility and measurement of the reduction rates of F-Green House Gases, (F-GHGs or F-gas) established by this measure. The evaluation of carbon emissions should be calculated not only on the basis of the manufacturing process but also taking into account the raw-material-input and waste processes. Her delegation was worried that the adoption of the point-of-use abatement system could prevent the adoption of another, more efficient abatement system—for example, the centralized abatement system that Korean LCD panel-makers have developed. The centralized abatement system prevented F gas emissions at all stages of the process, beginning even before the manufacturing stage with the substitution of raw materials that will not emit F gases. Moreover, the CAS was also more cost effective than the POU system.

25. Her delegation believed that allowing alternative and more efficient abatement systems was very helpful for the LCD industry and could contribute to the fulfilment of the US Environmental Protection Agency's (EPA) objectives. In order to provide more detailed information, the Korean LCD industry was planning to submit a report to the EPA regarding the CAS as soon as possible. In addition, Korean industry believed that the gradual target rate and the date for the reduction of F-GHGs were highly unfeasible. In their view, the 90 per cent reduction rate was impossible to achieve by 30 September 2012, because it would require the full operation of abatement equipment 365 days a year without defects or deterioration of its main components. It would take at least two years to install, test and adjust new equipment and verify its efficiency in one factory alone. Therefore, she requested that the EPA phase in the new requirements over a reasonable period of time to allow the industry to adapt, with the aim of achieving a 30 per cent reduction-rate by 2015, a 50 per cent rate by 2018 and a 60 per cent rate by 2020.

26. Lastly, her delegation believed that Nitrogen Trifluoride (NF3) should be excluded from the EPA's F-GHGs list because neither the 1997 Kyoto Protocol nor the Third Conference of the Parties (COP) of the United Nations has identified NF3 as one of the greenhouse gases that must be regulated worldwide. She noted that the Kyoto protocol listed only HFCs, PFCs and SF6 as F-gases as subject to regulate and COP reports did not cover NF3 as GHGs. Moreover, according to her delegation's own research, no other country other than the US included NF3 as F-GHGs. Considering that emissions of NF3 were extremely lower than those of other F-GHGs, the effort to regulate NF3 emissions was too premature and economically inefficient.

27. The representative of the <u>United States</u> said that it would relay Korea's comments back to capital for review. He observed that the ENERGYSTAR program was voluntary and, therefore, the US was under no obligation to notify many of its specifications to the WTO. Nevertheless, his

delegation would consider making such notifications during the EPA's next draft revision of the ENERGYSTAR requirements which would most likely be posted for comments in late November. He noted that there had been already two earlier comment periods. He also encouraged Korea and other Members to consider notifying to the WTO the voluntary measures they were developing, in those cases where demonstrating compliance with such measures could be an important factor for placing products on their markets. The EPA had been accepting comments through its website during the development of these and other ENERGYSTAR specifications, and his Government was taking them into account. Some of those comments were made by Korean stakeholders. Finally, he took note of Korea's offer to provide the EPA with a new report on the CAS and suggested that this report be transmitted as soon as possible.

(vi) United States - Amendments to Sterility Test Requirements for Biological Products (G/TBT/USA/633)

28. The representative of <u>Korea</u> expressed her delegation's view that the proposed amendments appeared to provide manufacturers of biological products with greater flexibility and to encourage the use of the most appropriate and state-of-art test methods for assuring the safety of biological products. Nevertheless, her Government was interested in learning more about the exact functioning of the proposed measure, and how the US Food and Drug Administration intended to verify sterility assurance under these amendments. Korea understood that cell and gene therapy products were included in this amendment. She asked the US to provide background information concerning this addition. Lastly, she requested the US to update the Committee on the current situation and future prospects of this measure.

29. The representative of the <u>United States</u> said the intention of the amendment to this measure was to provide manufacturers of biological products with greater flexibility and to encourage the use of the most appropriate state of the art test methods for ensuring the safety of such products. This was part of the US' continuing efforts to review retrospectively and, if necessary, update its biologics regulations. According to its own analysis, the net effect of these amendments was going to be the reduction of manufacturers' costs. His delegation was not aware of Korea's interest and concerns regarding the proposed amendments as this issue was never raised during the regular bilateral meetings; that during the 90-day comment-period, neither Korea nor any Korean industry group presented comments and that his delegation was not aware of any Korean company providing licenced biological products to the US market that had been affected by the proposal. Nevertheless, he would send Korea comments to capital for review and further discussion.

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

30. The representative of the <u>United States</u> expressed his Government's support for Argentina's objective of protecting its citizens from exposure to potentially hazardous substances. However, there was concern that Argentina could lack sufficient testing capacity domestically to conduct the testing required by this measure. Moreover, Argentina had indicated that it could only accept test reports from foreign conformity assessment bodies if there was a mutual recognition agreement in place. His delegation was not aware of the existence of any such agreement. Therefore, it appeared that this constituted a *de facto* requirement that the necessary testing had to be done in Argentina. There were only one or two laboratories recognized in Argentina to conduct these tests. Based on the apparent lack of domestic testing capacity coupled with the lack of recognition of foreign laboratories to perform testing activities in the country of production, the US anticipated significant delays and additional market costs and burdens for the industries affected by this measure.

31. His delegation suggested that Argentina recognize laboratories that were accredited by the signatories of the International Laboratory Accreditation Cooperation Mutual Recognition Agreement

(ILAC MRA) with expertise in lead testing as more regulators around the world had already done. The US considered this option as a more trade-facilitative alternative that did not compromise the fulfilment of Argentina's objectives. Finally, it appeared to the US that this resolution applied only to foreign producers. Hence, he requested a clarification from Argentina as to whether domestic producers of graphic products were subject to these, or equivalent requirements.

32. The representative of the European Union recalled that her delegation had exchanged written communications with Argentina and had bilateral discussions on this issue. Nevertheless, her delegation sought more information about the reasons for introducing compulsory certification for the lead content in inks, lacquers, varnishes and printed graphic products. She noted that in the EU lead in paints was prohibited but there was no compulsory certification or testing for those products. Her delegation shared the US concerns on the certification procedures and the recognition of tests. She noted that Article 2 of this resolution mentioned the European standard EN 71-3 as well the international standard ISO 8124-3 as the reference against which graphic products had to be tested and certified. Article 5 indicated that certificates had to be issued by an Argentinean certification body and that certificates had to be based on tests carried out in a "recognised laboratory". The EU asked whether tests carried out for compliance with standard EN 71-3 in the EU in internationally accredited laboratories would to be accepted by the Argentinian certification body for the purposes of issuing the required compliance certificates. If this was not the case, she requested an explanation why the tests had to be conducted locally. She also invited Argentina to clarify the criteria for foreign laboratories to be formally recognised. Since only two Argentinian laboratories had been approved to conduct the respective certification tests, how did Argentina plan to ensure the necessary capacity to handle the potentially very high number of requests. Finally, the resolution seemed to imply that the certification body was to take samples from each imported lot; the EU asked whether all imported lots from the same manufacturer had to be tested.

33. The representative of <u>Argentina</u> said that his delegation had already had an exchange with the US enquiry point on this issue, and had responded to a request for information that led to a joint resolution and the identification of the applicable standards. Thus, a number of concerns regarding this measure had already been dealt with. Further, Argentina's enquiry point had been in contact with the EU's enquiry point and his delegation was not aware of any other attempt to submit comments or to request consultations on this matter. However, he would relay the comments submitted by the US and the EU to the competent authorities in Argentina for a response in due course.

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

34. The representative of the <u>United States</u> recalled that this measure was enacted by China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) on 18 April 2011 and it entered into force on 1 July 2011. He observed that this measure required the disclosure of formulas for imported food additives sold in China. While his delegation supported China's goal of improving food safety and food quality, these objectives could be accomplished without unnecessarily impacting trade.

35. The US had procedural and substantive concerns regarding this measure. Procedurally, this measure was not published in draft form, thereby preventing interested stakeholders from submitting their comments. The measure claimed to have two objectives, namely ensuring food quality (a TBT issue) and food safety (an SPS issue). Nevertheless, the measure was not notified to either the TBT or SPS Committee, despite the fact that the measure appeared to have taken effect less than six weeks after it was announced by China. Thus, China did not grant sufficient adaptation time to importers before the specification entered into force. Substantively, he recalled that the US and China had a productive bilateral discussion on this issue before the Committee meeting. During this discussion, it was confirmed that Article 6 of this measure required suppliers to disclose their formulas on product

labels. Where the product contained at least one additive, labels on these products needed to include a list of each additive in its percentage of the product by weight in descending order. The US was concerned that this requirement would force suppliers to disclose business confidential information (BCI), i.e. the product formulation, against their legitimate commercial interests. His delegation did not believe that regulators needed this kind of information in pursuance of a legitimate objective, and in compliance with the TBT Agreement. Rather, the US worry was that the measure forced suppliers to make public what could be considered BCI.

36. The US was concerned that that the requirement to disclose these formulas on product labels seemed to apply only to imported food additives, as suggested by the fact that this requirement was contained in the food additives import chapter of the measure. If this was not the correct interpretation, he asked if there was a measure requiring Chinese suppliers to disclose their formulas on product labels as well. The US also expressed its interest in learning more about the objective pursued by the measure, i.e. to provide information for supply chain customers or to ensure that the products in question met the relevant regulatory requirements in China. If these were indeed the objectives pursued by the measure, other alternatives could be explored such as empowering customers to request, under confidentiality agreements, information on additives in manufacturing, which was already an accepted practice. In conclusion, the US urged China to suspend the implementation of this specification, to notify the measure to the WTO, and to receive and consider comments from interested stakeholders. His delegation intended to engage in future technical discussions with Chinese authorities on this matter.

37. The representative of the <u>European Union</u> echoed the US concerns. She reiterated the EU's desire for enhanced transparency in China's development, adoption and enforcement of standards and technical regulations in the area of food safety. Moreover, her delegation had been recently informed that on 30 September 2011, the Chinese Ministry of Health published a draft food safety standard on the labelling of food additives. It was the EU's understanding that a one-month comment-period was established and that such period had expired on 30 October 2011. Thus, the EU understood that all food additives, with the exception of flavours, needed to comply with this measure as of March 2011. She asked if China intended to notify this mandatory standard to the WTO, in order to provide Members with an opportunity to submit their comments. Finally, the EU stressed the need for China to provide an adequate period of time between the adoption and the implementation of this measure so as to allow economic operators to adapt.

38. The representative of <u>China</u> reported that on 18 April 2011, the AQSIQ issued a Specification for Import and Export of Food Additives Inspection, Quarantine and Supervision which consolidated several provisions on food additives contained in the Food Safety Law and its implementing regulations, and the Circular on Enhancing the Supervision and Management of Food Additives, issued by nine Chinese Governmental ministries. The objective of this measure was to ensure the quality and safety of imports and exports of food additives and to protect consumer health, which in China's view was consistent with the legitimate objectives recognized by the TBT Agreement. The mandatory disclosure of food additive formulas was not a new requirement; it was already established in Article 42.2 of the Food Safety Law of China, which had been notified to the WTO several years ago. For this reason, China did not consider it necessary to make a new notification concerning this new specification to either the TBT or the SPS Committees. The mandatory disclosure of food additives formulas applied to both imported and domestic products. Thus, there was no infringement of the national treatment principle. He believed that the EU's concerns referred to other measures which he invited the EU to raise under "Other Business" during this meeting.

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

39. The representative of the <u>United States</u> said that his delegation believed that China intended to integrate several draft voluntary standards in the information and communications technology sector that it was in the process of finalizing into certification schemes. This would turn otherwise voluntary standards included a series of six information security voluntary standards released for public comment in July 2011 by the China National Information Security Technical Standards Committee (TC260 WG5). The United States wished to refer to two of these draft standards under this specific trade concern. First, on 20 September 2011, a draft voluntary standard related to information security requirements for office equipment, including printers, was released for a public comment-period of 30 days by a standardization institute under China's Ministry of Industry and Information Technology, China's Electronic Standardization Institute (CESI), in conjunction with TC260 WG5. The US considered this standard to be an office equipment information security standard, designed as an alternative to the IEEE 2600 international, information security standard.

Second, on 20 September 2011, a second draft voluntary standard, related to wireless 40. broadband, was released for public comment for 15 days by another Ministry of Industry and Information Technology (MIIT) sponsored standardization institute, the China Communication Standards Association (CCSA). It was US opinion that this standard appeared to be a local area network standard designed as an alternative to the IEEE 80211 standard (the WiFi standard). Some brief ,bilateral discussions on these two standards had taken place between the US and China. However, the US wished to learn more about the purpose of these standards and the reasons for the apparent differences between them and the existing international standards and other Chinese standards. The United States also hoped that comments submitted by the US industry would be taken into account and reflected in the final drafts. The US also requested more information on the conduct of the respective conformity assessment procedures, and on whether China was planning to maintain these standards as voluntary or turn them into mandatory regulations. The US also requested that China notify these standards and receive comments from the affected industries, if they became requirements for manufactures to obtain type approval, China Compulsory Certification (CCC) mark registration, or other type of approval in order to sell their products in China. Finally, the US also asked if there was a timetable for the finalization of these two draft standards.

41. The representative of <u>China</u> reported that the standard *Information Security Technology-office Devices Security* was voluntary and was still being drafted. China also explained that the drafters were taking into account the relevant international standards, China's particular circumstances, and the experiences of other Members.

42. In relation to the standard of *High Spectrum efficiency and high throughput wireless LAN technical requirements*, China reported that it was still under the approval process of MIIT. In order to solicit opinions from all interested parties, China posted the full text of this draft standard on the official website of MIIT. China intended to take all reasonable comments into consideration. He announced China's disposition to participate in the drafting of the relevant international standard on this subject along with all interested parties.

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

43. The representative of the <u>United States</u> informed the Committee of bilateral discussions with Indonesia, including some on the margins of the Asia-Pacific Economic Cooperation (APEC) toy safety work. The US recalled that a toy safety standard, i.e. the underlying standard, was adopted by Indonesia's Ministry of Industry in May 2010. The US concerns were not directed towards this standard, but towards the draft conformity assessment measure, i.e. the technical guidelines, that related to the toy safety standard. The US understood that the development of the draft conformity assessment measure was at an early stage. However, the US asked if Indonesia would confirm that that it was going to notify this measure to the WTO, once it was completed. The US also asked if, under this measure, producers were going to able to become certified under ISO 9001, and not only under the Indonesian version of this standard. The US also asked about the definition of a "brand" for testing purposes under this draft measure, who would be able to conduct the corresponding sampling, and whether the mark required on the product needed to be placed on the product itself or on the product packaging. The US was also concerned about ensuring equitability in relation to the fees paid by domestic and imported products.

44. He identified the testing issue as his delegation's most important concern regarding this draft measure. Indonesia's National Accreditation Body was a signatory to the ILAC MRA. The US hoped that Indonesia was going to accept test results from laboratories that had been accredited by ILAC MRA signatories, even if they were located outside Indonesia, provided that they were qualified to perform toy testing. Recognition of test results from ILAC accredited laboratories in the toy safety area was already a common international practice and his delegation was concerned that there could be a lack of laboratories in Indonesia accredited to conduct toy testing. The US was also concerned that Indonesia might require, in addition to an accreditation under the ILAC MRA, the execution of a Memorandum of Understanding (MoU) between the governments involved. The US expressed doubts about whether such requirement could add value to the reliability of the accreditation or testing processes, and noted that such requirement could cause trade disruptions. His Government's would continue to hold bilateral technical discussions with Indonesia on this issue.

45. The representative of <u>Indonesia</u> confirmed his Government's intention to develop regulations on toy safety, but that he had no information on any timetable nor indication of a possible date for the conclusion of this draft measure. However, Indonesia's intended to notify the finalized measure. His delegation welcomed the US intention to continue bilateral discussions on this issue.

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

46. The representative of the <u>United States</u> pointed out that the Korean National Tax Service published an official notice under the number 2011-17 on 11 July 2011 requiring both, imported and domestic whiskey bottles to have a radio frequency identification tag or an RFID. The US invited Korea to notify this measure to the WTO and to establish a reasonable period of time for comments by interested parties. Additionally, the US wanted to learn more about the rationale behind the requirement, in particular, why whiskey was specifically targeted, as opposed to other products. The US understood that Korea was implementing this to prevent counterfeiting and to detect illegal (untaxed or black market) transactions which was a legitimate objective. However, the US believed that these goals could be met through other less costly and burdensome methods. He noted the costs associated with installing the RFID readers in the warehouses where the products in question were stored and adding machines or additional labour to apply the tags. He asked if Korea had considered achieving these objectives through other means such as tax stamps, bar codes, or the use of a prototype system before the implementation date. If so, what were the reasons why Korea chose the RFID option over any of these alternatives.

47. The US was aware of the industry's struggles to design a tag that would be able to fit on whiskey bottles of different sizes; in some cases this task had proved to be unfeasible. Moreover, the RFID readers sometimes malfunctioned when the bottle cap contained metallic materials. Therefore, the US requested Korea, if it decided to maintain this measure, to establish a reasonable interval for the implementation of this measure, taking into account the technical difficulties described by the US, so as to provide stakeholders with sufficient time to comply with the measure.

48. The representative of the <u>European Union</u> considered that these requirements contained technical regulations and were thereby subject to the notification obligation contained in Article 2.9.2 of the TBT Agreement. Thus, the EU shared the US interest in knowing whether Korea intended to notify this measure to the TBT Committee for Members' comments. Her delegation had already sent questions to the Korean TBT Enquiry Point on 8 November 2011 and it looked forward to receiving Korea's response.

The representative of Korea explained that the purpose of the requirement was to to use 49. mobile phone technology to verify the brand authenticity of each bottle of whiskey they purchased, and also to be sure how much tax importers and whiskey dealers are paying. This requirement was in force since 1 November 2011 for domestic whiskies in six Korean provinces, and would apply to all whiskies sold in Korea, including imported whiskies, as of 1 October 2012. There would be no discrimination between domestic and imported products. The tagging RFID requirement on imported whiskies was applicable to the importers and not to the exporters. This was because of differences in radio frequency from nation to nation as well as differences in terms of compatibility between tag readers. Therefore, whisky exporters did not have to be concerned about increasing costs as a result of the application of this measure. The reason for the introduction of RFID tags instead of barcodes was that RFID provides information unique to a specific product-for example, a specific bottle of whiskey—not just a group of similar products as a barcode does. Regarding concerns about potential RFID malfunctioning caused by the use of metallic materials and the difficulties of tagging small bottles, Korea expected that these technological difficulties could be solved in the near future through the advancement of the RFID technology. One alternative of these problems is to tag the box], as specified in the notice. Korea's would notify this measure to the WTO through the Korean National Tax Service in November 2011.

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

50. The representative of the <u>United States</u> expressed concern that Mexico's National Water Commission (NWC) was refusing to allow corrugated high-density polyethylene (HDPE) pipes, mostly produced by US companies, to become certified to the mandatory technical standards that were codified under Mexican law. He recalled that these technical standards had granted market access to US products for many years. According to the US, the NWC changed its policies and started requiring compliance with an ISO standard that only covered Polyvinyl chloride (PVC) pipes, which were produced mostly by Mexico-based companies. Thus, this change in policy by the NWC effectively precluded the sale of HDPE pipes in the Mexican market. The standard previously applied by the NWC was based on performance characteristics, thus outlining minimum performance requirements to achieve sufficient strength, longevity, and hermeticity. This standard covered three types of pipes for use in Mexico, including HDPE pipes. By contrast, the ISO standard that Mexican authorities were enforcing more recently was based on design and covered only PVC pipes. The US believed that the effect was to exclude HDPE pipes from the Mexican market, even though they performed the same function than PVC pipes.

51. The US was also concerned that the NWC decided to require compliance with the ISO standard, abruptly and without any warning. The US was unaware of any WTO notification related to

this policy change. Therefore, the US requested Mexico to continue applying the piper standard that was on the books in Mexico, that permitted access of HDPE pipes to the Mexican market, and allowed HDPE pipe producers to be certified. If Mexico intended to change its policy on this matter, the US asked what objective pursued by Mexico was, and whether Mexico considered the adverse impact on US pipe exports arising from this change in policy. Finally, the US intended to follow this issue closely and looked forward to receiving the requested information.

52. The representative of <u>Mexico</u> recalled that the concerns raised during bilateral meetings with the US on this issue had already been sent to the NWC. In January 2011, Mexico published in its Federal Official Gazette, a draft amendment to the Official Mexican Standard *NOM 001 CNA*. This standard was applicable since 2009 and dealt with drinking water, sewerage, and domestic collectors for sewerage. The purpose of this amendment was to establish specifications for products that were in the drinking water system, sewerage and also household collectors, to make sure that these systems were water-tight over the long-term so as to avoid leakages, to establish proper operating and maintenance conditions, and to guarantee a minimum longevity of these systems.

53. Information regarding this amendment was transmitted to the WTO and distributed to Members on 5 January 2011 in document G/TBT/N/MEX/206 and a 60-day comment-period was established. This draft amendment was also notified directly to the US on 6 January through its contact point. Finally, during the public consultation period, the US did not submit any comments regarding this document. Mexico thus asked the US to submit its comments directly to Mexico's NCW even though the consultation period had elapsed.

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

54. The representative of <u>Mexico</u> expressed concerns with regard to the law on hygienic production of milk and milk products and the regulation of their sale in El Salvador. Article 21 of the relevant law prohibited the marketing of milk, cream and cheese emerging from the reconstitution and recombination of powdered milk, as well as the marketing and sale of these products using additives. Aspects of milk product production, such as producing cheese using milk powder, were acceptable at the global level and foreseen in the Codex Alimentarius. Thus, there was no problem accepting this practice. In Mexico and in other countries, there was neither any hurdle to overcome when marketing milk products based on powdered milk, nor any legislation prohibited their sale.

55. Mexico did not believe that there were any international precedents indicating that the use of milk powder for producing milk products could have negative consequences on nutrition. At present, there was no method of proving whether a milk product had been produced on the basis of liquid or powdered milk since both products had the same chemical properties. Cheese containing vegetable fat was now considered to be an additive in El Salvador. The use of vegetable fat or lard was authorized in Mexico, although it had to be labelled as an imitation on the label.

56. Mexico's request to export products with these characteristics freely to El Salvador had been rejected. Though Mexico recognized Members' rights to establish necessary measures to ensure the quality of products for the protection of health, human, animal and plant life, or the environment should be respected, it was important to ensure that the levels of protection were recognized and to prevent any unnecessary trade restrictive measures. Since a number of concerns had been raised regarding this provision, it was necessary to examine the scientific evidence. The prohibition discriminated against Mexican exports since a number of El Salvador's products did not indicate use of these so-called additives, nor bear the word imitation on their labels. Powdered milk was often used in the relevant products in El Salvador, however not always listed on the label.

57. The representative of <u>El Salvador</u> took note of the concerns raised and said that he would relay these to capital for a reply.

- (b) Previously raised concerns
- *(i)* European Union Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH)²

58. The representative of <u>India</u> said that many of his delegation's concerns had not been addressed in EU bilateral discussions. Specifically, his delegation was concerned with the criteria and definition of small and medium enterprises (SMEs) given the labour intensive industries in developing countries like India. This could result in unfair treatment for these enterprises. His delegation also sought clarity on the registration to be made by merchant exporters which were not manufacturers under this legislation. This created particular problems for the trade and industry which operated through such merchant exporters. Hiring of the Only Representative had been a burden for many SMEs and added to the cost. His delegation therefore requested the EU to review the provision for permitting direct registration by the exporters. He also reiterated earlier concerns about the creation of the Substance Information Exchange Fora (SIEFs) and consortia which were outside the purview of regulatory control and had the potential to be dominated by the EU industry.

59. The representative of <u>Argentina</u> reiterated his delegation's concern with the complexity of the regulation which constituted an unnecessary obstacle to trade without complying with environmental and health concerns. The complexity of REACH was seen in the continual modifications of the regulations and the explanatory guides for compliance. REACH had been modified 19 times, and the 24 guides which existed for interpretation were continually changed. In 2011 alone, the regulatory text was modified six times and three explanatory guides were changed. In 2012, there was to be a general revision which might add further modifications. Also, the changes foreseen for 2013 by the European Agency for Chemical Substances (ECHA) for classification, packaging, and labelling of substances and blends were even more discouraging for companies. ECHA claimed that the timeframes for some of the REACH processes had to be modified as well as changes in the prerequisites to justified alternatives to animal model tests and in the evaluation of the security of different chemicals.

60. The situation was worrisome, especially for SMEs, because the continuous changes gave rise to confusion and it was difficult for companies to meet their obligations. Costs accumulated for having an Only Representative (OR), a lot of bureaucratic formalities, as well as for the registration of each substance. In this context, the forthcoming reduction of costs for substances for SMEs would be offset by other costs. Figures provided by ECHA showed some 1500 chemicals which should have been registered in 2010, were not. This accounted for more than 30 per cent of the total of the substances on the registry, for a sector exporting large volumes. This meant greater cost had to be borne to comply with REACH. For the above reasons, his delegation asked the EU to make the process more transparent, to avoid the huge number of changes, and to provide greater reductions in the registration cost for SMEs. His delegation understood the need to protect the environment and human health, but REACH was an obstacle to trade. If the various problems were not solved, a number of companies, especially SMEs, would not be able to export their chemicals to the European market. This would result in a loss of a large number of jobs in their home countries.

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

61. The representative of the United States sought clarification as to whether ORs under REACH were able to apply for authorization. If the ORs were unable to apply for an authorization, then each importer of a substance would have to apply, which would have a significant impact for US and other foreign manufacturers who would potentially have to submit multiple authorization requests for the same substance, whereas a new producer of the same substance would only have to submit one request. In general, many of the problems encountered by ORs and, by extension, their non-EU customers which tended to be SMEs since they didn't have a European presence, stemmed from the lack of clarity regarding the role of the OR in Article 8 of REACH. It could be useful for the Commission to consider writing an official technical guidance document for ORs, in the context of the REACH review, to help remedy some of these problems. The OR organization had already submitted its ideas for such a document, including allowing ORs to be used by companies in the context of the CLP regulation as well. This could be an important initiative, given the large percentage of OR customers that were SMEs. Lastly, his delegation would continue its bilateral discussions on other issues related to SIEFs including data compensation rules with the EU, not just on REACH, but on other EU legislation too.

