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Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 15-16 JUNE 2011

Chairperson: Ms Denise Pereira (Singapore)

Note by the Secretariat[1]

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

I. ADOPTION OF THE AGENDA

1. The Committee adopted the agenda contained in WTO/AIR/3751.

II. IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

A. STATEMENTS FROM MEMBERS UNDER ARTICLE 15.2

2. The Chairperson said that the latest list of statements submitted under Article 15.2 of the TBT Agreement is contained in document G/TBT/GEN/1/Rev.10, issued on 22 February 2011. She noted that, since the last meeting, Kuwait (G/TBT/Add.2/105) and Zambia (G/TBT/2/Add.106) have submitted their statements under Article 15.2 and Croatia (G/TBT/2/Add.73/Rev.1) and Ukraine (G/TBT/2/Add.100/Rev.1) have submitted Revisions to their original statements. In total, since 1995, 123 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 (the IMS). The latest list of enquiry point contact is contained in document G/TBT/ENQ/38, issued on 30 May 2011.

B. SPECIFIC TRADE CONCERNS

1. New Concerns

(i) Australia – Tobacco Plain Packaging Bill 2011(G/TBT/N/AUS/67)

3. The representative of the European Union raised some questions about Australia's proposed "Tobacco Plain Packaging Bill 2011" notified to the TBT Committee. She noted that the draft measure aimed, *inter alia*, at restricting advertising or promotion on packaging of tobacco products by imposing "plain packaging" for all tobacco products sold in Australia by 1 July 2012. According to the proposal, the only allowed feature on the package would be the brand name, displayed in a standardised font, size, colour and location on the package. The rest of the package would contain textual and pictorial health warnings.

4. The European Union noted that it was also in the process of revising its so-called "Tobacco Products Directive" and that plain packaging was among the possible future policy options being considered in the on-going impact assessment. In this context, the European Union asked Australia what scientific data or other relevant information had been considered that focused on the link between plain packaging and reducing the appeal of tobacco products to consumers, and whether these studies could be made available to the Committee. Furthermore, while the European Union had examined the "Plain Packaging of Tobacco Products Consultation Paper"[2], the EU delegation asked for some additional information. In particular, should an impact assessment have been carried out prior to the on-going consultation, the EU enquired with Australia whether it could share this document, or a summary of its conclusions, with other Committee members.

5. The representative of the European Union also asked whether Australia had evaluated other legislative solutions and why these alternative solutions had been considered less effective for achieving the legitimate health objective pursued. Furthermore, the European Union noted that Australian authorities had in the TBT notification referred to Australia's obligations under the WHO Framework Convention on Tobacco Control (FCTC), which the European Union and 26 of its Member States were also parties to. In this context, the European Union was interested to know how Australia had taken into account its commitments under other international agreements, including the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Finally, the

[2] http://www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/content/plainpack-tobacco.

representative of the European Union asked Australia to provide information about the envisaged legislative process and the timing for the adoption of the proposal.

6. The representative of the Dominican Republic raised a number of concerns and questions with respect to the Australian draft measure. These are reflected in full in G/TBT/W/339, dated 21 June 2011.

7. The representative of Indonesia also raised a number of concerns and questions with respect to the Australian draft measure. These are reflected in full in G/TBT/W/336, dated 8 June 2011.

8. The representative of Mexico noted that while her delegation shared Australia's interest in protecting the health of consumers, Mexico nevertheless had some concerns - both on TBT and TRIPS.[3] Essentially, Mexico was of the view that the measure was more trade restrictive than necessary to achieve the stated policy objective. It was Mexico's understanding that there was no scientific information that indicated that the design of the box had a direct impact on the level of consumption or the attractiveness of tobacco amongst the population. Hence, in this case, trade would be restricted because producers would need to manufacture a plain or generic box to access the Australian market - and this without evidence that such efforts would lead to a drop or reduction in attractiveness of tobacco amongst the population, particularly amongst young Australians.

9. The representative of China said that his delegation shared the concerns expressed by other Members and would closely monitor this issue.

10. The representative of Chile joined the concerns expressed by delegations before him. While supportive of the legitimate public health objective sought, the proposal, in his delegation's view, raised several issues. To begin with, it appeared to be more restrictive than necessary because there did not seem to be any scientific evidence lending support to "plain packaging" as a means of effectively addressing the objectives that Australia wished to achieve; indeed, what was the scientific basis Australia was relying on? Could not, he asked, the same objective be achieved through the use of better, newer information in visible health warnings *without* affecting the legitimate use of the brand names to differentiate between manufacturers. With respect to the WHO, the FCTC provisions were extremely general in nature - they did not go to the level of specificity set out in the Australian draft measure. Also, special and differential treatment needed to be considered; in particular Article 12.3 of the TBT Agreement was relevant. The article emphasized that in the preparation and application of technical regulations, standards and conformity assessment procedures, Members needed to take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such measures did not create unnecessary obstacles to exports from developing country Members. The representative of Chile also asked Australia to confirm the viability and effectiveness of the dates for adoption and entry into force.

11. The representative of Colombia questioned the justification of the measure under Article 2.2 of the TBT Agreement; in Colombia's view, the measure appeared to be more trade restrictive than necessary to achieve the public health objective sought. In fact, the imposition of the proposed policy could have an impact on other legitimate objectives set out in the TBT Agreement regarding the prevention of deceptive practices. Indeed, pictograms and holograms were currently being implemented by several countries with the aim of informing the consumer of various adverse health effects. Yet it had not been scientifically proven that these labels directly induced a drop in consumption of tobacco. Could Australia, therefore, provide evidence (scientific studies) that proved that the prohibition of the use of cigarette brands would lead to a drop in consumption of tobacco by

[3] Comments on aspects related to intellectual property rights were made in the context of the 7 June 2011 meeting of the TRIPS Council.

consumers under the age of 18? These studies were important because they needed to serve as the basis for impact analysis. In addition, had Australia carried out a cost-benefit analysis?

12. The representative of Cuba acknowledged the priority given to the public health objective as such. Nonetheless, by prohibiting the use of brand designs on packaging, the proposed legislation made it difficult for retailers and consumers to identify and recognize the brand of their choice. Clearly, this undermined the value of brands, which had been built up over the course of many years. In addition, the new regulation would oblige manufacturers exporting to Australia to comply with a new packaging requirement for that market *alone*. This would lead to very high costs which would be practically impossible to bear for companies from developing countries. Moreover, if this same regulation were applied to other products, the impact on international trade would be significantly expanded. In addition, there was the risk that price would become the only differentiating factor between tobacco products on the market, driving down the average and premium price of products, meaning that smoking would become cheaper, having the unwanted effect of *increasing* total consumption. A drop in prices would also have a negative effect on international trade, particularly for those countries that produced tobacco. It was also likely, in the view of the Cuban delegation, that plain packaging would lead to an increase in the illicit trade of tobacco products in the Australian market, given that it would be easier to counterfeit a plain package. This could, in addition, promote the smuggling of genuine packages to satisfy the demand.

13. The representative of Cuba stressed that there was no reliable proof or evidence that showed that plain packaging influenced consumers' behaviour, or contributed to dissuading young people from smoking. Indeed, there was no guarantee that after having imposed this new technical regulation the Australian authorities would achieve the health objectives they were seeking. Existing studies did not examine or validate the genuine effect of the packaging design on the decision to smoke or not; therefore, packaging design was not a reliable benchmark to take into account when regulating a smoking or tobacco use. For these reasons, the representative of Cuba was of the view that the draft measure was not consistent with Article 2.2 of the TBT Agreement because it restricted trade more than necessary to obtain the public health objectives declared by the Australian government. He noted that a number of questions posed by Cuba, and which had also been delivered to the Australian Enquiry Point were circulated separately in document G/TBT/W/338, dated 10 June 2011.

14. The representative of Nicaragua supported the statements made by previous speakers, in particular the points relevant to articles 2.2 and 12.3 of the TBT Agreement. Specifically, she noted that when assessing risk under Article 2.2, relevant elements of consideration were *inter alia* available scientific and technical information, related processing technology or intended end-users of products. In Nicaragua's view, there was no available scientific and/or technical information clearly showing that packaging would impact on consumers' behaviour. Instead, the bill would create difficulties in particular for products entering the Australian market. She recalled Article 12.3 of the TBT Agreement and noted that the measure would create an unnecessary obstacle to products originating in developing countries. Indeed, the law would affect the productive capacity of the tobacco sector in Nicaragua. Moreover, the measure was not only contrary to the TBT Agreement but also the TRIPS Agreement as well as other international agreements, such as the Paris Convention for the Protection of Industrial Property - a point Nicaragua had made at the meeting of the TRIPS Council on 7 June 2011.

15. The representative of Ukraine drew the Committee's attention to an appeal from the Ukrainian tobacco industry concerning the effect of the proposed measure on international trade. After careful examination of the notification and proposed legislation, Ukraine had come to the conclusion that adoption of current version of the proposal would violate a number of WTO obligations, including

those under the TBT and TRIPS Agreements. Ukraine made a statement at the TRIPS Council[4] regarding the TRIPS-related concerns. With respect to TBT, Ukraine considered that the proposed legislation was more trade-restrictive than necessary to fulfil the legitimate objective. The effect of the enactment would be the removal of all distinguishing trademarks, designs, logos, and colour characteristics from the packaging of branded tobacco products. This would make it difficult to identify and recognize specific branded products. In turn, this would make it extremely hard, if not impossible, for any manufacturer of tobacco products not currently present in the Australian market to enter it. The potential adverse impact on international trade of tobacco products with Australia was therefore significant. In addition, the measure could not - in Ukraine's view - be justified under the FCTC because plain packaging requirements went far beyond the obligations set out within the FCTC.

16. The representative of Ukraine then asked a number of questions: Had Australia examined the extent to which the proposed limitation on the use of brands would have an impact on trade in the different like products covered by the proposed measure? Had any studies other than those listed in the consultation paper been examined? If there had indeed been such studies and their outcomes differed from those of the studies listed in the consultation paper, how had these outcomes been factored into the proposed legislation? Had Australia examined the material contribution of existing measures to the achievement of the health policy objectives of the proposed legislation? If so, had improving existing measures been considered as an option? Had Australia analysed the potential trade impact of the proposed measures, including the potential impact on trade with developing countries? If so, what were the results of these analyses? To what extent had Australia considered alternative measures that would achieve the same health objectives without creating an unnecessary obstacle to trade? If less trade-restrictive alternative measures had been considered and rejected, why had they been rejected?

17. The representative of Turkey expressed interest in Australia's responses to the questions raised at the meeting.

18. The representative of Switzerland said that while his delegation shared Australia's concern about the damaging effects of smoking on individuals and public health, the right balance needed to be struck between health measures and WTO obligations; and the measure had to be supported by relevant evidence. Switzerland therefore invited Australia, when reviewing the plain packaging bill to bear in mind that technical regulations needed not to be more trade-restrictive than necessary to fulfil a legitimate objective. Switzerland had also raised concerns in the TRIPS Council.

19. The representative of Honduras, like other delegations, understood the underlying health objective. Nevertheless, her delegation had concerns of a systemic nature in relation to Article 2.2 of the TBT Agreement. Because there was no evidence that plain packaging would in any way affect consumers' behaviour, imposing the said measure would restrict trade without necessarily meeting the objective that Australia had set out to achieve. Moreover, the TBT Agreement in Article 12.3 stated that Members had to ensure that technical regulations would not create unnecessary obstacles to exports from developing country Members.

20. The representative of Norway stressed that it was well within Members' rights to implement the necessary measures in order to protect public health. Australia's proposed measure was interesting in this respect and merited further consideration. Norway trusted that the Australian measure would be implemented in a manner that was consistent with its WTO obligations. She noted that Norway had also implemented a number of measures to combat smoking.

[4] Comments on aspects related to intellectual property rights were made in the context of the 7 June 2011 meeting of the TRIPS Council.

21. The representative of Uruguay stressed that Article XX of the GATT (General Exceptions) stated that no provision should be interpreted as impeding any contracting party from adopting or applying any necessary measures to protect the life and health of people. Uruguay was strongly of the view, as a general principle, that public health protection was under the competence and sovereignty of all States. This had also been recognized in the WHO Framework Convention on Tobacco Control (FCTC). The 172 parties to that Convention had reaffirmed their efforts to give priority to applying health measures for tobacco control, and said that this was crucial for establishing national health policies to protect the population. In Uruguay, for example, tobacco control policies had led to a decrease of 24 per cent of daily smokers; reduced air-pollution in enclosed areas by more than 90 per cent; and, reduced hospital admittances for heart-attacks and other tobacco-related afflictions by more than 17 per cent as compared to the situation before the policies had been implemented.

22. Considering the devastating consequences at several levels (health, social and environmental) there was a clear trend among States to apply measure for tobacco control. Clearly, tobacco control was a legitimate objective to protect health and life of persons under Article 2.2 of the TBT Agreement. Indeed, the representative of Uruguay stressed, Article 2.2 referred specifically to "risks of non-fulfilment". Moreover, in respect of Article 12.3, which stated that Members needed to make sure that their technical regulations would not represent an unnecessary obstacle to exports of developing countries, Uruguay stressed that the protection of life and health of persons was not an unnecessary obstacle - it was, in fact, a very important requirement. Hence, the measure proposed by Australia was in line with the commitments which Uruguay had taken before the WTO.

23. The representative of the Philippines shared the concerns expressed by other delegations who had spoken, particularly on how the draft measure appeared to be more trade restrictive than necessary and the apparent lack of evidence to back it up.

24. The representative on New Zealand noted that the negative effects of tobacco could not be overstated. In New Zealand this was one of the leading preventable causes of early death. Therefore, New Zealand welcomed the Australian Government's decision to take this measure in order to protect public health and human life, and trusted that it would be implemented in a TBT-consistent manner.

25. The representative of Australia said that the proposed legislation on plain packaging of tobacco products was being implemented in the interest of public health. The draft legislation had been subject to an open consultation process, including with Australia’s trading partners, which had begun 7 April 2011. The consultation period closed on 6 June 2011 and comments lodged were being considered by the Australian Government. The legislation was expected to commence on 1 January 2012, and would require all tobacco products offered for retail sale on or after 1 July 2012 to be compliant. In crafting the legislation and other measures related to tobacco, Australia had paid full regard to the rights and obligations under the TBT Agreement and other relevant WTO commitments. Australia would ensure that the policy would be implemented in a manner that was consistent with those commitments.

26. In terms of context, the measure was neither surprising nor new. Australia had been a global leader in tobacco control for over 30 years and had implemented, over that period, a number of measures designed to reduce smoking rates. These measures included: 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, particularly on children; bans and restrictions on the retail display of tobacco products; and mandatory graphic health warnings on tobacco product packaging. Over the years, Australia had made some progress in reducing smoking rates and thereby the health impacts of smoking on individuals and the community at large but, despite all of these actions, the fact remained that some 3 million Australians

smoked every day. Smoking still killed over 15,000 Australians every year and cost Australia's society and economy over AUD 31.5 billion every year.

27. The proposed plain packaging legislation was therefore one of several of new measures designed to further decrease smoking rates. Other elements of the current package included a 25 per cent increase in tobacco excise tax. Australia's tobacco excise and excise-equivalent duty was high by international standards; it currently amounted to around AUD 8.40 on a packet of 25 cigarettes, and AUS 10.09 on a packet of 30. Australia had increased investment in anti-smoking social marketing campaigns and had also added legislation to bring restrictions on tobacco advertising on the internet into line with restrictions in other media and at retail points of sale.

28. It was noted that the suite of measures had been recommended by Australia's leading public health experts on the National Preventative Health Taskforce, and these had been accepted by the Australian Government. The Taskforce had considered that plain packaging would improve public health by: (i) reducing the attractiveness and appeal of tobacco products to consumers; (ii) reducing the ability of tobacco packaging to mislead consumers about the harmful effects of smoking; and, (iii) increasing the noticeability and effectiveness of mandated health warnings.

29. The representative of Australia noted that tobacco packaging was, simply put, one of the last remaining forms of tobacco advertising in Australia and plain packaging legislation was therefore the next logical step in Australia's tobacco control efforts. It was noted that guidelines had been agreed by the Conference of the Parties to the WHO FCTC, in 2008, for the implementation of Articles 11 and 13 of the FCTC: these recommended that Parties consider the introduction of plain packaging.

30. The recommendations of the National Preventative Health Taskforce had been based on extensive research and evidence that carefully explored the impact of tobacco packaging, and had tested the reactions of respondents exposed to different packaging options under experimental conditions. The research evidence was set out in the reports of the Preventative Health Taskforce in 2009 and listed 12 peer-reviewed research papers since 2004 alone. All of these were available publicly and the representative of Australia offered to distribute them. A further nine studies had been submitted in the Consultation Paper that accompanied the draft legislation. In addition, on 24 May 2011, the Cancer Council of Australia had released a review presenting evidence from research over two decades across five countries from 24 published experimental studies. Key findings (also available in the public domain) were as follows:

(a) young adult smokers associate cigarette brand names and package designs with positive personal characteristics, social identity and aspirations;

(b) packaging can create misperceptions about the relative strengths, level of tar and health risk of tobacco products;

(c) decreasing the number of design elements on a cigarette pack reduces its appeal and perceptions about the likely enjoyment and desirability of smoking; and,

(d) plain packaging increases the impact of health warnings.