62. The representative of <u>Australia</u> had raised his delegation's concerns previously, which were still valid. His delegation maintained its reservation on these issues, including those related to the data costs on SMEs and the overall burden on trade.

63. The representative of the <u>Kingdom of Saudi Arabia</u> reiterated its previously raised concerns regarding REACH, and supported those raised by other Members.

64. The representative of the <u>Philippines</u> echoed the concerns raised by other Members, particularly on the complex and costly procedures of REACH and how they might adversely and disproportionately impact the small and medium enterprises. His delegation believed that this regulation could potentially lead to unnecessary disruptions in trade, and would be grateful for answers from the EU on its concerns.

65. The representative of <u>Cuba</u> reiterated her delegation's concerns, and supported statements by other Members, in particular regarding the high costs involved in this REACH regulation and the modification which had been made. They led to a great deal of uncertainty for developing country businesses. Furthermore, her delegation was concerned by the scientific evidence provided by the EU regarding nickel being damaging to public health. Her delegation asked the EU to bolster its collaboration in line with Article 2 of the TBT Agreement and to take into account the situation of developing countries, particularly concerning technical assistance and other such issues.

66. The representative of the <u>European Union</u> noted that most of the points raised were reiterations of previous concerns expressed. The Indian concern on the SME definition had been addressed at the last meeting in detail; as had Argentina's concern on the complexity and changes to the regulation of the guidelines.

67. Regarding the functioning of the Substance Information Exchange Fora (SIEF), she had already stressed in the Committee that it was up to industry to organize itself and that every individual SIEF had to establish its own working practices, transparency schemes, times schedules, legal agreements and the cost sharing mechanisms. She said that the European Commission and the European Chemical Agency (ECHA) could not interfere in the organisation and agreements between SIEF members, but that they continued their proactive approach to help industry, including SMEs. She informed that there was a new report of 20 September 2011 by the Director's contact group, created by the European Commission, to discuss actions to solve certain practical problems. This report contained an analysis of the lessons to be learned from the first registration date of December 2010, and it contained solutions and recommendations to certain problems encountered. It was available on the ECHA's website. The ECHA and the Commission were also working on a full update

of the guidance document on data sharing, so the Commission remained open to improvements in this respect and welcomed receiving any information including concrete examples of difficulties encountered.

68. Regarding the possibility for the Only Representative to apply for authorisation the representative of the European Union informed that this was still under discussion in Brussels. She could not provide any answers at this meeting but was aware that an urgent solution was needed. She promised to transmit to the relevant authorities the US proposal that the EC issue a new guidance document for the Only Representative related to Article 8.

(ii) European Union – Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE)³

69. The representative of <u>Korea</u> said that Korean industry continued to be concerned about the revised Directive. Due to the introduction of CE marking, companies needed more transition time to comply with the system and to develop substitutes for restricted substances. She asked the EU to explain how it would control spare parts manufactured before the implementation date but still on the market after the date.

70. The representative of the <u>European Union</u> explained that after the agreement between the European Parliament and the Council of Ministers, the new RoHS Directive was published in the Official Journal of the European Union on 1 July 2011. The Directive must be transposed by all EU member States into national law within 18 months after publication, in other words, by January 2013. Until then, the current RoHS Directive continued to apply. As Members were aware, the scope of the Directive had been extended to all electronic equipment, cables and spare parts. Exemptions could still be granted in cases where no satisfactory alternative was available. In view of the significant extension of the scope, the new Directive introduced transition periods of up to 8 years for the new products affected by the rules. The new Directive would continue to ban lead, mercury, cadmium, hexavalent chromium and the flame retardants Polybrominated biphenyls (PBB) and Polybrominated diphenyl ethers (PBDE). However, the list of banned substances would be periodically reviewed.

71. The first review of the list of banned substances was foreseen in July 2014, and WTO Members would be notified in due time. Furthermore, any review of the list of substances would be undertaken in consultation with interested parties, would be based on scientific evidence and an assessment of the socio-economic impacts and would take into account information on the availability and reliability of possible substitutes. His delegation had discussed this issue bilaterally with Korea and hoped that the explanation provided was helpful in alleviating Korean concerns.

(iii) European Union - Proposed Measures on the Labeling of Wine (G/TBT/N/EEC/366)

72. The representative of the <u>United States</u> raised his delegation's concern regarding the restricted ability of non EU wine producers to use common descriptive or commercially valuable terms to describe their products on the grounds that those terms were traditionally associated with European wines. His delegation's concerns were known in this Committee and negotiations on this issue were ongoing. Some progress had been made and, perhaps in March, his delegation would have new information to report. His delegation would also be interested in any updates.

³ G/TBT/N/EEC/247, G/TBT/N/EEC/247/Add.1, G/TBT/N/EEC/247/Add.2 and G/TBT/Notif.00/310, Corr.1.

73. The representative of the <u>European Union</u> said that her delegation was currently examining the applications filed by the US, and was discussing this issue bilaterally with countries concerned and would continue to do so.

(iv) India – Pneumatic tyres and tubes for automotive vehicles⁴

74. The representative of <u>Japan</u> expressed his delegation's concern with regard to the compulsory certification system for automobile tyres in India, due to the Indian Government's enforcement of the relevant system, although his delegation had requested a postponement and improvement of the implementation on several occasions. In addition to the problem of tyre companies not being able to obtain factory certification due to the lack of capacity of the certification authority, the acquisition of certification by each tyre size had not been completed. His delegation requested India to improve and speed up the certification process for currently applied sizes and those that would be applied in the future.

75. In the previous meeting, India had said that a legal modification would be made regarding clause 6.3 of the template, which prohibited exports of the BIS marked tyres to countries other than India. This modification had not yet been done. Therefore, Japan's relevant companies were suspending export from Japan to India, and requested the immediate deletion of clause 6.3 which was nothing but a technical barrier to trade.

76. The representative of the European Union said that her delegation shared Japan's concerns on the Indian Quality Order on Pneumatic Tyres and Tubes for automotive vehicles. India had indicated in the last meeting that its Government was looking at the options to change the requirement that the ISI marking for tyres could not be used on tyres sold outside India. This prevented manufacturers from producing tyres for various markets and obliged them to produce tyres for the Indian market alone, constituting an unnecessary barrier to trade. India also promised in the last Committee meeting that its Government would look at the issue of the royalty fees which were calculated on the basis of the total number of tyres produced and marked with the ISI marking and not on the basis of the total number of ISI marked tyres *de facto* imported to India which, together with the aforementioned prohibition to use the ISI marking of tyres sold outside India, rendered the export of tyres to India extremely costly. Her delegation would appreciate an update on the current state of discussions in this respect and urged India to find a solution to this trade barrier. Finally, her delegation remained concerned about the delays in the certification process of certain tyre manufacturers and the lack of availability of accredited laboratories inside and outside India to carry out the required tests. In this respect, the EU urged India to accept test reports carried out in ILAC accredited laboratories in the EU.

77. The representative of <u>Korea</u> echoed the comments made by Japan and the EU and continued to be concerned about the capacity of the certification authority, and the unreasonably long grant process. Currently, one Korean manufacturer was facing severe delays in certification without any problem from the company side. As a result, its exports to India had been immensely disrupted. His Government had not received any explanation on this situation from the Indian authorities. Additionally, upon request from the Indian delegation at the June Committee meeting, Korea sent concerns to both the BIS and the Indian Mission on 1 July 2011. However, it had not received any reply. Korea strongly asked India again to accelerate the process and explain the situation.

78. With regard to the severe delays, Korean tyre manufacturers believed that the one year validity was unreasonably short. Considering the severe delay in certification, manufacturers might have to reapply as soon as they got certification. Also, most countries did not specify the term of validity for just one year. Korea and the European Union granted permanent certification and many

⁴ G/TBT/N/IND/20 and G/TBT/N/IND/20/Add.1; G/TBT/N/IND/40 and G/TBT/N/IND/40/Rev.1.

other countries granted five years. Korea asked India to expand the term of validity to at least five years. With regard to Article 6.3 of the BIS Agreement, Korea invited India to explain the situation of the legal amendment and believed that the requirement created unnecessary burdens.

79. The representative of India recalled that his delegation notified the original measure in July The last notification in November 2010 stipulated May 2011 for its entry into force. 2006. Therefore, the time period of five years from the original notification was more than reasonable and well beyond those mandated in the TBT Agreement and TBT Committee Decisions. Moreover, on 8 September, his Government had notified the exemption of some 316 sizes of types of types imported by the original equivalent manufacturers for the replacement market. He pointed out that most of the applications for certifications by tyre companies had been cleared and those still pending were only because of incomplete information from companies or unavailability of test reports. In a bilateral discussion with Japan, his Government was given a list of some specific applications which were pending. However, these were additional size requirements sought by these companies so they were effectively new applications. His Government had given positive consideration to the removal of Article 6.3 of the BIS Agreement, which was now only subject to certain approvals. The marking fees were fairly low and reasonable and equitable in terms of unit costs of tyres for both domestic and foreign manufacturers. Finally, on the capacity of the Indian labs to carry out certification, he said that around 85 licences were granted and there were very few pending Japanese or Korean applications.

(v) Canada – Compositional requirements for cheese (G/TBT/N/CAN/203 and G/TBT/N/CAN/203/Add.1)

80. The representative of <u>New Zealand</u> registered her delegation's concern that Canada's compositional cheese standards were inconsistent with Codex standards, which did not prescribe limitations on the sourcing of milk proteins for use in cheese manufacture. New Zealand had accepted Canada's offer at the TBT meeting in June 2011 to discuss this issue bilaterally. Unfortunately, the discussion did not give New Zealand any confidence that Canada intended to provide more clarity on how its cheese compositional standards complied with Codex standards or addressed NZ's concerns. Canadian dairy farmers had lobbied the Canadian Government for a yoghurt standard. Like other WTO Members, New Zealand was concerned that any compositional standards for yoghurt would also be inconsistent with Codex standards, and encouraged Canada to adhere to the Codex standard when making decisions on any future federal dairy regulations/standards for yoghurt. New Zealand said that it would continue to monitor these developments closely.

81. The representative of <u>Australia</u> also raised concerns about Canada's regulation on the compositional standards for cheese and access for milk proteins. His delegation supported the concerns raised by New Zealand and expressed dissatisfaction with Canada's assertion that it had taken international standards into account when developing the measures.

82. The representative of <u>Canada</u> noted that it was unfortunate that New Zealand was not satisfied in the wake of bilateral discussions. As previously stated, the Committee had not seen evidence that Canadian regulations have constrained the overall use of milk ingredients such as milk protein concentrates and that all imported cheeses to date had been deemed to be in compliance with Canadian standards. He confirmed that the Canadian Government had not initiated any regulatory processes for establishing compositional standards for other dairy products.

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

83. The representative of the <u>European Union</u> thanked the Indian Government for postponing, to April 2012, the enforcement of this measure. The EU delegation proceeded to ask whether a revision of the notified text was being considered by the Indian health authorities. In particular, would the

validity of the importing licences be increased from three to five years in order to bring it in line with the validity of domestic licences. The EU also inquired whether India had considered accepting test reports carried out in foreign laboratories, attesting compliance with international standards, as an alternative to local testing. Finally, would India accept labelling to be carried out in bonded warehouses as an alternative to labelling in the country of origin?

84. The representative of the <u>United States</u> said his delegation shared the EU concerns about the differential period for the licensing and the test report and the supplementary labelling. He also asked how the regulation fee would apply to particular brands of products, whether the proposal referred to the trade name or the product line; and whether the placement of the import registration numbers could only be required on the outer package, rather than on the inner package as well. In view of the delay in implementation, the US hoped to resolve some of these technical issues bilaterally. US industry was very interested in having a dialogue with India. He asked India to update the Committee on any progress made in the establishment of technical level meetings.

85. The representative of <u>India</u> reiterated earlier comments on automotive tyres, in which the particular rules took approximately 5 years from the initial intention to regulate. The validity of the registration certificate was three years as per the rules, primarily because of the difference in the technicality of the inspections and testing carried out in the two processes. While there was just a one-time inspection of documents at the time of registration for importers, domestic manufacturers had to obtain a manufacturing license that was issued after a comprehensive inspection of premises, equipment and capability. Since the firm could also be inspected at any time between the grant and the renewal of that licence, the validity was kept separate. Therefore the validity period of the licence and registration were different taking into account the risks of non fulfilment. India would pass on the comments of the EU to the regulatory authorities. The Indian delegate had already relayed the US concerns to the Indian ministry regarding an appropriate forum to hold technical discussions on these rules.

(vii) Colombia – Draft Decree Establishing Provisions to Promote the Use of Biofuels⁵

86. The representative of the <u>European Union</u> thanked Colombia for the written reply of 4 October 2011 on the new version of the draft decree notified under G/TBT/N/COL/96/Add.5. The EU delegation maintained its opinion that Article 1 of the new version should be clearer in expressing that, from 2015 onwards, there would be a parallel supply of E10 gasoline for conventional cars and E25-E85 gasoline for flex-fuel vehicles. The EU noted that Colombia had assured that all changes concerning the percentage of alcohol in gasoline would be subject to technical analysis, internal stakeholder consultation and to a notification under the TBT Agreement. In case of a change, a time period would be provided to permit producers to adapt to new percentages. The EU also highlighted Colombia's assertion that petrol stations had to provide a clear separation and labelling of different mixes to help consumers become aware of the kind of fuel they purchased. Given that the new version of the decree should replace Decree 1135 requiring engines to be capable of running with E85 gasoline as of 1 January 2012, the EU urged Colombia to ensure that the new decree entered into force before this date and that E10 gasoline continued to be available as of the same date.

87. The representative of <u>Mexico</u> said that his delegation believed that special marking or labelling in petrol stations would be necessary so as to avoid confusion by consumers when filling the fuel tank of conventional vehicles, given that E25-E85 were designed exclusively for flex-fuel engines. Furthermore, it considered a detailed analysis of the impact upon performance, durability of fleets, available technology and infrastructure and distribution equality of biofuels unnecessary.

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

Mexico also requested further information regarding the availability of fuel after 2015. It was important for the Colombian Government to introduce a transitional period that would allow vehicle manufacturers to adapt their engines and to avoid any damage due to levels of ethanol and biodiesel. Likewise, Colombia should also take into account the impact that this legislation would have on the vehicles that were already in circulation. Indeed, there could be technical damage to the engines due to the presence of ethanol in fuel. Finally, Mexico requested more information regarding the date of entry into force of Decree 11/35, which demanded that engines of less than 2,000 cc operate on flex-fuel E85. Originally, the date was set for 1 January 2012.

88. The representative of <u>Argentina</u> requested Colombia to clarify which products were being covered by this draft standard.

89. The representative of <u>Colombia</u> said that, with respect to decrees 2629 of 2007 and 1135 of 2009, his Government had met all of the various requirements for the preparation of regulations in this area. In relation to the draft decree under TBT/N/COL/96/Add.4, Colombia notified a new version of the draft under G/TBT/N/COL/96/Add.5. Due to the modifications of content, comments were accepted until 30 August 2011. Colombia received comments from the European Union and Mexico and provided answers through the Colombian TBT enquiry point. Consequently, the Committee on biofuels met in September 2011 and approved the text, including some of the submitted comments. The Colombian delegate predicted that this decree would be sanctioned before 15 December 2011.

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

90. The representative of the <u>United States</u> expressed his delegation's concerns on the proposed warning label requirements for alcoholic beverages. His delegation had submitted comments and had raised questions about the warning labels including their scientific basis, the size and the rotational requirements as well as other technical issues. He requested an update on the measure's status.

91. The representative of the <u>European Union</u>, <u>Chile</u> and <u>New Zealand</u> supported the concerns made by the United States and looked forward to receiving updated information.

92. The representative of <u>Thailand</u> clarified that alcohol labelling was aimed at protecting human health. The Thai Government's campaign sought to address social problems related to alcohol, by prohibiting alcohol consumption during festivals so as to reduce accidents and domestic violence. Representatives from the Ministry of Public Health and from the Industrial Standards Institute had come to the TBT Committee meeting to explain the measure and listen to comments. These comments would be taken into consideration when reviewing the proposed measures. The Ministry of Public Health was in the process of appointing a sub-committee to study the impact of the draft regulation.

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

93. The representative of <u>Japan</u> emphasized the importance of maintaining transportation security. However, his delegation was concerned about the this measure from the perspective of consistency with the United Nations Recommendation on the Transport of Dangerous Goods and the technical instructions of the International Civil Aviation Organization (ICAO), as well as of the impacts on trade. If the purpose of the regulation was to ensure safety, its scope did not have to extend to goods which were safety assured. Japan asked not to exempt lithium ion batteries with low SOC (State of Charge) for safety reasons. Furthermore, the Department of Transportation website indicated that it would invite public comments from December 2011 until February 2012 as the stage of Supplemental Notice of Proposed Rulemaking. The Japanese delegation requested that the US

commence this. The website also stated that there was a new proposed regulation concerning lithium ion batteries. Japan asked for information on this and the TBT notification schedule.

94. The representative of the <u>European Union</u> requested an update of the state of play of the proposed requirements on the transport of lithium batteries in the Hazardous Materials Regulations. She considered that they went beyond the UN Recommendations on the transport of Dangerous Goods and the Technical Instructions on the Safe Transport of Dangerous Goods of the ICAO. The EU recalled its previously stated concerns.

95. The representative of <u>Korea</u> agreed with Japan and the EU, and requested the United States to update the Committee on the current status and future prospects of this measure. The Korean delegation insisted on the need for including an exemption for lithium based secondary cells that were shipped at no more than 50 per cent SOC, if the Pipeline and Hazardous Materials Safety Administration (PHMSA) chose not to adopt existing UN and ICAO regulations for the shipment of lithium batteries.

96. The representative of <u>China</u> supported the previous statements and urged the US to comply with Article 2.4 of the TBT Agreement on the use of international standards as a basis for domestic regulation. In particular, China drew the US attention to the ruling of the Appellate Body in the EC - Peru sardines case regarding its interpretation of what constituted a relevant international standard. China called upon the US to make concrete efforts to base this regulation on relevant international standards, in this case the UN and ICAO regulations.

97. The representative of the <u>United States</u> explained that this issue had been discussed with the Members who had previously raised this issue. There had been no changes in the status of the measure since the last Committee meeting and it continued to be discussed internally. The US was aware of Members' concerns and had been taking their comments into consideration. In addition to the comment period, a public hearing and stakeholder meetings, had been provided by the Office of Management and Budget to which several delegations had attended. These events brought great transparency to this measure and discussions on these particular guidelines continued in ICAO. The US agreed with Japan that the website was slightly confusing and agreed to discuss the issue with colleagues to make proper adjustments. He believed that the proposed measure remained at the same juncture as in the last meeting. Article 2.4 was not meant to cut and paste an international standard into the measure, but rather to use it as a basis when relevant, unless it was ineffective or inappropriate to fulfil the government's objective. He reiterated concerns raised in previous Committee meetings on the use of the international standard due to the lack of consensus and inclusiveness.

(x) Brazil – Alcoholic Beverages (G/TBT/N/BRA/348 and G/TBT/N/BRA/348/Suppl.1)

98. The representative of the <u>European Union</u> recalled that, at the last meeting, Brazil informed Members that the draft legislation on alcoholic beverages was still under analysis and that its publication was not foreseen in the near future. The EU recently became aware that a MERCOSUR alcoholic beverages labelling proposal which was meant to supersede the Brazilian measure notified under G/TBT/N/BRA/348 was under discussion. She requested an update from Brazil on the state of play of the draft proposal, on the eventual MERCOSUR proposal and an indication of when the new draft proposal would be made available and notified to the TBT Committee.

99. The representative of the <u>United States</u> also asked whether this measure would go ahead or be superseded by a future MERCOSUR regulation.

100. The representative of <u>Brazil</u> informed the Committee that this measure had not been published as a final regulation, and the regulatory process involved had been stopped. Preliminary

discussions were developing in the context of MERCOSUR, but it was too early for any kind of notification. If the regulatory process resumed in the future, comments provided during the public consultation phase of the previous text would be taken into account and properly addressed.

(xi) Turkey – New Conformity Assessment Procedures for Pharmaceuticals (Circular issued by the Directorate General of Drugs and Pharmacy of the Ministry of Health re: "Important Announcement regarding GMP Certificates")

101. The representative of the United States said that his delegation continued to find certain aspects of Turkey's GMP decree for pharmaceutical imports problematic and urged Turkey to take immediate steps to restore market access for safe high-quality pharmaceuticals. The US recalled their past opposition to inspection requirements and maintained concerns based on the latest update received from the industry. The number of pharmaceuticals waiting market authorization in Turkey had reached approximately 550 products. While the US was pleased with positive discussions on good manufacturing practices over the past year in bilateral trade meetings, workshops and regulatory dialogues, market access was becoming an urgent issue both for US exporters and for patients in Turkey. The US urged Turkey to consider the following measures to immediately alleviate the current blockage of pharmaceutical imports: 1) to process registration files submitted prior to March 2010 as filed, so that the GMP requirement would not be applied retroactively without notice; and 2) to give priority to innovative drug applications that provided new medicinal therapies to patients in Turkey. The US also noted that the measure had not been published in the official Turkish gazette and that it was not notified to the WTO. Finally, he said members of US Congress had recently sent a letter to Turkey's Ambassador in Washington urging Turkey to take immediate steps to restore market access for imported pharmaceuticals.

102. The representative of the <u>European Union</u> shared the US' concerns and urged Turkey to continue discussing this issue bilaterally in order to find a suitable solution.

The representative of Turkey explained that good manufacturing practice certificates required 103. in licensing applications for pharmaceutical products, ensured that the products were manufactured in conformity with the licence requirements and that human health was not at risk due to safety and/or quality deficiencies in the production process. Pharmaceutical products were by nature different from other commercial products in that, when entering the market, they were highly regulated by health authorities through licensing schemes. GMP certificates were an indispensable part of that licensing process. With the GMP certification, Turkey sought to ensure that the pharmaceutical market in Turkey conformed to GMP rules. The Turkish Ministry of Health had the necessary capacity to accept and process applications for GMP certificates. All applications were processed immediately provided the application files were complete. For public health concerns, the Ministry of Health used a classification system based on therapeutic priorities of pharmaceuticals which were determined according to scientific criteria. The same process was applied to all countries and all products equally, including national products. GMP inspections conducted by Turkey did not seek to restrict trade but to secure public health. A dialogue with the European Commission had been held on this subject.

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

104. The representative of <u>India</u> said that the primary concern of his delegation was the absence of a notification of the 2001 and 2004 directives. India was also concerned about the requirement of 30 years of traditional use, including 15 years of traditional use in the EU, to establish the efficacy of the product. The Indian delegate requested that the EU consider acceptance of 15 years of traditional use even of those medicines to be used as food supplements in the EU. The common technical document format, was inappropriate for multicomponent traditional medicinal formulations. Furthermore, India requested the EU to recognize the GMP certificates issued in India for the purpose of this particular

directive. They also suggested a bilateral interaction with the traditional medicinal experts from the European Directorate for the Quality of Medicines, the European Policy Centre, and the European Medicine Agency. Finally, the delegation announced that his Government was working with some experts but requested closer interaction in both fields.

105. The <u>European Union</u> took note of India's concerns regarding Directive 2004/24/EC on Traditional Herbal Medicines. The EU reiterated that this Directive introduced a lighter, simpler and less costly registration procedure for traditional herbal medicinal products as compared with medicinal products falling under the full market authorization procedure (Directive 2001/83/EC). Extensive technical clarifications were provided in previous meetings and were in the minutes of those meetings. Several bilateral meetings were organized to discuss the Directive's scope and eligibility criteria, and the EU remained open to discuss remaining issues bilaterally at an expert level.

(xiii) Colombia – Shelf life for milk powder⁶

106. The representative of the <u>European Union</u> continued to have concerns with respect to the proposed revision of Decree 16/73 of 2010, notified by Colombia in January 2011. This revision required imported milk powder to have a minimum shelf life of at least 12 months at import, which was six more than previously required. The extension of this period could impair EU exports of milk powder to Colombia. The EU provided written comments to Colombia in April 2011, raised these concerns at the last Committee meeting; but no reply had been provided. The EU delegate asked Colombia to clarify the risk that the authorities sought to address by extending the required shelf life of milk powder, and provide an update on the draft.

107. The representative of <u>Colombia</u> said the modification of resolution 16/73 of the Ministry of Social Protection, was under discussion by the country's national institutions. Colombia did not yet have a specific response for the EU's request but hoped to have a response as soon as possible.

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

108. The representative of the United States recalled that solar panels sold in Korea had to be certified by the Korean Management and Energy Corporation (KEMCO). The mandatory Korean standard was based on the IEC61646 standard for solar panels, but was only being applied to one particular type of solar panels. As a result, other leading types of film solar panels were essentially excluded from the Korean market because they could not be tested or certified under the KEMCO. The United States was not aware of any scientific or technical evidence indicating there were risks from using thin film solar panels that were not covered by the Korean version of this standard. This measure not only hurt US companies but kept the most innovative solar panel products out of Korea and limited Korean producers from moving into next generation technologies - critical for energy conservation. The US continued to believe that Korea should adopt the IEC61646 standard and not limit its application to only the one type of thin film solar panel produced by the Korean industry. His delegation had previously discussed Korea's assertion that it meant to perform additional studies on the dangers of cadmium. Like Korea, the US maintained legal requirements on the safe and effective use of cadmium and ensured that the cadmium used was in the form of a cadmium compound and not the more toxic elemental cadmium. In all the US products currently blocked from obtaining KEMCO certification, the total amounts of cadmium included in their modules were well below most regulatory levels. Given the prevalence of these materials, and the fact that these solar panels were being used in a number of markets around the world, the exercise in studying the cadmium issue seemed to have needlessly delayed market entry for innovative products that were already in use in other markets. The US continued to question the need for these studies, and urged Korea to complete

⁶ G/TBT/N/COL/67,G/TBT/N/COL/67/Add.1 G/TBT/N/COL/67/Add.2, G/TBT/N/COL/67/Add.3, G/TBT/N/COL/67/Add.4, G/TBT/N/COL/67/Add.5

them as expeditiously as possible. The US also proposed allowing US companies to pre-test the thin film solar panels in question according to IEC61646, so that the data and materials would be ready if and when Korea enabled these panels to receive KEMCO certification.