31. Thus, in Australia's view, 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. The representative of Australia noted that a number of Members had specifically referred to studies by the firm Deloitte released in May 2011 which claimed to find no relationship between the tobacco regulation on packaging and changes in consumption. In this respect, Australia noted that this study had been commissioned by, and funded by, British American Tobacco. Moreover, history suggested that Members needed therefore to treat this study with considerable care

because, from the Australian perspective, it contained a number of misleading statements. Moreover, aspects of its analysis were based on assumptions which were incorrect or highly selective in the use of data - which, again, had been provided solely by the tobacco industry.

32. The representative of Australia noted that there had been some claims to the effect that Australia's plain packaging proposal would have a significant impact on the illicit trade in tobacco products. Australia did not accept this. As a matter of fact, it was important to understand that counterfeiters already had very little trouble replicating branded tobacco packages. Nevertheless, the use of anti-counterfeiting markings would be allowed on packaging, provided that these markings were not associated to tobacco marketing or promotions. In any event, smoking any tobacco product, licit or illicit, was fundamentally harmful to human health.

33. The representative of the WHO said that tobacco use was one of the greatest threats to public health the world had ever faced. Consumption of tobacco currently killed nearly six million people a year through direct use and the deadly effects of second-hand smoke. An average of one person every six seconds and one in 10 adults succumbed to tobacco use. Tobacco was indeed the single most preventable cause of death in the world today. He said it was the only legal consumer product that killed up to half of those who used it as intended and recommended by the manufacturer. Moreover, tobacco was a prominent risk factor for 6 of the 8 leading causes of death in the world. The economic costs of tobacco use were as devastating as the public health costs, killing people at the height of their productivity. Yet these disastrous consequences continued in large part due to aggressive and widespread marketing and practices by multinational tobacco companies, including through the use of targeted and precisely designed tobacco product packaging aiming to initiate and maintain addiction among consumers.

34. The representative of the WHO noted that 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. For example, detailed analyses of tobacco industry documents had illustrated that tobacco companies viewed product packaging as a critical marketing strategy in promoting brand image in order to increase their market share, and target vulnerable segments of the population, including women and children.

35. Peer-reviewed research indicated that plain packaging on tobacco products would increase the impact of health warnings, reduce false and misleading messages that deceive customers into believing that some tobacco products were safer than others, and reduce the attractiveness of products to segments of the population specifically targeted by tobacco companies. Given that the majority of smokers began a lifetime of addiction before the age of 18, plain packaging would severely restrict the industry's capacity to appeal to young people. The representative of the WHO also noted that in the context of the tactics employed by the tobacco industry to use tobacco packaging to mislead consumers concerning the level of risk to which consumers were exposed, plain packaging also circumvented and avoided communication of disparate levels of harm.

36. The representative of the WHO went on to note that even in the face of overwhelming evidence, the tobacco industry would vehemently lobby in opposition to the introduction of plain packaging legislation. Fundamentally, the introduction of plain packaging would represent the inability of tobacco companies to appeal to consumers in ways to which they were accustomed, and, in this way, could affect the tobacco industry's economic interests. It was important to note, he said, that this nature of opposition to effective tobacco control policies was a traditional tactic employed by the tobacco industry as tobacco companies for decades had operated to expand market share.

37. WHO was of the view that the legitimate tobacco control measures being discussed at the WTO would have a substantial impact on tobacco consumption and, in turn, on the national burden of

disease attributed to non-communicable diseases, which represented 60 per cent of all deaths worldwide.

38. It was pointed out that the WHO FCTC was the first international treaty negotiated under the auspices of the WHO. It had been developed in response to the globalization of the tobacco epidemic and was an evidence-based treaty that reaffirmed the right of all people to the highest standard of health. It had been adopted by the World Health Assembly on 21 May 2003 and had entered into force in February 2005. It had since become one of the most rapidly and widely embraced treaties in UN history. The Convention currently had 173 Parties; indeed, of the 153 WTO Members, 138 were also Party to the FCTC and thus subject to the obligations contained in the FCTC.

39. The representative of the WHO noted that Article 3 of the FCTC Convention set out the collective objectives of the Parties in negotiating the Convention as follows:

> "to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke."

40. It was pointed out that the general obligations of the Parties to the WHO FCTC were set out in Article 5 of the Convention, and included the development and implementation of comprehensive multisectoral national tobacco control strategies, plans and programmes, in keeping with the Convention and any future protocols. In addition, Paragraph 2b of Article 5 made clear that each Party to the Convention had committed itself to adopting, implementing and periodically updating and reviewing effective legislative, executive, administrative and/or other measures aimed at *inter alia* preventing and reducing tobacco consumption.

41. In addition to these general obligations, the representative of the WHO noted that the convention contained a number of specific obligations to which parties had committed themselves, including in Article 7, the Parties' obligation, through the Conference of Parties, to propose appropriate guidelines for the implementation of Articles 8 to 13 of the Framework Convention. Also in terms of specific obligations, Article 11 of the Convention required Parties to adopt and implement effective measures in respect of the packaging and labelling of tobacco products, including health warnings and other appropriate messages.

42. The representative of the WHO said that in relation to the obligation in Article 13 of the Framework Convention, which needed to be read in light of the broad definition of "tobacco advertising and promotion" which was contained in Article 1(c) as follows: "'tobacco advertising and promotion' means 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". Article 13 of the Convention required Parties to undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship.

43. On the Guidelines for implementation, Article 7 required the Conference of the Parties, which comprised all Parties to the Convention, to adopt guidelines for the implementation of certain of the obligations outlined above. The preparation of these Guidelines was, it was emphasized, an intergovernmental process in which the Parties to the Convention created working groups where the text of the guidelines was elaborated by representatives nominated by those Parties before being sent to the Conference of the Parties – the governing body of the convention – for consideration and adoption. The Conference of the Parties had, in fact, adopted all guidelines by consensus. In

addition, the resources and references used in the development of the guidelines for implementation were available to the public on the WHO FCTC website.

44. The Guidelines on Article 11 stated as their agreed purpose "to assist Parties in meeting their obligations under Article 11 of the Convention, and to propose measures that Parties can use to increase the effectiveness of their packaging and labelling measures." The Article 11 Guidelines specifically included the adoption of plain packaging of tobacco products. The Guidelines of Article 13 indicated that their stated purpose "is to assist Parties in meeting their obligations under Article 13. They draw on the best available evidence and the experience of Parties that have successfully implemented effective measures against tobacco advertising, promotion and sponsorship". The guidelines then, for the implementation of Article 13, also specifically addressed the issue of adopting plain packaging of tobacco products as a means of implementing Party obligations to undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship pursuant to Article 13.

45. In addition, the representative of the WHO noted two recent decisions of the Conference of the Parties of the FCTC, which had taken place in November 2010 (its fourth session in Punta del Este, Uruguay). The first Decision of interest was the Punta del Este Declaration (FCTC/COP4(5)), regarding public health policy, international trade and the activities of the tobacco industry. It specifically referenced provisions of the TBT Agreement and the TRIPS Agreement, and the Doha Declaration on the TRIPs Agreement and Public Health. The second COP Decision requested, *inter alia*, the FCTC Secretariat to cooperate with the WTO Secretariat with the aim of information sharing on trade-related tobacco control issues.

46. The representative of the WHO also noted that with respect to counterfeit products and illicit trade there existed a protocol on illicit trade in tobacco products currently under negotiation by the Parties to the FCTC. The final session of this intergovernmental negotiating body was expected to be held in March 2012.

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

47. The representative of China expressed appreciation for the fruitful bilateral discussion of the above-mentioned regulation with the Korean delegation, and was pleased to learn that a formal reply to China's written comments was forthcoming. He raised three points of concern. First, the representative noted the content of the regulation was unclear in several parts. For example, the "Presidential Proclamation" and "Order of the Ministry of Environmental Protection" were cited many times in the regulation but no references were given to specific clauses. He invited the Korean authorities to further clarify the draft regulation in order to improve understanding.

48. He also observed that toxic chemicals were classified in the draft regulation according to the "Presidential Proclamation", which was not in accordance with the provisions of Globally Harmonized System of Classification of Labelling of Chemicals (GHS) of the United Nations. The representative invited Korea to use the GHS as the basis of its regulation so as to avoid unnecessary obstacles to international trade in accordance with Article 2.4 of the TBT Agreement. In addition, the draft regulation failed to consider existing actions and outcomes of international chemical risk evaluation and international data for mutual recognition, which contravened the recommendations of the United Nations. He quoted Article 19.4 of United Nations Agenda 21, which explicitly proposed: "expanding and accelerating international assessment of chemical risks; harmonization of classification and labelling of chemicals; and, information exchange on toxic chemicals and chemical risks."[5] The representative of China emphasized the critical role of international cooperation in reducing chemical risks, while ensuring smooth trade flows. He asked the Korean delegation to

[5] http://www.un.org/esa/dsd/agenda21/res_agenda21_19.shtml.

explain its future plans for this legislation and its implementation, and how international work had been - and would be taken into account.

49. While the representative of the United States shared Korea's objectives of safeguarding public health and the environment, he noted concerns about the broad implications of the regulation; implications which applied not only to US industry, but to Korean industry as well. He said US industry had expressed various concerns with the proposed measure, and noted that Korean manufacturers relying on imported chemicals could be faced with a decision to curtail or stop domestic production as a result of costly and burdensome elements of the regulations. Given the complexity of the measure, the United States had requested an extension to the comment period in May 2011 which was declined. Nevertheless, he hoped that Korea would be able to fully engage with US industry to address concerns before finalizing the measure. The US Environmental Protection Agency (EPA) had already begun discussing this issue with Korean regulators in Washington to explore working together to share information, and to discuss respective approaches to chemicals assessment and management systems.

50. The US representative raised a number of preliminary questions and comments on the draft measure. First, he understood that there would be additional implementing regulations forthcoming, namely a Ministry enforcement rule and a Presidential Decree. Assuming that these were TBT measures, he inquired whether Korea intended to notify them. He also sought information on which Korean agencies would be responsible for enforcing the proposal. He explained that the US industry had expressed concern regarding the provisions requiring extensive annual reporting of information concerning manufacture and import. He inquired as to the basis for requiring annual reporting of this kind, as well as reiterated queries about the potential scope of this reporting requirement. He observed that multiple reports did not necessarily increase safety or reduce risk, but certainly increased costs for companies significantly. He asked if Korea had considered other ways to streamline and reduce the burden of the required reporting.

51. The representative of the United States asked whether applicants or registrants could submit data to Korea using the OECD's software, the International Uniform Chemical Information Database[6], and whether such submissions would satisfy the registration requirements. He also noted that the regulation lacked prioritization of the chemicals subject to the authorization restrictions and prohibitions, and he asked whether Korea was considering defining the criteria for prioritizing substances. Also, despite recent proposed changes, Korea's minimum tonnage threshold for pre-registration and registration of substances of 500 kg was still much lower than those in other chemical regimes, and he sought explanation as to why Korea had chosen such a low threshold. He noted that the overall scope of the regulation was very extensive. Industry was expressing a desire for exemptions for some categories of chemicals, such as those used solely for research and development, and the representative hoped that Korea would take these requests into consideration.

52. Although the US Government believed that information relevant to health and safety should not be claimed or otherwise treated as confidential business information, both the US Government and industry were concerned about protecting such information under the Korean measure. He asked what measures Korea would take to protect confidential business information, including trade secrets, while registering and evaluating chemical substances under this proposal, should it be adopted.

53. The representative of the European Union welcomed Korea's efforts to introduce rules on the registration and evaluation of chemicals. The European Union indicated that it supported the objective of these rules, namely the protection of human health and the environment, which the EU also pursues with its own legislation on chemicals. The European Union had the following queries on the Korean draft regulation.

[6] http://iuclid.eu/.

54. Firstly, the EU noted that many parts of the notified regulation referred to presidential decrees or actions that were still to be adopted to implement this regulation. Since these additional rules would also contain very substantial criteria, that were necessary to judge the impact of the regulation, the European Union was interested to know when these criteria would be determined and whether WTO Members would have an opportunity to comment on them. More generally, the European Union was also interested to know more details about the envisaged timeline to make the regulation applicable and enforceable.

55. Secondly, the European Union noted that the regulation requires the evaluation of hazards of chemicals and their classification, but did not include an explicit reference to the UN Globally Harmonized System for the Classification and Labeling of chemicals (GHS). The European Union was therefore interested to know whether Korea had already defined the criteria to be used for the evaluation and classification of hazards of chemicals and whether these criteria were in line with those of the UN Globally Harmonized System.

56. Thirdly, the EU was interested to receive confirmation from Korea that data from test facilities complying with the OECD principles of Good Laboratory Practice would be accepted under the regulation. Finally, the EU stressed that it would be open to more in-depth discussions with Korea at technical level, also in order to share the experience that the European Union had gained from the application of its own legislation on chemicals.

57. The representative of Japan shared the position China and the United States by requesting the amount of production and import of the Chemical Substances required to be registered, not be more than 0.5t/year but more than 1.0 t/year under the new law in order to ensure consistency with other countries' legislation such as EU REACH. Moreover, the total amount of existing chemicals' production and import in the previous year to be reported is not clearly provided. Japan requests the amount required to be reported be more than 1.0 t/year to avoid the excessive burden to businesses. Japan also requests that the documented procedures and instructions in foreign language at least in English be developed and published in order for businesses to comply with the new law appropriately in a short period.

58. The representative of Switzerland informed the Committee that this regulation was been examined by experts. He looked forward to further discussion either bilaterally or in future TBT Committee meetings.

59. The representative of Korea explained the regulation concerned the registration, evaluation, authorization and restriction of new chemicals and existing chemicals that were manufactured in or imported to Korea. Similar to the EU's REACH programme. He said the purpose of the regulation was to protect human health and the environment by managing chemical substances according to the results of assessment of a chemical's hazard and risk. He reported that the regulation was currently under review by the Ministry of Government Legislation.

60. Korean competent authorities had received comments on the proposed regulation from domestic and foreign industry and stakeholders, and had sought to take these into account. With respect to comments from the United States, the European Union, China and Chile, he said the Ministry of Environment was preparing responses and would provide official replies shortly. After taking all the comments into account, he explained that the Ministry of Environment foresaw the review of the proposal during the August 2011 Cabinet meeting, and its subsequent submission to the National Assembly in September.

61. On the specifics, the representative stated that the 0.5 ton provision had been selected in order to cover 80 per cent of the chemical substances produced in and imported into Korea. He noted that the 1.0 ton provision in the EU REACH programme was also set to cover 80 per cent of chemical

substances produced in and imported into the EU. However, he explained that unlike the EU REACH programme, the regulation would not apply to all the existing chemicals, but only those chemicals announced by decree after the enforcement of the regulation. The Ministry of Environment had aimed at 1 January 2013 as the date of entry into force, and implementation from 1 January 2014. With regard to comments on harmonization with international standards, the representative of Korea noted that the definition of chemical materials in the regulation had been adopted directly from OECD documents.

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

62. While the representative of Korea understood France's desire to protect the environment and human life, he expressed concerns about the potential negative impact on international trade caused by the Grenelle 2 Law. He explained that according to Articles 85 and 228 manufacturers should, through labelling, provide information on the amount of carbon emission embodied in products and packaging, and also on the environmental impact throughout the product life cycle, including during the manufacturing, packaging, and transportation and waste stages. He was concerned that the labelling requirements were mandatory. He noted that, unlike France, many other countries had adopted and implemented carbon labelling regulations on a *voluntary* basis. He called on French authorities to consider the fact that carbon labelling involved considerable time and cost increase for manufacturers and exporters.

63. In addition, the Korean industry was concerned about the inclusion of transportation emissions in the life-cycle assessment, which would disadvantage products manufactured outside France due to emissions associated with long-distance transport. He observed that French consumers could choose to purchase less environmentally friendly products manufactured in France over more environmentally-friendly non-French products only because of transportation distance. He recalled that his delegation had requested detailed information from the EU enquiry point about the law and notification but had not yet received a reply. He reiterated his request to French authorities and the EU enquiry point to provide further information on detailed technical guidance and the status of the one year trial implementation.

64. The representative of Argentina noted that France had not notified the complete text of the Grenelle 2 Law in line with the obligations stipulated under Article 2.9 of the TBT Agreement, and he requested that they do so. He also sought clarification on a number of questions:

(a) What would be the implementation timelines of the law, bearing in mind that a pilot phase was to begin in July 2011

(b) Was the law compatible with related European standards, and how would it relate to the current development of a methodology by the European Union on environmental footprints?