109. The representative of the <u>European Union</u> joined the United States in recalling its concerns on Korea's standard for thin-film solar panels. Her delegation requested an update on this issue, in particular on the on-going study of the environmental impact of thin-film solar panels, and its foreseen timeline for completion.

110. The representative of <u>Korea</u> reiterated that the standard and its related certification system was not mandatory. Currently, non-amorphous silicon types of thin film solar panels, Cadmium Telluride (CdTe) and Cooper Indium Gallium Selenide (CIGS), could enter the Korean market, without the KS certification. Furthermore, the feasibility study would be completed by 30 May 2012. Following completion, the Ministry of Knowledge Economy (MKE) would decide whether those two types should be included in KS61646. The Korean Government could only then provide updated information. In response to the EU's comments in the June WTO TBT Committee, noting that national authorities had been encouraging investment and research and development activities in CIGS solar panels, she confirmed that those activities were related to making cadmium-free CIGS solar panels. She would relay the stated concerns to her competent authority.

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

111. The representative of the <u>United States</u> had a remaining concern with the revised telecom security regulations, in particular with the in-country security assurance testing. Clause 23.7(a) of the amendments state that, as of 1 April 2013, all product certification of network elements would be done in India. The US understood the need to certify the product to the appropriate standard, but was not clear on whether having the product tested domestically could enhance security. Another concern focused on the facility instructions, which was also part of the same clause and would require vendors, or its designated agencies, to carry out inspections of the hardware/software design development manufacturing facility and supply chain. This raised numerous concerns, such as the proprietary and sensitive issues surrounding the design of products, including the fact that security requests could infringe on intellectual property rights and legal obligations and intrude into the business operations of vendors. The US asked that India notify the revisions to the WTO, so as to allow comments from industry.

112. The representative of the <u>European Union</u> identified the same concerns as the United States with regard to the in-country testing as of 1 April 2013, and asked for some explanation of the rationale for this requirement. Since India was a contracting party to the Common Criteria Recognition Agreement (CCRA), there was scope for continuing to recognize the certificates issued by other Members to that Agreement. The EU requested that the legitimate commercial interests of vendors be adequately protected in the framework of inspections and checks. The current provisions were not precise enough to give full confidence to vendors that they would not have to disclose any proprietary information in the context of these inspections and checks. Finally, the EU raised concern on the scope for mandatory testing. The current rules required that only network elements tested according to the relevant standards could be used in telecom networks. The EU suggested that this scope for mandatory testing could be clarified as being limited to those elements that were essential for ensuring the security and integrity of the system.

113. The representative of <u>Japan</u> supported the US and the EU. Japan was concerned with India's regulations on the licensing conditions for telecom services, which were announced on 31 May. Japan thought that this approach might not be in accordance with the CCRA because the new rules (February 2013) dictated that only network elements approved by Indian certification agencies would be allowed. Japan reminded the Committee that India accepted the scheme of CCRA. Furthermore, he asked India to ensure that their telecom regulations did not impede market access for foreign companies.

114. The representative of <u>India</u> stated that India's regulations on the licensing conditions for telecom services were transparent despite being an issue with security implications. His Government extensively engaged with stakeholders at the highest administrative level and had taken into account comments from several Members through joint meetings at the highest level. The regulation that was issued on 31 May 2011 was a consolidation of those inputs. No other Member had such an open, transparent process on such a sensitive issue as security guidelines for telecom equipment. Regarding the CCRA, India would continue to recognize the process based on performance tests conducted by international laboratories for general guidelines on products that were covered under the CCRA. However, these were security testing guidelines of telecom equipment. They called for the application of other parameters different from the general guidelines, technical regulations and conformity assessment procedures. India had taken, and would continue to take many of these inputs and concerns into account. He offered to revert to Members on specific issues and to forward these concerns to the Department of Telecom for consideration.

(xvi) Brazil - Instructions for Registration for Labels of Imported Products of Animal Origin (G/TBT/N/BRA/385, G/TBT/N/BRA/385/Add.1, G/TBT/N/BRA/385/Add.2)

115. The representative of the <u>United States</u> appreciated Brazil's willingness to address the US concerns including potential for disclosure of confidential business information and other data points that were considered unnecessary. While the US had already received some useful clarifications from Brazil, US regulatory agencies were being asked to certify to Brazilian standards and this was beyond their scope of authority. US regulators were willing to certify that products with animal content were produced in accordance with US requirements, but did not find it appropriate to certify that those products were in accordance with another country's requirements. Additionally, the US regulatory agencies had already issued a health certification for these products; the need for an additional certification was unclear and most likely redundant.

116. The representative of the <u>European Union</u> maintained concerns on the need to register the labels of products of animal origin for approval before being marketed in Brazil. It must be ensured that this requirement did not create unnecessary delays and costs for the EU's economic operators.

117. The representative of <u>Brazil</u> reminded Members that the aim of these measures was to facilitate trade of products of animal origin. This measure had simplified requirements related to registration of labels of such products, in comparison to previous Brazilian requirements in this area. Brazil had not received any reports on interruption or disturbances of trade due to these measures. These regulations were notified at the end of 2010 and were followed by comments from interested Members. Brazil modified the regulations in order to take those comments into consideration, including the requirement mentioned by the United States on the authority of the exporting country declaring whether products complied with Brazilian standards. This was no longer present in the regulation. Brazil had tried to organize a bilateral video conference with the US on this issue, but due to technical difficulties, it would have to be rescheduled. Brazil remains available for such bilateral talks.

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

118. The representative of the <u>European Union</u> clarified that while her delegation did not question the obligation to label goods in the Indonesian language, it queried why labelling had to be approved by Indonesian authorities before importing products and that labelling had to be done before the goods entered Indonesian customs. Indonesia had said in the previous Committee meeting that these rules were for pre-market surveillance purposes and helped to control imported goods. However, the EU found these measures burdensome for importers and encouraged Indonesia to pursue the option of providing at least the possibility of re-labelling products in a specific zone after entering Indonesian customs. This would ensure a less burdensome procedure for importers, while still fulfilling the objective of control and consumer protection.

119. The representative of the <u>United States</u> said that the supplementary labelling for processed food products should be allowed to be applied at the importers' select warehouse and other approved locations. The products could be released to the importers' warehouse where the supplemental labels could be applied prior to full customs clearance. The delegation thought that this would be sufficient to meet Indonesia's objectives and the Indonesian regulator, BPAM, would retain the right to inspect the importers' selected warehouse and other approved locations. An important trade issue for the US; it could affect approximately \$250 million US dollars' worth of processed food exports to Indonesia.

120. The representative of <u>Australia</u> shared these concerns and was interested in hearing responses from Indonesia. Australia's preference was to allow exporters to use labelling stickers upon the entry of a good into the market. They encouraged Indonesia to ensure that any labelling standards be consistent with international standards, such as Codex, which provided guidance in relation to using a secondary label in a country.

121. The representative of <u>Indonesia</u> informed the Committee that because its territory was spread throughout many islands, the Government had to conduct tight market surveillance. Affixing labels in Bahasa Indonesia was an instrument of pre-market surveillance which would be done by the relevant officers. The pre-market mechanism was applied to facilitate officers' control of goods, particularly of imported goods in accordance with the respective regulations. Implementation of this regulation was aimed at giving consumers the right to obtain sufficient, correct, clear and accurate information, as stated in the Act No 8/1999 concerning Consumer Protection. It was also a tool of surveillance as well as a means to minimize the entrance of illegal goods into the Indonesian market. Indonesia provided the opportunity for importers to use stickers, as stated in annex I, II, III, and IV in the Decree of the Ministry of Trade. However, the importer had to comply with the provisions of the regulations, which required goods to be labelled before entering the Indonesia market.

122. Indonesia's interest in tightening market surveillance did not specifically target the relabelling of goods after entering Indonesian customs, but to minimize and avoid the possibility of having illegal goods enter the Indonesian market. Therefore, the decree regulated that imported goods were to be labelled before entering the Indonesia custom area. The label would also be used for the Government of Indonesia to trace the origin of the mentioned goods. Indonesia acknowledged the importance of receiving comments in the reviewing process.

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

123. The representative of the <u>United States</u> urged Turkey to take action to eliminate the Social Security Institution (SGK) documentation requirements in communiqué SUT 2010, so that suppliers of medical devices could continue to place their products on the Turkish market, provided that their products met the requirements of the Medical Device Directive and by the Ministry of Health. As this measure was not notified to the WTO, interested stakeholders had no notice or opportunity to

comment on the measure in draft form; and the measure went into effect only seven days after publication. Therefore, suppliers did not have a reasonable interval for implementation. It was unclear what purpose it served to require companies to provide these additional documents, given that Turkey's Ministry of Health did not require companies to prove the safety and efficacy of medical devices. It was also unclear why SGK selected medical devices used in three specific areas to provide these additional requirements. Documentation requirements were problematic also because some devices were manufactured in a country where they had not been used, so producers did not have to obtain these documents and many medical device regulators did not provide documentation on product usage or proof of reimbursement even when devices were used in the country of manufacture. The US understood that the SGK was currently reviewing this measure, and looked forward to receiving updated information.

124. The representative of <u>Turkey</u> explained that both domestically produced and imported medical devices had to comply with the applicable national technical regulations and the 'CE' marking was assumed to be the indicator of that compliance. While the Ministry of Health regulated the entrance of medical devices into the market, it was SGK that had to decide which devices would be reimbursed. In this decision-making process, the institution's primary consideration was to ensure that high-quality products were provided to patients. Secondly, the SGK took into account public expenditure and budgetary constraints. As TBT Committee had been previously informed, the SGK issued a communiqué in relation to the reimbursement of medical devices and this was still bein revised. The concerns of the US would be taken into account during the revision process.

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

125. The representative of <u>India</u> asked for an update from the EU on the status of implementation of Italy's labelling law. This labelling law covered a large number of regulations and provisions of information at each stage of processing, which created difficulties for an industry that was premised on global and multiple sourcing. There was also concern about certain non-product-related processes and production methods (the nPPMs) which were sought under the law such as details of employment in the sector. India expressed concern and requested an update on this Italian labelling law.

126. The representative of the <u>European Union</u> announced that there had been no new development on this measure. Italian authorities had decided to postpone the application of this law as it depended on the adoption of implementing measures which had not yet been adopted and no adoption date was foreseen.

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

127. The representative of the <u>European Union</u> referred to comments made at the previous two Committee meetings on this measure. The proposed measure would imply discontinuation of European exports of traditionally blended tobacco products to Brazil, and would also affect European exports of additives that were currently used in tobacco products. The EU supported Brazil's objective of protecting human health, in line with the WHO Framework Convention on Tobacco Control (FCTC). It explained that it was itself in the process of revising its Tobacco Products Directive and had identified regulation of ingredients as one area of possible change. She recalled questions raised by the European Union at previous meetings to help facilitate understanding of the measure; for instance, had Brazil evaluated alternative legislative solutions to a ban on all additives and why had these alternatives not been considered as effective for achieving the legitimate health objective? She requested an update on the status of the proposal, and a reply, prior to adoption of the notified draft, to the EU's written comments.

128. The representative of <u>Mexico</u> requested information on the implementation of Brazil's draft resolution, and a formal response from the Brazilian Government on Mexico's comments regarding the draft resolution presented on 31 March 2011.

129. The representative of <u>Nigeria</u> said his delegation was concerned with this draft resolution because his country had a long tradition of both growing and manufacturing tobacco products, and because the draft resolution came from Brazil, the world's third largest grower of tobacco leaf, behind only China and India in both the number of hectares devoted to tobacco growing and the number of tonnes of tobacco leaf harvested each year. ANVISA, Brazil's National Health Surveillance Agency responsible for the draft resolution, continued to review its content and to gather public input. He asked for an update on the latest developments in the public hearing process.

130. He further asked Brazil to reassess the resolution prior to adoption, so as to ensure coherence between the rights and obligations of Nigeria, along with the other African, Caribbean and Pacific countries (ACP) and African Union (AU) member States in the WHO, WTO and other international fora, particularly with respect to agricultural and rural development objectives. He expressed concern with Brazil's intention to impose a regulation that would create an unnecessary obstacle to trade for an agricultural product of great importance to many developing countries. He encouraged Brazil to modify the proposed resolution to ensure that it was fully WTO compatible.

131. The representative of the <u>Philippines</u> echoed concerns raised. In particular, the resolution to ban the use of various types of additives with no reasonable justification equated to a total ban of traditionally blended tobacco products in the Brazilian market. Philippines shared the objective of protecting young people's health. However, this objective could be achieved through less restrictive measures; her delegation encouraged Brazil to base any final decision on this resolution on scientific and technical evidence.

132. The representative of <u>Indonesia</u> informed that her delegation had consulted with Brazil on the follow up of its official letter of 4 April 2011 to the Minister of Development, Industry and Foreign Trade. She asked Brazil to clarify the date of the public hearing on the Draft Resolution No. 112.

133. The representative of <u>Turkey</u> said her delegation was closely following this measure.

134. The representative of <u>Colombia</u> supported the concerns raised, and asked Brazil to explain any progress made with respect to this resolution. He was concerned that the draft resolution could be confirmed as notified, and believed it ran counter to Article 2.1 of the TBT Agreement.

135. The representative of <u>Honduras</u>, <u>Zambia</u> and the <u>Dominican Republic</u> reiterated previously raised concerns on the draft resolution and requested an update from Brazil on the measure. The latter asked if Brazil could reassess the resolution in favour of a less trade restrictive alternative?

136. The representative of <u>Zimbabwe</u> joined other delegations in requesting an update from Brazil on the status of this draft resolution. His delegation had submitted written comments expressing its concerns and awaited Brazil's response.

137. The representative of <u>Chile</u> shared the concerns raised, in particular that the measure was more trade restrictive than necessary. Her delegation did not oppose the legitimate objective of the measure, but believed there were alternative measures to achieve the objective in a less trade restrictive way. She asked for an update on the current status of this measure.

138. The representative of the <u>Russian Federation</u>, speaking as an observer shared Brazil's objective of protecting human health and of reducing the incidence of smoking amongst young people and the general population. Nevertheless, he supported concerns raised, in particular that the measure

was more trade-restrictive than necessary and violated Article 2.2 of the TBT Agreement. There was insufficient scientific evidence to demonstrate that additives used in blended tobacco made those products either more attractive to consumers, more harmful to health, or more addictive. Could Brazil provide the evidence upon which the draft resolution was based? His delegation was particularly interested in comparative data on the health impact of blended versus non-blended cigarettes, and on the risk to human health of additives used for blended products versus additives that give characteristic flavours.

139. The representative of <u>Brazil</u> reiterated that the objectives of this measure were to protect public health by reducing the attractiveness of certain tobacco products particularly to children and youth. Tobacco addiction usually began at a young age, when individuals were more vulnerable to tobacco products' appeal; flavourings could increase their appeal. A previously cited study conducted by the National Institute on Cancer in Brazil showed that 45 per cent of smokers in Brazil between 13 and 15 years of age consumed tobacco products with flavour. In addition, the WHO, through its partial guidelines linked to the implementations of Articles 9 and 10 of the FCTC, had recognized that from the perspective of public health there was no justification for permitting the use of ingredients such as flavouring agents which help make tobacco products attractive. With respect to the status of this measure, the draft resolution had not yet been published as a final regulation. His delegation was consolidating comments received on the draft resolution; given the large amount received, additional time had been required but all comments would be answered prior to final adoption. Also, a public hearing on the draft regulation was tentatively scheduled for December 2011.

140. Regarding the scientific basis of the measure, Brazil had compiled the scientific references that served as a basis for this measure. These had been shared with Members that expressed concerns during the last TBT Committee meeting; he would offer it to other interested delegations. On the question of why Brazil had chosen to prohibit additives instead of flavoured products, he reiterated that previous attempts in Brazil to prohibit flavoured products rather than additives proved inefficient, given the subjective nature of the assessment regarding the presence of flavours and smells in a product. Moreover, certain additives, such as acetaldehyde, levulinic acid, gamma-valerolactone, and ammonia, apart from their flavouring properties, could potentiate the addictive effects of nicotine. Finally, studies indicated that in addition to increasing the addictiveness of tobacco products, some additives when burned could augment the carcinogenic properties of cigarettes.

141. Regarding the impact of the draft resolution on traditional blended products, the tobacco industry had possessed the technology to produce blended tobacco products without additives since 1996; for example, processing burley tobacco without sugar. Finally, both domestic and foreign producers were required to comply with the requirements of the draft resolution.

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

142. The representative of the <u>European Union</u> reiterated his delegation's concerns about the Chinese measures on information security products. He requested an update on the timeline for the revision of the regulation on commercial encryption products managed by OSCCA, and sought assurance that the process would be conducted in a transparent manner, allowing for consultation of interested parties, and that the draft revised regulation would be subjected to TBT notification. He mentioned that China had, in the previous meeting, confirmed that the revision was on the agenda (for 2011) of the State Council Legislative Office, and requested an update from China. He also reiterated concerns about the Multi Level Protection Scheme (MLPS) managed by the Ministry of Public Security (MPS) and by the Ministry of Industry and Information Technology (MIIT) for

implementation. While the stated objective for the scheme was national security, it had an impact on areas not considered sensitive for national security, including commercial sectors of economic significance such as banks, financial institutions, public transport, energy, etc. He requested more transparency on the classification criteria used to establish the level of security sensitivity of IT systems, triggering restrictions on the kind of products and technology which could be deployed in such systems . He noted, further, that European IT industry did not know whether they would be able to continue conducting business in China in sectors impacted by MLPS.

143. The representative of the European Union was also concerned about standardization practices in the area of information security, mainly carried out by the Information Security Standardization Technical Committee (TC 260) managed by the China Electronics Standardization Institute (CESI). The standardization procedures followed by this technical committee did not allow foreign companies, or even foreign invested companies established in China to participate directly in the standardization process. The European Union stressed the need for more ample opportunity for such companies to participate in the standards development process, especially since these standards could potentially be applied beyond areas traditionally covered by national security, and beyond areas which were covered by government procurement. He welcomed the comment period that had been provided for the six draft information security standards that had been developed by the Technical Committee in the Summer of 2011, and expressed hope that such consultation practices could continue and be expanded, and allow for more meaningful contributions – for instance, in this case, only 30 days had been allowed for comments, the documentation had been very comprehensive and technical and related legislative measures were often not publicly available.

144. The representative of the European Union also raised concerns about the relationship between these standards and the regulatory framework being discussed i.e. the OSCCA regulation and the MLPS. He said that the standards appeared to be developed for the purpose of implementing requirements embedded in those regulations. Therefore, the European Union was concerned that the standards would become *either de facto or de jure* mandatory once adopted, via a reference to them in the OSCCA regulation and the MLPS or related conformity assessment procedures. He requested clarification on the subject. In the event that the European Union observation was correct (that the standards were likely to become mandatory) he recalled the transparency obligations under the TBT Agreement.

145. Finally, he also highlighted the need for greater dialogue on the subject. He noted that the complex legal framework put into place by the Chinese authorities prevented the deployment of foreign technology in areas which were important from an economic perspective, but not necessarily security sensitive. With reference to other specific concerns, preventing the deployment of foreign technology was not necessarily the best means of enhancing information security. Moreover, this was a field where there were global challenges and could not be handled by one country alone – indeed, there was a need for greater international engagement on this issue. The European Union therefore would welcome a platform to discuss these issues with interested trading partners.

146. The representative of <u>Japan</u> supported the European Union's position. He noted that the various schemes and regulations in China on information security continued to pose difficulties for trade in information security products and prevented the placement on the market of certain technologies; furthermore, the schemes could not be regarded as being coherent with global norms and approaches. He recalled that delegations had requested China to be prudent in introducing additional measures on information security, whether or not they were related to the OSCCA regulation and MLPS. From the transparency perspective, it would be desirable for China to provide additional information on information security regulations.

147. The representative of <u>Japan</u> supported the European Union's position. He noted that the various schemes and regulations within China, concerning information security continued to pose

difficulties for trade in information security products; in particular the schemes could not be regarded as being coherent with global norms and approaches. He recalled that delegations had requested China to be prudent in introducing additional measures on information security, whether or not they were related to OSCCA and MLPS. From the transparency perspective, it would be desirable for China to provide additional information on information security regulations.

148. The representative of China noted first that the Regulation on Commercial Encryption Products had been listed in the legislative agenda of the State Council and that OSCCA was focusing on a revision. OSCCA would fully consider openness and transparency during the process and would undertake scientific discussion and public consultations, taking into account comments from the European Union and other interested parties. Regarding the State Administrative Measures on Classified Protection of Information Security (MLPS), she noted that Article 9 of the Regulations for Safety Protection of Computer Systems specified that the classified protection of information security would be implemented for computer information systems and that the classification standard and the specific measures for classified protection would be formulated by the Ministry of Public Security, in conjunction with other relevant authorities. In 2007, the Ministry of Public Security, jointly with other competent agencies, had issued the State Administrative Measures on Classified Protection of Information Security. The objective of the system was to protect the basic information network and key information system of China, and to safeguard national security and public interests. Five different levels of protection were envisaged. The commercial sectors which were not sensitive to national security would not be affected by those measures.

(xxii) Brazil - Canned Sardines - Ministerial Act Nº 406, 10 August 2010

149. The representative of <u>Peru</u> referred to the above-mentioned documents and noted that Peru had engaged constructive bilateral consultations of technical nature in Brasilia in September 2011. Unfortunately, it had not been possible to find a solution. Peru was concerned that Brazil was not using relevant international standards as a basis for national regulations, in particular: Resolution 1 was not covered. Further consultations could not be ruled out and neither could recourse to the dispute settlement mechanism of the WTO.

150. The representative of the <u>European Union</u> referred to the above-mentioned notification which set the identity and quality requirements for canned sardines marketed in Brazil. She was concerned over the final Brazilian text measure which still showed a significant divergence from the international Codex standard for canned sardines and sardine-type products (Codex Stan 94- 1981).

151. The representative of <u>Brazil</u> reaffirmed Brazil's openness to pursuing the issue bilaterally with Peru, aiming to achieve a mutually satisfactory outcome.

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

152. The representative of <u>Korea</u> noted that while the proposed decree had not yet been adopted, she asked the Indonesian authorities to update the Committee on the measure. In particular, she requested that Indonesia only regulate final products, not intermediate ones.

153. The representatives of the <u>European Union</u> and <u>Japan</u> supported Korea's statement. In addition, Japan expressed serious concern about the possible future expansion of mandatory standards to cover steel imported from Japan which was already produced under a strict quality management system at ISO 9001 certified steel mills. If the scope of mandatory standards was extended further, it would add to the cost required to receive and maintain certification. This would have serious implications on foreign trade, such as increasing distribution costs and delaying deliveries for specific industries in Indonesia. Indeed, this might even make industries in Indonesia less competitive in

G/TBT/M/55 Page 32

global markets. The European Union doubted that mandatory third party certification was necessary in this case and asked why acceptance of foreign tests was not possible without a mutual recognition agreement.

154. The representative of <u>Indonesia</u> said that the draft regulation of Ministry of Industrial Mandatory Implementation of Indonesian national standard for electrolysis tin-coated steel had not yet been finalized. His government was working on technical guidance documents.

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

155. The representatives of the <u>European Union</u>, <u>Japan</u> and <u>Korea</u> asked for information on the state of play, particularly on the progress of discussions about the product catalogue and certification procedure (Management Catalogue of Standard-Reaching for the Control of Pollution caused by Electrical and Electronic Products). The representative of the European Union remained concerned about mandatory third party certification and requested further clarification on the voluntary standards currently developed for six product categories, and on how those standards were linked to the notified draft.

156. In addition, the representative of <u>Korea</u> also asked the Chinese authorities for detailed information on the requirements for certification bodies and laboratories for State Recommendation Voluntary Certification on Electric Information Products, which had entered into force on 1 November 2011. The representative of <u>Japan</u> recalled had his delegation had recommended that China facilitate a voluntary suppliers' declaration of conformity certification (SDoC) on the "National certification system for the control of pollution caused by electronic products." The Chinese Government had replied to these comments suggesting that it would plan to designate a catalogue of the target products of the regulation as a positive list, and would notify the TBT Committee upon completion of the catalogue which was an indispensable part of the conformity assessment procedure scheme.

157. The representative of <u>China</u> said that the revision had commenced in 2010 and that China had solicited suggestions from relevant stakeholders and had notified it to the WTO. China had considered and adopted some suggestions received, but there was no timetable yet for the publication of the regulation or the Management Catalogue of Standard-Reaching for the Control of Pollution caused by Electrical and Electronic Products. Regarding the State Recommendation Voluntary Certification on Electric Information Products, the voluntary certification product catalogue had been jointly promulgated by the Ministry of Industry and Information Technology (MIIT) and the Certification and Accreditation Administration (CNCA) in August 2011. Certification was voluntary and the catalogue covered six kinds of products and accessories. The relevant documents could be found on the official website of the MIIT. Requirements for certification laboratories were still under discussion.

(xxv) India – Food Safety and Standards Regulation - Food labelling requirements (G/SPS/N/IND/69)

158. The representative of the <u>European Union</u> noted that this measure had not been notified to the TBT Committee despite several requests and the fact that the regulation contained several TBT components, such as labelling and packaging requirements, which did not fall under the SPS Agreement. She asked India to confirm that the current practice of allowing labelling to take place in customs bonded warehouses, as an alternative to labelling in the country of origin, would be maintained permanently. For labelling requirements applicable to alcoholic beverages, the European Union would continue to seek an exemption from the indication of date of manufacture, and the

acceptance of the "single ingredient status" for the list of ingredients. She reiterated that the Indian legislation deviated from Codex Alimentarius on certain aspects.

159. The representative of the <u>United States</u> said that his delegation continued to be concerned about why India considered that the data production label needed to apply to distilled spirits given that such products did not have an expiration date. He noted that identification numbers could provide better information should a product recall be necessary and therefore urged India to remove the labelling requirement for distilled spirits. He also expressed continued concern about requirements for the listing of ingredients for alcohol, since international practice did not require an ingredient list for non-nutritive products as this provided little useful information for the consumer.

160. The representative of <u>India</u> said that many of the specific information requirements had been taken from the Prevention of Food Adulteration Act, which was the main act under which the particular regulation in question was made; this took into account the specific needs of India. The representative of India would nevertheless convey the concerns and suggestions mentioned.

(xxvi) Korea: PVC flooring material and Wallpaper and paper linoleum, and toys⁷

161. The representative of the <u>United States</u> said that Korea had informed the United States about a study on the release of phthalates in construction materials which was the basis for a proposed phthalates concentration limit for PVC flooring material in paper and paper linoleum. While the United States had requested a copy (letter of 2 June 2011) a response had been received in July about a different study of a safety assessment for PVC-flooring and wallpaper, one that had been conducted between July and October 2010. He asked that both studies be made available so as to better understand how the results had been obtained and to compare them with other existing studies. The EPA, he said, had published an action plan on phthalates which outlined a number of actions being pursued, or which were under consideration because of the toxicity of phthalates and pervasive human and environmental exposure to the substances. This action plan was available online. The United States was unaware of any scientific or technical data showing the significant release of phthalates from PVC flooring or wallpaper or data showing the impact of these products on human health.

162. The representative of <u>Japan</u> supported the US statement and stressed the need for a scientific basis for the regulation as well as the need for Korea to disclose their safety assessments.

163. The representative of <u>Korea</u> said that the proposed measure could help protect children's health from the three phthalates. Her delegation had previously explained that all Korean houses used a very unique floor-heating system called Ondol which had been in use for centuries and as a result most houses in Korea used PVC flooring materials and wallpaper. As children tended to play on the floor, regulations for PVC flooring materials were necessary, as in the case for toys. The competent authority, KATS, had received comments from stakeholders and was in the process of taking these into account.

(xxvii) Colombia - Alcoholic Beverages⁸

164. The representative of the <u>European Union</u> noted that on 2 November 2011, Colombia had notified an amended text which incorporated some of the comments made by the European Union, particularly those on the definitions of brandy, fruit spirits, and rum. However, she expressed continued concerns about the recently notified text (Add.4) – particularly regarding the definitions of

⁷ G/TBT/N/KOR/303 and Add.1 and G/TBT/N/KOR/304 and G/TBT/N/KOR/304/Add.1, G/TBT/N/KOR/304/Add.2. ⁸ G/TBT/N/COL/121, G/TBT/N/COL/121/Add.1, G/TBT/N/COL/121/Add.2, G/TBT/N/COL/121/Add.4.

alcoholic beverages (e.g., vodka, gin and liqueur) and asked for clarification. Moreover, fixing labels of origin could be problematic, particularly for low-volume imports; she suggested that for imported products, labeling in warehouses be explicitly accepted as an alternative to labeling at origin. In addition, the draft legislation continued to require the presentation of a quality certificate at the time of importation - she asked Colombia to clarify if the requirement was also applicable to locally produced goods. She also asked what treatment would be given to stocks of products legally imported into Colombia before the legislation entered into force, and whether they would be subject to the new requirements.

165. The representative of the United States acknowledged progress in discussions with Colombia but wished to highlight a few outstanding concerns. Colombia continued to use its chemical composition limits to define alcoholic beverages rather than the raw materials used for their production, which was standard international practice for traded alcoholic beverages. Also, Colombia had decided to maintain the three year minimum aging requirement for whiskey; this would negatively impact trade in blended whiskeys. Since neutral spirits were almost never aged, if those were added to straight whiskies the resulting blend would not meet the ageing requirement. Micro distillers in the United States that were able to age whiskey in less than three years (with different barrel technology) would also be excluded by this requirement. Could US whiskies be marketed in Colombia even if they did not meet the three year aging requirement given that in April 2011 Colombia had stated in a written communication that it accepted US sanitary registration on whiskies? He understood that Colombia was also considering revising the process to apply a health warning label to the bottle, and requiring all bottles to have a blue stripe through the brand label. If that was the case, could Colombia provide more information on the initiative and the basis for the blue stripe requirement.

166. The representative of <u>Colombia</u> said that his country had been transparent in the way the measure had been developed and that the modifications made to the measure were technical justifications based on international practice.

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

167. The representative of the <u>European Union</u> reiterated concerns about Korea's Good Manufacturing Practice Requirements for Cosmetics (KCGMP). It was the EU understanding that the Korean Food and Drug Administration (KFDA) was considering how to extend the KCGMP regime to foreign manufacturers or importers, to allow them to benefit from the preferential treatment therein and, in this regard, she asked for confirmation and more information as to how Korea would ensure the same treatment to domestic and foreign manufacturers – for instance, whether the KCGMP Regulation would be revised in order to allow foreign manufacturers or importers to apply for GMP inspection and, if so, how the Regulation would be implemented with respect to foreign manufacturers, given current resource constraints on the KFDA's side.

168. She also asked for confirmation that KCGMP was fully in line with the international cosmetics GMP Standard ISO 22716 with no substantial deviations; in the past Korea had indicated that the KCGMP was meant to be harmonized with ISO 22716., but there was yet no clarity whether the KCGMP was in any way different from the ISO standard In this context, the EU also reiterated its query whether the KFDA would accept the assessments performed or certificates issued by independent third parties proving compliance with the ISO 22716, or even consider self-certification by cosmetic manufacturers, as was the case in the European Union and other major cosmetics markets.

169. In addition, the EU asked Korea to provide more details with regard to the exact scope of the preferential treatment provided under the KCGMP Regulation – in the previous Committee meeting, Korea had indicated that this would imply an exemption from the requirement of conducting batch

tests and conducting quality management by lot number; however, as the text of the KCGMP Regulation was not very specific in this regard, the EU was concerned that there may be room for different interpretations at the implementation stage.

170. Lastly, the European Union had been informed that Korea was in the process of revising the Enforcement Regulation of the Cosmetics Act, in light of the revision of the Act adopted in June 2011. She expressed concern that the revision might eliminate or restrict the existing waiver of quality inspections for imported cosmetics in the territory of Korea, provided for by Article 8.2 and Article 9 of the current enforcement regulation. She asked for confirmation that these provisions would be maintained in their current form in the revised Enforcement Regulation, in accordance with the bilateral arrangements agreed to in the year 2000.

171. The representative of the <u>United States</u> shared the concerns raised by the European Union and, similarly, sought clarification on similarities between the Korean standard and ISO 22716. He was particularly interested in the information that Korea would recognize GMP certificates from foreign manufacturers, so that all manufacturers – foreign as well as domestic – could obtain such certification. In his view as Korean Pharmaceutical Traders Association (KPTA) had been in charge of certifying compliance to the standard, this appeared to create a potential conflict of interest. Since the GMP standard seemed to be based on the ISO standard, one alternative could then be to accept certification to that standard from an independent third party, instead of requiring a KPTA review.

172. Regarding the KPTA in particular: contrary to assurances provided in 2008, the KPTA continued to participate in customs clearance process for imported cosmetics and, in that capacity, was responsible for reviewing conformity assessment related (and other) documentation provided by US companies. While the United States understood that KPTA only required the frame formula (not the formula including percentages of ingredients), responses provided to US questions had been somewhat ambiguous and inconsistent and this situation was not reassuring to the US cosmetic industry. There appeared to a clear conflict of interest and the United States requested an explanation. He also invited Korea to review Article 5.2.4 which provided that confidentiality of information provided in connection with conformity assessment must be respected in a manner that ensured that legitimate commercial interests were protected.

173. The representative of <u>Korea</u> confirmed that KFDA was at that moment going through reviews so that KCGMP certification for foreign manufacturers could be made possible. In line with Article 2.1 of the WTO TBT Agreement, KFDA was proposing to give equal treatment to both domestic and foreign manufacturers of cosmetics through onsite inspection when importers applied for KCGMP certification. In this same vein he noted that domestic manufacturers required an independent KFDA certification even if they had third party certification from overseas certification bodies, proving compliance with the ISO standard – therefore foreign manufacturers were not being treated differently from domestic ones. Regarding import clearance, the submission of a frame formula and sales certificate (which had to be submitted if the product had been imported for the first time) to KPTA via EDI system was to confirm minimal requirements in order to access the Korean market. On the EU's last query on the article on existing exemptions, Korea indicated that, as already confirmed to the EU in their bilateral meeting, Korea was not planning to remove this exemption for importers from the text of the Regulation.

(xxix) China - Provisions for the Administration of Cosmetics Application Acceptance (G/TBT/N/CHN/730 and G/TBT/N/CHN/821)

174. The representative of the <u>European Union</u> acknowledged China's efforts in clarifying and streamlining the new requirements and dealing with the backlog of product applications. Regarding remaining concerns, the most significant one was about the registration of products containing new ingredients which had been initially hampered by the lack of guidelines on the definition of a "new"

ingredient. On 8 June 2011 China had notified a set of guidelines on the requirements for application and evaluation of new ingredients and the European Union had provided written comments (22 September 2011). The European Union had welcomed the issuance of the guidelines which would eliminate existing hurdles in registration and grant impetus to the approval process of cosmetics. However, concerns remained: with regard to the treatment of complex ingredients commonly used; the possibility to omit certain required information, such as molecular weight structure in the case of naturally extracted ingredients; the acceptance by the China State Food and Drug Administration (SFDA) of the internationally used mutagenicity tests. She asked whether the guidance document would be applied to pending ingredient and product applications made before the entry into force of the guidelines on 1 July 2011.

175. The representative of Japan supported the EU statement. In addition, he noted that several widely-used cosmetic raw materials originating from minerals with various surface treatments, as well as plant extracts which were mixtures of several substances existed. Based on international practices, safety assessments needed to be conducted. He requested to review the application of the said guidelines. The Article 3 Clause 3 of the guidelines require a summary and flow chart of the manufacturing process for new ingredients. Some of examples requested detail information related with manufacturing process including reaction process and reaction temperature etc., these are industrial properties and know-how of the applicants. He also requested to review the scope of publication for the newly examined ingredients, not to disclose information related with industrial properties etc. The SFDA made public not only the name of the two new ingredients of which examination had been completed, but probably a part of application document as well. Japan also requested clarification, or feed-back, in terms of applications "examination postponed" for new ingredients submitted prior to the implementation of the measure at issue.

176. The representative of <u>China</u> said that the Guidance of Application and Evaluation for the New Cosmetics Ingredients had been notified to the TBT Committee in June. The SFDA had solicited public opinion several times on cosmetics manufacturers including those from the European Union and Japan, and indeed adopted some of their advice. After the release of the Guidance, the SFDA had carried out fruitful trainings for foreign and domestic cosmetics manufactures. At the moment, the application and evaluation of a new cosmetic ingredient was proceeding smoothly. In respect of Article 2.2 of the TBT Agreement, he stressed that the objective was to strengthen the regulation for cosmetics as consumers around the world were now paying more and more attention to the safety of cosmetics, especially after the safety problems that emerged with cosmetics in particular with child bathroom products and talcum powder in 2009. There was no difference in the way the guidelines affected domestic and foreign manufacturers.

(xxx) Ecuador - Certification of Ceramic Tiles (Resolutions 17 and 18 of CONCAL)⁹

177. The representative of the <u>European Union</u> referred to the Add.1 which had informed Members of significant modifications to the originally notified conformity assessment procedure. Changes had been adopted on 17 December 2010 and had entered into force on 19 January 2011; there had been no notification at a draft stage even though the changes were significant. She understood that Ecuador no longer accepted suppliers' declarations of conformity (SDoC) from enterprises certified according to ISO 9001 as this standard was not product related and therefore not, according to Ecuador, an appropriate tool for certifying requirements for ceramic tiles. She noted that certification according to ISO 9001 had the objective of providing authorities with assurance that the manufacturer possessed an appropriate quality management system. She asked why SDoC had to be changed into a system of third party certification (in the European Union ceramic tiles were not subject to mandatory third party certification, even though an adequate level of safety was ensured). As an alternative, would Ecuador consider accepting tests conducted in accordance with the ISO

⁹ G/TBT/N/ECU/63, G/TBT/N/ECU/63/Add.1, G/TBT/N/ECU/63/Add.2.

standard 13006? She enquired if such tests could only be recognized if they were conducted by certification bodies recognized by the Accreditation Body of Ecuador of whether tests conducted by laboratories accredited by ILAC/IAF would be recognized? Ecuador had previously mentioned that it had started to increase the number of laboratories and certification bodies – had more such bodies been recognized since the previous TBT Committee Meeting?

The representative of Ecuador said, regarding the acceptance of ISO 9001 certification, that 178. the ISO and IAF themselves had determined that ISO 9001 accredited certification did not imply that the organization was providing a superior product although the product itself was certified as meeting the requirements of an ISO standard or specification. This meant that ISO 9001 certification was not the most appropriate tool to measure the technical qualities of a specific product, ISO 9001 certification was needed to ensure the trustworthiness of the *management* system of the organization. Regarding SDoC, Ecuador had seen cases where compliance with ISO 9001 had nevertheless resulted in several problems with the products at issue. Tests conducted in line with ISO 13006 by accredited laboratories were recognized in Ecuador in line with Article 26 paragraph 2 of the Ecuadorian Ouality System Law. Certificates of conformity were recognized under Article 1 paragraph (a) of Resolution 018 of Ecuador's National Quality Council, if the certificate was accredited and recognized by OAS and their period of validity was one year and they related to imports of products carried out during the period of validity and were in line with Article 9 of Resolution 010 of CONCAP. However. he stressed that the certificates of recognition INEN 1 under ISO 9001 were no longer valid since the deadline had lapsed. In conclusion, the representative of Ecuador stressed that the measure was not trade restrictive: this was demonstrated by the fact that for the period of January to April 2010, 7.6 million USD worth of imports had been registered, while for the same period in 2011 imports had amounted to 15.5 USD, which was a 108 per cent increase in imports.

(xxxi) Australia – Tobacco Plain Packaging Bill 2011 (G/TBT/N/AUS/67, G/TBT/N/AUS/67/Add.1, G/TBT/N/AUS/67/Add.2)

179. The representative of <u>Ukraine</u> reiterated his delegation's concerns about the proposed legislation, noting that if enacted into law as drafted, the plain packaging requirements would violate a number of Australia's WTO obligations, including under the TBT Agreement. He noted that the Tobacco Plain Packaging Bill 2011 and the accompanying Trade Mark Amendments Bill 2011 passed the House of Representatives of the Australian Parliament in August 2011 without any substantive amendments, and passed the Senate on 10 November 2011, again without any substantive amendments that would, in his delegation's opinion, render the legislation compatible with Australia's obligations under the WTO. Among the technical amendments was a provision to delay by five months the effective date for compliance by foreign manufacturers until 1 December 2012. Following approval by the Senate, the legislation would soon become law in Australia. His delegation regretted this development, but hoped that Australia would still be able to ensure conformity between the legislation and WTO requirements.

180. While WTO Members could implement domestic measures they deem appropriate for the health and welfare of their citizens, it was also the right of other WTO Members to question whether such measures were consistent with the provisions of WTO Agreements, and to challenge such measures under the WTO's dispute settlement system. As stated by his delegation at the recent TRIPS Council meeting, the Australian plain packaging measures were highly controversial and of concern not only to Ukraine, but to many governments, intellectual property owners, and business groups, both within Australia and around the world. Ukraine made a written submission to the Australian TBT Enquiry Point and also to the Australian Senate Legal and Constitutional Affairs Committee. In the latter submission, Ukraine expressed its regret that the Australian Government had provided no substantive responses to Ukraine's questions and concerns regarding WTO consistency, or effectiveness, of the proposed plain packaging measures. In this submission, his Government urged the Australian Senate to amend the law to ensure conformity with Australia's WTO obligations; this

unfortunately appeared not to have been the case. Ukraine had only received an update on the status of the measures without any substantive explanation or justification for the measures.

181. He reiterated that the Australian legislation was more trade-restrictive than necessary to fulfil its stated objective and, as such, was contrary to Article 2.2 of the Agreement. The effect of the legislation would be to remove all distinguishing designs, logos, colours, and other similar marks from the packaging of branded tobacco products. This would commoditize the appearance of tobacco product packaging, making it virtually impossible to identify and recognize specific branded products, therefore making it near impossible, for foreign manufacturers new to the Australian market, such as Ukrainian manufacturers, to enter it. The potential adverse impact on trade in tobacco products with Australia was significant. While, his delegation appreciated Australia's review of its internal process regarding this measure, and its willingness to seek public comments, it deeply regretted that trade-related committees in the Australian parliament had not been given the opportunity to review the measure, and that the measure had not been modified to ensure WTO consistency. Ukraine reserved all its WTO rights in this matter.

182. The representative of the <u>Dominican Republic</u> expressed concerns about Australia's measure. 10

The representative of the European Union referred to previous comments made, and noted her 183. delegation's support for Australia's objective of protection of human health. The EU was in the process of revising its Tobacco Products Directive, and plain packaging or other limitations on packaging were among the possible future policy options being considered in the on-going impact assessment. She thanked Australia for its replies to the questions raised by her delegation but had further questions. First, when did Australia intend to make public all comments received in the TBT notification process? She reiterated her delegation's request for a written reply to its comments and questions on Australia's notification sent in June 2011, and also requested that Australia include a list of research evidence and other relevant background material used in the legislative process. She recalled the importance of an efficient and effective handling of comments, which included responding to written comments in writing. Second, had Australia evaluated other alternative legislative solutions to plain packaging, and why these solutions had been considered less effective for achieving the legitimate health objective pursued. Finally, she appreciated the information recently received from Australia on the state of play of the draft measure and the timeline for its future implementation, and stressed the need for sufficient time to be provided to economic operators to adapt to the new requirements, once the final measure was adopted.

184. The representative of <u>Mexico</u> sought information on the status of its comments submitted on 31 May 2011 and 22 July 2011; he formally requested a reply from the Australian Government on these comments. He reiterated his delegation's request for scientific and technical information demonstrating that plain packaging would reduce numbers of smokers in Australia, and explaining how obligations under Articles 2.2 and 2.4 of the TBT Agreement were respected in this measure. Had an analysis of less trade-restrictive regulatory options that could help to achieve the objective pursued by the legislation been conducted. While his delegation shared the objectives, he asked Australia to explain how it took into account the particular circumstances of Mexico as a developing country, and how it would afford special and differential treatment under this legislation.

185. The representative of <u>Nigeria</u> believed that this measure related to branding and its effects on both the market and the consumer. She highlighted several elements that were related to ensuring effective consumer protection, such as brand identity, protection against product imitation, confidence and trust in a product and finally, product description. Consequently, although Nigeria appreciated

¹⁰ See: G/TBT/W/346, 1 December 2011.

Australia's efforts towards protecting consumer health, the representative stressed the need to avoid causing confusion in the market and for consumers.

186. At the October Meeting of the TRIPS Council, her delegation had described the manufacturing facilities in the tobacco sector which generated substantial economic activity, tax revenue and employment in Nigeria. Tobacco provided employment and income to many Nigerian farmers, and her delegation was therefore concerned about the systemic implications of the Australian measure, and its direct and indirect commercial consequences for the national economy. At the TRIPS Council, her delegation had observed that the Bill was inconsistent with Australia's obligations under the TRIPS Agreement, was more trade restrictive than necessary to fulfil legitimate health objectives, and was contrary to the provisions of Article 2.2 of the TBT Agreement. The legislation also failed to take into account adverse impacts on developing countries as required by Article 2.13 of the TBT Agreement. While the Australian Government had asked the Australian Senate to consider certain technical amendments to the legislation regarding entry into force, the latter had not considered any substantive amendments. Her delegation sought information on the status of the legislation, and the intentions of the Australian Government given the numerous concerns raised by Members. She urged Australia to live up to its WTO obligations.

187. The representative of <u>Colombia</u> highlighted two documents relevant to this measure¹¹, and reiterated previous concerns that the stringency of the measure in question may adversely affect the protection of other legitimate objectives recognised by the TBT Agreement, namely the prevention of deceptive practices and misleading consumers. The removal of differentiating criteria would prevent consumers from identifying their preferred products.

188. The representative of <u>Chile</u> shared concerns raised by other Members and said that, while her delegation was not against the legitimate public policy objective pursued by the measure, there was concerns that the regulation was more trade-restrictive than necessary. She requested information from Australia on when it would reply to comments received, and whether they were taken into account. She also requested continued exchange of information on this matter.

189. The representative of <u>Honduras</u> understood that the Australian Senate adopted the Tobacco Plain Packaging Bill on 10 November 2011. Although Honduras recognized that the aim of the measure was to protect health, it was of systemic concern to his delegation because it ran contrary to WTO Agreements. Many international undertakings and intellectual property organizations had also lodged concerns with the measure, in particular in relation to geographical indications, marks of origin, trademarks, designs, and copyrights, among others. Although the Australian measures had an obvious health objective, they would create unnecessary barriers to international trade because they were more trade-restrictive than necessary to attain the objective pursued, having regard to the risks that non-fulfilment would create. They therefore infringed upon Article 2.2 of the TBT Agreement. He explained that the Australian measures were "technical regulations" because they established characteristics of products, such as their packaging. However, they constituted a significant restriction on trade because they made it difficult, if not impossible, for brand-name products to penetrate the Australian market, creating a disincentive to export such products to Australia.

190. Given that there was a lack of persuasive evidence that the measures would help in attaining the health objectives pursued, they constituted an unnecessary obstacle to trade. In fact, the measures might have unwanted consequences that undermined achievement of the health objectives, such as, the uniformity in goods resulting in an increase in unlawful trafficking and price suppression, which

¹¹ G/TBT/N/AUS/67/Add.1, notified on 3 October, on the regulation of tobacco product packaging in Australia, specifically in relation to proposed new graphic health warnings; the second document is G/TBT/N/AUS/67/Add.2, notified on 4 October, on the plain packaging requirements for non-cigarette tobacco products.

could lead to an increase in smoking. Moreover, there were equally effective and less trade-restrictive measures by which those objectives could be attained. Finally, he considered that Australia was creating obstacles to exports from developing countries, like Honduras, which was contrary to Article 12.3 of the TBT Agreement.

191. The representative of <u>Norway</u> said that public health in general, and tobacco control specifically, were topics very dear to Norway. Norway was in the process of implementing revisions to its tobacco control strategy, and a new five-year strategy would be implemented from 2012-2016. Her Government was, thus, interested in following similar processes under way in other jurisdictions. Implementation of the WHO Framework Convention on Tobacco Control (FCTC) could make the greatest single contribution to preventing non-communicable diseases, and implementation of FCTC provisions was thus a pressing public health issue. She noted that most WTO Members, including the majority of those who have asked for the floor under this agenda item, are parties to the FCTC.

Her delegation did not see any contradictions between regulating tobacco products and other 192. international obligations, including the mutually supportive rights and obligations of the FCTC and the WTO. It was within the rights and obligations of each WTO Member to regulate to take into account the legitimate objectives and health needs of its people. Tobacco control policies and preventive measures, such as that proposed by Australia, pursued the legitimate objective of protecting public health by reducing smoking. In fact, Article 11 of the FCTC and the accompanying guidelines for implementation explicitly mentioned plain packaging as one of the options to achieve the objective of health protection. Regarding the scientific evidence or basis for these kind of measures, she quoted the WHO statement made at the June 2011 TBT Committee meeting: "a strong and irrefutable body of evidence had demonstrated that product packaging has traditionally served as one of the tobacco industry's central vehicles in initiating and maintaining addiction to the lethal products among consumers". Norway believed that the regulation of tobacco product packaging was a vital measure for reducing tobacco consumption, and signalled its support for Australia's right to introduce plain packaging as a measure designed to fulfil its FCTC obligations to protect public health, while at the same time being in line with WTO commitments. She trusted that the measure would be implemented in such a way that it complied with all of Australia's international treaty obligations. Finally, her delegation would continue to follow this case with interest, and would continue to defend the interest of public health while complying with its international obligations.

193. As an important tobacco producing and exporting country, the representative of <u>Turkey</u> expressed caution about the Australian Tobacco Plain Packaging Bill. A full impact assessment of the measure, both the intended health benefits and the impact on trade in tobacco, should be conducted before further steps were taken. His delegation would follow developments in this measure closely.

194. The representative of <u>Uruguay</u> reaffirmed its support for Australia's measure. In this regard, he quoted Article XX of the GATT. Uruguay considered it a general principle that the protection of public health fell within the sovereign authority of States. Every country was entitled to legislate in its public interest, as had recently been recognized in the Punta del Este Declaration on the implementation of the WHO FCTC. Australia made efforts so as to not infringe upon its international obligations while defending its public health interests, and Uruguay endorsed the explanations and justifications provided by Australia. The measure proposed by Australia should raise no objections since it was consistent with the provisions of WTO Agreements.

195. The representative of <u>New Zealand</u> welcomed Australia's decision to implement plain packaging for tobacco products. The negative effects of smoking could not be underestimated; in New Zealand, smoking was one of the leading preventable causes of early death. She noted Australia's assurance that it had paid close attention to its WTO obligations in developing its proposal. The TBT Agreement recognised that no country should be prevented from taking measures necessary to protect human health. Numerous scientific studies demonstrated that plain packaging of tobacco

products could lead to positive public health outcomes by reducing the attractiveness and desirability of smoking, and increasing the prominence of public health warnings. As part of a suite of tobacco control measures, plain packaging could contribute to reducing smoking rates.

196. The representative of <u>Indonesia</u> had previously submitted her delegation's concerns. At the June 2011 TBT Committee meeting, Australia had clarified that the main purpose of this measure was to improve public health, and had argued that packaging could influence cigarette consumption decisions. For this reason, Australia made the assumption that the implementation of plain packaging could reduce cigarette consumption. However, her delegation requested that Australia provide further information in this respect, and respond in writing to questions raised by Indonesia.

The representative of Zambia echoed concerns regarding Australia's measure, which had 197. implications for Australia's obligations under the TBT and TRIPS Agreements. On the TBT side, plain packaging of tobacco products, if implemented in the form as contained in this legislation, would unjustifiably infringe upon Australia's obligations under the TBT Agreement. Article 2.2 of the Agreement provided that technical regulations, such as in this legislation, must comply with two requirements so as not to constitute unnecessary obstacles to international trade: they must pursue a legitimate objective, and they must not be more trade restrictive than necessary to fulfil the objective. Mandatory plain packaging was a disproportionate response to the stated health objectives of the legislation. While the TBT Agreement acknowledged human health as a legitimate objective for technical regulations, it also provided guidelines to ensure that measures were not more trade restrictive than necessary. There was no credible evidence that tobacco plain packaging, and in particular the measures identified in Clause 31 of the draft bill, would achieve any legitimate health related objective or improve public health. Her delegation considered the research presented by Australia in support of the legislation speculative, as it relied on asking individuals what they would do in a given hypothetical situation. The legislation assumed that changes in packaging would lead to changes in tobacco product consumption behaviour.