(c) Had affected stakeholders, particularly in developing countries, been consulted during the standard preparation phase?

(d) Would the law apply to both industrial and agricultural products?

(e) Would the law lead to voluntary or compulsory labelling for carbon footprint and environmental footprint?

(f) What methodology would be used to calculate the carbon footprint under the law, and would emissions from international transport of products to export markets be

included in this methodology. If this was the case, had the situation of geographically affected countries been taken into account, since this would lead to a change in competitiveness with respect to French national producers and competitors from nearby countries?

Were any clauses for special and differential treatment foreseen for developing countries as per Article 12 of the TBT Agreement? In other words, had the needs of developing countries been taken into account and had measures been put in place so as not to affect the exports of those developing countries. Apart from trade, had the needs of developing countries been also taken into account with respect to special development and finance? Had articles on technical assistance for developing countries been included, particularly for small and medium sized enterprises (SMEs) located in those countries?

65. The representative of the European Union noted that the Grenelle 2 Law included 257 Articles which provided rules for protecting the environment in various areas, *inter alia*, buildings, cities, transport, energy, climate, biodiversity, health and waste disposal. She noted the law had not been notified because France had not considered that it had a significant impact on trade, since the articles related to products did not comprise criteria as such, which still needed to be specified by implementing measures that would be specified at a later stage. However, any implementing measures containing technical regulations or conformity assessment procedures would be notified to the TBT Committee.

66. Concerning carbon labelling, the representative explained that the initial draft of the law had indeed contained a provision aimed at introducing an obligatory carbon labelling in the future, but this provision no longer figured in the final version of the law. Carbon labelling remained therefore voluntary in France for the time being. Instead, Article 228 of the final law provided for a year-long pilot phases to be carried out, so as to gradually inform consumers on details concerning the carbon footprint of products, and studies were currently ongoing concerning the methodology for the calculation of the carbon footprint. However, she reiterated that no decision had been taken yet in this regard - discussion in the TBT Committee was therefore premature.

(iv) European Union – Renewable Energy Directive (EU - RED)

67. The representative of Indonesia expressed concern regarding the European Union Renewable Energy Directive (EU-RED), as Indonesia was one of main suppliers of Crude Palm Oil (CPO) to the European Union. She understood the purpose of the implementation of these regulations was to replace the use of petroleum-based fuels with renewable energy fuels in order to reduce vehicle emissions containing carbon dioxide (CO_2), and therefore reduce greenhouse gas emissions. She noted that the EU-RED required criteria for environmentally sustainable biofuel production processes. In this regard, she requested clarification from the European Union on a number of issues.

68. To begin with, she said that Article 17, paragraphs 4 and 5, allowed for the revision of default values based on scientific evidence compiled by independent experts at the Joint Research Center (JRC). The representative requested confirmation as to whether default values had already been revised, and if not, how long would the revision process take and which procedures would follow, including decision-making. Also, she noted that the EU sustainability scheme provided alternative methods, other than the default values, that could be used to show compliance with the sustainability criteria for minimum greenhouse gas savings. The representative asked if the Commission could confirm whether this alternative data had been received and accepted, the duration of the process following the receipt of submissions, and the decision making process. The representative of Indonesia understood that the independent experts referred to in the Directive were part of the JEC

Biofuels Programme[7] financed by the European Union. She asked if the Commission would include experts from outside the Community in order to ensure independence.

69. In respect of the biofuel market, she noted that although the Commission had explained that the EU-RED would not restrict imports of palm oil, Indonesia was of the view that the biofuel market in Europe was shaped by the EU-RED in terms of default values and financial support provided and that there was no meaningful market outside of the mandatory targets being set for the use of biofuels. In this respect, she asked if the Commission could confirm, on the basis of an independent market study, that an EU biofuel market existed outside of the market created and shaped by the EU-RED.

70. She also asked if the Commission could explain, in accordance with Article 16.4, the number of voluntary schemes that had been recognized to demonstrate compliance to the sustainability criteria set out. Furthermore, could information be provided on the duration of the assessment process prior to a decision being reached? In accordance with Article 16.4, the representative inquired as to whether bilateral agreements were being negotiated and/or had been concluded with third countries to meet the sustainability criteria. Finally, according to Article 19, paragraph 6, the Commission would submit a report to the European Parliament and Council reviewing the impact of indirect land-use change on greenhouse gas emissions and assessing ways to minimize that impact by 31 December 2010. The representative sought further information about the report, and whether it had been made public.

71. The representative of Argentina put on record his delegation's concern with the EU-RED.

72. The representative of the European Union was aware of Indonesia's concerns regarding the EU-RED and noted that extensive bilateral discussions had been held with Indonesian authorities on this issue over the past three years. Most recently, this issue had been discussed during the visit of EU Trade Commissioner Karel de Gucht to Jakarta in May 2011. She reported that the European Union had also started a specific palm oil dialogue with Indonesia, including both Indonesian authorities and industry.

73. It was recalled that the EU had notified the draft Renewable Energy Directive to the TBT Committee in July 2008 (G/TBT/N/EEC/200) due to the existence of TBT elements in Articles 18.2 and 18.3 of the original proposal. However, these elements had not been retained in the final Directive. The concerns expressed by Indonesia related, either directly or indirectly, to the sustainability criteria for biofuels outlined in the Directive, which fell outside the scope of the TBT Agreement. Therefore, her delegation considered that the TBT Committee was not an appropriate forum for discussing this issue, or for providing a reply to Indonesia's queries. However, the EU remained open to further bilateral exchange with Indonesia in this regard.

(v) Brazil – ANVISA Enforcement of CATEC Technical Opinions 4, 5, 6 and 7 of 21 December 2010

74. The representative of the United States noted that on 21 December 2010 the *Câmara Técnica de Cosméticos* (CATEC), which he explained was the scientific technical body that advised ANVISA on matters of cosmetics regulation, issued four technical opinions with respect to ingredients in cosmetics products. He explained that Technical Opinion 4 recommended maximum concentration levels for certain forms of Vitamin A in cosmetic products. It classified products containing certain forms of Vitamin A at a particular risk level for purposes of registration and mandated that suppliers submit certain tests and evidence of chemical stability, and recommended that such products carry warning labels.

[7] http://ies.jrc.ec.europa.eu/jec-research-collaboration/about-jec.html.

75. The representative of the United States said that Technical Opinion 5 recommended maximum concentration levels for Urea for certain cosmetic products, and the submission of safety tests that, in some cases, would be assessed by ANVISA. He also noted that certain products containing Urea would be classified at risk levels for purposes of registration, and that warning labels would be made compulsory for all cosmetics products containing this substance. He noted that Technical Opinion 6 recommended maximum concentration levels, restrictions, and compulsory warning labels for additional substances contained in cosmetics. In addition, Technical Opinion 7 recommended that Saw Palmetto be banned as an ingredient in personal care products, cosmetics, and perfumes. While not taking a position on the substance of these technical opinions at present, the United States was concerned about a lack of transparency with respect to the opinions. He explained that although ANVISA was of the view that these technical opinions were voluntary recommendations without any binding legal effect, the opinions contained mandatory language, including, compulsory warning labels, the requirement to submit test results, and provisions that products would be classified in a particular way for purposes of registration. Furthermore, he reported that industry representatives had come away from recent meetings with ANVISA with the impression that the opinions would, in fact, be enforced in Brazil as binding.

76. The representative of the United States requested written clarification from ANVISA on its website as to whether the opinions were voluntary or binding. If they were voluntary, he requested that ANVISA correct the language in the opinions that seemed to signal otherwise, which would eliminate the uncertainty in the marketplace. If, on the other hand, the opinions were binding, or if ANVISA sought to make them binding, whether through developing a measure at the national level or at Mercosur, the representative requested that they be notified to the WTO as they contained elements of technical regulations and conformity assessment procedures that significantly affected trade. Furthermore, he requested an adequate transition period for industry to comply. Finally, he sought any information from the Brazilian delegation as to the legal status of these opinions, and what measures Brazil may take to clarify the situation for the cosmetics industry and for consumers.

77. The representative of the European Union echoed the concerns raised by the United States, and sought clarification as to whether the technical opinions were in any way mandatory. In other words, she asked whether cosmetics not complying with the opinions, in terms of maximum concentration or labelling recommendations, would still be allowed to be sold in Brazil. If these opinions were voluntary, she asked if there were any plans to make them mandatory, either at the national level or at the regional level through a Mercosur technical regulation. Should they become mandatory, the representative reminded Brazil of the obligation to submit a notification to the TBT Committee at an early draft stage.

78. The representative of Brazil responded that the technical opinions in question were issued by CATEC, which was a technical committee established in 2004 to advise on issues relating to cosmetics. Such technical opinions had the status of recommendations and served as a technical scientific reference for ANVISA. He stressed the fact that they were *not* binding. He explained that the technical opinions covered substances for which there was not yet any specific regulation in Brazil, but which could pose health risks. The representative of Brazil noted that when preparing technical opinions, CATEC took into account international references, including the United States Food and Drug Administration (FDA), the Cosmetic Ingredient Review[8], Health Canada, and the European Scientific Committee. Since the technical opinions from CATEC were not binding, he said they could be questioned at any time and that ANVISA was open to receiving scientific data from interested parties so that it could better assess the merits of the technical opinions. Hence, the Brazilian delegation was of the view that CATEC technical opinions were not technical regulations, given that they were not mandatory. Therefore the TBT Committee was not the appropriate forum to

[8] http://www.cir-safety.org/.

discuss them. However, his delegation remained open to further bilateral discussion on this issue with interested delegations.

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

79. The representative of the United States noted that the Indian Ministry of Consumer Affairs, Bureau of Indian Standards (BIS), was proposing to issue a new Toys and Toy Products Compulsory Registration Order. While his delegation fully supported the objectives of protecting health and safety, especially children's health and safety as regards toys and toy products, he raised a number of concerns with the Order. To begin with, India had not notified the Order in draft form to the WTO, denying Members and others the opportunity to comment on the process. The US industry was concerned that the new requirements would be overly burdensome and potentially duplicative of existing requirements. In particular, the order appeared to mandate a new registration procedure requiring the provision of very specific information from production. The required information pertained to each factory's management composition, the raw materials used, factory components, factory layout, production process, packaging and storage, details of quality control of staff, and information regarding all machinery in the factory, including the serial numbers for all equipment on the factory floor. He noted that, in addition, a notification was required whenever a piece of equipment was removed from the factory, even for the purpose of maintenance.

80. The representative of the United States asked what the rationale was for providing such detailed information; his delegation was concerned about how the confidentiality of this information would be ensured, and legitimate commercial interested protected. The representative understood that the order as imposed would require that sampling, inspection and test reports be conducted by either a BIS recognized laboratory in India, or an overseas laboratory covered by an MRA with BIS. His delegation was not aware of any such MRAs, and therefore this provision would amount to an in-country testing requirement. In this regard, he suggested the alternative of recognizing test results from internationally recognized labs such as those that had been accredited by an ILAC MRA signatory. This was the current practice of India's Directorate-General of Foreign Trade, which had a notification procedure covering imported toys.

81. In addition, the US delegation was concerned that should this Order be adopted, two separate Indian measures would cover imported toys whereas there would only be one regulation covering domestic toys. The representative of the United States inquired why it was necessary for two agencies to be regulating imported toys and whether there were plans for the two ministries to coordinate in streamlining the respective requirements so to facilitate compliance by industry without sacrificing the protection of health and safety.

82. The representative of the European Union also expressed concern about the Order and requested that it be notified under the TBT Agreement in order to allow a more detailed examination of the consequences of this proposed change in India's conformity assessment regime for toys. He reiterated the concerns expressed by the previous speaker that the Order implied a shift to a more stringent conformity assessment regime than what was currently in place (supplier's declaration of conformity (SDoC)). The new system had the significant limitation of requiring in-country testing, compared to the current regime which accepted test results from foreign independent ILAC accredited laboratories. He also said the system would be coupled with an onerous registration procedure. The EU representative hoped India would ensure transparency if this planned change was implemented, and his delegation wished to have an opportunity to further discuss this matter bilaterally in the margins of the TBT Committee meetings.

83. The representative of Switzerland echoed the concerns raised by the previous speakers and invited India to notify the new regulation to the TBT Committee.

84. The representative of India reported that the Bureau of Indian Standards (BIS), which formulated standards on toy products, was in the process of formulating a standard for the use of phthalates in toys. This standard was currently in the draft stage; it was open for comments from Members until 20 June 2011. Nevertheless, he emphasized that the standard had not been operationalized into any sort of technical regulation. The Department of Industrial Planning and Promotion was contemplating the development of certain regulations based on these BIS standards, but they were still in the process of drafting them. The representative assured all interested parties that his delegation would notify the draft technical regulation once it was finalized. He also noted the concerns raised by the US delegation on the detailed factory information, among other issues, and he pledged to revert back to the responsible administrative ministry while they were still formulating the draft Order.

(vii) India – E-Waste (Management and Handling) Rules 2010 (G/TBT/N/IND/41)

85. The representative of the United States said his delegation fully supported the objectives of India's Ministry of Environment and Forests in their E-waste Management and Handling Rules, which sought to protect human health, safety and the environment. He expressed appreciation for India's notification of the measure in response to requests from Members. He noted that numerous comments had been submitted by US companies and industry associations through the Indian enquiry point. The representative expressed further appreciation for India's many significant revisions to the regulation in response to the comments received, such as: reducing the scope of substances covered from twenty down to six, revisions to the *de minimis* thresholds, and changes to product scope.

86. However, the representative of the United States raised some additional questions about elements of the measure. The representative said that certain provisions could be overly burdensome, work against the stated objectives of the measure and even restrict trade. For example, he cited a provision that required producers to submit detailed information on the constituents of the equipment used in the recycling process, and he questioned the objective behind producers revealing potentially proprietary information in this context. He observed that not only could this provision jeopardize legitimate commercial interests and stifle industrial development, it could also make it more difficult for companies to use innovative substitute materials.

87. The representative of the United States asked whether India planned to provide additional guidance with respect to the provision of the regulation that called for producers to provide information on the hazards of improper E-cycling. Furthermore, he understood that producers were responsible for funding and organizing a system to meet the costs involved in environmentally sound management of E-waste from their products. He noted this requirement could pose challenges for Indian, American and third countries' small and medium-sized enterprises (SMEs). In this regard, the representative asked whether there could be a general fund set up for SMEs so that they could collaborate, particularly when they may not have the resources or contacts to set up their own system. Finally, the US representative recommended that India increase the three month implementation period given that producers would need time to establish E-waste collection, handling and recycling systems in India. Also, it would take time for E-cyclers and E-waste handlers to be established and approved by Indian authorities. He urged India to take these factors into account in evaluating the measure further.

88. The representative of India said the E-waste (Management and Handling) Rules 2010 had been notified to the TBT Committee on 4 October 2010, and a 60 day comment period had been provided. He explained that the Rules would enter into force on 1 January 2012, and the reduction in the use of hazardous substances (RoHS) would be implemented with effect 1 January 2014. The representative appreciated the constructive suggestions of the US delegate on the draft rules. He agreed that the issue of the SMEs would need to be looked at by Indian regulators in terms of permitting collaborative applications in the context of the various norms established by these rules.

He asked the US delegation, and other delegations, if they had and suggestions with regard to the specific format of collaboration between SMEs in submission of data. Finally, he said he would forward to capital the suggestion of increasing the implementation period.

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

89. The representative of Mexico expressed concern about the Alcoholic Controls Act 2010, published by Kenya on 7 December 2010, and notified 1 March 2011. She said Mexico shared Kenya's interest in protecting human health, and protecting consumers against misleading information. Mexico also shared Kenya's interest in disclosing relevant scientific information about the consumption of alcohol, establishing programmes for alcohol treatment and rehabilitation, as well as adopting measures to eliminate illegal trade in alcohol which affected the health of the world population. Nonetheless, in her delegation's view, the legislation contained criteria which would give rise to unnecessary barriers to trade. She cited Article 32.3, which required that at least two of the three warning texts (as specified in Annex 2 of the notification) take up not less than 30 per cent of the total surface of the product. The representative said this requirement was unnecessary for achieving the legitimate objective of protecting public health; in her delegation's view, there were more effective mechanisms in the fight against the excessive consumption of alcohol.

90. In addition, Article 32.4 established that the combination of text or lettering be rotated every 50 packets of each brand's beverage. However, the legislation did not explain how this rotating requirement would be implemented in practice, which would lead to uncertainty in the cost of labelling and related logistical details. Her delegation believed that Kenya could apply a less restrictive policy to moderate the consumption of alcoholic beverages in its territory. For example, Kenya could use information campaigns as well as public policies to control the problems of alcohol consumption. In addition, she requested information on studies, including those supported by the Kenyan Government, which justified the imposition of the aforementioned measures.