Zambia believed that there were less trade restrictive alternatives to achieve the stated public 198. objectives. The stated health objectives of the legislation would be best achieved through alternative regulatory solutions that were consistent with Australia obligations under the WTO, including those in Article 2.2 of the TBT Agreement. Packaging was fundamental to consumer choice and brand navigation in a competitive market, particularly where other channels of interaction with consumers such as advertising and point of sale display were restricted. Indeed, packaging conveyed guarantees of origin and quality of a given product. Australia's legislation could expose consumers to more harmful tobacco products due to the proliferation of counterfeit products whose quality was not controlled by any regulatory body. Due to the lack of credible evidence that the assumed public health objectives would be achieved by plain packaging, and to the availability of less trade restrictive alternatives measures, her delegation believed that Australia's measures had implications for its obligations under the TBT Agreement. Specific trade concerns relating to tobacco had become more frequent, and would continue to be discussed as individual Members adopted measures aimed at meeting national objectives whilst fulfilling regional and multilateral obligations. To promote coherence and coordination at the national level and to ensure the supportiveness of obligations undertaken in various regional and multilateral fora, she proposed that the TBT Committee organise a joint meeting with WHO FCTC to exchange information; this would address tobacco trade concerns in a holistic manner.

199. The representative of <u>El Salvador</u> shared the concerns expressed by the delegations of Ukraine, the Dominican Republic, the European Union and Mexico. El Salvador recognised and endorsed the objective of protection of human health, as explained by Australia. However, his delegation maintained the view that Australia's measure went beyond the parameters of international regulations and guidelines in this area. He requested that this measure remain under consideration by

the TBT Committee to ensure that Australian authorities give due consideration to any challenges posed by the measure.

The representative of Zimbabwe supported concerns raised by Ukraine, the Dominican 200. Republic, Nigeria and Zambia. His delegation took note of the announcement by the Minister of Health and Aging that plain packaging would remove the last channel of tobacco marketing, as part of a government strategy to reduce the toll of 15,000 annual tobacco-related deaths in Australia. While he expressed appreciation for Australia's efforts to protect public health as per its sovereign right; he expressed concern that the proposed measure was more trade restrictive than necessary to achieve the stated policy objective. Although the WHO FCTC provisions encouraged the use of plain packaging to control tobacco consumption, the measure was not supported by scientific evidence, and was not consistent with the TRIPS and TBT Agreements, in particular, Articles 2.2 and 12.3 of the TBT Agreement in view of the trade restrictive nature of the legislation, and the adverse impact on exports. Article 12.3 of the TBT Agreement required Members to ensure that technical regulations did not create unnecessary obstacles to exports from developing country members, like Zimbabwe, where some 200,000 farmers and their families depended on tobacco production for their livelihood. Also, if passed, the bill would violate the Paris Convention for the Protection of Intellectual Property. He urged Australia to take into consideration the views and concerns raised by Members so as to come up with alternative measures that provided the right balance between public health objectives and WTO obligations, and to implement measures that were supported by relevant information and scientific evidence. Finally, he requested that Australia provide responses to questions raised by delegations at the October 2011 TRIPS council meeting.

201. The representative of <u>Japan</u> said his delegation would continue to follow this measure's progress because the number of different arguments indicated that this was an important issue from the point of view of compliance with the TBT Agreement.

202. The representative of <u>Cuba</u> noted that the Australian Senate approved the Bill under consideration on 10 November 2011. Her delegation had submitted several questions¹² to which it had not yet received a reply. On 24 October 2011, Cuba's TBT enquiry point sent a reminder to Australia; no reply had yet been received. Her delegation acknowledged the damage that tobacco products caused to human health and the responsibility of governments to protect their citizens' health, and Cuba was adopting measures to this end. However, Australia could have adopted a less trade-restrictive measure than plain packaging. It would have been possible to apply a measure that neither nullified intellectual property rights nor raised the threat of counterfeit goods being marketed. In addition to these general concerns, her delegation learned on 30 September 2011 that the legislation would be applied to products other than cigarettes, especially cigars and twisted tobacco, sold by Cuba on the Australian market. These products were not marketed in a single format such as a cigarette box. Instead, there were over 300 different forms of packaging. Such a variety of packaging meant that application of the Australian measure would hugely increase marketing costs to Cuban exporters in the Australian market, threatening the continued export of these products.

203. Cuban concerns on increased counterfeiting had been expressed to Australia, through various channels. Cuban cigars had been the targets of counterfeiting over many years and in many markets, forcing the industry to adopt various measures to minimize this risk. These measures were not advertising measures. Rather, their aim was to indicate origin and prove the authenticity of the product. Plain packaging would defeat those measures; it would no longer be possible to use the "Habanos designation of origin" seal, or the "National Guarantee of Origin" seal, used by Cuba on all its cigars for almost 100 years. Nor would it be permissible to use the ring on the upper part of each cigar bearing the brand name and place of origin, La Habana, Cuba. Furthermore, these products were aimed at a market segment completely different from that of cigarettes. Cigars were for the

¹² G/TBT/W/338 dated 9 June 2011.

most part consumed by people over 40 years of age with high purchasing power. Moreover, they were consumed on an occasional basis, and were often purchased for collections and not in order to be smoked. These concerns were lodged with the Australian Government, but she was concerned they were not taken into account prior to the adoption of the Bill.

It was therefore vital that Australia present scientific evidence demonstrating the link between 204. the measure applied and the specific health objectives for cigars and twisted tobacco. Hitherto only studies on cigarettes had been presented, and the results of such studies could not be extrapolated and applied to a hugely different market segment such as that for cigars. Australia needed to respond to questions raised, especially in relation to the analysis used to quantify the impact of the measure on trade from developing countries like Cuba, where tobacco products were a significant part of the economy and accounted for thousands of families' livelihoods. Moreover, was it possible to prevent illicit trade in counterfeit products? In addition, she endorsed Zambia's proposal for a debate on achieving better consistency between the implementation of the FCTC and WTO provisions. According to the Cuban national authority, over 80 measures had been notified to the TBT Committee (including at least 23 since 2008) associated with the implementation of various provisions of the WHO FCTC, and there was significant variability and differences in the stringency of requirements between notifying countries. Article 2 of the FCTC encouraged Parties to implement measures beyond those required by the Convention and its protocols. As a result, there was a wide variety in the types of measures applied, with some measures more restrictive than others. 38 notifications with very dissimilar requirements had been presented relating to labelling and health warnings, ranging from the minimum requirements laid down in the Convention, namely that warnings and messages be rotated and cover no less than 30 per cent of the principal display areas, to the maximum restriction now applied by Australia in the form of plain packaging.

205. Although this wide range of rules among markets was consistent with the legitimate objectives of health protection under the FCTC, it was causing serious competition problems for traders of these products, especially in developing countries which were required to bear high adjustment costs to be able to trade on different markets with different requirements. Tobacco was significant to tobacco growing countries' economies, representing thousands of families' livelihoods. She proposed that the Secretariat review notifications related to implementation of the FCTC.

The representative of Nicaragua expressed concerns with Australia's measure, which would 206. contravene provisions of the TBT and TRIPS Agreements. These had been expressed in the TRIPS Council. Adoption of this measure would be incompatible with Article 2.2 of the TBT Agreement, which applied because plain packaging was a technical regulation. In the absence of any evidence that this type of packaging influenced consumer behaviour, the imposition of this technical regulation would unnecessarily restrict trade without attaining the legitimate objective pursued by Australia, namely the protection of its population's health, the validity of which she did not dispute. Article 12.3 of TBT Agreement provided for Members to ensure that their technical regulations did not constitute unnecessary obstacles to exports of developing country Members. Through this measure, Australia would be creating unnecessary obstacles to market access for products from developing countries, and would therefore be breaching its WTO commitments by establishing unjustifiable new measures governing access to its market. The FCTC guidelines merely recommended the use of plain packaging; they did not require Parties to implement it. As a producer of tobacco as a raw material, his delegation was concerned this Bill would damage Nicaragua's economic interests, where production in this sector generated numerous direct jobs and supported many families, attracted ongoing investment, and was a source of foreign exchange revenues. He urged Australia to revise the Bill, so that in exercising its right to apply health protection measures, it did not prejudice Nicaragua's rights under the TBT and TRIPS Agreements.

207. The representative of <u>Jordan</u> said his delegation supported Australia's objective of protecting public health and deterring minors from smoking. However, it believed that this technical regulation

was in breach of Article 2.2 of the TBT Agreement. The TBT Agreement required technical regulations to not be more trade restrictive than necessary to pursue a legitimate objective. Since there was no evidence that plain packaging influenced consumer behaviour, imposing this technical regulation would restrict trade without doing anything to achieve a legitimate objective. Plain packaging had not been introduced anywhere in the world; this meant there was no real evidence to demonstrate that it would be effective and achieve Australia's stated aims. His delegation further believed that the bill was in breach of Article 12.3 of the TBT Agreement. In light of the investment needed to comply with the bill, his delegation requested that Australia reconsider its approach in favour of less restrictive alternatives. Finally he reiterated support to all countries in their efforts to adopt regulations to protect health objectives; however, developments in Australia could set a damaging precedent that other countries may follow by implementing unsound and ineffective health policies that violate international obligations. If this type of regulation, which undermined the legitimate rights of brand owners, were to take hold in other product categories, the impact on international trade would be even greater.

208. The representative of <u>Hong Kong, China</u> noted a Member's right to implement measures necessary to protect human health. Australia had given a rather substantive account at the last meeting as to how it had developed the legislative proposal in question, reflecting the scientific evidence it had found over the years. In light of the trade concerns expressed by a large number of Members, his delegation trusted that Australia would continue to give due consideration to its obligations under the TBT Agreement, with a view to ensuring that the enactment and implementation of the proposal would not be more trade restrictive than necessary to fulfill its legitimate objectives. Consultations and dialogue with affected Members would be helpful in easing and minimizing the impacts in the course of its implementation. His delegation would closely monitor this in the WTO.

209. The representative of the <u>Russian Federation</u>, speaking as an observer, said his delegation recognised the health risk associated with tobacco product use; Russian experts participated in activities of the appropriate international forum with the aim of formulating the international framework regarding trade in these products. His delegation considered the Australian measure to be more trade restrictive than necessary and asked Australia to evaluate alternative measures for achieving the public health objective, and to provide additional information regarding the link between plain packaging and reduced consumption of tobacco products.

The observer of the World Health Organization reiterated what had been stated concerning 210. public health evidence in the context of the plain packaging issue at the June 2011 TBT Committee meeting.¹³ He added that economic costs of tobacco use were equally as devastating as the public health costs. Though the tobacco industry routinely cited the economic contribution of tobacco, in reality, tobacco use placed an enormous financial burden on countries, in addition to the fact that tobacco and poverty were inextricably linked at the individual level. The costs of tobacco use encompassed increased health-care costs, lost productivity due to illness, premature death, and widespread environmental damage. As tobacco consumption rates and tobacco-related illnesses increased in developing countries so did tobacco-related healthcare costs. Conservative estimates suggested that tobacco imposed a US\$500 billion drain on the world economy, exceeding total annual health expenditures in low and middle-income countries. Further, the economic burden of NCDs, with tobacco representing the largest risk factor, was staggering. Recent macroeconomic simulations suggested that over the next two decades cardiovascular disease, chronic respiratory disease, cancer, and diabetes, would cause a cumulative output loss of more than US\$30 trillion, representing 48 per cent of global GDP in 2010. This, in turn, would push millions of people across the planet below the poverty line.

¹³ G/TBT/M/55, paras 33-46.

211. He informed the Committee that the impact of tobacco on NCDs on both public health and national economies was highlighted at the recent United Nations General Assembly High Level Meeting on the Prevention and Control of NCDs, held in September 2011 in New York. At that meeting, Heads of States adopted a political declaration which recognised the fundamental conflict of interest between the tobacco industry and public health, and wherein member states unanimously committed to advancing the implementation of multi-sector, cost effective, population-wide interventions in order reduce the impact NCD risk factors. The WHO believed that the implementation of tobacco plain packaging, representing a legitimate tobacco control measure, would have a substantial impact on tobacco consumption, was in the spirit and intent of the UN High Level Meeting, and was in accordance with international legal obligations under the WHO FCTC.

Concerning the Framework Convention on Tobacco Control, the observer explained that the 212. FCTC, in force since 2005, was negotiated under the auspices of the WHO in response to the globalization of the tobacco epidemic. Its provisions were based on evidence and had been specifically designed by the international public health community to effectively address the tobacco epidemic. Like other international legal instruments, States party to the FCTC undertook certain obligations pursuant to its implementation. Since the June 2011 TBT Committee meeting, the number of States that were party to the Convention had risen to 174; only 12 of the 153 WTO Members were not party to the FCTC. The WHO FCTC contained a number of provisions relevant to plain packaging of tobacco products. Article 3 set out the collective objectives of the Parties in establishing the FCTC, and Article 5 established general obligations on Parties, including, *inter alia*, the obligation to "develop, implement, periodically update and review comprehensive multi-sectoral national tobacco control strategies, plans and programmes in accordance with" the FCTC. Recognition by Parties of the importance of comprehensive, multi-sectoral measures in the fight against the global tobacco epidemic was a theme that recurred throughout the Convention and its obligations, and that comprehensive, multi-sectoral approaches ensured that tobacco control measures contained in the FCTC were most effective.

With respect to plain packaging for tobacco, Article 11 of the Convention required Parties to 213. adopt and implement effective measures in respect of the packaging and labelling of tobacco products, including health warnings and other appropriate messages. According to the most recent reports on implementation, which were required pursuant to Article 21 of the Convention, 65 per cent of Parties (88 States) had banned descriptors on packaging and labelling that were misleading, deceptive or likely to create an erroneous impression of the product. Furthermore, 82 per cent of Parties (111 States) had adopted policies requiring tobacco product packaging to carry health warnings describing the harmful effects of tobacco smoke. Finally, 74 per cent of Parties (100 States) had introduced measures to ensure that health warnings were large, clear, visible and legible. After five years of implementation, Article 11 attracted one of the highest implementation rates among Parties. Another specific provision of the FCTC was Article 13, which required Parties to undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship. The comprehensive ban must be read in light of the broad definition of "tobacco advertising and promotion" which, according to Article 1(c) meant "any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly." Additionally, the Guidelines for the implementation of Article 13 adopted by consensus by the Parties included "packaging and product design features" on the indicative list of forms of advertising, promotion and sponsorship. The most recent reports indicated that 55 per cent of Parties (74 States) had introduced a comprehensive ban on tobacco advertising, promotion and sponsorship.

214. Finally, information submitted by Parties allowed for an analysis of the progress in implementation of various obligations under the Convention. Between one-third and one-half of reporting Parties registered progress in introducing stronger health warnings and in banning advertising, promotion and sponsorship. This indicated that Parties were undertaking progressively more stringent tobacco control measures in keeping with their Article 11 and Article 13 obligations.

The Conference of the Parties (COP) of the FCTC, met for its 4th session in November 2010. At that session, the COP adopted the Punta del Este Declaration¹⁴ regarding public health policy, international trade and the activities of the tobacco industry. The declaration reiterated the firm commitment of Parties "to prioritize the implementation of health measures designed to control tobacco consumption" and made specific reference to Article XX(b) of the GATT and Article 2.2 of the TBT Agreement, including its reference to "protection of human health or safety" as a "legitimate objective". Regarding illicit trade in tobacco products, negotiation of the first protocol, the draft Protocol to Eliminate Illicit Trade in Tobacco Products, was in its final stages, and the last session was planned for 2012. Lastly, work was continuing with respect to the identification of economically sustainable alternatives to tobacco growing in relation to Articles 17 and 18 of the Convention.

215. The representative of <u>Honduras</u> informed the Committee that Honduras was a member of the WHO and a Party to the FCTC. He understood and respected the principal objective of the FCTC, namely to reduce tobacco consumption in order to address health-related matters. This was embodied in its national law. Moreover, his delegation had conducted campaigns, regulated packaging and had reduced the number of smokers. However, in these processes, Honduras had always complied with its WTO commitments. He asked the WHO if its statements were consistent with WTO Agreements and with the trade perspective. Could the WHO indicate if the studies it referred to on plain packaging provided scientific evidence, or a clear scientific conclusion, that plain packaging would stop people from smoking cigars and cigarettes. If such evidence existed, he requested the WHO to circulate these studies, which should be scientifically conclusive, and not just provide inconclusive scientific evidence. If such studies did not exist, he asked that it be recorded that the WHO intervention was made from the public health perspective, and not from the WTO Agreements perspective.

216. The representative of <u>Mexico</u> said his country was a Party to the FCTC, and a member of the WHO, and he regarded the technical and scientific information presented by the WHO representative useful to the WTO and to the TBT Committee. However, he disagreed with the notions that an observer body was drawing conclusions as to the compatibility or otherwise of specific measures with WTO law, which was self-contained. The structures capable of ruling whether the measure was compatible with a Member's commitments were WTO panels and the dispute settlement mechanism. His delegation was not objecting to the WHO. Rather he objected to the important precedent that may be set whereby an international organization endorsed, in one direction or another, a measure taken by a WTO Member and argued its validity on the basis of WTO law. He hoped that other organizations would not be able to make similar statements to this or other WTO Committees in support of a particular measure; that debate was better suited to other forums.

217. The representative of the <u>Dominican Republic</u> shared the concerns of Honduras and Mexico. His national authorities had also imposed strict restrictions in terms of advertising and taxation of cigarette consumption. However, WHO regulations were one matter, and regulations of other multilateral bodies, such as the WTO, were another matter. His delegation was concerned about a precedent whereby the TBT Committee may be discussing other items that the WHO viewed as dangerous to health. On that basis, existing regulatory constraints of an organization such as the WTO may be infringed upon by another multilateral organization.

218. The representative of <u>Zimbabwe</u> reminded the Committee that Zimbabwe was a member of both the WHO and the WTO. He expressed concern that the WHO's intervention seemed to insinuate that what Zimbabwe said at the WTO was inconsistent with the Heads of State declaration (of the United Nations General Assembly High Level Meeting on the Prevention and Control of NCDs). He and his fellow delegates represented those same countries involved in the declaration. Discussions in this Committee were related to obligations under the TBT Agreement. His delegation agreed with

¹⁴ FCTC/COP4(5).

Honduras that scientific evidence should be presented in an unbiased manner, rather than in a way to favour certain positions, which could inadvertently influence the discussion in the Committee.

219. The representative of <u>Australia</u> updated the Committee on the measure's status. The Tobacco Plain Packaging Bill 2011 and associated Trade Marks Amendment (Tobacco Plain Packaging) Bill 2011 were introduced into the Australian Parliament on 6 July 2011. Both Bills passed the House of Representatives on 24 August 2011 with no amendments. However, there was some delay in consideration of the Bills by the Australian Senate. As a result, amendments to the entry into force of the Bills were proposed in order to allow a longer lead time for implementation and to provide an additional two weeks for retailers to sell through any product in non-compliant packaging before retail offences commenced. Under the proposed amendments, most of the preliminary provisions that would have commenced on 1 January 2012 would now commence once the Bills had been passed by both Houses of Parliament and had been signed by the Governor-General. All tobacco products manufactured in Australia would be required to be sold in plain packaging by 1 October 2012, extended from the previous date of 20 May 2012. All other tobacco products would be required to be sold in plain packaging by 1 December 2012, extended from the previous date of 1 July 2012.

A further amendment to address a technical implementation issue relating to requirements for 220. the inside of cigarette packs was also proposed and passed by the Senate on 10 November 2011. The Bills would need to return to the House of Representatives for consideration of the amendments, which was likely to occur in the sitting week of 21 November 2011. With respect to the specific question of cigars, there was a consultation process underway regarding Plain Packaging for non cigarette tobacco products, including cigars. Her delegation was considering the submissions received, and intended to finalise relevant regulations by the end of 2011. Australia had been very open and transparent with its trading partners throughout the process of introducing this measure. In recent months, her delegation had met or offered to meet with all WTO delegations that raised this issue in previous meetings of the various Committees of this organization, in order to explain the purpose and details of the proposed measures and to provide detailed information in relation to questions raised. In addition, Australia's overseas posts had conveyed information to Ministries of Trade and Health in all WTO Members' capitals. Her delegation had provided a significant amount of written information in response to Members' concerns, both in hard copy and electronically and had made detailed statements in the TBT and other WTO Committees that responded to questions and issues. Therefore, it was unreasonable to claim that Australia had not responded to questions.

221. The Committee should keep this measure in perspective; while respecting the systemic issues, and she noted that Australia was a minor importer of tobacco products, and that Australia's imports represented a half of one per cent of global trade. Many of the Members that raised concerns exported almost no tobacco to Australia, and in some cases none. In recalling the purpose of the measure, namely promoting public health, she noted that 15,000 Australians die every year from smoking, 3 million Australians still smoke, and smoking cost over A\$31.5 billion every year. Her delegation was confident that, as part of a comprehensive package of tobacco reforms, this measure would make an effective contribution to reducing smoking, and thereby would reduce the health impacts of smoking on Australian individuals and the community at large. Tobacco packaging was one of the last remaining forms of tobacco advertising in Australia, and the plain packaging legislation was the next logical step in Australia's tobacco control efforts. The effect of the legislation would be that tobacco company branding, logos, symbols and other images that may have the effect of advertising or promoting the use of the tobacco would not be able to appear on tobacco products or their packaging. The brand name and variant name would be allowed on packaging, and she said that information which was required by other legislation or regulations, such as trade descriptions and graphic health warnings, would also be allowed to appear.

222. Plain packaging was designed to: reduce the attractiveness and appeal of tobacco products to consumers, and particularly young people; increase the noticeability and effectiveness of mandated

health warnings; reduce the ability of the tobacco product and its packaging to mislead consumers about the harms of smoking; and through the achievement of these aims in the long term, and as part of a comprehensive suite of tobacco control measures, contribute to efforts to reduce smoking rates. The proposed legislation was consistent with recommendations made to the Government by Australia's National Preventative Health Taskforce, which were based on extensive research and evidence that explored the impacts of tobacco packaging and tested the reactions of respondents exposed to different packaging options under experimental conditions. The weight of the evidence indicated that a plain packaging requirement, as part of a comprehensive suite of tobacco control measures, would help to reduce smoking rates. Guidelines agreed by the Conference of the Parties to the WHO FCTC in 2008 for the implementation of Articles 11 and 13 of the FCTC recommended that Parties consider the introduction of plain packaging.

223. With respect to alternative measures, plain packaging needed to be considered in the context of Australia's overall efforts on tobacco control, which spanned over 30 years. In this period, Australia had implemented a number of measures to reduce smoking rates: extensive and continuing public education campaigns on the dangers of smoking; age restrictions on tobacco purchase; pricing measures through excise and customs duties; comprehensive bans on tobacco advertising, promotion and sponsorship; bans on smoking in certain places to reduce the impact of second-hand smoking; bans and restrictions on the retail display of tobacco products; mandatory graphic health warnings on tobacco product packaging; and quit smoking' support services including free counselling and subsidised pharmaceutical products.

224. She added that Australia had been responsive to comments from trading partners and other stakeholders, and was fully committed to its international obligations, including its obligations under the TBT Agreement. Prior to the introduction into Parliament of the Bills, the Australian Government consulted widely with trading partners, including tobacco exporting developing countries, through a series of outreach meetings to explain the proposed measures. The comments received were taken into account and led to some changes to the Bill and draft regulations, where those changes were in line with the policy objectives. This included responding to concerns about the protection of the rights of trademark owners, with changes made to ensure their effective operation. Amendments to the Tobacco Plain Packaging Bill had been proposed to ensure the ability to register, and maintain registration, of a trademark. Additionally, a parallel Trade Marks Amendment Bill has been introduced to allow the Government to strengthen those protections should uncertainty arise.

225. Her delegation had also eliminated import offences for non-compliant tobacco products, in response to submissions received. This change would allow tobacco products to be imported into Australia in non-compliant retail packaging, and then be repackaged for retail sale in Australia. In this respect, the Bill required compliance with plain packaging requirements from the first point of sale (whether wholesale or retail) of imported products in the Australian supply chain. Regarding claims that Australia's plain packaging proposal would increase illicit trade in tobacco products, her delegation disagreed. Trade in illicit tobacco in Australia was low and her delegation did not expect this to change with the new measures. At present, counterfeiters had little trouble replicating branded tobacco packages, and, regardless, she stressed that smoking of any tobacco product, licit or otherwise, was fundamentally harmful to human health. Nevertheless, given expressed concerns, allowances had been made to ensure that protective markings could be used for anti-counterfeiting purposes. These included the use of unique alphanumeric code markings on each pack and cigarette stick, and covert markings in compliance with other aspects of the Bills.

226. She underscored that the proposed plain packaging legislation related only to tobacco products and retail packaging of those products. The Australian Government was not considering extending the measure to other products. Tobacco was a singular product, which caused extraordinary harm and required appropriate measures. She quoted the World Health Organisation:

"tobacco is the only legal consumer product that kills up to half of those who use it as intended and recommended by the manufacturer". She reiterated her delegation's commitment to Australia's international obligations, and assured Members that in framing this measure, Australia had paid full regard to obligations under the TBT Agreement and other WTO Agreements. Her delegation would ensure that the new policy was implemented in a manner that was consistent with those obligations.

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

227. The representative of <u>China</u> requested a clear timetable on the issuance of the supporting regulation in order to facilitate bilateral trade and improve transparency. He urged Korea to consider mutual recognition of test data as well as the classifications of Chinese laboratories, through cooperation at multiple levels including government and technical organizations. He suggested the recognition of test results issued under the EU REACH framework and similar frameworks so as to avoid repeated registrations, and multiple testing. In addition, this recognition would provide a faster approach for registrants having access to the EU market.

228. The delegate of the <u>United States</u> noted that the US industry had expressed serious concerns about some of the provisions of the proposal which would create significant changes to Korea's current chemical regulatory regime – and which would affect both producers and importers of chemicals in Korea. It was the US understanding that Korea had taken many of these comments into consideration and had made revisions to the proposed act. While acknowledging the considerations given to the comments regarding the potential effects of the proposal, he asked Korea whether any updates could be provided to the Committee on key issues raised by the United States and other delegations at the last meeting, in particular with respect to the proposed annual reporting requirements and the minimum tonnage threshold for pre-registration and registration of 500 mg.