91. Furthermore, she said Kenya did not appear to uphold the obligation stemming from Article 2.9 of the TBT Agreement, since the legislation entered into force before it had been notified to the WTO: the measure was notified in March 2011 but had been enforced in December 2010. Therefore, Members had not had a chance to submit their comments for consideration prior to the adoption of the measure, which she said was important given the potential economic and trade impacts of the measure. The representative of Mexico therefore requested that the Kenyan authorities consider comments made by the Government of Mexico with respect to the legislation in question, and provide the scientific information upon which they based their decision to impose these measures. She requested that Kenya comply with the provision of the TBT Agreement by imposing a less restrictive measure to moderate the consumption of alcohol in its country, for example through public policies that raise awareness amongst the population of the problems deriving from excessive consumption of alcohol.

92. The representative of the United States reiterated concerns raised by Mexico with respect to the size of the warning label in proportion to the bottle, as well as the rotation requirement for the warning statements. He enquired as to the rationale behind the possible inclusion of pictures in the alcohol warning statement. With respect to notification, the representative asked why the measure had been notified under Article 2.10 rather than Article 2.9 of the TBT Agreement. His delegation had subsequently been able to submit comments, which was appreciated, and he requested a dialogue on those comments with the Kenyan authorities. The representative further requested that the implementation period be extended to allow for the major modifications proposed under the new requirements, if they did indeed enter into force. At present, his delegation's understanding was that implementation of at least some parts of the measure had been postponed due to pending legal action.

He asked if Kenya could confirm this understanding and, if so, clarify which sections were postponed, and the expected length of the implementation delay.

93. The representative of the European Union also expressed concerns with the measure, which contained technical regulations that had not been notified under the TBT Agreement. Her delegation had recently taken the opportunity to submit detailed comments on the above-mentioned notification and was awaiting a written reply from Kenya. The representative of the European Union enquired whether Kenya had considered less burdensome alternatives to modify drinking behaviour other than mandatory health warnings labelling. The European Union's experience in this area had demonstrated that drinking behaviour needed to be addressed in a holistic manner. Education and information activities seemed to be appropriate means to address the public health objective pursued, and she therefore asked Kenya to reconsider this measure. With respect to the form of labelling information provided, she sought confirmation that products would be able to gain market access in Kenya as long as the importer added an extra sticker containing the requested warning messages.

94. The representative of Kenya noted the comments and concerns expressed and said that her capital would soon issue written responses.

(ix) Korea – Amendment to Radio Waves Act 1/2011 (RRA)

95. The representative of the United States expressed several concerns with the amendments of the Radio Waves Act which put into place new marking and labelling and certification requirements for a host of information technology products. First, Korea had not notified the implementing regulations of the Radio Waves Act to the WTO for comment. Although he understood that the Korean Communication Commission (KCC) had belatedly opened a comment period on the measure from 2 May to 20 May (18 days), he nonetheless hoped that Korea would still notify the measure to the WTO, and provide an adequate comment period.

96. With respect to implementation, the representative of the United States noted significant confusion amongst industry with respect to what was required by the Act, particularly in terms of marking and labelling requirements. Unfortunately, compliance was required by 1 July 2011, and importers were required to comply with this deadline in terms of date of importation, while for domestic manufacturers, the deadline referred to the date of manufacture. Given the fact that the labelling requirements were still the subject of discussion, he said this deadline did not provide sufficient time for industry to re-label and repackage products, and had drastic consequences for foreign products which were already in the pipeline for shipment to Korea.

97. The representative of the United States understood that industry had requested a two year adjustment period. This would mean that products that were certified under the previous system would be able to continue using prior markings until January 2013 and he noted that compliance periods this long were not unusual in other markets for such complicated and broadly applicable requirements. In addition to a longer adjustment period, he stated that the compliance date needed to be based on date of manufacture for both imported and domestic products. Industry had raised numerous questions with respect to the labelling issues and he requested that the KCC work closely with industry representatives to resolve these concerns so to ensure companies understand how to comply.

98. He encouraged the Korean authorities to make the labelling requirements applicable only to products meant for retail sale to consumers. Indeed, his delegation believed that this was in fact the intent of the measure; namely, that the measure applied only to products meant for retail sale, and not to business-to-business sales. He noted a lack of written guidelines on this point, and said industry had been told that Korean customs would make a decision on whether labelling was required on a case-by-case basis, and this lack of clarity was very disruptive for commerce. Finally, under the

amendments set forth, new electrical safety and certification requirements would enter into force in January 2012 and he asked whether non-Korean laboratories would be able to demonstrate that they could test and certify to these requirements.

99. The representative of Korea said that his authorities could postpone implementation no longer, given that the requirements in question had originally been notified on 1 July 2009 under the Framework Act on National Standards. He noted in light of the 30 June 2011 implementation deadline, that the Korean competent authority had provided a very reasonable 2-year adjustment interval, which was sufficient for international industry to adjust their products and processes. With respect to the different implementation dates for imported and domestic products, he reconfirmed that the Radio Research Agency (RRA), which fell under the auspices of the KCC, had changed the implementation date for imports from the date of importation to the date of manufacture, which therefore applied the same conditions to imported and domestic products. The representative of Korea noted that the RRA had visited the United States and had held several meetings in order to explain the new measures to US companies and related industries.

(x) Korea- Proposed Cosmetics Labelling and Advertisement Guidelines (G/TBT/N/KOR/308); KFDA draft Guidelines for Management of Nanomaterials in Cosmetics

100. The representative of the United States noted that this trade concern related to three different measures. First, with respect to the Cosmetics Act revision, he understood it had been passed at the Korean National Assembly Welfare Committee and the full vote in the National Assembly was currently pending. He relayed the concerns of US industry with a provision of the Act that would require cosmetics manufacturers to indicate, in Korean, the product name, company name, batch number and expiration date or period after opening, on both the primary package and on the labelling and the secondary or outer package.

101. While the US delegation supported the objective of enhancing consumer information, he nonetheless raised a number of industry's concerns. First, the potential costs of the additional labelling could be substantial. Second, there could be delays at the border while the packages were inspected, and he noted that opening the secondary packaging to inspect the primary package could damage the product's quality and contents. In addition, he said translating the name of the products and company into Korean could be problematic, since some US products were known to Korean consumers under their English name (all advertisements were made using English names). As a result, he suggested the requirement could negatively impact the image of a product. However, he emphasized that the concern with translation was not related to directions for product use or safety information, but with respect to the brand name. If all the necessary and detailed information on the product, including the ingredients, were already labelled on the secondary packaging his delegation believed that it should be sufficient to fulfil Korea's objective.

102. With respect to the Guideline for Cosmetics Labelling and Advertising, the US representative said they set out positive and negative lists of claims that could be made with respect to cosmetics. He recalled that US industry had filed comments in late April, and he understood that the Korean Food and Drug Administration (KFDA) planned to finalize the measure after the National Assembly passed the Cosmetics Act. He noted two particular concerns raised by industry. First, there were already two measures in Korea that covered cosmetics labelling: a Korea Fair Trade Commission regulation and the Product Liability Act, and he enquired how a third measure would interact with the other two should there be instances of overlap.

103. Second the representative of the United States observed that if a company wanted to make a claim not found on either list, the procedure for doing so was not clear. For example, he asked whether a company could make a claim where the wording was different from that indicated on the negative list, or make a claim not mentioned on either list. Moreover, he noted that the negative list

of claims was very broad and included claims that were normally accepted around the world, which could have a negative trade impact. For example, the negative lists included claims on anti-ageing properties and claims for hair care products. While his delegation fully supported Korea's objective of ensuring that consumers understand the claims being made, he underscored concerns about proposed requirements for the use of foreign languages, and in particular brand names, which the representative also mentioned with respect to the Cosmetics Act Revision.

104. With respect to the KFDA Guidelines for Management of Nanomaterials in Cosmetics, which required the labelling of nanomaterials contained in cosmetics products, the representative of the United States noted that US industry had sent comments in April. He asked Korea to confirm that it would notify the guidelines to the WTO once drafting was complete. The representative expressed concern with the requirement to note the presence of nanomaterials in cosmetics. In 2007, the US Food and Drug Administration Task Force analysed this precise issue and had determined that the scientific evidence did not support a finding that classes of products with nanoscale materials necessarily created greater safety concerns than classes of products without nanoscale materials. The task force had indicated there did not appear to be a basis for requiring that a product containing nanoscale materials be labelled as such, and did not recommend that FDA require such labelling. He offered to provide copies of the report as background information. While labelling of cosmetics to include relevant information, such as the consequences which may result from the use of the product under prescribed or customary conditions of use, was appropriate, he argued that requiring across the board labelling when a nanomaterial was present was not necessary, since it provided no useful information to the consumer, and was potentially misleading as it suggested that the product may be different than an equivalent non-nano product in some material way, or was potentially unsafe.

105. However, the representative of the United States noted that having specific criteria to establish whether a material should be considered a nanomaterial within a specific regulatory context could be useful where that information was relevant to the determination of safety or efficacy for example. In this context, he noted that the Nanomaterials Working Group of the International Cooperation on Cosmetics Regulation (ICCR)[9] had identified criteria for determining whether an ingredient in cosmetics could be considered a nanomaterial. He suggested that Korea might consider this work in the interest of promoting harmonization. In addition, his delegation would welcome Korean government and industry participation in that forum.

106. The representative of the European Union supported the concerns raised by the United States with respect to the Cosmetics Act revision and the KFDA Guideline for Cosmetics Labelling and Advertising. She highlighted concerns about the requirement to indicate the product name and company name in Korean on the label of the primary package. To comply with this requirement, importers would potentially have to open and re-label all products destined for the Korean market with stickers, which would increase costs and time to market, and could also damage brand image. She asked when Korea intended to notify the Cosmetics Act revision to the TBT Committee which, as the United States had said, was already pending before the National Assembly. She noted the importance of providing WTO Members with the opportunity to comment on measures while still in draft form.

107. With regard to the KFDA Guidelines for Cosmetics Labelling and Advertising, containing negative and positive claim listing, her delegation was currently in the process of finalizing its comments on the TBT notification, and sought certain clarifications. She asked Korea to clarify what type of documents would be required from producers to substantiate the claims that they used. As currently elaborated, the draft guidelines simply stated that the methods to be used for the substantiation of claims be "adequate" and "objective", without further details. Second, with regard to

[9] "http://www.fda.gov/Cosmetics/InternationalActivities/ConferencesMeetingsWorkshops/InternationalCooperationonCosmeticsRegulationsICCR/default.htm".

the testing requirements, she inquired as to the rationale for the substantiation of claims requiring certain tests – for instance "in-vivo" testing - which were usually reserved for higher risk products such as pharmaceuticals. Third, she asked Korea to clarify the relationship between these guidelines and the revision of the Cosmetics Act, which also covered cosmetics labelling. In general terms, the representative of the European Union expressed her delegation's concern with the multitude of rules applicable to cosmetics in Korea, which were either being developed or had recently been adopted, which were contributing to a climate of confusion and legal uncertainty for economic operators.

108. The representative of Korea explained that the purpose of the proposed Cosmetic Act was to regulate labelling of cosmetics and protect consumers. He said that the Act was currently being reviewed by the National Assembly, and that the competent authorities had received comments on the proposed guidelines from industry and stakeholders since December 2010. In addition, a public hearing had been held on 16 December 2010. The Act had been developed based on the idea that customers usually threw away the package of cosmetics after they had opened the package for initial use. Therefore, it was deemed important to affix or print information on the containers or the products themselves, such as the brand name, company name, importer name, and expiration date, in order to ensure that customers continued to have access to this information.

109. The Act required that the Korean language be used along with any other foreign languages, and his delegation understood that other countries, such as the United States, the European Union, and Japan had the same requirements in their domestic market. He noted that the competent Korean authorities provided a very reasonable two and a half year interval with a view to allowing international industries sufficient time to adjust to the new requirements. The representative also noted that all products manufactured during this grace period were allowed to enter into the Korean market after the implementation date.

110. With respect to the Guidelines for Cosmetics Labelling and Advertising, he explained that it included three lists of claims and expressions, which were either: (i) Prohibited, (ii) Allowed, or (iii) Acceptable under the conditions that the claims and expressions were supported by trial and test data. He further explained that the methods and standards included labelling claims and expressions such as "can be used on acne-prone skin" or "delays skin ageing". Regarding the negative list, he reported that it was developed on the basis that some expressions used in advertisements and labelling of cosmetics could cause consumers to mistake them for pharmaceuticals, resulting in adverse outcomes associated with the safety and efficacy of products. Hence, the proposed guidelines were designed to ensure appropriate advertisement and labelling of cosmetics, and therefore protect consumers. Furthermore, he explained that the guidelines were necessary to provide the cosmetic industry time to prepare for an additional upcoming amendment of the Cosmetics Law which would introduce an Advertising Substantiation Policy, currently under review by the National Assembly.

111. The representative of Korea noted that the competent authority had received comments on the proposed guidelines from industry and stakeholders beginning December 2010, and that a public hearing was held on 16 December 2010. In addition, the competent authority had also considered the regulations of OECD members such as Japan, Australia and Canada. The draft Guidelines for Management of Nanomaterials in Cosmetics were under internal discussion and consultation within the KFDA. Therefore, there were no specific contents to notify to the TBT Committee at the current stage and his delegation believed it was premature to engage in a discussion of them in the TBT Committee. Once a specific guideline was available it would be notified and a reasonable comment period provided.

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

112. The representative of the United States raised some concerns about Mexico's Energy Labelling measures encompassed by: the Law for Sustainable Use of Energy (28 November 2008); Regulation of the Law for Sustainable Use of Energy (11 September 2009); National Program for Sustainable Use of Energy 2009-2012 (27 November 2009); and the Catalogue of equipment and appliances used by manufacturers, importers, distributors and marketers that require mandatory inclusion of energy consumption information (10 September 2010). While the Government of the United States and its industry supported Mexico's efforts to raise consumer awareness of energy consumption to encourage energy efficiency through a labelling system, concerns were expressed about the lack of transparency and the overly burdensome nature of the current Mexican law and regulations. While the representative of the United States understood that the measure had perhaps been notified recently, he requested Mexico to ensure their notification and delay the implementation of the new requirements until after the consideration of comments.

113. On certain substantive issues in respect of the catalogue, the US delegation noted that the scope of the products to be subjected to energy output labelling listed in the catalogue was very broad. For instance, the United States was not aware of another energy labelling programme covering the breadth of products that would include can-openers and other types of devices characterized by very low energy use. Indeed, the actual testing and labelling for such small appliances would probably consume more energy than the product itself in actual use. He asked the representative of Mexico to consider narrowing the scope of the products included in the catalogue to reflect those covered by other energy-labelling guides. He also pointed out that some of the concepts like "stand-by mode" that appeared in the catalogue probably did not apply to all products. It was also unclear what the proposed label would look like and where on the product it would be placed; this could confuse consumers. The delegate of the United States also pointed at a lack of clear guidance on the testing procedures to be used for the purposes of labelling. Since different manufacturers of the same product could be using different test methods, it could be very difficult for consumers to compare one device with another because the numbers on the label would be derived from different testing procedures. Moreover, test methods had still not been developed for many of these products. Given that these methods would be product-specific and take time to develop, the United States asked Mexico for a delay in the implementation and enforcement of the law, which was set for September 2011. Different industry associations, including those of the electrical, appliance, and information technology industries, had submitted comments. They were working with their counterparts in Mexico and willing to work with the Government of Mexico in order to come up with a workable solution. The delegate of the United States concluded by asking Mexico whether energy efficiency could be part of the on-going North American harmonization work, as suggested by many stakeholders.

114. The representative of the European Union echoed the concerns raised by the United States. While the European Union supported the objective of energy efficiency and environmental protection, further clarification regarding the legislation at issue was necessary. The representative of the European Union asked why neither the law for sustainable use of energy, nor the catalogue of products subject to energy-labelling requirement had been notified according to Article 2.9.2 of the TBT Agreement. Second, she inquired how the Mexican authorities would ensure that missing relevant and applicable tests for some products would not lead to the use of different measurement procedures, resulting in different outcomes and potentially misleading consumers or reducing their trust in energy efficiency policy. Third, it was unclear whether the labelling requirements set out

would apply to products already placed on the market, including products already distributed to sales floors or to warehouses. If this was the case, this would lead to a logistically burdensome and energy consuming re-labelling of products already placed on the market. As well as urging Mexico to provide a reasonable transitional period, the delegate asked whether the option to apply stickers to the external surface of the retail packaging would be allowed. Finally, the European Union asked Mexico whether and how international standards had been taken into consideration when developing the labelling requirements and tests methods. In addition, the EU noted that a request for clarification had also been sent to the Mexican Enquiry Point on 10 June 2011, to which the EU hoped to receive a written reply.

115. The representative of Japan supported the position of the United States and the European Union. Although Japan recognized the objective of the requirement, including the idea of supplying pertinent information to assist customers in selecting products with outstanding energy-saving performance characteristics, Japan was concerned about the above-mentioned measure. First, the catalogue of products targeted would include items for which hardly any effects could be expected from the regulation. Second, the details of the design of the labels to be displayed; the measuring methods and other areas remained unclear. The delegate of Japan was of the view that some requirements could be difficult to address by manufacturers. He also argued that consumers could be negatively impacted if they failed to obtain appropriate information. Accordingly, implementing the system in the proposed format would run the risk of diversifying the content of the label, ultimately generating confusion not only for manufacturers but also consumers. He stated that Mexico should file a TBT notification about these measures in order to give Members the opportunity to express opinions. He invited Mexico to narrow down the product scope of the measure and to clarify the terms of use and the specific labelling methods. A period of one year following the official announcement of the labelling requirements was suggested in order to allow manufacturers, importers and other concerned businesses time to prepare, given the considerable inventories maintained by individual companies.

116. The representative of Argentina stated his country's interest in learning more about how exactly the proposed measure would function.

117. The representative of Mexico confirmed that the catalogue of equipment was notified to the WTO on 15 June 2011(G/TBT/N/MEX/214). According to the notification, the entry of force of the measure was envisaged for 11 September 2011. In line with Article 2.9 of the TBT Agreement and on the basis of this notification, a 60-day period for comments would allow all parties concerned to comment. All comments would be taken into account. The representative of Mexico indicated that a Working Group, established in collaboration with the Secretariat of Energy of Mexico, was in charge of drafting the measure and was currently considering all the criteria, in particular the tests, evidence and scope associated with the implementation of the measure. In addition, the Woking Group was also working closely with industry and the Chamber of Commerce. In fact, as part of the administrative regulatory procedure, the drafted version of the catalogue had been submitted for public consultation on a website of the Federal Commission of Regulatory Improvements in August 2010, allowing the private sector to comment extensively.

(xii) South Africa – Liquor Products Act of 1989

118. The representative of the United States expressed concern with the Liquor Products Act of 1989, setting out quality and identity standards for spirits to be marketed in South Africa. He argued that the way South Africa defined the spirits on the basis of alcohol content was at the root of the problem. In particular, he noted that there was a gap in the measure between a “spirit cooler” defined by a maximum alcohol content of 15 per cent and a “liqueur” with a minimum alcohol content of 24 per cent. As a consequence, a product characterized by an alcohol content between 15 and 24 per cent could not be marketed in South Africa.

119. The representative of the United States explained that a US company had been trying to market a product with an alcohol content of 17 per cent in South Africa since the beginning of 2009. Given the impossibility to change the product formulation to modify the alcohol content without changing the product, this firm had applied to market the product both as a spirit cooler and a liqueur, but both applications were rejected due to the middle range alcohol content of the product. The delegate of the United States concluded that this problem was related to the definition of spirits based on alcohol content rather than on the raw materials and production process. He was not aware of any health or safety reason explaining why liqueurs could not be between 15 and 24 per cent alcohol. In fact, he noted that South Africa made an exception for Amarula, a domestic product containing 17 per cent alcohol and sold as a liqueur in many other markets. According to the representative of the United States, this provided evidence that South African authorities did not have health or safety concerns about this product which also contained 17 percent alcohol and was sold in other markets. This raised potential issues of differential treatment for foreign and domestic producers of liqueurs. For that reason, the representative of the United States asked South Africa whether the liqueur definition could be revised to be based on raw materials and production processes rather than on alcohol content, or to consider another more trade-facilitative approach to allow this US company to sell its product in the South African market.

120. Although the company's application had been discussed bilaterally and the relevant documentation had been provided, the company still had not received approval or an explanation or response from the South African Liquor Products Division of the Department of Agriculture, Forestry and Fisheries. Given that this company had been waiting several years to export its product, the representative of the United States asked South Africa for a status update on the application and an explanation for the undue delay.

121. The delegate of South Africa noted that, to the extent of his knowledge, no specific international standard existed with regard to liqueur on which all countries needed to base their technical regulation. Liqueur definitions relied, therefore, on national regulations which could differ from country to country. In fact, the guidelines and resolutions on wine and all products of vine, including grape spirit, provided by the International Organization for Wine and Vine (OIV), would not necessarily apply, because the spirit normally used in liqueurs could be from agricultural origins, such as cane, grain or any other vegetable articles cheaper than grape spirit. The representative of South Africa explained that, in general, liqueurs were usually produced by the maceration of fresh or dried fruit, or fruit peels or aromatic plants in a spirit or the adding of flavourings of vegetable origins, herbs or extracts thereof to a spirit and adding thereto a sugary syrup and colorants, if applicable. He said that although the OIV was working on a draft resolution proposing 15 per cent minimum alcohol content and no maximum alcohol level for spirit-based liqueurs and a maximum of 100 grams per litre of sugar, no guideline or resolution describing a minimum level of alcohol for liqueurs had been accepted by the organization or its member countries, including South Africa.

122. Moreover, the delegate of South Africa explained that the Liquor Products Act, which had been in place since 1989, was based on the technical specifications for production of liqueurs set out in the Wine, Other Fermented Beverages and Spirits Act which dated back to the 1950s, because the liqueurs continued to be produced in that way today. He confirmed that according to the Act of 1989, the minimum alcohol content of liqueurs was set to 24 per cent, without any maximum alcohol requirement. In line with the national treatment obligation contained in Article 2.1 of the TBT Agreement, the minimum requirement of 24 per cent volume of alcohol did not differentiate between locally produced or imported liqueurs. In addition, the existence of legitimate divergences of taste, income, geographical and other factors between countries were acknowledged in the TBT Agreement.

123. With regard to Amarula sold in the South African market, the representative of South Africa explained that it was a wine-based product, classified as an aperitif or cocktail, and did not comply with the definition of liqueur. According to the Liquor Products Act, a cocktail marketed in South

Africa was defined as a product produced by the combination of wine with herbs, natural extracts of herbs, other flavours of vegetable origin, or extracts thereof, or flavours of nature-identical, egg or a dairy product, in order to produce a distinctive taste and aroma differing from that of wine or a class of wine and composed of an alcohol volume between 15 and 23 per cent. He explained that Amarula for the export market complied with the definition of a cream liqueur, since it was produced to have a spirit base. Since Hpnotiq - the product the United States wished to export - could not be considered as a wine-based aperitif or cocktail, or as a cream liqueur since no cream had been included, it could not be compared with Amarula. The US product in question could be sold in the local market only if the exporter was willing to comply with the local regulation, which would involve either reducing the alcohol content to below 15 per cent to meet the spirit definition or raising it above 25 per cent to comply with the liqueur definition. Alternatively, the US company could adapt the product to an Amarula-type beverage by converting it to a wine-based product, just like South African producers would adjust their products to the regulations of the importing country. Finally, he noted that a proper evaluation of the product which the United States wished to export was taking a bit more time than expected. South African regulators were still investigating the different laws and options under which the product could be accommodated for importation into South Africa.

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

124. The representative of the United States expressed concerns about a series of notices and documents issued by the Government of Viet Nam over the last three months with suggestions for new conformity assessment procedures requirements for a diverse group of imported products. He referred in particular to the notice on the importation of spirits and cosmetics, which had been issued on 7 April 2011 under the Ministry of Finance document no. 4629, and notice no. 197 on the import of alcohol, cosmetics and mobile phones, which had been published by the Ministry of Industry and Trade on 6 May 2011.

125. The representative of the United States explained that notice no. 197, apparently establishing a quality control procedure requirement through the submission of a quality conformity certificate, had been raised as a priority issue in a letter sent on 24 May 2011 to the Viet Nam Vice-Minister of Industry and Trade from five foreign embassies in Hanoi, including that of the United States. According to him, further clarifications regarding the legal status of both documents were necessary. In particular, he asked for confirmation whether any quality control procedures implemented were also applied to domestic producers and if that was the case, what mechanism was used to ensure that local producers undertake the same or comparable procedures. The representative of the United States also requested confirmation about the entry into effect of notice no. 197, which had been set as 1 June 2011.

126. The representative of the United States noted, more generally, that it was unclear why and which criteria were used by Viet Nam to select alcohol, cosmetics and mobile phones to be subject to these procedures and not other products. Since US exporters were still trying to understand how to comply with these measures, the representative requested a precise description of the goods subject to the measures, preferably by indicating the HS codes. He also requested clarification on the quality control requirements, the nature of the quality conformity certificate and the identity of the authority issuing it as well as the relevant standards used to evaluate each product in terms of quality. It was also not clear why the quality control procedures were limited to three ports.

127. The representative of the United States noted that none of these measures had been notified to the WTO for comment even though the implementation period provided appeared to be less than one month after the issuance of the final notice. Viet Nam was strongly urged to notify these measures,

suspend their implementation until the measures were appropriately modified to take into account the comments made and provide a reasonable period for suppliers to comply. He explained that if it was the case that no quality control procedures were in place, Viet Nam should clarify it in writing through the issuance of another notice. In such a case, he concluded that there would be no reason to restrict the entry to three ports.

128. The representative of the European Union joined the delegation of the United States in expressing concern about Viet Nam's recent measures to regulate imports of various products such as spirits, cosmetics and mobile phones. She explained that the European Union was one of the signatories of the letter mentioned by the United States and sent to the Ministry of Industry and Trade. She was looking forward to Viet Nam's replies to the questions raised by the United States and reminded Viet Nam of its obligation to notify draft measures to the TBT Committee insofar as they contained TBT elements, and to provide for an adequate implementation period in order to allow economic operators to adapt to new requirements.

129. The representative of Australia shared the concerns of other delegations about both notices issued by Viet Nam. In particular, he expressed concern with the conformity assessment procedures set out in document no. 4629, including with respect to the compliance of these measures with the TBT Agreement. It was unclear whether the conformity assessment procedures would also apply to domestic producers and what the basis to identify the products was. More specifically on document no. 4629, Australia requested further information on the identification of the products, namely alcohol and cosmetics, and the nature of the quality check. In addition, more information about the certification of quality conformity, together with the timeline for issuing the certificate, was needed. The representative supported the calls requesting Viet Nam to suspend the measure until clarification and adjustment of the measure to the comments provided by trading partners. He concluded by explaining that limiting the entry points to the three international seaports, as referred to in the document, would potentially lead to extra costs of exporting products to Viet Nam by precluding air and road traffic as possible transport options.

130. The representative of New Zealand supported the interventions made by other delegations and requested clarification and details regarding the quality conformity certificate requirements both to ensure exporters would be able to comply with these requirements and to be assured that Viet Nam would take account of its WTO obligations.

131. The representative of Canada also expressed interested in obtaining more information about the conformity assessment requirements associated with these notices.

132. The representative of Viet Nam said that all the comments, concerns and questions raised would be sent to capital to get an official reply. He nevertheless asked that those Members having taken the floor send their written comments to Viet Nam's national TBT enquiry point.

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

133. The delegate of the United States expressed concern about Malaysia's draft protocol for halal meat and poultry products. While acknowledging Malaysia's desire to institute a reliable halal system, as well as the opportunity provided for comment prior to the implementation of the revised protocol, he requested Malaysia to take into account the US comments. He was concerned that the protocol would require dedicated halal establishments and, therefore, requested Malaysia to indicate whether the protocol would require an entire supply chain to be dedicated exclusively to halal. In this regard, he highlighted the fact that sufficient processes, consistent with the Codex halal guidelines, were already in place in the United States to prevent any co-mingling of halal and non-halal product produced in the same establishment, segregated by time and space. He argued that exclusive dedication should not be required as long as a foreign producer could sufficiently demonstrate that

halal and non-halal products had been completely segregated. He urged Malaysia to adopt a similar approach as part of its halal protocol.

134. The representative of the United States also noted that food safety and halal were two separate issues. Halal was a religious and processing issue which needed to be audited separately from food safety. Consequently, it was important to ensure that Malaysia would continue to allow mechanical slaughter of both poultry and meat as long as the process would fully allow for the required ritual slaughter methods.

135. The representative of the European Union joined the United States in expressing concerns about the draft Protocol for halal meat and poultry production. She mentioned that comments had been sent to Malaysia on 30 May 2011 and her authorities were looking forward to a written reply. Several points needed to be clarified. To begin with, she asked if Malaysia had the intention to notify the draft protocol to the SPS Committee, given that beside TBT-related issues, some aspects of the notified protocol (among them those related to slaughtering process and techniques) appeared to be covered by the SPS Agreement. In addition, she noted that the purpose of the draft Protocol was to support the implementation of Malaysian compulsory standard MS 1500 of 2009 on "halal food preparation, production, handling and storage, general guidelines", making the standard, in effect, a technical regulation; it should, hence, have been notified in accordance with Malaysia's WTO transparency obligations. The EU therefore invited Malaysia to also notify this mandatory standard to the WTO, and make it freely available to economic operators.

136. On a separate point, the representative of the European Union reminded Malaysia of the obligation to use international standards as a basis for its requirements, and enquired to what extent Malaysia had taken into account the relevant international standards in this area, most notably CODEX standards CAC/GL24 and CAC/GL26 of 1997. Moreover, it was also unclear whether establishments carrying out both halal and non-halal activities would be eligible for approval, provided that a strict separation between halal and non-halal products was guaranteed. Furthermore, the EU highlighted the importance of implementing the procedures proposed with the greatest transparency and objectivity, including, for instance, by providing a clear indication of the timeline in which the inspection of facilities and approval of foreign products could be expected. The representative of Malaysia was urged to ensure that its procedures for assessment of halal establishments were not more trade restrictive than necessary to give Malaysian authorities adequate confidence that its requirements were met. In this regard, she was interested to know whether Malaysia would also accept inspection results and certificates from the competent authorities of the exporting country. This would facilitate trade, be in line with international standards and lead to an effective use of human resources.

137. The representative of Argentina also expressed his concern about the notified protocol in respect of guidelines for the slaughter, stocking and transportation of halal products, including poultry. In particular, he argued that the requirement that establishments had to dedicate exclusively to Halal production in order to export to Malaysia would create unnecessary obstacles to trade and be more restrictive than necessary. Malaysia should have considered the Codex guidelines specifying the general directives regarding the use of halal meat and labelling. According to these guidelines, halal foods could be prepared and stocked in different sections or different lines within the same building or establishment producing also non-halal products, as long as there was no contact between halal and non-halal products. In addition, halal foods could be processed, transported and stocked in places which were used for non-halal foods as long as the appropriate cleaning techniques in line with the Islamic requirements were observed. Based on the information received from the Argentinian sanitary authorities, the delegate explained that the seven argentine establishments authorized to export to Malaysia were suspended by DVS on November 2010 without receiving any official Malaysian communication in this regard.

138. The delegate of Brazil thanked the Malaysian delegation for the opportunity to discuss the issue bilaterally and indicated that he was looking forward to receiving answers to written comments sent to Malaysia.

139. The representative of Malaysia thanked all the delegations that had provided written questions and raised comments regarding the draft protocol for halal meat and poultry production, notified in document G/TBT/N/MYS/23. He explained that technical experts in capital were currently reviewing all the comments and questions received. Written answers to these questions would be provided as soon as possible. In addition, he indicated that bilateral discussion with interested Members would continue in order to clarify and resolve this issue.

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

140. The delegate of the United States was concerned about Resolution 2604 issued on 24 December 2009, which provided mandatory emissions limits for commercial diesel trucks sold in Colombia. He noted that the measure in question had not been notified to the WTO and the domestic comment period provided had been approximately 15 days. Consequently the US industry had not been made aware of the opportunity to provide input into the process for developing the measure. He urged Colombia to notify the measure to the WTO, take comments into account, and revise the measure before its entry into force, scheduled in 2013.

141. The representative of the United States noted that although he supported Colombia's objective to lower emissions from commercial diesel trucks for health and environmental reasons, he explained that according to the US industry the diesel fuel currently available in Colombia was not compatible with the US Environmental Protection Agency's 2010 emission standards (EPA 2010), which was what Colombia would be requiring for US trucks subject to this measure as of 2013. In particular, engines built to meet the EPA 2010 or even the EPA 2007 rules required ultra-low sulphur diesel fuel with a sulphur content of less than 15 parts/million, while the sulphur content in Colombian diesel fuel was at least 50 parts/million. According to industry, the high sulphur content of this magnitude would clog the diesel particulate filters installed on trucks that met those two EPA sets of rules. Since the appropriate fuel was not available in Colombia and would not be for at least several years, the delegate concluded that this measure would effectively bar US diesel trucks from the Colombian market, representing a very large market for US suppliers. He suggested that requiring diesel trucks sold in Colombia to meet an earlier version of the EPA rules, such as the EPA 2004, would be workable for US industry and still help reduce emissions in Colombia.