229. The delegate of <u>Korea</u> confirmed that the Ministry of Environment was taking into account all the comments from various stakeholders and it had not yet been determined when the new legislation would be finalized. Once it passed in the National Assembly, a subordinate statute or enforcement ordinance would be proposed within a year. The Ministry of Environment would notify members when it was preparing to draft the subordinate statute and would invite comments from stakeholders at that time. With regard to the minimum tonnage threshold of half a tonne and the annual reporting requirement, the Ministry of Environment was positively considering whether to amend these provisions following consultations with the industries concerned. With regard to the question of which chemical substances would be subject to these regulations, studies were under way to determine which ones should take priority. The details would be set forth in the enforcement ordinance.

230. In response to some of the comments at the last TBT Committee meeting, she confirmed that the Ministry of Environment would publish a document in English explaining the procedures in detail so that foreign industries could comply without undue inconvenience. This legislation was in accordance with the provisions of the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which Korea adopted for substances on 1 July 2010. Beginning 1 July 2013, the GHS would also apply to mixtures. Regarding the submission of data using OECD software, she indicated that the Ministry of Environment would also assess the compatibility of the software with the Korean system. Furthermore, certain chemicals, such as those to be used solely for research and development, would be exempted from the new regulations. The enforcement ordinance would specify the list of exempted substances. Finally, she confirmed that according to the Ministry of Environment, if test data were reliable and met the standards prescribed in the applicable laws and guidelines, data produced abroad would also be accepted. When new tests were carried out, however, the OECD Good Laboratory Practices must be followed.

(xxxiii) Viet Nam – Conformity assessment procedures for alcohol, cosmetics, and mobile phones (Notice regarding the import of alcohol, cosmetics and mobile phones, No.: 197/TB-BCT (6 May 2011)

231. The representative of the United States recalled that Viet Nam had released a Ministry of Finance Document 4629 on the import of spirits and cosmetics and a Ministry of Industry and Trade Notice on the import of alcohol, cosmetics and mobile phones (on 7 April 2011 and 6 May 2011, respectively). Both notices, involving new conformity assessments procedures, appeared to have gone into effect on 1 June 2011. The United States was concerned that these measures were legally binding or created new requirements; they appeared to require specific quality control procedures, such as the submission of a quality control certificate and the designation of specific ports in charge of control. It was unclear how Viet Nam would ensure that domestic Vietnamese manufacturers of these products would undertake comparable procedures. The justification and criteria used to select some products and not others remained missing. Details of the product codes subject to the Notice 197 were also unavailable. The representative of the United States emphasized that although Viet Nam claimed that this measure did not create new requirements, US companies were facing compliance problems since procedures were not set out in writing. Details were also lacking on: quality control procedures; specificities for the quality conformity certificate; the identity of the body issuing the certificate; and, the standards used for the certification. It was also not clear why the quality control procedures had been limited to three ports. Obtaining a stamp and paying a fee at the consulate prior to shipment would not help ensure products quality or prevent counterfeiting, but only added unnecessary cost in delays for exporters.

232. The representatives of <u>Australia</u>, <u>Chile</u>, the <u>European Union</u> and <u>New Zealand</u> supported the statement made by the United States and noted that the measure would be monitored closely. It was also suggested that the measure be suspended until further clarification was provided. The representative of <u>Canada</u> expressed an interest in any further information that Viet Nam was able to provide with regard to the measure.

233. The representative of <u>Viet Nam</u> stressed that the measures were aimed at the prevention of smuggling and counterfeit of spirits, cosmetics and mobile phones, the protection of consumers' safety and health; these measures were in favour of foreign exports. He also confirmed that the document No. 4629 issued by the Ministry of Finance of Viet Nam was not a legal document; therefore there was no legal enforcement to apply it.

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

234. While recognizing Malaysia's desire to institute a reliable halal system for meat and poultry products, the representative of the United States noted that the Department of Islamic Development had not addressed his country's main concern that sufficient processes were in place to avoid any commingling of halal and non-halal products processed in the same establishment. Although Malaysia explained that the entire supply chain did not need to be dedicated exclusively to halal, the United States remained confused by some of Malaysia's responses, which would require confirmation. While Malaysia indicated that separate transport was not required for halal and non-halal products, the US sought to confirm a completely separate supply chain would in fact be required for products from pigs. In addition, Malaysia indicated that the measure would require all halal meat to be stored in freezers in approved halal establishments, which to the US indicated a separate supply chain for halal products would, de facto, be needed. Likewise, the measure would also forbid any commingling between halal carcasses' meat from several establishments. The United States questioned the need for a dedicated supply chain if an American company could sufficiently demonstrate a complete segregation between halal and non-halal products. In particular, it was unclear whether a US establishment currently certified to export meat and poultry products would be allowed to export Malaysia also needed to provide a reasonable interval for those under the existing rules.

establishments to comply before formally scheduling Halal audits. In this regard, it was the US understanding that educational outreach to US-Islamic centres and other US establishments was expected in order to ensure proper understanding of the new protocol.

235. The <u>European Union</u> said that exporters continued to face numerous difficulties in meeting halal related import requirements due to lack of transparency and non-alignment with international standards. Given the mandatory nature of these import conditions, she urged Malaysia to ensure clear, transparent and more easily available halal import requirements and standards. In particular, she reiterated her delegation's request for the measure to be notified to the SPS Committee, as some aspects appeared to be covered by the SPS Agreement.

236. The European Union further noted that Malaysia required an audit for every foreign meat establishment that wanted to export to Malaysia. The EU considered this requirement to be not only unnecessarily burdensome and costly, but also not in line with the international Codex standard on audits (CAG/GL26-1997): for instance, the Codex standard recommended the evaluation of official inspection and certification systems rather than the inspection visit of specific commodities or establishments. The standard also clearly indicated, *inter alia*, that all cost should be borne by the importing country, that inspection visits should be announced in advance and results should be communicated to the applicant. The European Union also requested the measure to fully comply with the international Codex standard on halal (CAC/GL 24-1997), which would allow the certificates granted by the religious authorities of the exporting country to be accepted in principle by the importing country. Finally, the representative concluded by asking Malaysia to provide some information on the state of play of the so-called "Trade Description Act" 2011, which also included halal labelling requirements.

237. The representative of Argentina was concerned because seven establishments, which had previously been able to export to Malaysia, had been suspended since November 2010 by the Veterinary Services Department. In Argentina's view the requirements of the standard did not comply with Article 2.2. of the TBT Agreement because they were more stringent than necessary to achieve the objective, i.e. to ensure that food satisfied halal conditions throughout the production chain thereby avoiding fraudulent declaration of halal meat. Argentina considered that the Article 4.2 of the protocol, stating the obligation for establishments to rely exclusively on halal production without any possibility of production shift to other types of meat, created an unnecessary barrier to international Since the draft protocol was inconsistent with the CODEX Standard for halal products trade. (CAC/GL 24 1997), Malaysia should have, according to the TBT Agreement, justified any departure from the international standard. For instance, Article 2.2.1 of the general guidelines of the CODEX Standard for halal products referred to the possibility for the same establishment to have different production lines for halal and non-halal products. Hence, according to Article 2.2.2 of this CODEX standard, halal meat could also be transported and stored in areas previously used for non-halal meat, as long as these areas were properly cleaned following Islamic standards. Thus the production of Halal and non-halal meat in line with Islamic Law was possible on condition that the necessary health steps were taken on the premises but without relying on separate lines of production. So setting up different shifts on a weekly basis could be one way to comply with the established Islamic requirements.

238. The representative of <u>Turkey</u> noted that recognizing the globalisation of halal food market and the growing needs and expectations of Muslim consumer for halal food standards, several Muslim countries had taken the initiative, under the Organization of Islamic Cooperation (OIC), to develop standards for halal foods. After three years of technical work, three guidelines on halal food certification and halal accreditation bodies had been adopted (in 2011). In addition, an affiliate body, called the Standard and Metrology and Certificate of Islamic Countries (SMIC) had been established by the OIC to take care of the standardization of halal food. With currently 13 members, including Turkey, the SMIC encouraged new membership. It was important to address the increasing number of regional standards by developing a consolidated, global halal food standard so that divergences could be eliminated and international trade enhanced.

239. The representatives of <u>Brazil</u> and <u>New Zealand</u> remained concerned about the measure and would continue to monitor the issue.

240. The delegation of <u>Malaysia</u> confirmed that Malaysia's TBT focal point had already provided answers to the written concerns and welcomed further bilateral discussion with interested Members.

(xxxv) Mexico – Energy Labelling Measures (G/TBT/N/MEX/214)

241. While the representative of Japan recognized the purpose of the measure, namely the protection of the environment through the provision of pertinent information so that consumers could choose energy efficient products, he was concerned that manufacturers were facing considerable difficulties in complying with some of these provisions. It was problematic that the TBT notification had been issued just before their implementation, undermining the transparency principle as stated in Article 2.9.2 of the TBT Agreement. As a consequence, the measures had entered into force while several concerns concerning about details of label designs and the measuring methods remained unresolved. In the absence of clarifications, the implementation of these provisions would result in confusion for both consumers and producers. He requested to standardize details of label designs and measuring methods and ,at the same time, to conduct market surveys of compliance by a reliable third party to ensure fairness.

242. The representative of the <u>European Union</u> echoed the concerns raised by Japan. She noted that although Mexico had indicated its intention to take comments into account, none of the questions raised at the last meeting of the Committee (and sent in writing to the enquiry point) had been answered.

243. The representative of Korea supported Mexico's objectives with regard to energy efficiency and environmental protection, however, further clarification is necessary regarding market surveillance, the use of pictograms on product labels, and the placement of those pictograms. During a bilateral meeting in September in Mexico, Korea had been informed that PROFECO planned to begin carrying out market surveillance at the end of November. However, Korean industry representatives in Mexico had informed the Korean Government that market surveillance commenced in October and this was a source of great concern. This was because important details had yet to be clarified. For example, no recognized energy efficiency tests existed either in the international standards or in Mexico's NOM for some of the products subject to labeling. These included industrial electric ovens, as well as both industrial and household ovens fuelled by liquefied petroleum gas or natural gas. The scope of some products listed in the catalogue was also problematic because of its breadth. Therefore, the delegation of Korea urged Mexico to narrow down the product list and provide a clear labelling pictogram and information on the placement of the label. Korea further requested Mexico not to apply the measures on a business-to-business basis and to grant a grace period for products for which no recognized tests existed. She asked Mexico to explain the registration process to PROFECO and CONUEE. Without clear guidelines, manufacturers were confused regarding which of these organizations they must submit data to, or if they must go through both organizations.

244. The delegation of the <u>United States</u> supported Mexico's efforts to raise consumer awareness of energy consumption and to promote energy efficiency. However, concerns remained. The scope of the measure was unnecessarily broad and could cover products with minimum energy use. The testing procedures lacked flexibility and clarification; it was important that producers were allowed to select their own test procedures and, moreover, additional time was needed for producers to comply with the measures. It was also unclear whether manufacturers or importers could submit the required

test report electronically. The United States requested Mexico to provide in a publicly available document clarification regarding the labelling format and placement – this document needed to be transmitted to Mexican ports. A transition period was needed to delay the entry-into-force until six months after the implementation date, so that producers would have sufficient time to comply. The United States also requested Mexico to confirm that the measures would not apply to products that entered the Mexican market prior to the entry into force of the measures. He suggested that the US and Mexico could collaborate on an agreement on common test procedures for specific products as had been discussed in a high level regulatory cooperation council earlier in the week.

245. The delegate of Mexico explained that in September 2010, the "catalogue of equipment and machines" had been published requesting producers, importers and distributors not to regulate the energy consumption of equipment and machines, but to include information on energy consumption for consumers. In March 2011, the Official Gazette had published the "formats and requirements for the submission of information by manufacturers and importers of equipment using energy to function", which had been mandatory since 11 September 2011. These mandatory requirements had entered into force a year after the original notification in the Official Gazette, providing producers reasonable time to come into line with the requirements. On the 15 June 2011 the catalogue of equipment and machines had been notified to the Committee under G/TBT/N/MEX/214, providing a 60 days period for comments. This had allowed the United States, Japan, the European Union and stakeholder businesses to send their comments during that period. Korea had also comments, but after the expiry of the comment period. The National Commission for the Efficient Use of Energy responded to the questions raised by the United States, Japan and the business stakeholders and was currently reviewing the comments provided by the EU and Korea. The National Commission was not currently considering any modification to the catalogue until further details had been obtained about the results of its implementation.

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

246. The representative of <u>Mexico</u> asked for information on the implementation of this regulation published on 17 December 2010. He requested a formal response to comments presented on 12 May 2011.

247. The representative of the <u>United States</u> reiterated previous questions and concerns on the rationale behind the possible inclusion of pictures in the alcohol warning statement, the size of the warning label in proportion to the bottle, the necessity of the warning statement rotation requirement to meet the stated objective, ambiguities in the measure, its impact on industry as well as the lack of an implementation period. The US was open to discussing these comments with Kenya on a technical level; it understood that the implementation of some sections of the measure had been postponed due to domestic litigation. Could Kenya confirm this understanding, and, if this was the case, clarify which sections were postponed as well as the expected length of the implementation delay.

248. The representative of the <u>European Union</u> supported the Mexican and US concerns. In April 2011, subsequent to Kenya's notification of the measure, the EU had provided detailed written comments. Despite the issue being discussed in the last TBT Committee, no written answers had been received. She asked if Kenya had considered less burdensome alternatives to modify drinking behaviour than mandatory health warning labelling, and if it was reviewing the requirement that health warnings make up at least 30 per cent of the total package. She sought confirmation whether products could be imported with a sticker with the requested warning information added.

249. The representative of <u>Kenya</u> noted that the Alcoholic Drinks Control (Licensing) Regulations ("the Regulations") 2010 had been adopted on 16 December 2010 and published in the Kenya Gazette Supplement No 91 of 17 December 2010, pursuant to the Alcoholic Drinks Control Act No. 4 of 2010

("the Act"). The Regulations had been enacted as emergency measures as a result of popular public interest, consideration of the adverse effects of alcoholic drinks in Kenya, to safeguard against the continued loss of life, and for the protection of public health. This was a problem for the last few years and Kenya had consulted with various stakeholders on possible measures. Kenya had fully complied with the provisions of Article 2.10 of the TBT Agreement. In March 2011, it had notified the Regulations to the TBT Committee as they had a significant effect on international trade.

250. Article 32(2) of The Alcoholic Drinks Control Act 2010 provided that "every package containing an alcoholic drink shall bear a statement as to its constituents, and have at least two of the health warning messages prescribed in the Second Schedule of the Act". Such information might indeed be provided on extra stickers added to the products, as laid down in Article 32(6) of the Act. At the time of notification, Article 32(3) had provided that the statement and health warnings referred to in Article 32(2) should comprise not less than 30 per cent of the total surface area of the package to ensure prominent warnings to inform the public of the dangers of excessive alcohol consumption. The 30 per cent requirement was currently under review. A bill had been tabled in Parliament seeking to amend several provisions of the Act. With regard to the concerns raised by the US on rotation requirements for the warning statements, this was meant to ensure that all four health warnings were distributed evenly in the Kenyan market. If any additional materials were added to the warning statements, Kenya would notify the WTO accordingly.

Moreover, as a standard requirement for all packaged food and chemical products covered by 251. the Food Drugs and Chemical Substances Act, Cap 254 Laws of Kenya, manufacturers would be expected to label all ingredients used in the manufacture of the alcohol. A list of "harmful constituents", as prescribed in Section 68(c) and (d), would be given in subsequent regulations, and any two of the four health warnings prescribed in Section 32(2)(b) of the Act should be labelled. A company might advertise its alcoholic drink in magazines as long as it met all the requirements of the laws and regulations, especially as provided for in Articles 45, 46, 47 and 48 of the Act. Further, the sale of alcoholic drinks had been restricted to certain hours of the day, and sales to minors below 18 were forbidden. Fines for the violation of these laws had been enhanced to promote responsible drinking and deter excessive alcohol consumption. Public education campaigns regarding the drinking age and responsible drinking had been on-going to nurture responsible citizenry. As a standard practice, legislation would be regularly reviewed, and any further changes would be communicated to the WTO. Kenya would notify the WTO accordingly if and when the list of "harmful constituents" became available. Submissions were based on currently available information and Kenya was open to consultations with any delegation wishing to engage in further discussions.

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

252. The representative of the <u>United States</u> supported efforts to regulate to protect children's health and understood that the document was still a working draft. If it became a formal proposal, he asked if India would notify it to the WTO for comments. In the last meeting, the United States had flagged some issues in the working draft. One was that the draft appeared to mandate a registration procedure that seemed to go beyond such requirements in other areas of the world. The required information to be registered pertained to each factory's management composition, the raw materials used, serial numbers for all equipment on the factory floor, factory layout, production process, packaging and storage, details of quality control of staff, and notification upon removal of a piece of equipment from the factory. He asked if India would allow recognition of sampling and test reports conducted by overseas laboratories provided that they had been accredited by an ILAC MRA signatory. If this became a proposal, two agencies with separate regulatory regimes in India, the BIS and the Director General for Foreign Trade, would be responsible for the product safety of imported toys; while domestic toys and coordination would be regulated by BIS. He asked that these concerns be taken into account in developing the draft, and that India notify a draft proposal.

253. The representative of the <u>European Union</u> supported the US concerns while also supporting the objective of enhancing toy safety for the protection of children. He asked for further clarification on the rationale for the envisaged change in conformity assessment, and for the shift to a more stringent regime based on mandatory testing carried out in India without scope for recognition of test results from foreign ILAC accredited laboratories. Moreover, onerous registration procedures would add burdens to the procedure envisaged. Due to the potential significant impact on exports of toys to India, he requested guaranteed transparency in the process and that India notify a draft at the appropriate stage to the TBT Committee so as to allow for comments and dialogue.

254. The representative of <u>India</u> reported that the Department of Industry Policy and Promotion was still in the process of formulating the draft guidelines on the proposed order. He took note of the issues raised by the US, especially on the existing DGFT import notification and the alignment of the guidelines therewith. He considered it premature to comment, and gave assurances that India would decide on notifying a draft once the process was completed.

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

255. The representative of Argentina asked the European Union to notify the law to the WTO and inquired about its consistency with relevant EU legislation. He asked for confirmation that the Grenelle Law 2 was still at a pilot stage since July 2011, and what was its status this year. He inquired whether a calculation method for carbon footprint was defined and whether this would apply to agriculture exports from developing or just developed countries, taking into account common but differentiated responsibilities. He further inquired whether the Law would lead to compulsory labelling for carbon footprint during its pilot stage with regard to developing countries. He asked for a reply to Argentina's questions raised in the previous meeting, including whether, and if so, which stakeholders had been consulted, particularly in developing but also developed countries. Moreover, Argentina was interested in knowing whether there were any clauses on special treatment for developing countries not included in Article 12 of the TBT Agreement and taking into account the development, financial and trade possibilities of these countries. Argentina also asked if technical assistance provisions, particularly for small and medium-sized businesses, in developing countries had been included and whether an analysis of the regulatory impact of the standard had taken place. Lastly, Argentina asked for additional information on how the carbon footprint would be quantified, such as details, variables and assumptions to be used.

256. The representative of the <u>European Union</u> clarified that the Law did not contain any provision foreseeing compulsory environmental labelling. the Law had provided for an experimental run for a minimum period of one year, starting as of 1 July 2011, to inform consumers on the carbon equivalent used for product packaging and to look at consumption of natural resources as well as environmental impacts due to products during their life cycle. This experiment would have to be submitted to Parliament which was considering the general application of this measure. This trial would apply to companies on a voluntary basis to assess the feasibility of environmental labelling with the purpose of creating a pool of ideas. A high degree of flexibility was left to the implementation of this experiment. Since 1 July 2011, 168 companies had participated on a voluntary basis, representing a great diversity in terms of companies' origin, size and production. Several third-country companies had been involved, either directly as was the case for individual companies in South and North America, or indirectly via projects run by distributors, particularly Asian companies.

257. The French authorities wanted to contribute to the on-going thinking related to environmental labelling that was currently being looked at in a number of national and international bodies. Nevertheless, the adoption of a provision on national labelling had not finally been decided and no provision regarding the types of products concerned or the implementation of labelling had been proposed. Discussions in this Committee were premature and her delegation could not yet respond in

detail to the questions raised by Argentina. The EU was willing to provide information on the experiment's results that would probably be made known at the beginning of 2013.

(xxxix) Korea – KFDA draft "Guideline for Cosmetics Labeling and Advertising" (G/TBT/N/KOR/308)

258. The representative of the <u>United States</u> had raised two concerns. First, since the current Fair Trade Commission Regulation and Product Liability Law already covered personal care products, how would the new Guideline interact with those measures to ensure that these would not be redundant and confusing for companies. Second, regarding transparency, if a company wanted to make a claim that was not found on either of the lists set out in the Guidelines, the relevant procedure and whether companies would have to file a petition on a claim by claim basis with KFDA was unclear. Additional clarification was needed in cases where the wording was different than indicated on the negative list. As an example, if a company could not state that a product could reduce a scar, he questioned whether it could argue that the product would reduce its appearance. Moreover, he asked whether claims could be made if they were not mentioned in either of the positive or negative list. He asked about the Korean rational for a broad negative list which included claims that were normally accepted in other jurisdictions since it could have a negative impact on trade.

259. Regarding the use of foreign languages on labels, the US was concerned about the problem of companies translating product names on labels. Since some U.S. products were known to Korean consumers under the English names, this requirement could negatively impact sales and provoke a lack of understanding for consumers on claims being made. He asked if these translations would need to be placed on the packaging or on a separate document accompanying the product. Given the confusion caused by the Guideline for both domestic and foreign industry, the US urged Korea to revisit this after discussions with relevant stakeholders, and to provide clarity on questions in order not to disrupt legitimate trade. He asked Korea to update the Committee on these discussions.

The representative of the European Union supported the US concerns. Her delegation had 260. sent written comments on 22 June 2011, and received a reply from Korea on 28 July 2011. While the EU was grateful for Korea's reply, it continued to have a number of concerns, that had been submitted to the Korean Enquiry Point on 7 November 2011. The EU continued to consider that some elements of the Guidelines were still not sufficiently clear or specific, and contributed to a significant level of uncertainty for foreign cosmetics companies operating on the Korean market. She reiterated the EU's request that KFDA provide more specific indications on how these Guidelines would apply, particularly in conjunction with Article 14 of the new Cosmetics Act passed by the Korean National Assembly on 29 June. Secondly, the Cosmetics Act would have to be complemented with lower level legislation to make the new legal framework for cosmetics fully operational. These implementing Decrees would also cover claims substantiation. It was not clear how the notified Guidelines would fit into the new legal framework or whether they would have to be modified once the implementing rules were adopted. Thus, she asked Korea to delay the implementation of the Guidelines until the legal framework was fully established so as to avoid confusion and lack of predictability for economic operators. The EU stressed the need for these measures to be developed in a transparent and participatory manner, involving consultation with industry. Third, the new Guidelines might also prove problematic with the control of claims in languages other than Korean. Since the list of prohibited and permitted claims in the Guidelines was provided in Korean only, there was a lack of clarity on how claims in foreign languages would be treated. Her delegation asked if KFDA also interpreted names of globally marketed products such as brand names as within the Guidelines' scope.

261. The representative of <u>Korea</u> said that KFDA could not exempt items written in foreign language from labelling. If the concern was that the labelled product name of an imported cosmetic would lead to consumer deception or cause the item to be considered a pharmaceutical product, this was to be regulated not only by the amended Cosmetics Act, but also by the current one. The

Guideline specified methods, such as correction, deletion, over-labelling for advertisements or foreign language labels, for importers to modify them to conform with the Guideline. She clarified that some standards were currently going through internal review to establish more specific standards for regulations related to cosmetic labelling and advertising under the Cosmetic Act, including, *inter alia*, the preparation of details for the substantive target, scope and requirements for substantiation data or method of submission. Once finalized, Korea would notify the amended regulations to WTO Members. KFDA would refer to the relevant standards of other countries such as Canada, Australia and Japan to apply international standards as much as possible. Even though the Guideline was not legislation, it had been notified to the WTO for comments as requested by the EU.

(xl) Colombia – Commercial Truck Diesel Emissions Regulation (Resolution 2604, 24 December 2009)

262. The representative of the <u>United States</u> noted that Resolution 2604 had been withdrawn, that the Ministry of Environment had published a draft Regulation in Colombia's Official Journal entitled "Modification of Resolution 2604" in July 2011, and that the industry had been invited to submit comments which it did on 27 July 2011. In addition, an inter-agency process was on-going in Colombia to discuss mandatory emission limits from commercial diesel trucks. He asked if this was the correct status of the measure and, if not, could Colombia explain. The US supported Colombia's objective to lower emissions from commercial diesel trucks for health, safety and environmental reasons. He was concerned that the diesel fuel currently available in Colombia, and required for U.S. trucks as of 2013, was not compatible with the US Environmental Protection Agency's (USCPA) 2010 emission standards. Engines built to meet this specification required ultra-low sulphur diesel fuel that would not be available in Colombia until 2019. This requirement barred US diesel trucks from the Colombian market. He suggested requiring diesel trucks sold in Colombia to meet EPA 2004 rules that would help reduce emissions in Colombia and keep trade flowing. The US welcomed further bilateral discussions at a technical level.

263. The representative of <u>Colombia</u> clarified that Resolution 2604 of December 2009 was currently being reviewed. It would set maximum emission levels for those vehicles that transported people as well as trucks. Consequently, this would affect hybrid transport as well as transportation of goods and people. Colombia was also looking at Resolution 9/10 that focused on the number of contaminants allowed in motor vehicles. Colombia would review standards of diesel vehicles in the course of these various reforms to improve air quality, the environment and people's health with a particular focus on children. Standards based on international standards, as well as possible problems of conformity with regard to health protection of Colombia's population in the short, medium and long-term had to be borne in mind. Inter-departmental agencies, such as the Environment Mine Energy, Trade, and Tourism, that had raised these issues could together decide on a standard. Once set, the standard would be notified to the TBT Committee for third country comments.

(xli) Korea – Amendment to Radio Waves Act 1/2011 (RRA) G/TBT/N/KOR/334, G/TBT/N/KOR/339, G/TBT/N/KOR/343

264. The representative of <u>Japan</u> appreciated Korean Government to extend the dead line for comments on TBT notification. However, the Korean Government announced revised EMC regulation on 21 January and had already enforced it on 1st July 2011 without TBT notification. By reflecting this movement, Japanese industries quickly tried to collect information in order to follow the revised EMC regulation. However lack of uniform explanation by RRA officials caused confusion which imposed unnecessary burden on Japanese industries.

265. The representative of the <u>United States</u> said that US industry had been working closely with Korean Regulators on the implementation of these regulations. The US appreciated the close cooperation with the Korean Government to ease the transition to the new labelling regime. On 29

August 2011, a joint US-Japan industry letter had been sent to the RRA outlining a number of specific technical concerns and questions with respect to the electro-magnetic compatibility element of the regulation. He reiterated the US request that Korea respond to the letter and work on the issues raised by the industry. Industry still had questions and concerns on the electrical safety certification portion of the measures. First, the US requested Korea to use the second edition of the IEC 60950 that was more widely used internationally. Second, he appreciated clarification from Korea on the scope of products covered under the safety and certification requirements, and in particular whether non-consumer products, such as business to business products, could be excluded. Third, industry requested that the KATS, which was implementing the electrical safety portion of the measure, utilise the IECEE CB scheme as part of its safety certification programme, as well as a one year implementation period to comply with the new requirements. He asked Korea to confirm whether KATS was planning to postpone implementation until 2013 as well as provide any other updates on the specific issues raised in its intervention.

266. The representative of <u>Korea</u> informed that it had held bilateral meetings with the US and Japan, and its newly introduced certification system for EMC and electric safety regulations was better understood. With regard to overlaps between the *Radio Waves Act* and the *Electrical Appliances Safety Control Act*, the responsible authorities (the Korea Communications Commission (KCC) and the Korean Agency for Technology and Standards(KATS)) agreed to split responsibility for certification not along product lines but according to the kinds of tests that must be carried out. The KCC was responsible for ensuring EMC, whereas KATS was responsible for ensuring that electrical appliance manufacturers comply with safety regulations] from January 2012 onwards. With regard to the acceptance of EMC certification, the KCC recognized test results from testing laboratories located outside of Korea if they were members of the IECEE CB Scheme or if they signed MoUs with Korean CBs. Test results for EMC issued by 76 CBs in the US were currently accepted.

267. In response to the US comments on the reference standard for new safety requirements, although currently the first edition of IEC 60950-1 was used, the second edition would also soon be introduced. With regard to Japan's comments on the Conformity Assessment System for Broadcasting and Communications Equipment, noted in G/TBT/N/KOR/334, RRA had notified the amendments on 11 October 2011 and had extended the deadline for comments until December 2011. She encouraged Members to submit comments to be taken into account by the RRA while amending the regulation. She would deliver the points raised by the US and Japan to the competent authorities.

(xlii) South Africa – Liquor Products Act of 1989

268. The representative of the United States referred to the June Committee meeting, in which he had explained that a US company that had not been able to export one of its products to South Africa due to a gap in South African definitions for alcoholic beverages. While "liqueurs" required a minimum alcoholic content of 24 per cent, "spirit coolers" could only contain a maximum alcohol content of up to 15 per cent by volume. Thus, there was a gap in the rules between 15 and 24 per cent of alcohol content since the product in question had an alcohol content of 17 per cent. Due to this, the product had been excluded from the South African market, although it had been classified as a liqueur in a number of countries including the US and had been sold in several countries. Like many other countries, the US defined liqueurs based on raw materials and production processes, rather than factors such as alcohol content. The US was not aware of any health or safety reasons why alcoholic beverages could not contain between 15 and 24 per cent of alcohol by volume. South Africa had made an exception for a domestic product, Amarula, which contained an alcohol content of 17 per cent. Thus, a domestic alcoholic beverage with 17 per cent alcohol content could be sold in South Africa, while a beverage of foreign origin containing the same alcohol content and sold all over the world was excluded from sale on the South African market.

269. South Africa had not provided any justification for this disparate treatment between foreign and domestic producers of alcoholic beverages. The issue had been discussed bilaterally and the US company had provided the requested labelling and ingredient documentation to the South African regulator. Although the process had been on-going since 2009, the company had neither received approval in marketing its products, nor an explanation for the lack of reply. The US asked South Africa to provide a status update on the application, and an explanation for the delay

270. The representative of <u>South Africa</u> referred to the South African Liqueur Products Act of 1989 and the comprehensive response provided at the June Committee meeting. South Africa drew the attention to on-going bilateral efforts within the confines of the South Africa - U.S. Trade and Investment Framework Agreement (TIFA) that aimed to find a mutually acceptable solution to the US' concern. The matter had also received attention at a 21 September 2011 meeting between senior trade officials and representatives of both the US and South Africa in Pretoria. As for the progress of the application, South Africa informed that comments and questions would be relayed to the relevant competent authority.

(xliii) 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)

271. The representative of the <u>European Union</u> referred to India's mandatory certification requirements for steel discussed at the meeting in June 2011. At that time, India had abolished third party certification for several steel products. By means of an addendum to notification G/TBT/N/IND/32 of 22 July 2011, India announced that the products were now again subject to mandatory third party certification without providing for a period for comments by WTO Members. The EU had sent detailed written comments on 6 September 2011, but had not received any reply.

272. She asked why India considered a mandatory third party certification necessary for the products in question. Steel products were intermediary goods that could be used for different purposes, and it would be more appropriate to verify conformity with regard to the specific final product. Moreover, international standards existed that were recognized and used world-wide. The EU had also been informed that the third party certification procedure, which already existed for galvanized steel products, was applied in an extremely burdensome, costly, and time-consuming manner and that importers were still waiting for the necessary certification after more than one year. Could India provide clarifications on (i) the fees importers would have to pay; (ii) if these fees were equal to fees due by domestic producers; (iii) tests that could be recognized in the certification procedure; and (iv) how a timely conformity assessment procedure would be ensured. Since Article 5.1.2 of the TBT Agreement prohibited conformity assessments more strict than necessary or from being applied more strictly than necessary, the EU urged India to reconsider the introduction of third party certification for the steel products in question and to postpone its entry into force until all concerns were solved.

273. The representative of <u>Japan</u> supported the EU. It was pointless to impose mandatory certification regulations on intermediate products such as iron and steel to secure human safety because protection of consumer health or safety depended on final, not intermediate, products. This objective could be achieved by safety regulations targeted at final products, as implemented by Japan.

274. The representative of <u>India</u> said this measure had originally been announced through a draft regulation in 2007 in notification G/TBT/N/IND/32. After more than four years, addendum 2 was introduced to finalize steel and steel products. India did not understand why this was a surprise to some Members as the amendment actually reduced the initial 2007 list to only nine products for certification. Since intermediate products constituted the bulk work of the structural safety issue with regard to steel and steel products, they were necessary to regulate. Even for electrical products, steel

sheets for the use of transformers and other electrical products were the critical components in need of standards. India would revert to the EU questions on costs at the next Committee meeting.

2. Follow-up

(i) Chile – Resolution 1114 on Emission Standards

275. The representative of the <u>United States</u> updated the Committee on the status of one particular trade concern. This was with respect to a draft measure that had been proposed by Chile regarding emission standards applicable to heavy duty motor vehicles (Resolution 1114 from 15 September 2011). The United States thanked Chile for having issued a revision to its diesel truck emissions requirements. The previous version of the requirements, which had mandated compliance with EPA 2007 emission standards for US diesel trucks, would have blocked export of US diesel trucks to Chile because outside of the Santiago metropolitan area, the low sulphur fuel that was needed by diesel trucks engineered to these standards was not currently available. The proposed change in the draft revision to the EPA 2004 emission standards, which would be in effect until such time as the appropriate low sulphur fuel was available throughout Chile, alleviated this potential market access barrier while still lowering emissions and providing enhanced public health and environmental protection in Chile.

3. Streamlining the Committee's discussion of specific trade concerns

276. The <u>Chairperson</u> reported that the Committee had held an informal meeting on 6 October 2011 to discuss a proposed mechanism (JOB/TBT/14) to make more efficient and effective the Committee's discussion of STCs, while, at the same time, giving each Member adequate opportunity to address STCs they considered important. She recalled that while Members generally agreed that more information about the status of the various STCs was useful, there had been some debate at the informal meeting on the categories for the classification of STCs. In light of the discussion, the Secretariat revised the document which was before Members at the current meeting (JOB/TBT/14/Rev.1).

277. The representative of Japan was of the view that the revised note (JOB/TBT/14/Rev.1) reflected his delegation's earlier comments and took into account the discussion at the informal meeting. For Japan it was important that Footnote 6 of the document clarified the meaning of the status of STC (to the effect that classifications were intended solely for the purpose of facilitating the WTO TBT Committee's review of specific trade concerns and had no legal implication). However, Japan was of the view that more precision could be useful with respect to the category "progress reported". For more accuracy, this category could be usefully divided into two categories: (i) progress reported and still *active* and, (ii) progress reported and *inactive*.

278. The representative of <u>India</u> noted that his delegation had come across instances where Members were raising concerns about measures where a draft of the measure itself had not even been finalized. It was India's view that such concerns were premature for the Committee. Therefore, there needed to be a category that would capture these "premature" STCs. He also queried on the difference between "active" and "progress" report.

279. The representative of the <u>European Union</u> stressed the need to keep the administrative burden, for both the Secretariat and the Members, to a minimum. So while further sub-categorization might better capture specific cases, the European Union warned against an overly detailed categorization of measures. His delegation supported the initiative on the understanding that there would be only a few basic categories: the active and inactive categories (as set out in the revised draft) needed to be the default categories. Any "progress report" needed to be voluntary – and entirely up to Members to provide. In this regard he said that it was important to consider *who* should be the

source of information about status (under "progress reported"). It was the EU understanding that this would be the Member *raising* the concern.

The representative of the United States said that it was important for the Committee to have 280. better data on *how* specific trade concerns were being addressed, including resolved, in its work. This information could streamline the agenda for Committee meetings and could contribute to reducing the length of the discussions under the STC agenda item. The United States agreed with other delegations that the "inactive category" needed to be the default category; most of the items would probably automatically fall under this category. However, the United States was of the view that there needed to be a fifth category of "unresolved" STCs – and that this needed to be separate from "inactive". If there were no category for "unresolved" measures, the risk was that Members would continue to raise STCs over and over again just to be able to show to their stakeholders that the matter was being pursued even after the measure had been adopted and implemented. A category for "unresolved" measures would enable delegations to show (their constituents back home) that even if the issue had not been raised at the meeting it remained unresolved. It was suggested that there could be a trigger mechanism whereby the Secretariat could list all the STCs that had not been raised for the past six consecutive meetings, and those could be moved to inactive. Unless a Member remarked otherwise, these STCs would, thus, at that point be "automatically" classified as "inactive". This would also be an opportunity for a Member to offer information about whether the measure could be classified as "partially resolved", "resolved", or "unresolved". In terms of what kinds of issue that could be raised and at what point in time – the lesson learned from the Workshop on Regulatory Cooperation was: the earlier the better. Moreover, in his delegation's view there was no reason to circumscribe what type of measure Members could raise in the Committee.

281. The representative of <u>Canada</u> stressed the importance of finding ways for Members to express concern about a measure without necessarily raising it in the Committee, particularly considering that the STC-part of the agenda was taking up increasingly more of the Committee's time. In this sense, Canada supported the US statement to the effect that delegations needed to be able to convey to stakeholders at home that they had signalled concern. It was thus necessary to avoid moving a concern to the "inactive status" if the underlying concern was still there and, at the same time, the Committee needed to find a way to avoid a series of interventions simply to maintain the "active status". An alternative to adding more categories was to consider the category "progress reported" as a form of status report – for instance, it could be reported that the matter was being "pursued bilaterally".

282. The representatives of <u>Switzerland</u>, <u>Norway</u> and <u>Pakistan</u> supported the approach taken in the revised document and emphasized the importance of simplicity.

283. The <u>Chairperson</u> noted the importance all Members attributed to simplicity and, in general, to finding ways of providing more information on the status of specific trade concerns discussed in the TBT Committee. She recalled that the existing TBT IMS contained a slot for information on "status" of STCs which was, currently, by default set to "Not Reported" for all STC raised since 1995.¹⁵ She noted that while in the discussion a number of categories had been raised, the clearest were: "resolved" and "unresolved". Members could initially, and on a voluntary basis, provide information in respect of these two categories. Hence if Members were aware of an STC that had been resolved, this information could be communicated and fed into the IMS. Indeed, the category "unresolved" could be particularly useful considering the purpose of this streamlining exercise (to make the Committee's discussion of STCs more efficient) – as it would enable Members to flag an issue as "unresolved" without necessarily raising it (again) for discussion under the agenda item "previously raised STCs".

¹⁵ Also reflected in the G/TBT/GEN/74/-series of documents.

C. EXCHANGE OF EXPERIENCES

1. Good Regulatory Practice

284. A Workshop on Regulatory Cooperation between Members was held on 9-10 November 2011. The <u>Chairperson</u> provided an oral summary of this workshop. The oral summary statement, as well as a summary report, is contained in document G/TBT/W/348.¹⁶

2. Standards

285. The representative of <u>India</u> introduced his delegation's submission on international standards (G/TBT/W/345) and stressed that the paper was preliminary, to be considered as a basis for further work. The paper considered the *Decision on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the TBT Agreement* from 2000 (hereafter the "Committee Decision").¹⁷ It was India's view that 11 years down the road there was perhaps a need to review these principles and consider the potential need for additional principles.

286. The representative went on to stress some suggestions contained in the paper, for instance: an increased reference to electronic working tools and procedures (under transparency), and using principles and elements from the Code of Good Practice to increase transparency in the standards area. In the area of openness, the representative of India stressed the importance of considering resource constraints and finding means of actually operationalizing this principle. On the Development Dimension, which India considered to be the most important principle, two specific areas were highlighted: standard setting bodies needed to have a specific action plan for developing country Members; and there was a need to operationalize the TBT Agreement in respect of the special development, financial and trade needs of developing countries. Other proposals on the existing principles are reflected in detail in the paper. The representative of India also suggested three additional principles dealing with (i) institutional mechanisms for standard setting; (ii) stakeholder consultations; and (iii) guidelines for transposition to national standards.

287. The representative of <u>Mexico</u> said that his delegation agreed with India that problems arose from the lack of a definition of international standards. Indeed, the lack of clear concepts and concrete definitions had created a number of challenges in implementing the TBT Agreement. While it would probably be difficult for Members to agree on a definition for international standards, the Committee could consider building on the principles contained in the Committee Decision, as had been suggested by India. On transparency, Mexico agreed that there was a need to ensure that international standard setting organizations, or at least the bodies that were observers in the TBT Committee, better define their work plan. In particular, these bodies could become better at spreading information, including to developing countries. With respect to openness, Mexico stressed the importance of technical assistance mechanisms to bolster the participation of LDCs. Another important point was the decision – to be taken by each Member - of which committees required involvement; it was not efficient (or even necessary) for all countries to be involved in all committees.

288. On the issue of impartiality and consensus, and the reference to different geographical and climatic conditions, Mexico did not see the appropriateness of the proposal given that the TBT Agreement already contained language to this effect. Also with respect to the "90 per cent" criteria on consensus, Mexico expressed concern and said that the subject needed further discussion. On the Development Dimension, the representative of Mexico said that there was a need to foster the use of

¹⁶ More information on the Workshop is available at: <u>http://www.wto.org/english/tratop_e/tbt_e/wkshop_nov11_e.htm</u>.

¹⁷ The full text of this Decision is contained in Annex B of G/TBT/1/Rev.10, dated 9 June 2011.

other languages, in particular Spanish. While Spanish was an official language in many international organizations this was not generally the case in the standard-setting context, and this was a significant hurdle for Mexico. He also noted that the institutional mechanism by which standards were set might need some form of appeals procedure.

289. The representative of <u>Hong Kong, China</u> agreed with India on the usefulness of revisiting, and even clarifying, the six principles contained in the Committee Decision and to explore new ones, if necessary. He recalled that in the discussion that had taken place in the context of the NTB-related negotiations in the Group on Non-Agricultural Market Access (hereafter "NAMA Group") there had been consensus on the importance of upholding the six principles. The Committee therefore needed to consider how to leverage these discussions in the course of the Sixth Triennial Review.

290. The representative of the European Union recalled that the Committee Decision had been the outcome of complex and lengthy discussions. Therefore, Members needed to reflect on whether they wanted to revisit the Decision in the context of the Sixth Triennial Review knowing that it would not be an easy task, and that it would risk monopolizing the work of the Committee while the prospects for progress were perhaps better in other areas. On the issue of defining an international standard, the European Union recommended - based on its experience - that the Committee focus on the process through which a standard was developed, rather than attempting a *definition* of an international standard per se. On the issue of geographical and climatic variations, the representative of the European Union agreed with Mexico: it was not realistic to envisage that an international standard could capture all possible geographical, climatic and technological variations that might exist across different regions and Members. The TBT Agreement, and in particular Article 2.4 thereof, already provided clear criteria under which variations from international standards were acceptable; there was no need for such variations to be exhaustively enshrined in the international standard itself.. On consensus, the representative of the European Union recalled that the ISO IEC Guide 2, 2004 version, (referred to in Annex I to the TBT Agreement), contained a definition of consensus. It was important to consider in this regard that consensus was not linked to voting: it was a process through which different views were accommodated. Indeed, this process sought "to reconcile any conflicting arguments" with a view to ensuring "the absence of sustained opposition to substantial issues by any important part of the concerned interests" in the draft standard; it took into account the views of all parties and reconciled any conflicting arguments. Therefore, the European Union did not consider that it was appropriate for Members to attempt to define a minimum benchmark on voting requirements to define consensus.

291. Finally, the representative of the European Union recalled that the recommendations contained in paragraphs 25(b) and (c) in the Fifth Triennial Review were relevant to the current discussion. These recommendations referred to the importance of ensuring the effective application of the Code of Good Practice, as well as the importance of applying the six principles in the Committee Decision – and the sharing of experiences with respect to their use. It was suggested that the Committee could elicit contributions from Members and from their standardization bodies on how the Code of Good Practice was being effectively applied. In addition, with respect to the six principles, observers could be asked to offer their experiences in this regard. Indeed, in the European Union, the European Commission had requested European standardization bodies and their national members to integrate the six principles into their work because these were, in effect, an expression of good practice in standards development and their application should therefore not only limited to the development of international standards but could also be promoted, *mutatis mutandis*, at national or regional level.

292. The representative of <u>Canada</u> referred to the negotiations that had taken place in the NAMA Group and said that it would be important to elicit input from standards experts. On the Committee Decision, he noted that it was a reflection of a very careful balance that had been struck in previous work of the Committee; revisiting them was a tall order.

293. The representative of the <u>United States</u> agreed with the points made by the European Union. In addition, he said that the Committee might wish to consider what Members could do to enable meaningful participation in international standards development (not just attendance). Much useful information on this had been discussed at the Committee's March 2009 Workshop on the Role of International Standards in Economic Development.¹⁸ For instance, several delegations had talked about their experiences (e.g., Colombia, Peru and Pakistan) including on the subjects of asparagus, coffee, building codes and textiles in organizing their domestic stakeholders to successfully influence international standards development, thereby increasing exports. On consensus, the United States agreed that it would be very difficult to come up with a number; getting the right procedures in place was perhaps more important.

294. The representatives of <u>Australia</u>, <u>Brazil</u>, <u>Chile</u>, <u>Cuba</u> and the <u>Philippines</u> said that their delegations would carefully consider the Indian proposal and would provide feedback. The representative of Cuba expressed particular interest in the subjects of transparency, impartiality and development and emphasized the importance of participation in the standard-setting process. The representative of Australia also recalled that many of the issues raised in India's paper had been debated in the NAMA Group and would benefit from the wider input from the Committee.

295. The representatives of the <u>ISO</u> and <u>OIML</u> supported a discussion of the six principles by the Committee and noted that these principles were embodied in their work.

3. Conformity Assessment

296. The representative of <u>New Zealand</u> recalled the recommendation contained in paragraph 19 of G/TBT/26, particularly in relation to developing practical guidelines on how to choose and design efficient and effective trade facilitation mechanisms. She also recalled her delegation's submission contained in document JOB/TBT/5 (September 2010) which contained a possible structure for the guidelines. She recalled that the objective of the guidelines was to develop a practical resource that Members could choose to use to guide their decisions on the choice and design of trade facilitation mechanisms. These would be based on concrete examples studies and experiences. For instance, the joint ILAC/IAF presentation at the TBT Committee (June 2011) had been a useful contribution in this regard, as well as the various contributions on Regulatory Cooperation in the context of the recently held Workshop (November 2011). These presentations provided rich material to draw on in further developing the guidelines. In considering what to do in the context of the Sixth Triennial Review, the Committee needed to take stock of what was already on its "to do" list (from the Fifth Triennial Review) and take the necessary steps to progress that work, before taking on too many new initiatives.

4. Transparency

297. The representative of <u>India</u> referred to the on-going work in the NAMA Group negotiations which was aimed at modifying the TBT notification formats; this work, he said, was primarily aimed at encapsulating all information pertaining to various stages of the development process of technical regulations or conformity assessment procedures. In this regard, India intended to make a proposal where, essentially, the idea would be to amend the TBT notification format to facilitate the provision – on a voluntary basis – of pertinent additional information about the various stages of technical regulation. For example, India had notified a *final* regulation on steel standards¹⁹ (discussed under STCs) although there was no obligation to do so under the TBT Agreement. This type of information

¹⁸ A summary report by the Secretariat is contained in G/TBT/W/310. The full presentations made by speakers are available on the WTO TBT Website (http://www.wto.org/english/news_e/news09_e/tbt_16mar09_e.htm).

¹⁹ G/TBT/N/IND/32/Add.2 dated 22 July 2011

was an important means of populating the TBT-IMS database²⁰, and could be particularly useful source of information for SMEs.

The representative of the European Union noted, on the issue of transparency, that the 298. communication of adopted texts and/or unofficial translations was the subject of existing recommendations in the Fifth Triennial Review, and that the European Union regularly availed itself of these procedures (see, in particular, paras 49 and 52 of G/TBT/26). She indicated that a lot of information was already communicated to the Secretariat and was available for WTO Members, but that she had observed that much of that information was actually not accessed by all WTO Members. The European Union drew the Committee's attention to its own website where all the information about a particular measure was collected on one page and recommended that the WTO IMS take a similar approach for all notifications.²¹ The representative of the European Union also pointed out that it was important for improved transparency that the notifications were published quickly after their sending to the Secretariat. The European Union would be very much in favour of a system that would allow the direct online notification by members, while avoiding, however, that information needed to be copied in the notification from by the notification authority, as it is the case in the SPS management system. The representative of the European Union also stressed that many Members, including the EU, did not indicate the HS codes, which made it difficult to process notifications automatically and instead required processing them manually and individually. To develop common classification categories could perhaps be an area that the Committee could work on. Further ideas and more detail would be transmitted through an upcoming EU contribution on transparency for the Sixth Triennial Review.

D. OTHER MATTERS

(*i*) Preparation of the Sixth Triennial Review

299. The Chairperson noted that in light of the mandate in Article 15.4²², the Committee was scheduled to complete its Sixth Triennial Review of the Operation and Implementation of the TBT Agreement at its last meeting in 2012. The Sixth Triennial Review would follow a similar approach to previous Reviews: it needed to be based on substantive proposals from Members. Based on a proposal contained in JOB/TBT/13 (dated 6 September 2011), the Committee <u>agreed</u> on the timeline for the preparation of the Sixth Triennial Review as follows:

- (a) **10-11 November 2011**: TBT Committee meeting (discussion on approach and any substantive proposals submitted)
- (b) <u>end-February 2012</u>: circulation by Secretariat of background document compiling information available relevant to the review
- (c) **20 22 March 2012**: TBT Committee meeting: discussion of substantive proposals.
- (d) <u>1 June 2012</u>: deadline for the submission of substantive proposals by Members.

²⁰<u>http://tbtims.wto.org</u>/

²¹ <u>http://ec.europa.eu/enterprise/tbt/index.cfm?fuseaction=WhatNew.viewLast&dspLang=en</u>

²² Article 15.4 of the TBT Agreement provides: "Not later than the end of the third year from the date of entry into force of the WTO Agreement and at the end of each three-year period thereafter, the Committee shall review the operation and implementation of this Agreement, including the provisions relating to transparency, with a view to recommending an adjustment of the rights and obligations of the Agreement where necessary to ensure mutual economic advantage and balance of rights and obligations, without prejudice to the provisions of Article 12. Having regard, *inter alia*, to the experience gained in the implementation of the Agreement, the Committee shall, where appropriate, submit proposals for amendments to the text of this Agreement to the Council for Trade in Goods".

- (e) **13 15 June 2012**: TBT Committee meeting: discussion of substantive proposals.
- (f) <u>July 2012</u>: circulation by Secretariat of first draft report of the Review.
- (g) <u>end-August 2012</u>: submission of written comments from Members on the first draft.
- (h) <u>end-September 2012</u>: circulation of second draft report of the Sixth Triennial Review.
- (i) **6-8 November 2012**: TBT Committee meeting: adoption of the Review Report.

III. TRANSITIONAL REVIEW MANDATED IN PARAGRAPH 18 OF THE PROTOCOL OF ACCESSION OF THE PEOPLE'S REPUBLIC OF CHINA

300. The <u>Chairperson</u> recalled that, in accordance with Paragraph 18 of the Protocol of Accession of the People's Republic of China (WT/L/432), the TBT Committee would undertake an annual review after ten years of the implementation by China of the TBT Agreement.

301. The representative of <u>Japan</u> said that his delegation appreciated past dialogues with the Chinese Government, at regional and bilateral levels and through this Committee. These efforts contributed to more transparent introductions of TBT measures. His delegation observed that China had made progress but still did not appear to notify all new or revised standards, technical regulations and conformity assessment procedures as required by WTO rules.

302. He highlighted some points from document G/TBT/W/342. First, China appeared to continue to pursue the development of unique Chinese national standards as a means of protecting domestic companies from competing foreign technologies and standards. In addition, his delegation understood that, in China, there were not only national standards, but also sector/professional standards established by each department of standardization administration under the State Council or the local government, and local standards of the local government. These also had a huge impact on international trade. Japan would like to know how the central government had fulfilled its obligations under Article 3.1 of the TBT Agreement.