142. The representative of Colombia noted that a bilateral meeting would be held to resolve the concerns expressed by the United States.

2. Previously raised concerns

(i) European Union – Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH) (G/TBT/N/EEC/52 and Adds.1-6; Add.3/Rev.1; G/TBT/N/EEC/295 and Add.1; G/TBT/N/EEC/297; G/TBT/N/EEC/333-6)

143. The representative of India expressed concern about the definition of Small and Medium sized enterprises (SMEs) in the European Union for purposes of lower registration costs citing that the European definition of SMEs did not account for labour intensive industries such as those in India. He noted that the criteria using both annual turnover and the number of employees in the organisation would be unfair since it would place Indian SMEs in the large enterprises category. He urged the European Union to reconsider the definition of the SMEs within REACH.

144. He also stressed the high burden placed on SMEs as a result of the creation of the Substance Information Exchange Fora (SIEFs) and consortia beyond the purview of regulatory control and with potential to be dominated by European industry. He highlighted some specific concerns with SIEFs, such as a high joining fee, penalties associated with joining the consortia late, annual maintenance fee, non-uniform rules of different consortia, high fee for lead registrants, refusal by Members to accept participants, prohibitive cost of letter of acceptance etc. Moreover, there was a lack of transparency in the functioning of the Steering Committee, responsible for establishing the rules of the consortia particularly in the areas of cost sharing and determination of fees.

145. He added that as data costs became extremely high, the letter of access (LoA) had emerged as a default option for SMEs and that the European consortia were encouraging and advising upfront in favour of the use of the LoA as opposed to data sharing as a more practical solution while providing inadequate information on the comparison of the costs entailed in either option, or the basis for determining LoA costs or the cost-sharing. He underscored that the real concern was not with the costs themselves but with the practices involved in the determination of these costs.

146. The representative of India acknowledged the principles set forth in ECHA Guidance Document on Data Sharing, for example, the need to agree on terms and conditions for cost-sharing and data between registrants and data holders at an early stage in the data sharing process. However, he noted that the principles were not followed regularly and that the consortia tended to inform registrants of the costs of the LoA at the last minute, allowing them little option but to pay. He requested, therefore, that the European Union consider the application of some special and differential treatment for data sharing in the consortia set-up.

147. Furthermore, the representative of India asked for clarification on the logic of registration of monomers under REACH given that the life cycle of the monomer ended once it was reacted into a polymer. He noted that monomers were normally stable within the polymers and did not pose any separate risks. He also highlighted that the information on monomers did not provide any conclusions on the risks posed by the polymers. India was also concerned about the registration of the entire tonnage of the substance in an article, even if not all of it (less than 100 per cent) of the substance was intended for release upon use of the article. This increased the tonnage band for registration, and made it harder for the registrant.

148. On animal testing he noted that the principles of REACH emphasized avoidance of animal testing and stressed the sharing of animal testing data. Additionally, the Joint Research Centre (JRC), he said, had found that in the best-case scenario, REACH would require testing of 2.1 million to 3.1 million animals by 2018. He noted, however, that the scientific magazine "Nature" had recently reported that generation of REACH data could require testing of up to 54 million animals and cost approximately €10 billion, within the next ten years; hence, the estimates by the JRC were under-estimations. This, he noted, would make the legislation unfeasible and raised concerns over the economic and regulatory rationale of REACH. He also noted that the high costs of data-sharing in SIEFs made a case for computer simulation of chemical testing, and requested the European Union to consider the option.

149. The representative of Argentina reiterated concerns with the complexity of REACH due to its various phases of implementation and underscored that the regulation, in its current form, was an unnecessary obstacle to trade. He pointed out the uncertainty and lack of transparency that result from the complexity of REACH as well as the frequent amendments to the legislation, noting that the regulation had been amended 19 times, six modifications of which had been introduced within the past four months. He mentioned Regulation no. 143/2011, which added six substances to Annex 14 of REACH, that referred to substances requiring marketing and use approval from ECHA ; Corrigendum of Regulation no. 143/2011 modifying the time-frame for the procedure; Regulation No. 252/2011 modifying Annex 1 to adjust classification criteria in other provisions of Regulation

1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures; Regulation 253/2011 modifying Annex 13 containing the criteria to identify the persistent bio-accumulative and toxic substances as well as very persistent and very bio-accumulative substances; Regulation No. 366/2011 modifying Annex 17 - Restrictions to the manufacturing, marketing and use of specific substances, mixtures and dangerous articles, introducing new provisions on the particular substance called aklomide; and Regulation No. 494/2011 modifying Annex 17 as well - restrictions to the manufacturing, marketing and use of specific substances, mixtures and dangerous articles, banning as from 2012, cadmium in jewellery, plastics and welding bars. The European Union referred to its explanatory guidelines trying to facilitate the understanding of REACH amendments, but as these guidelines were constantly updated, the exporters faced scarce predictability and transparency in their commercial operations.

150. Argentina was also concerned about any new modifications and amendments that would be brought about by the general review of REACH, which would be conducted on 1 June 2012 by the European Commission in accordance with paragraph 6 of Article 138 of the Regulation. He noted that this would add to the costs to enterprises of hiring or contracting services of consultants. Additionally, he highlighted the required cost of designating an Only Representative (OR) in order to be able to accede to the European market, a cost which was not borne by European producers, as well as the administrative costs for procedures required for the registration of each substance which together made the situation worse for SMEs.

151. Currently, the reduction of rates for SMEs that REACH allowed were still quite restrictive and this reduction was offset by the above mentioned indirect costs which SMEs would have to face. He underscored the need, therefore, for the European Union to enhance the transparency of the REACH implementation process, to reduce continuous modifications to the regulations and to reduce the costs of registrations for non-European SMEs allowing them to align with and compete with European companies in line with the national treatment principle. Of course, Argentina supported the objective of protection of health and the environment - but there was a need to ensure that REACH did not continue to pose an unnecessary obstacle to trade. In the absence of a solution a large number of companies would be left out of the European chemicals market.

152. The representative of Canada shared concerns raised by India and reiterated the need for information on the measures taken by the European Union to ensure that membership to SIEFs would not be unduly or arbitrarily restricted. He expressed concern with REACH impacting the competitiveness of SMEs on the European market. He also asked what measures the European Union was taking to ensure that provisions related to substances in articles were implemented uniformly across its member States. It was also important that compliance with the measures would not be overly burdensome for industry.

153. The representative of the United States reiterated its support for the objective of protecting human health and the environment but continued to express concerns with REACH, noting that the European Union had yet to address several trade-related concerns with the regulation that have been raised repeatedly, such as the OR concern, or the monomers and polymers issue. He also raised a new issue with the OR provision of REACH and the process for authorization. He indicated that Article 62.2 of REACH did not expressly list ORs as possible applicants for authorization, leaving it unclear as to whether an OR would be allowed to submit an application for a REACH authorization. He noted that if that was not the case and ORs could not apply, each importer of a substance would have to apply for authorization. This would adversely impact foreign manufacturers since they would need to submit multiple applications as they would tend to use multiple importers. On the other hand, he noted, European producers of substances would only need to submit one application. He asked the European Union to clarify how it would resolve that issue. He also highlighted that the issue was particularly bothersome for SMEs since they would not have European operations and therefore would have to resort to the OR solution as the *de facto* option. He also mentioned that the United

States hoped to discuss the issue bilaterally with the European Union through a new chemicals dialogue initiated in 2010.

154. The representative of China shared concerns of other Members on the subject. He also mentioned that China was awaiting the response of the European Union to the question of the unreasonable cost sharing mechanism, as well as the high costs - issues that had been raised at the previous meeting of the Committee. He underscored that the European Union explanation of a number of successful registrations did not constitute justification.

155. The representatives of Australia, Cuba, Philippines, and Thailand, echoed the concerns expressed by other Members - in particular with respect to the complexity of the regulation and its potential adverse impact on SMEs.

156. The representative of the European Union noted that the matter raised by the United States (on the possibility for ORs to apply for authorization) was under discussion in Brussels and no answer could yet be provided in the TBT Committee. She also noted that since most other comments were reiterations of previous concerns that had been answered, she would focus on recent developments on REACH, connected with the issues raised.

157. On the subject of the functioning of SIEFs, she noted that the European Commission and ECHA would continue their efforts to help industry and would provide as much guidance as possible. However, she noted that, as had already been indicated on several occasions, it would be up to industry to organize itself within the SIEFs, and neither the Commission nor ECHA could interfere. She also noted that a Directors' contact group, chaired by the European Commission, had been created to facilitate contact with industry to understand concerns regarding SIEFs and informed the Membership that the mandate of the group had been extended to enable it to tackle issues which were relevant for the second registration deadline in 2013. She indicated that the group would continue working on outstanding issues to find solutions.

158. With respect to abuses discovered in the SIEFs, these needed to be forwarded to ECHA where it would be determined if a response was necessary and whether it was possible to intervene.

159. On the issue of requirements on substances in articles, she noted that the guidance on the requirements for substances in articles had been updated and had been published on 1 April 2011. However, she confirmed that there was no change in the Commission's position on the subject. In addition, Article 7, paragraph 2 of REACH was applicable since 1 June 2011 and ECHA had already received their first notifications for articles.

160. With respect to enforcement, it remained to be seen whether EU Member States would interpret Article 7 differently than as explained in the guidelines. As previously explained, the European Court of Justice was the institution that had the final decision on the interpretation of the REACH Regulation.

161. On the issue of the "one-ton" presence criteria for substances in articles, instead of the amount that was released from the article, –as well as the rationale for the registration of monomers in polymers, the EU referred to its previous explanations in the TBT Committee.

162. Regarding the definition of SMEs, the representative of the European Union said that the issue had already been discussed and the definition of the SME was laid down in a European Union Recommendation No 2003/361/EC and that definition was used not just for the purposes of REACH, but in all legislation and policies within the European Union. She noted that, given that, it would be impossible to take into account all definitions of third countries, as it could not be ensured that this would not result in discrimination between EU and third countries' industries. Therefore the SME

definition of the European Union would apply to all SMEs, irrespective of their origin, adding that the number of employees was an important criterion for the definition of SMEs in the European Union as well.

163. Regarding the changes to REACH, quoted by Argentina as proof of its complexity, the representative of the European Union noted that the amendments *per se* were not indicative of complexity - they had been foreseen from the beginning. She explained that REACH had several steps and, subsequent to the adoption of REACH, many substances still had to be identified, and certain annexes to the regulation needed to be filled in. This was a normal process which resulted from the implementation of REACH. The same was true of the guidance documents, which were also updated due to the progress of various stages of REACH, and in order to clarify certain questions, such as those raised in the interventions of WTO Members in the TBT Committee. . ECHA would therefore continue to update the guidance documents in 2011, in order to help industry submit registration dossiers and comply with REACH.

164. With reference to the draft Commission regulation amending REACH Annex XVII (CMR substances) the representative of the European Union informed that the draft had been revised after discussions in the legislative procedure, and that a new draft had been sent to the WTO Secretariat and would be available soon under G/TBT/N/EEC/297/Rev.1. She invited written comments from interested delegations, and informed that a period of 60 days had been allowed for comments.

(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) (G/TBT/N/EEC/247, Add.1 and G/TBT/Notif.00/310, Corr.1)

165. The representative of China expressed concern about the use of certain hazardous substances in electrical and electronic equipment. He requested information on the status of implementation of RoHS (it was implemented in 2003) and on how the European Union monitored the state of compliance of enterprises. He also requested clarification on the conformity assessment procedure after RoHS and how it conducted market surveillance and government supervision and if there was any difference between the procedures of different European Union member States. He also requested further information on the RoHS since the introduction of the CE marking and asked if the testing standard was IEC 62321-2008 and if a new category of electrical and electronic equipment, not covered in previous regulations, had been added to Annex 1. Furthermore, he requested details on the other equipment mentioned in the category. The representative of China also asked about the treatment of national mutual recognition of RoHS testing results.

166. The representative of Korea acknowledged the adoption of the directive without a priority list in line with Korea's request to remove the list. He noted, however, that Korean industry continued to be concerned about the revised directive, in particular, with reference to the adoption of homogenous material test methods. He argued that according to Korean industry estimates the cost of additional tests and certification was expected to be large and this would translate into higher production costs and be passed on the consumers. He noted, therefore, that this would make the directive unnecessarily burdensome in proportion to its objective. He requested the European Union to reduce the burden on companies, particularly on SMEs in the spare parts industry. Further, he requested the European Union to extend the date of implementation to allow industries an adequate adjustment period.

167. The representative of the European Union provided delegations with an update on the status of the recast of RoHS indicating that, as had been outlined at the previous TBT Committee meeting, the European Parliament had adopted a first reading position on the proposal of the European Commission on 24 November 2010. She also said that the European Union had notified the document

as an addendum to the original TBT notification EEC/247 on 21 March, and had provided detailed explanations of the European Parliament's proposed changes in both the addendum to the notification as well as to the European Union intervention during the previous TBT Committee meeting. In the interest of time, she referred Members to the minutes of the previous TBT Committee Meeting, for details.

168. The European Parliament, the Council, and the Commission had worked together to achieve a first reading agreement on the draft Directive. The Directive had been formally adopted by the European Council on 27 May 2011 with the agreement of the Commission. The Directive was expected to be published in the Official Journal in June or July 2011; it would enter into force immediately after publication. She also indicated that the Directive would have to be transposed by all European Union Member States into national law within 18 months. With respect to Korea's comments, she noted that her delegation had discussed the issue bilaterally with Korea and that she hoped that the explanations provided had helped alleviate Korean concerns.

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

169. The representative of the European Union was disappointed about the non-postponement of the entry into force of the quality order on pneumatic tyres and tubes for automotive vehicles despite significant outstanding concerns on the compatibility of the measure and the BIS license procedure with the TBT Agreement. She recalled that at the previous TBT Committee meeting, India had informed Members that the Indian Bureau of Standards (BIS) was reviewing the requirement that the IS marking could only be used on tyres exported to India and not on those that were sold outside India. She indicated that the requirement was unnecessarily burdensome and was not based on a legitimate objective: it obliged manufacturers to produce tyres specifically for the Indian market. She requested an update on the developments on the subject and on whether paragraph 6.3 of the BIS Agreement would be omitted, as had been requested by Japan in the previous Meeting.

170. In addition the European Union continued to be concerned about the method of calculation of royalty fees on the basis of the total number of tyres produced and marked with the IS marking and not on the basis of the total number of IS marked tyres *de facto* imported into India. This, she said, increased the cost of exporting tyres to India. She also underscored that the issue was even more serious since producers were charged with a marking fee calculated per tyre marked. She noted that the European Union recognized that the requirement also applied to Indian producers but also stressed that the difference in the fees was beyond what would be necessary for the conformity assessment costs and contributed to the impression that India was using the measure to discourage imports of tyres. Furthermore, she expressed dissatisfaction at the continued bottlenecks created by the laboratories accredited to conduct relevant testing noting that it hindered exports of tyres to India. She urged India to resolve the issue, for example, by accepting tests from international ILAC accredited laboratories at least until the lack of adequate facilities in India was resolved.

171. The representative of Korea acknowledged the fact that India had already extended the implementation period of the measure twice but noted that certain Korean tyre manufacturers continued to experience severe delays in factory inspections. He noted that the issue was one of frequent changes in schedules of Indian inspectors resulting in delays in payment. This, he noted, had disrupted export plans to India. He urged India to accelerate the process and to provide detailed explanations of the situation.

172. The representative of Japan expressed concerns over the mandatory certification system for automobile tyres in India and said that Japan had discussed the concern in detail, both at the TBT Committee meetings as well as bilaterally with India. He acknowledged the fact that India had postponed the implementation of the Directive in line with concerns raised. He also informed the

WTO Members that in light of continued concerns, the Ministry of Economy, Trade and Industry of Japan and the Japanese Automobile Tyre Manufacturers' Association Inc. had visited the Indian Ministry of Commerce and Industry Department of Industrial Policy and Promotion, the Ministry of Consumer Affairs, Food and Public Distribution Department of Consumer Affairs and the Bureau for Indian Standards in early May, to request a postponement of the implementation of the measure. He expressed regret over the fact that the Indian government still went ahead with implementation.

173. Highlighting specific problems with the measure, he noted that one of the areas of concern was the capacity of the certification authority. Certain tyre manufacturers had been unable to receive factory certification in spite of having applied for it with the Bureau of Indian Standards (BIS). In particular, he mentioned issues with the increased tyre size, subject to mandatory certification since May 2010, noting that as a result, tyre manufacturers who had applied for factory certification in June 2010 had not fully acquired the certification. Additionally, he noted that the addition of certified tyre sizes to the factory certificates had not been completed by the date of implementation. As a result of the circumstances thus created, Japanese companies had been forced to suspend exports to India, as well as further sales of stocks in India. He underscored that the measure was a technical barrier to trade.