303. Secondly, Japan had asked about conformity assessment measures several times under this agenda item. It was not clear that China could directly accept Certification of Conformity of the China Compulsory Certification (CCC) system, issued by foreign based certification bodies, if the Chinese Government concluded an MRA with a foreign government. In addition, Japan understood that China did not accept EMC (Electro-Magnetic Compatibility) test results conducted by foreign based laboratories under international frameworks, such as IECEE/CB Scheme. His delegation would appreciate China's view on this question.

304. Thirdly, Japan observed that China, despite modifications regarding the certification scheme of information security products, still seemed to be pursuing policies that hindered the use of foreign information security products in China. As Japan and other concerned countries had continually expressed, it was expected of China to exercise prudence in such policies and to conform to global practices. This issue was also important because of the intellectual property protection aspect and his delegation was looking carefully at any progress in this area.

305. He noted finally that, according to China's "Regulations of the People's Republic of China on Certification and Accreditation" and "Measures for the Administration of Certification Bodies", certification bodies must receive approval of each scope of certification practices from the CNCA in order to carry out certification practices in China. However, his delegation understood that there were some certification practice fields where certification rules were not provided by CNCA. His

delegation asked whether certification bodies in China could conduct a certification practice by registering their own certification rules with the CNCA under the "Measures for the Administration of Certification Bodies" in cases where the CNCA had not yet formulated the certification rules. He reiterated the importance of dialogue with the Chinese Government here and in other relevant fora in order to facilitate legitimate international trade.

306. The representative of the <u>European Union</u>, noted that since joining the WTO, China's economic transformation and its leading role in international trade was spectacular. China was now a global economic power whose domestic policies and measures increasingly affected international trade. With power went responsibility and his delegation believed it essential that China take full ownership of its international trade and seek to integrate global regulatory practices in a systematic way in this regulatory process.

307. His delegation's paper focused on four areas of systematic concern. Each was illustrated with some examples taken from the specific trade concerns currently on the agenda of the TBT Committee meeting. The first area was good regulatory practices and transparency. His delegation welcomed the improvements in transparency in China's regulatory process and, in particular, welcomed the increasing number of public calls for comments. However, it considered that these practices were still not uniform and the application very much depended on the regulatory body in charge. In addition, old systems in certain areas remained which were detrimental to the predictability business needed to operate. His delegation, therefore, requested China to consistently call for public consultation on all new, draft laws and administrative measures that might have a significant effect on trade, and to allow for a reasonable period for comments on these drafts. His delegation also encouraged China to expand its use of regulatory impact assessment analysis in order to ensure that technical legislation was not more burdensome than necessary to achieve a legitimate objective. His delegation's paper provided some illustrative examples. He mentioned the ICT sector, information security, and cosmetics, which offered food for thought on what kind of measures could be taken to enhance good regulatory practice in China.

308. The second area of focus in his delegation's paper was about the level of regulation. His delegation noted with concern that China's regulatory framework in the TBT area was characterised by the systematic use of mandatory standards that were almost always combined with a third party conformity assessment. The best illustration was the CCC system which remained a major obstacle for foreign companies, in particular for SMEs. The CCC was complex, costly and lengthy. Since its implementation in 2003, its scope had steadily grown and now CCC extended well beyond its original objective of protecting consumer safety to new areas such as environmental protection or information security. The EU appreciated China's efforts to alleviate some of the administrative burdens of the CCC. However, his delegation stressed the need for China to consider a comprehensive review of the system to abandon the approach of "one size fits all" and to embrace one that took account of products having different levels of risk and safety, by applying a risk based approach to conformity assessment, and by considering lighter approaches such as Suppliers' Declaration of Conformity for products which posed a very low level of risk like office equipment, most electrical equipment, and ICT equipment. The potential introduction of mandatory third party conformity assessment in relation to the management of legislation on the restriction of hazardous substances was also a concern which had been covered in detail under the specific trade concerns. His delegation also recommended that regulation be focused on what was necessary to ensure health and safety, and not extend into issues like qualitative aspects of products that should be left to the market to decide.

309. The third area of focus in the paper was regulatory coordination. In some areas, his delegation observed that several ministries or agencies exercised concurrent regulatory powers over the same products and for the same objectives like safety. This led to situations where the products which had been tested and certified by one regulatory body needed approval from another regulatory body. This led to duplicative procedures and added to the burden for companies. His delegation, therefore,

underlined the need for improved coordination to eliminate this overlap in requirements. His delegation's paper provided illustrative examples in IT security, medical devices, and motor vehicles. For the latter, the situation was particularly revealing with no less than four entities having regulatory competence over almost the same regulatory aspects.

310. The fourth and final area of focus was standardisation. With regard to participation of foreign stakeholders in the domestic standardisation process, his delegation noted that in some sectors, like ICT, participation of foreign companies, although they were established and incorporated in China under Chinese law, was still constrained to observer status. In other sectors, more involvement of foreign companies was allowed. As some of the standards underpinned mandatory certification schemes such as the CCC system, foreign companies were, in effect, deprived of providing input in the regulatory process. His delegation, therefore, called for more transparency, more inclusiveness of the standard setting process, and sufficient time for public enquiries which would allow stakeholders to react to draft standards. Concerning the implementation of international standards and the commitment in the 12th five year-plan to the continued alignment of domestic technical regulations and standards without such deviations being justified on the ground that international standards were inadequate or ineffective for the objective pursued.

311. Another aspect his delegation asked China to consider was the timely adoption of international standards or the latest versions thereof. Outdated versions of standards would obviously cause trouble to manufacturers, especially foreign manufacturers, who were already used to working with the latest version of the standard. His delegation continued to encourage China's increased participation in international standard setting bodies, particularly in areas where issues were global and there was common interest in developing common global solutions instead of divergent national ones. Such areas included green technology, information security, smart grids, etc. One additional area of remaining concern in the IT sector was the emergence of home-grown standards that featured unique Chinese technologies. This resulted in blacklisting certain features of products by preventing innovative products that did not incorporate the technology embedded in the standard from being placed on the Chinese market.

312. Finally, in some areas, his delegation observed a tendency to make voluntary standards mandatory through conformity assessment procedures without any prior warning about this change in the status of the standard. When this occurred, the obligation to notify under the TBT Agreement should be triggered. In conclusion, his delegation welcomed China's efforts to anchor its system in the WTO Agreements. Again it stressed that the effects of China's regulatory process were no longer limited to Chinese territory but had prolific effects on global trade. In this regard, his delegation insisted on good regulatory principles to be systematically followed in the Chinese regulatory process. His delegation would continue to use all bilateral opportunities for regulatory cooperation to work with China towards achieving this goal.

313. The representative of the <u>United States</u> said that his delegation would like to share its observations on the first ten years of China's WTO membership within the TBT context. He recalled that the TRM was created largely because China was admitted to the WTO before it had rendered all of its trade related laws and regulations WTO compatible; China was able to accept certain WTO obligations because of the variety of transition periods it was given. The annual TRM meetings, therefore, provided Members with opportunities to review with China, in a multilateral setting, the efforts China was making so as to implement specific commitments made in its Protocol of Accession. In the area of TBT, the Protocol was straight forward in requiring the key commitment of transparency, followed by the other obligations that all WTO Members had to meet.

314. His delegation agreed with many of the points raised by the EU both orally and in its submission. He wished to focus on two areas in particular: the continued lack of transparency in the development of China's technical regulations, standards and conformity assessment procedures, and China's policies on conformity assessment. In the area of transparency, China had made progress but had not yet implemented all of the commitments that it had made upon accession. Transparency was perhaps the most important TBT discipline in that it enabled regulators to have better access to the information they needed to make evidence-based determinations that would achieve the desired policy objective in the least trade restrictive way possible. It increased the accountability of the regulator to the public, and enhanced the legitimacy of the final results and the rule of law.

315. Early notice of impending proposals also enabled regulatory cooperation activities; regulatorto-regulator discussions could minimize unnecessary divergences between regulatory approaches and facilitate harmonization of technical regulations. Serious concerns remained about China's compliance with the WTO transparency obligations even after ten years of WTO membership. In several TRM discussions in different WTO Committees, his delegation had described concerns about China's efforts to comply with the cross-cutting commitments made in its Protocol that were designed to ensure that trade with China would be predictable and transparent.

316. First, with regard to China's commitment to publish laws, regulations and other measures, his delegation noted that, while China complied with the commitment in many respects, it did not appear that China published measures that provided "internal guidance". Second, with regard to China's commitment to publish measures for comments before implementing them, his delegation noted that China had made improvements over the years, but still did not institutionalise a notice-and-comment mechanism for all Chinese agencies. Third with regard to China's commitments to make available all laws and regulations and other measures pertaining to or affecting trade in one or more WTO language, it appeared that China had only made limited progress implementing this commitment. With respect to TBT, China had made considerable progress towards fulfilling its WTO notifications obligations. He acknowledged that China had notified over 800 measures to the TBT Committee and the number of annual notifications continued to rise. In particular, China's national "GB" standards, issued by the Standardisation Administration of China (SAC) under the jurisdiction of the General Administration of Quality Supervision, Inspection and Control (AQSIQ), had been consolidated into a centralised database and appeared to be regularly notified to the WTO.

He considered it regrettable, though, that China had not put in place such a database for 317. proposed technical regulations, standards, and conformity assessment procedures issued by other Chinese government agencies. Perhaps not coincidentally, China rarely notified such proposals, (including mandatory industrial standards) and conformity assessment procedures issued by Chinese government agencies other than AQSIQ and it sub-ministries such as SAC. For example, the United States was able to identify 25 measures proposed by the State Food and Drug Administration (SFDA) in 2010 that could have been but were not notified to the WTO. The US also discovered five measures developed by the Ministry of Industry and Information Technology (MIIT) in 2009-2010, as well as numerous measures developed by China's Association of Automobile Manufactures that were not notified. It appeared that China also failed to notify thousands of mandatory industrial professionals' standards to the WTO for comment. Such standards, which were frequently developed by Chinese agencies when GB standards did not exist, covered at least 58 industry sectors from oil and gas to textiles, automobiles and for environmental protection. Through its research, the US had identified unofficial listings for 15 of these sectors which set out over 20,000 industrial standards of which over 20 per cent (approximately 4000) were mandatory. For instance, the Ministry of Environmental Protection (MEP) developed 123 industrial standards from 2008 -2010 and none of them appeared to be notified to the WTO.

318. Lack of WTO notification for mandatory industrial standards was particularly problematic because in most cases they must be purchased through authorized resellers in China. The cost was

nominal but such resellers generally did not accept international credit cards and required the use of a Chinese bank account. In practice, this requirement had made it impossible for even the largest US companies and trade associations to obtain copies of the Standards if they did not maintain a presence in China. His delegation strongly urged China to take immediate steps to remedy this situation and allow persons located outside China to purchase these documents without requiring them to maintain a Chinese presence.

319. In addition, the US had compiled a list of over 50 conformity assessment procedures developed by CNCA covering wires and cables, motors, electrical products, power tools, welding equipment, audio-visual equipment, information technology products, lighting fixtures, and motorvehicles and parts, telecommunications, toys and other products that were never notified to the WTO. The US had provided this non-exhaustive list of examples to China for its consideration. This list did not include, for example, the MIIT requirement that mobile handsets be dual-enabled with China's WAPI wireless standard. The US had raised this measure in the Committee on numerous occasions without resolution. That particular measure had not been published nor notified to the WTO. This list demonstrated what the US believed to be systematic flaws in China's notification system. Perhaps China's enquiry point lacked the necessary authority to notify measures either in whole or in part that were developed in or by other Chinese agencies. There could be insufficient internal coordination between AQSIQ and the relevant agencies developing technical regulations and conformity assessment procedures that resulted in a lack of notifications of measures developed by certain agencies. Alternatively, non-transparent development of technical regulations and conformity assessments procedures by specific Chinese agencies could mean that AQSIQ was unaware of these measures because the agencies did not publicize them until they had already been finalised. Whatever the cause, the US urged China to resolve the issue so that China notified proposed technical regulations and conformity assessment procedures to the WTO irrespective of the agency that developed them.

He added that China's development of a centralised database for GB standards had been 320. extremely helpful for enhancing a number of WTO notifications for such measures. Perhaps that would be a useful model for China to follow for other agencies or, better still, on a global basis. In the US, maintaining a daily official journal of most central government measures, as well a separate official journal for each US state, had greatly facilitated regulatory transparency as well notifications to this Committee. Since most measures needed to be published in draft form in these journals, US enquiry point officials could access them directly each day without having to search for them on separate agency websites, call agency officials to ask them what they were working on, or request permission to notify them. His delegation would be happy to provide assistance based on its experience. If China opted instead for maintaining a number of journals on its website rather than having a centralised source, it must take steps to ensure that proposed technical regulations and conformity assessment procedures were made available at an early, appropriate stage so that Chinese enquiry point officials could access them and notify them to the WTO automatically. To the extent that the enquiry point lacked authority to notify certain types of proposed measures developed by certain agencies, his delegation urged China to clarify internally through appropriate means that it must notify these measures to comply with its WTO obligations and that AQSIQ had the authority to notify them.

321. The second area of serious concern for the US was conformity assessments. He cited Article 6.4 of the TBT Agreement while noting that China did not permit US suppliers to use competent conformity assessment bodies (CABs) (e.g. testing laboratories, product certifiers, and inspection bodies) located outside China's territory to demonstrate that their products complied with China's compulsory certification (CCC) and other technical requirements. This policy was highly disruptive to supply chains and competitiveness in the interdependent US and Chinese economies. This was an issue that his delegation had raised as a specific trade concern in many Committee meetings, and

would probably continue to raise in the future. He stressed that the issue was China's failure to recognise conformity assessment bodies in the absence of mutual recognition arrangements.

China claimed that MRAs could be used to recognise CABs located in the US. But his 322. delegation did not see any willingness by China to actually negotiate such arrangements, which were often unnecessary in any case given that Article 6.3 of the Agreement did not require MRAs for such recognition to be provided pursuant in Art. 6.4. China had also previously noted that US regulators regularly recognised conformity assessments bodies located in China to perform tests and services, and MRAs were not even required. While negotiation of MRAs in certain contexts may be appropriate, his delegation's experience found that the insistence of an MRA in other contexts was a policy that had less to do with ensuring regulator confidence and conformity assessment results, but more to do with protecting domestic suppliers of conformity assessment services and the fees that they could charge. This increased costs, burden and delays for foreign producers and much of the resulting costs were passed on to Chinese consumers. Government-to-government MRAs could also be infeasible in situations where one Member regulated and the other Member did not maintain a comparable scheme. As noted in previous Committee meetings, the US believed, bearing in mind its obligations under Articles 5.4 and 9.1 of the TBT Agreement, that the best way for China to liberalize its approach to recognising conformity assessment bodies as competent was either to use accreditation by ILAC MRA or IAF MLA signatories or relevant international standards, guides or recommendations as a basis for direct recognition of foreign CABs. US product safety regulators had employed both methods where relevant, effective, and appropriate. As a result, many CABs from outside the US enjoyed such recognition, and the ability of US regulators to protect public health, the environment, consumer safety and other objectives had not been compromised. The US urged China to take a similar approach. He noted that earlier in the meeting, China urged Korea to recognise conformity assessment procedures in China, showing that China recognised the importance of having its conformity assessment bodies recognized by foreign regulatory schemes.

323. The US also noted that China's national accreditation service for conformity assessment (CNAS) was a signatory to both ILAC MRA and the IAF MLA and, had a responsibility under the rules of those systems to promote their use in China. The complementary responsibility to WTO obligations in Article 9.1 of the Agreement was to adopt wherever practicable international systems for conformity assessment in instances where positive assurances of conformity with technical regulations of standards was required. The US would be interested in learning what programmes China and CNAS in particular had in place to promote the ILAC MRA, IAF MLA in China, and if China could report on any success that it had achieved in persuading Chinese agencies to adopt such schemes as a basis for their conformity assessment procedures.

Going forward, the US urged China to take steps to improve transparency in the development 324. of technical regulations, standards, and conformity assessment procedures. This would include ensuring that proposed mandatory industrial standards and proposals developed by agencies outside AQSIQ such as SFDA, MIIT, and MEP were notified to the WTO. Improving internal coordination, centralizing publication and dissemination and ensuring that the enquiry point had the authority it needed to perform its functions was critical in this regard. Secondly, the US urged China to revise its policy on recognition of foreign CABs in light of its WTO commitments and begin to allow non-Chinese CABs to be recognised to perform conformity assessments services within the Chinese market just as other WTO Members allow such bodies located in China to perform such services for This could best be done through reliance on relevant international standards guides, export. recommendations and international systems for conformity assessments. His delegation proposed, with respect to CCC, that China ensure that no rules, regulations or other legal measures prevented non-Chinese organisations from being designated by CNCA to conduct product testing, initial inspection, follow-up audits and certification for each CCC product category; that China publish the process by which organizations could be designated by CNCA to conduct product testing, initial inspection, follow-up audits and certification under the CCC system on the CNCA website; and that non-Chinese organisations be allowed to conduct such conformity assessment activities for the CCC by using the same equivalent procedures and criteria that CNCA applied for other designated Chinese organizations. The US would continue to engage China both here at the WTO bilaterally until these outstanding issues were satisfactorily resolved.

325. The representative of <u>Mexico</u> congratulated China for this ninth transitional review at the tenth anniversary of China's implementation of the Agreement. His delegation thanked the Chinese authorities for all the efforts made to notify the Members of both new and existing technical regulations, and the efforts towards conformity in line with the commitments they had made. His delegation added that there were instances, however, where it did not seem that China was complying with its transparency commitments. A number of companies had experienced related problems. His delegation invited China to strengthen efforts to make its relevant legislation available in the official WTO languages, and to strengthen the notification activities as previous delegations had stated.

326. The representative of <u>China</u> said that during the past decade, China had spared no efforts to fulfil most comprehensively and seriously its tremendous commitments made upon accession to the WTO. China had eliminated all non-tariff measures and reduced its average tariff on goods from 15.3 per cent at its accession to 9.8 per cent today. China had overhauled 2300 laws, regulations and departmental rules at the central level and 190,000 trade-related regulations, policies and measures at the local level. The above-mentioned, hard-won achievements not only contributed to China's full compliance with WTO rules, including the rules stipulated in the TBT Agreement, but also had a very positive effect on trade promotion and facilitation at the multilateral level.

327. As a developing country, China had tried its best to overcome great capacity constraints in order to fully honour the principle of transparency of the multilateral trading system during the past decade. Up to now, China had notified 842 TBT measures, and responded to more than 3000 enquiries on China's TBT measures mainly through the China WTO Notification and Enquiry Center, in particular, through China's WTO TBT Enquiry Point. China had also dedicated huge human and financial resources to publish in a timely manner its TBT measures, including through the official website of the China TBT/SPS National Enquiry Point. Furthermore, China had made its best endeavour to provide a sufficient comment period for new TBT measures, and to translate as many TBT measures as possible into at least one WTO working language in order to achieve greater transparency. In the same open and cooperative spirit, China had submitted to this Committee in document G/TBT/W/343 the information requested by Annex 1A in China's Protocol of Accession. China was committed to conducting effective and constructive discussions with other Members both under this final TRM and in the regular Committee in the future.

328. The Chinese delegation noted the questions received from Japan under this agenda item prior to this meeting. He also noted that the Chinese Mission received an informal email from the EU with a 5-page draft attachment of questions two days prior to the meeting, which left Beijing just two working days to translate and respond. He apologized to the EU because his delegation was willing but unable to cover all of the EU's concerns at such short notice. For the concerns expressed by the US delegate, he considered that some of the problems could have resulted from misunderstanding and confusion and warranted further clarification from China and further dialogue between the two countries.

329. Regarding standards in China, the Chinese Government had taken a series of measures to ensure the fulfilment of its obligations under the TBT Agreement. First, while formulating and revising technical standards, including industrial and local standards, China implemented strict requirements for adopting international standards as stipulated in the Administrative Measures for the Adoption of International Standards (AQSIQ's No. 10 Order in 2001). Secondly, pursuant to the Standardization Law of China, China's industrial and local standards, once formulated, shall be reported to the competent governmental authority for the record. Third, in 2009, in order to

strengthen the administration over mandatory standards in accordance with the requirements of the TBT Agreement, China started overhauling its industrial standards and launched a national standardization programme.

330. With respect to conformity assessment measures in China, there had been no change with the policies and guidelines governing the mutual recognition of the China Compulsory Certification system (the CCC system) since the last review. The mutual recognition of CCC was based on the mutual recognition agreements signed between the Chinese Government and foreign governments. Based on the bilateral agreements, the designated certification bodies could entrust foreign bodies to conduct follow-up checking. Under the Memorandum signed between China and Japan in 2007, such a mutual recognition mechanism had been put in place. He also clarified that China's membership in the IECEE/CB Scheme did not cover EMC product category. According to the rules of IECEE/CB Scheme, China did not recognize or accept IECEE EMC Test Results (and Certificates).

331. As to questions on the restriction of hazardous substances (RoHS), China's Ministry of Industry and Information Technology had published on its official website the Catalogue for Products subject to Voluntary Certification under RoHS in August 2011. In the meantime, he confirmed that, as suggested by the EU, a "lighter" approach similar to the system of Supplier's Declaration of Conformity had been integrated into the Certification process under China's RoHS legislation regulation.

332. Regarding internal regulatory coordination, China had made great progress in enhancing the clarity, transparency and predictability of its TBT regulatory framework during the last ten years. He mentioned medical devices, as an example. In 2008, the AQSIQ and the SFDA of China jointly published the Announcement on the Market Access Related Questions regarding some of the Imported Medical Devices (No. 94, in 2008), which fully addressed the problem of duplicative conformity assessment practices by streamlining the regulatory work to carry out one time inspection, one time on-site test of quality system of the product concerned, and one time collection of fees by only one of the competent agencies in charge. Finally, regarding regulation for information security, since this question had been fully addressed earlier under Specific Trade Concerns, he did not wish to repeat China's remarks. He believed he had covered everything and reassured Members that his Government was ready and willing to continue its discussions in all appropriate fora in future.

333. The Committee adopted its report of the Ninth Annual Transitional Review (G/TBT/30).

IV. TECHNICAL COOPERATION ACTIVITIES

334. The <u>Chairperson</u> drew the Committee's attention to a document containing the Secretariat's technical assistance activities (G/TBT/GEN/128).

V. UPDATING BY OBSERVERS

335. The representative of the <u>IEC</u> drew the Committee's attention to the IEC report to the TBT Committee.²³ She highlighted the participation of developing countries in the 75th General Meeting which had taken place in Melbourne in October 2011. Other highlights included the participation of Affiliate Leader Phuntsho Wangdi and the marking of the 10th anniversary of the IEC Affiliate Country Programme. The report also cover the IEC's participation in an event organized by the African Electrotechnical Standardization Commission held in Nairobi in September 2011, where five AFSEC mirror committees of the IEC were launched. On conformity assessment, she drew attention to the IECEE- UNIDO collaboration establishing an electrical laboratory in Bhutan. The IEC, she said, looked forward to continued close cooperation with UNIDO through publishing joint manuals

²³ G/TBT/GEN/126.

and participating in common capacity building events for developing countries. Finally, the representative announced the launch of the IEC-IEEE 2012 Challenge, whereby academics were invited to submit a paper on how electro-technology can impact economic, social and environmental development.

336. The representative of the <u>UNECE</u> updated the Committee on the 21st Annual Session of the Working Party on Regulatory Cooperation and Standardization. Three recommendations had been adopted during the session - two in the area of risk management in regulatory system and one in market surveillance. One publication on "A Glossary of Market Surveillance Terms"²⁴ was launched, and another on "Risk Management in Regulatory Systems" was presented in draft form. Other events that took place during the session were the launch of a database containing international practice in market surveillance legislation²⁵, and a workshop on traceability as a tool for management of risks.

337. The representative of the <u>ITU</u> updated the Committee on recent developments in standardization. These included a new standard on future networks which would cater for multiple virtual networks and would also provide superior energy saving capabilities. Another new standard was for a protocol for secure transfer of biometric information for E-health. The third development the representative explained was an international agreement on green ICT methodology which was approved in September 2011. This, he said, would help towards assessing the impact of ICTs on greenhouse gas emissions and energy consumption. Also concerning ICT products, the representative informed the Committee that the ITU was studying the benefits and the advantages of standardization of batteries for mobile terminals and other ICT devices. This, he said, would lead to a reduction of harmful materials used in batteries and an increased lifespan of ICT products. During 2011 the ITU had also established a Standards Question and Answer Forum²⁶, and held three regional workshops on bridging standardization gaps. These took place in Fiji, Algeria and Moldova.²⁷

338. Concerning capacity building, the representative informed the Committee that a regional joint UNIDO/ITU seminar on conformance assessment and interoperability testing had taken place in Ghana in July 2011. A similar event was held in November in Moscow for the CIS and Europe regions. The ITU was also in the process of setting up a conformance and interoperability portal - a unique access point worldwide to all aspects of conformity and interoperability from standards to testing to certification to recognition agreements.

339. Finally, the representative gave details on a major project on conformity and inter-operability. This project consisted of four main pillars: setting up a conformity database; organizing ITU interoperability events; organizing capacity building on conformity assessment and testing in developing countries and lastly, the establishment of test facilities in developing countries.

340. The representatives of the <u>OIML</u>, <u>Codex</u>, and the <u>ITC</u>²⁸ provided updates to the Committee on their on-going activities in developing countries and other work relevant to the TBT Committee.

VI. REPORT (2011) OF THE COMMITTEE ON TECHNICAL BARRIERS TO TRADE

341. The Committee <u>adopted</u> its 2011 Report to the Council for Trade in Goods (G/L/962/Rev.1).

 $^{^{24}} http://www.unece.org/tradewelcome/publications/wp6/2011/glossary-of-market-surveillance-terms.html.$

²⁵ http://apps.unece.org/wp6/

²⁶ <u>http://groups.itu.int/itu-t/StandardsQA/tabid/1750/afv/topicsview/aff/323/Default.aspx</u>

²⁷ http://www.itu.int/ITU-T/worksem/bsg/201110/

²⁸ G/TBT/GEN/124, G/TBT/GEN/125, G/TBT/GEN/127.

VII. DATE OF NEXT MEETING

342. The next regular meeting of the Committee is scheduled for 20-22 March 2012.

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