174. He referred to Article 2.12 of the TBT Agreement noting that the Decision of the TBT Committee which provided for an implementation period greater than six months. However, he noted that the six month period was not inflexible and in a situation where the capacity for certification was lacking, the preparation period needed to be set with flexibility. He urged the Indian Government for retroactive withdrawal of the enforcement and for the implementation to be postponed by a minimum of six months.

175. The representative of India noted that the measure had already entered into force in May 2011. He also underscored that the original intent of notification to the Committee was made in 2006, informing industry and exporters of the intent of the Indian Government to institutionalize the certification system. Additionally, he noted that the notification had been made in 2010, allowing until May 2011 before the entry into force of the measure and that this time was sufficient, and more than stipulated by the TBT Agreement or Decisions of the TBT Committee pertaining to the Agreement. He therefore noted that the concern over inadequate time allowed for adjustment was not reasonable. He referred to a communication by the Indian Department of Industrial Policy and Promotion, listing the types of tyres exempt from the marking requirements under the regulation that could be imported by original equivalent manufacturers for the replacement market. He noted that this move would facilitate imports within the purview of the measure.

176. He noted that India had had bilateral discussion with the European Union and Japan on the subject and noted that a majority of the applications for certification for tyre manufacturers had been cleared. The remaining were pending only because of inadequate information or pending fee payments, which were being sought from the companies, or in one particular case, a pending inspection to Japan - which had not been conducted in light of the circumstances in Japan. He said that the government was attempting to ensure resolution of all issues and requested specific details from Korea so that those concerns could be pursued by the Ministry. On the subject of Article 6.3 of the BIS Agreement, raised by the European Union, he mentioned that the amendment would require legislative modifications and that the government was exploring the legal options available to amend the article in question, and resolve the issues raised by the European Union. Finally, while his government believed that the marking fee was reasonable it would look into the matter.

(iv) European Union – Regulation on Classification, Labelling and Packaging of Substances and Mixtures (ATPs and CLP) (G/TBT/N/EEC/151 and Adds.1-2; G/TBT/N/EEC/212 and Adds.1-3; G/TBT/N/EEC/163 and Adds.1-3, Add.1/Corr.1)

177. The representative of Canada reiterated Canada's concerns about the European Union's classification of nickel-containing substances. He acknowledged the opinion on the subject, dated March 2011, issued by the European Court of Justice. He reminded the European Union to take into account the potential negative impact of classification exercises not based on sound and transparent science. He urged the European Union to ensure that the measure did not become an unnecessary obstacle to trade.

178. The representative of Turkey reiterated her country's concern with the classification upgrades and downstream impacts, noting that Turkey had raised these concerns several times at Committee meetings. She requested further information from the European Union on future plans, if any, with reference to the existence of new scientific evidence. She recalled that the European Union had, in the previous meeting, confirmed the receipt of a study by Turkey, in China, in a boron mine. She urged the European Union to amend its regulation in line with the concerns raised.

179. The representatives of Australia, Cuba, Dominican Republic and Thailand reiterated concerns voiced on the subject at previous meetings and urged the European Union to consider those concerns. The representative of Thailand stressed the importance of ensuring that the substance classification was based on indisputable scientific evidence. Cuba, in turn, reiterated concerns about the inadequate extrapolation of the classification of nickel components and the lack of adequate scientific data justifying the need for the measure.

180. The representative of the European Union took note of the concerns raised on the classification of nickel and nickel compounds in the 30th and 31st ATP and said that the European Union had already furnished Members with long responses to the issues in writing, as well as orally, over several Committee meetings. She invited delegations to refer to the minutes of those past meetings for details. She also recalled that according to the CLP regulation, the initiative to change the classification lay with European Union Member States and that any revision could only be undertaken if a Member State submitted a proposal to ECHA. Once the proposal had been submitted and if the Commission found that the change in the classification was appropriate, it would prepare the decision to amend Annex VI of the CLP regulation and introduce the modification without further delay. She therefore recommended interested delegations to present any new scientific data to one or more of the European Union Member States in order to trigger the process of submitting a proposal to modify the classification of borate compounds. She also noted that the European Union had not, as yet, received any such requests from a third country or industry. With regard to the study conducted in China, mentioned by Turkey, she recalled the EU statement in the previous Committee meeting, namely that this study should be submitted to one or more of the European Union Member States.

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

181. The representative of New Zealand repeated his delegation's concerns about Canada's compositional cheese standards and requested Canada to confirm that these cheese standards, as per the above-mentioned notification and the relevant addendum were in compliance with the principles laid out in the TBT Agreement. She noted that the standards were inconsistent with Codex standards, indicating that Codex standards did not specify restrictions on the sourcing of milk proteins for use in the manufacture of cheese; she asked Canada to explain why it had used more restrictive standards. She also commented on the fact that Canadian dairy farmers had continued to lobby the Canadian Government for a standard on yoghurt. She expressed concerns that any standard on the composition of yoghurt would also be inconsistent with Codex standards and urged Canada to adhere to the Codex standards for any future decisions on federal dairy regulations and standards for yoghurt.

182. The representative of Australia expressed continued concern with the compositional cheese requirements imposed by Canada and on the access to milk protein concentrates and also voiced concern about any future measure on yoghurt or other such products.

183. The representative of Canada noted that his delegations had already accounted for both international standards and comments made by Members during the notification period. He commented that Canada had not initiated any process to establish standards for yoghurt or other dairy products. He also mentioned that in light of continued concerns from New Zealand and Australia these could perhaps be discussed bilaterally.

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

184. The representative of the European Union expressed continued concerns about the Indian order on the registration procedures for imported cosmetic products, which had entered into force on 1 April 2011. She acknowledged that some concerns raised by the European Union in 2008 had been taken into account by the Indian Government but noted, once again, that a notification system as opposed to a registration and authorisation system might have been less trade restrictive. She also noted that the Indian authorities were yet to provide a justification for the differing demands on the validity period of the cosmetics certificates for imported and domestic products. She urged the Indian Government to confirm that adequate action would be taken to ensure that the validity period of certificates for imported products would also be raised to five years, as for domestic products, from the current three years for imported products. Furthermore, she requested Indian authorities to ensure that the certificates were issued within a period of two months, at a minimum, and that the tests conducted in the country of origin, attesting compliance with international cosmetics standards were also accepted. She also stressed the importance of allowing for products to be packaged and labelled in bonded warehouses before being placed on the Indian market as an alternative to labelling in the country of origin.

185. The representative of the United States reiterated previous concerns, in particular with reference to the difference in the validity period of the certificates for domestic and imported products. He asked the Indian delegation to explain the difference in validity periods - or to bring the two periods at par with each other. He also requested India to allow producers of cosmetic products to conduct the required testing in the country of origin in accordance with internationally recognized testing procedures. Additionally, he raised concerns about over-labelling and use of stickers. He also noted that US industry had expressed concerns over a host of other issues including placement of import registration numbers, and other technical issues - these concerns had been submitted in January 2011. He echoed the interest of industry to engage in dialogue with Indian officials to allow them to understand how best to comply with the regulation, and to discuss the appropriate transition period. This was important as the current effective date was October 2011 and there were still several unresolved issues including the fact that the final regulation had not yet been published.

186. The representative of India noted that India's transparency obligations within the TBT Agreement had not been violated since the draft on the introduction of the new system had been provided in 2007, and the measure would be implemented on 1 October 2011. On the subject of the differential time periods, he explained that the difference existed in light of the rigorous licensing procedures and inspections carried out on domestic products in comparison with imported products, adding that the validity for all imported goods, both drugs and cosmetics would be three years. He also said that the concern would be forwarded to the regulators, in any case, for them to consider. He acknowledged US concerns and said that India was considering setting up a technical level meeting with the United States to engage in a discussion. He said that the EU suggestions with respect to warehouses was a new issue and would be forwarded to Indian regulators for them to consider.

(vii) Colombia – Draft Decree Establishing Provisions to Promote the Use of Biofuels (G/TBT/N/COL/96 and Adds.1-5 and Add.4/Rev.1)

187. The representative of the European Union acknowledged the notification from Colombia dated 8 June 2011, on the new draft modifying Decree No. 2629 Establishing Provisions to Promote the Use of Biofuels. She noted that the European Union was in the process of analysing the notification. As preliminary comments, she said that the European Union welcomed the modification of the draft that allowed conventional vehicles to use ethanol blends within a range of E8 to E10, as of entry into force of the new decree. Nevertheless she also observed that as per Article 2, the Colombian authorities could modify as of 1 January 2013 the amount of ethanol in fuel, at any time. She reminded Colombia of Article 2.12 of the TBT Agreement and requested that they provide a reasonable period of time between the publication and entry into force of any such modification. She also reminded Colombia that any such modification would have to be notified under the TBT Agreement. She also noted that parts of the written comments sent on 30 May 2011 on the previous notified version of the measure continued to remain relevant to the new draft as well. She expressed particular concern over the fact that not all ethanol blends would be available in Colombia in the future, or at least not in the entire territory. She also requested information on when the technical regulations regarding the quality of fuel would be defined - also with respect to diesel.

188. The representative of Japan shared concerns raised by the European Union and welcomed the new E8 to E12 regulation expected to enter into force on 1 January 2012. He was, however, concerned about the fact that relevant Colombian ministries would hold the authority to increase the biofuel regulation label for use in automobiles through administrative procedures. He reiterated concerns raised previously and requested the Colombian Government to take these into account.

189. The representative of Argentina asked Colombia to identify the scope of products covered by the Draft Decree.

190. The representative of Colombia noted that Colombia had complied with all the transparency requirements on the draft decree, notified under G/TBT/N/COL/96/Add.4. He informed delegations that Colombia had accounted for Members' comments and included these into the draft decree - the final draft had been notified under G/TBT/N/COL/96/Add.5, which was available for comments from 8 June 2011 until 30 August 2011. He also informed delegations that Colombia had entertained in bilateral discussions with both Japan and the European Union.

(viii) European Communities – Accreditation and market surveillance relating to the marketing of products (G/TBT/N/EEC/152)

191. The representative of Korea reiterated concerns with the above-mentioned notification noting that in spite of having raised the concern several times, Korea had yet to receive satisfactory responses. He was primarily concerned about the potential impact on recognition of non-EU accreditation bodies under the ILAC-MRA and the IAF-MLA and on acceptance of conformity assessment procedures conducted by laboratories accredited by non-EU accreditation bodies that were Members of the ILAC and IAF

192. The representative of the United States also expressed continued concerns with Regulation 765 that applied to all sectors and required each member State to appoint a single national accreditation body to operate as a public, not-for-profit entity to accredit conformity assessment bodies in the EU, thereby prohibiting competition between national accreditation bodies of member States. He was also of the view that the criteria used were in excess of those used by the ILAC and IAF and the European Commission had recognized that attestations of conformity issued under accreditation by non-EU accreditation bodies could be considered as reliable as those issued under the

accreditation of the European Cooperation for Accreditation (EA)[10] MLA signatory. He raised questions about the necessity of the additional criteria and noted that this could undermine the international accreditation system under the ILAC MRA and IAF MLA and disrupt imports from the United States to the European Union.

193. The representative of the United States asked for updates from the European Union on the on-going discussions between the EA and ILAC on the relationship between Regulation 765 and the standards set out in standard ISO/IEC 17011:2004 as well as the supplementary requirements and guidance from ILAC and IAF. He encouraged the European Union to issue written clarification on how the EA would cooperate with non-European Union accreditation bodies.

194. The representatives of Australia and Thailand shared concerns raised by previous speakers and expressed the hope that the European Union would provide clear, written guidance on the consistency of the regulation with the ILAC IAF requirements.

195. The representative of the European Union noted that the concerns raised were not new and referred in that respect to comments made by his delegation at previous meetings of the Committee. He informed delegations that the peer evaluation of EA by IAF and ILAC was in progress and a final report was expected to be submitted to the meeting of the multilateral arrangements operated by ILAC and IAF scheduled to be held in Bangkok in November 2011. He also referred to the activity report submitted by the EA to its general assembly held on 25-26 May 2011 in Berlin for a more general update on the current priority areas for EA. The report was available to the public on the EA website[11]

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

196. The representatives of Australia, Chile, the European Union, Mexico, New Zealand and the United States acknowledged consideration of comments provided and requested a further update from Thailand on the review of the draft legislation.

197. The representative of Thailand noted that the Ministry of Public Health had set up a new subcommittee assigned to study the impact of the regulation on alcoholic beverages, the scope of which would also include the regulation on health warnings under the said notification. Members would be kept informed.

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

198. The representative of the European Union requested an update on the state of play of the proposed requirements on the transport of lithium batteries, which were over and above the requirements agreed upon in the UN Recommendations on the Transport of Dangerous Goods and the Technical Instructions on the Safe Transport of Dangerous Goods of the International Civil Aviation Organization (ICAO). The EU remained concerned by the US unilateral approach to the issue. She expressed agreement with previous remarks from the United States to the effect that since the issue was already being dealt with in the ICAO and UNECE - the international standardizing bodies on international civil aviation - it need not have been brought to the WTO TBT Committee. She reiterated her delegation's position that the safe transport of lithium batteries had been discussed in these international bodies and that the proposals made by the United States to lay down requirements additional to those agreed upon internationally had already been rejected by the technical experts of

[10] http://www.european-accreditation.org.
[11] "http://www.european-accreditation.org/content/communication/EA_Updates/EA_Activity_Report-MAY_2011.pdf".

those bodies, which were not just European Union experts, as previous statements of the United States in the Committee had implied. She underscored that the experts had expressed the opinion that the agreed upon standards were sufficient, particularly since there was no accident data available on cases where such standards had been respected. She invited the United States to provide scientific data to dispute this to ICAO and UNECE, in which case the technical experts would be willing to look into this issue once more, and possibly revise the standards if necessary – however, no such sufficient data had yet been provided. She urged the United States to apply the agreed standards and refrain from unilateral requirements which would impose additional burdens on economic operators.

199. The representative of Korea said that the most effective means of securing safer transportation of lithium-ion batteries was to ensure harmonization and compliance with international standards and regulations, such as those of the ICAO. He noted that the UN and ICAO requirements had been discussed, adopted, and used by several countries after much testing and review of scientific evidence. It was also his delegation's understanding that discussions in the US Senate and the House of Representatives was on-going, and he requested the United States provide an update on the current situation and the future prospects of the discussion. If the PHMSA[12] chose not to adopt existing UN and ICAO regulations for transportation of lithium batteries, he urged that there be an exemption for lithium-based secondary cells (lithium-ion, lithium-polymer etc.) which were shipped at no more than 50 per cent of the charge. He re-emphasised that according to reports referred to by the Notice of Proposed Rule Making (NPRM), the severity of the result of an internal short-circuit was strongly affected by the state of charge; fires had a minimal impact on bulk packaged lithium ion cells with less than 50 per cent charge.

200. The representative of Japan said that while Japan understood the importance of maintaining security of transportation, Japan was concerned about the restrictions on transportation of lithium batteries by the United States, not just from the point of view of consistency with the UN Recommendations, and the ICAO Technical Instructions, but also from the perspective of the impact on trade. He noted that Japan had continuously claimed consistency with the UN Recommendations and the ICAO Technical Instructions. The delegation of Japan was of the view that some products did not need to be included in the regulation where their inclusion was not necessary for safety purposes. He requested the United States, therefore, to exempt lithium-ion batteries with low state of charge (SOC). He also noted that the final rule was expected to be released on 31 August 2011, and requested that the final rule take into account all opposing views expressed by governments, and private entities. Furthermore, he referred to the PHMSA website that was considering new proposed regulations, the impact of which was expected to be significant. However, Japan had not received detailed information on this matter and requested the United States for such information.

201. The representative of China also reiterated concerns previously stated and made particular reference to the use of international standards in domestic technical regulations, citing Article 2.4 of the TBT Agreement as well as the TBT Committee Decision on Principles for the Development of International Standards. He reminded the United States that consensus was not the only criteria to determine if a standard was relevant in the TBT context. He cited the Appellate Body report in the EC-Sardines dispute[13] which had upheld the conclusion of the Panel that even if an international standard was not adopted by consensus it could still constitute a relevant international standard under Article 2.4 of the TBT Agreement. Therefore, he urged the United States to review its position on the use of international standards in the current context, and adopt measures to base its regulations on the transportation of lithium batteries on relevant existing international standards, in this case the ICAO and the UNECE

[12] http://www.phmsa.dot.gov/.
[13] WT/DS231/AB/R.

202. The representative of the United States informed the Committee that there was no change in status since the previous meeting and that he did not have any information on the timing for the release of a final measure. He noted that the United States would keep Members updated once he had the information on any change in status. He also said that the United States had received comments both in support of the measure, as well as against it, and thus it would be impossible to agree with all the comments. He mentioned that the United States would make every effort to account for all comments, based on the evidence on record in shaping the final measure. He also said he was unable to comment on the legislative developments at present, but that the United States was monitoring the situation and would provide updates when available.

203. Regarding the absence of accident data, he noted that one of the other issues involved in the proposal was whether small batteries, not covered by the ICAO technical instructions, could combust aboard an aircraft and potentially bring the aircraft down, which no one has disputed. He referred to the comment from the European Union and said that the United States did not have to wait for such an event to happen before determining to regulate - and that the TBT Agreement should not be interpreted in such a manner. There were other issues besides accident data which US regulators were looking into to ensure the safety of aircrafts. On the subject of international standards and in reference to discussions in past meetings of the Committee on procedural deficiencies in the development process, he expressed the hope that the ICAO and UNECE would take adequate measures to address the systemic deficiencies in the technical committees where relevant documents were being developed. He noted that United States regulators did participate in the work of those committees and would like to, as far as possible, use the results. He noted, however, that in the current situation the requirements had essentially been unilaterally decided upon by the European Union member States as a majority in the technical committee, raising questions about the consensus principle. He also highlighted that the Secretariat could determine which Members could participate and which could not and had in the past denied at least one WTO Member permission to participate in the work so the process was not open to all WTO Members. In addition, he noted that there were clearly issues of conformity with the WTO Committee Decision (on international standards) and, in any case, neither body was mentioned in the TBT Agreement. He said that the United States was of the opinion that if the appropriate process had been followed there might have been an international standard that everyone could use.

204. The representative of the European Union noted that, since the United States was repeating the argument that the ICAO or UNECE recommendations were taken with the dominance of the European Union Member States, she felt it necessary to inform delegations that both bodies were composed of much more than just European Union Member States. The ICAO was a specialized agency of the UN for civil aviation, whose mandate was to foster the safe and organized development of international air transport, including by adopting standards and guidelines on air navigation. It had 190 contracting states, including developing countries. She also referred to the Council of ICAO on Air Navigation Issues, which was the body responsible for the development of technical standards and other provisions on air navigation. She said that the body was composed of 15 experts with the appropriate qualifications and experience in aviation to allow them to be a member of the body; however, they were nominated by the contracting states and appointed by the Council and were expected to function as independent experts, and not as representatives of their countries. Additionally, referring to the UN recommendation on the transport of dangerous goods of the United Nations Economic and Social Council (ECOSOC), she noted that the ECOSOC had 55 members, including several African and Asian countries

(xi) Brazil – Alcoholic Beverages (G/TBT/N/BRA/348)

205. The representative of the European Union, Mexico and the United States requested an update on the status of the comments submitted to the public consultation and in response to the TBT notification, which Brazil had mentioned in the previous meeting. They also requested information

on when the new draft proposal would be made available. The representative of the United States hoped to engage in a technical discussion with experts on both sides.

206. The representative of Brazil informed delegates that there had been no new development on the issues since the previous TBT Committee meeting; the draft legislation was still under analysis by Brazilian regulators, and that there was no forecast on the publication of a final regulation on the subject. He indicated that comments received from Members were being considered by regulators. On the substantive concerns he referred Members to the minutes of the previous meetings.

(xii) 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")

207. The representative of the European Union reiterated concerns with the Turkish regulation on good manufacturing practices (GMP) requirements for pharmaceuticals, which entered into force on 1 March 2010. She noted that to obtain the EU GMP certificates, EU manufacturers were inspected by competent authorities within the European Union Member States to ensure compliance with GMP. Furthermore, she noted that Turkey had not provided any indication on whether specific problems had been found with EU GMP certified products on its market. Therefore, she urged Turkey to recognise EU GMP certificates and standards without need for additional administrative requirements.

208. The representative of the United States expressed continued concerns with Turkey's conformity assessment procedures for pharmaceutical imports and requested Turkey to adopt measures to restore market access for high quality pharmaceuticals. He expressed concerns on behalf of industry in the United States on the mounting backlog of goods awaiting approvals, noting that it was a concern, not just for companies, but also for patients in Turkey who used those pharmaceuticals. He also underscored that the measure had never been notified and urged Turkey to give high priority to innovative drug applications providing new medicinal therapies to Turkish patients, and process registration files submitted before the measure went into force under the old regime, noting that the measure should not apply retroactively. He also proposed technical discussions with Turkey on the subject, noting that a delegation from Turkey was expected to visit Washington later in the month.

209. The representative of Turkey noted that the reasons for the measure on GMP certification of pharmaceuticals had already been explained at previous Committee meetings; he recalled that the Ministry of Health had been conducting GMP inspections since 1995, in accordance with GMP guidelines for pharmaceuticals and in compliance with the relevant guidelines of the WHO. He also mentioned that until March 2010, GMP certificates of other countries, along with those provided by the Ministry of Health were accepted - however automatic acceptance was seen as posing a serious threat to human health in the absence of relevant background information. The Ministry, he noted, had the legitimate right to conduct GMP inspections for the protection of human health and human life. In addition, he noted that thus far no issues had been reported with the implementation of the regulation; it had run smoothly with all applications being processed immediately by the Ministry, provided the related files were complete. He underscored that since September 2010 until May 2011, the Ministry of Health had inspected 38 manufacturing facilities, 34 manufacturing sites, and 236 products had received GMP certificates. Further, 62 manufacturing sites were under inspection.

210. Regarding the processing of GMP inspections, he noted that currently the Ministry of Health had applied a classification system based on the therapeutic priorities of the pharmaceuticals, determined according to scientific criteria - this was in line with public health concerns. On the subject of the processing of registration files submitted prior to 1 March 2010, he said that the request had, in line with previous practice, been brought to Turkish courts recently and he did not deem it

appropriate for to comment before the case was decided upon. As implementation continued, remaining issues would also be resolved.

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

211. The representative of China referred to Article 16C of the Directive which suggested that a medical product had to be used through a period of at least 30 years preceding the date of application, including 15 years within the European Union. He asked about the opinion of the European Union on traditional Chinese medicines (TCM) which had been is use for thousands of years but had been in use for less than 15 years within the Community. He noted that for such TCM products, which had entered the Community market post 1996 would not be able to prove that they were safe medicinal products since they have not been used in the European Union for 15 years, since the transitional period elapsed on 1 May 2011. He was concerned that this might be a violation of the National Treatment principle.

212. Referring to sub-clause 2 of Article 2, he noted that the competent authorities would apply the provisions of the Directive within seven years once it had entered into force. He mentioned that the United Kingdom and other concerned countries had announced a plan to terminate the import and wholesale of TCM finished products from 1 May 2011. He underscored that trade in TCM goods between China and the European Union had increased tremendously by 101.8 per cent between January and April 2011. The representative said that the EU had communicated to his delegation bilaterally that only one enterprise, or one country, had successfully met all the requirements of the Directive. He therefore questioned whether the Directive effectively banned traditional herbal medicines from outside the EU market. He also said that seven years was too short a period and proposed that the European Union extend the time till 30 April 2019. He also referred to the fact that registered TCM products were required to pass the EU GMP certification, before they could be distributed. He recommended that since the European Union was a PIC/S (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme) member, the European Union should consider the possibility to accredit TCM enterprises that already had EU GMP certification from PIC/S members. He requested the European Union to check accredited TCM enterprises that already had the GMP certification with Australia, a PIC/S member.

213. He also mentioned that according to the Sino-European Union Working Group Pharmaceutical Meeting held on 19 May 2011, where DG Sanco proposed to the SFDA that all Chinese made active pharmaceutical ingredients (APIs) exported to the European Union should comply with Chinese GMP standards for APIs. In his view, as per international practice, it should be the European Union importers that shouldered the responsibility of inspection.

214. The representative of India expressed support for China's statement and referred to minutes of the previous meeting where India had made a strong statement. On the subject of the notification, he mentioned that the measure, although already in force, had not been notified to the WTO. He also mentioned that the 15 years of use on medicinal products rule, which China had raised as a concern, also concerned India in that it excluded many products, including herbal medicinal products, from the regulation. He also said that the scope of products which were of mineral and animal origin was not clear since Ayurveda, Siddha and Unani products were covered under the regulation. He asked for a status update from the European Union in this regard. He also mentioned that India had already made a request for a simplified application dossier for the registration of traditional Ayurveda products as well as the acceptance of the Indian monograph as an authentic source of information for traditional use evidence in assessing applications for registration.

215. The representative of the European Union mentioned that they had had bilateral discussions on the issue several times and referred Members to minutes of previous meetings where the issue had been discussed. She highlighted that all medicinal products, including herbal medicinal products

required a marketing authorization to be placed on the European market, since 1965, based on pharmaceutical, clinical and pre-clinical data. She also highlighted that since traditional herbal medicinal products had particular characteristics by virtue of their longer tradition of use, the European Union took this into account and had introduced a lighter, simpler and less costly registration procedure for them via Directive 2004/24/EC. The Directive, she noted, allowed registration of traditional herbal medicinal products without the requirement of safety tests and clinical trials required under the full marketing authorisation procedure. She also underscored that in order to benefit from the simplified procedure the applicant was required to provide sufficient evidence of medicinal use of the product over a period of a minimum of 30 years, including 15 years in the European Union. She also said that monographs from India, China or any other country, submitted as part of the application dossier were assessed as any other bibliographical evidence submitted with the application. On the subject of the 15 years of use in the European Union, she noted that the requirement allowed for sufficient monitoring of side effects of the products and increasing confidence in its safety in the absence of tests and trials. She also confirmed that for products for which the 15 years use in the European Union could not be demonstrated, but which were in any case eligible for the simplified procedure, Directive 2004/24/EC allowed proving the safety of the products by other means to be assessed by the Committee for Herbal Medicinal Products of the European Medicines Agency (EMA).

216. On the subject of herbal substances, the representative of the European Union said that they could be used for manufacture of food or medicines. However, herbal products that did not fulfil the definition of medicinal products did not fall within the scope of registration. She also said that an herbal product would be considered a medicinal product when it had the properties to treat or prevent disease in human beings, or where it had pharmacological, immunological or metabolic action. She said that deciding on a case-by-case basis on whether an herbal product fulfilled the definition of a medicinal product was the responsibility of the national authorities. She also highlighted that the majority of medicinal products with a sufficiently long tradition of use were based on herbal substances. Therefore, she noted, it would be appropriate to limit the scope of the simplified registration to herbal medicinal products, as a first step. However, she also noted that the Directive allowed for the presence of vitamins or minerals in the herbal medicinal products as long as action of the vitamins and minerals in the product was ancillary to that of the herbal active ingredients. She also said that traditional herbal medicinal products that were designed or intended for use under the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment were excluded from the scope of the Directive 2004/24/EC. She noted that those products demanded the granting of marketing authorization since the greater risk or the need for medical supervision did not allow for the waiver of the requirement for preclinical and clinical data.

217. In addition, the representative of the European Union said that the Common Technical Document (CTD) was an internationally agreed format to avoid delays in submitting applications to the different International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) regions. This had facilitated information exchange between regulatory authorities for medicinal products. She reminded India and China that the 2004 Directive foresaw a long transition period of seven years for manufacturers to submit registration requests to relevant authorities for their products. The Directive was currently in force.

(xiv) Colombia – Shelf life for milk powder (G/TBT/N/COL/67/Add.3)

218. The representative of the European Union expressed continued concerns with the Decree adopted by Colombia in the previous year on requirements imposed on imported milk powder to have a shelf life of a minimum of 12 months, six more than what had previously been required. She expressed concern that the extension of the period could affect exports of milk powder from the European Union to Colombia. She also reiterated the request made at the previous meeting of the

Committee, to Colombia, to clarify the risk the authorities sought to address by extending the required shelf life of milk powder.

219. The representative of Colombia reiterated statements made at other meetings of the Committee, noting that the draft resolution modifying Article 50 of Decree 617 modified by the first Article of Decree 1673 dated 2010, on requirements on powdered milk, had been notified to the Committee in January 2011. He noted that the proposal had stated that the shelf life of the product at the time of entry into the country needed also to have the date of manufacture. She mentioned that on 27 January 2011, a document (G/TBT/N/COL/67 Add.3) had been submitted to the Committee and a period for comments was allowed until 19 April 2011, later extended to 19 May 2011. He noted that he did not have further update on the measure and that Colombia had not received any specific requests from the European Union on the subject. He requested that the European submit their comments in writing so that they could be responded to.

(xv) China – Regulations of the PRC on Certification and Accreditation (promulgated by Decree No. 390 of the State Council of the PRC on 3 September 2003)

220. The representative of the United States expressed continued concern about the long-running issue of the Chinese Government not recognizing competent conformity assessment bodies located outside China so that U.S. suppliers could more easily demonstrate compliance of products from the United States with Chinese certification requirements. Because the CCC requirements covered 20 per cent of exports from the United States to China, China's failure to recognize such bodies negatively impacted trade flows from the United States to China. He noted that the only bodies allowed to conduct conformity assessment procedures were Chinese bodies with no presence outside China, thereby forcing companies from the United States to organize funds and travel for Chinese inspectors to conduct premarket inspections at the manufacturers' location, submit to subsequent annual inspections and to pay for their products to be certified in China.

221. A solution to the issue needed to be found. The United States found it increasingly difficult to comprehend why China was unable to monitor conformity assessment bodies outside Chinese territory, particularly since US regulators had consistently recognized numerous conformity assessment bodies in China. For example, the U.S. Occupational Safety and Health Administration had recognized several sites as part of its programme in China, and the CPSC[14] had already recognized 104 conformity assessment bodies in China, including joint ventures with government laboratories. He noted that regulators in the United States had developed procedures and criteria, such as auditing and inspections as well as other procedures, to ensure that Chinese bodies met criteria when they were recognized and continued to meet them on an on-going basis. He said that China was free to do the same. He also mentioned that US regulators were conducting this recognition in the absence of an MRA and noted that China should do the same. In the event that the issue was technical, he noted that the United States would be willing to organize technical discussions and experience-sharing on the subject to find a quick resolution to the issue

222. The representative of China noted that the regulations on certification and accreditation for the People's Republic of China had been adopted by the State Council on 3 September 2003, and had entered into force on 1 November 2003. The objectives of the regulations were in compliance with the objectives of the WTO Agreement preventing deceptive practice, protecting human health and safety, animal or plant life or health, or the environment. On the subject of the foreign assessment bodies under the CCC scheme, he noted that China was involved in mutual recognition, both multilaterally and bilaterally. He said that as part of the multilateral framework, China was a member of the IECEE/CB scheme, as well as the ILAC MRA and accepted test reports from the CB testing laboratories of other countries within the IECEE/CB scheme. Additionally, he noted that in 2009

[14] http://www.cpsc.gov/.

more than 3,000 test reports from foreign laboratories were accepted by China, including test reports issued by the UL[15], a US conformity assessment body. China had concluded over 40 bilateral cooperative documents with over 20 countries in the area and certification bodies from other countries undertook part of CCC certification work, via cooperation with domestic CCC certification bodies. Moreover, he assured delegations that CCC certification could also be conducted by foreign certification bodies as part of an inter-governmental MRA within which the ILAC MRA was a key technical basis for mutual recognition between China and other countries.

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

223. The representative of the European Union remained concerned about the Korean standard for thin-film solar panels which prevented certain types of thin-filmed solar panels from being tested or certified, acting as a *de facto* market access ban for such technology due to the fact that they would not qualify for government incentive schemes. She also noted that the European Union had received information that Korean authorities had been encouraging investment and research and development activities in these technologies such as in copper-indium gallium selenium (CIGS) solar panels, which undermined the Korean argument that such technology posed a threat to the environment. She requested an update from Korea on the study on an environmental impact of thin-film solar panels, other than amorphous silicon (A-Si) solar panels, and the expected timeline for the completion of this on-going study.

224. The representative of the United States shared the concerns raised by the European Union. He noted that the United States was not aware of any scientific or technical evidence that would prove the risks to the environment from the use of thin-filmed solar panels. He also mentioned the study highlighted by the European Union, noting that it confirmed suspicions in industry that there was in fact a *de facto* ban in place, which would continue to exist until the research and development exercise in the field was complete and Korean producers were able to compete in those technologies; in other words: those products would only be allowed onto the market when domestic presence of such products had been established. This was an issue of concern. The representative of the United States also reiterated concerns about the issue on cadmium and noted that while several countries including the United States maintained rules for the safe use of cadmium, the small quantity of cadmium contained in the solar panels did not warrant being blocked from KEMCO[16] certification. This only created unnecessary delays for market entry of innovative products which were already being sold in other countries.

225. The representative of the Korea confirmed that the Korean certification system was not mandatory, therefore non-silicon based, thin-film solar panels did not face difficulties entering into the Korean market even without the KS certification. He also mentioned that the feasibility study on the environmental impact assessment had started in 2010 and was still in progress; it was expected to be completed by 30 May 2012. He noted that the Ministry would decide on the inclusion of solar panels KS 61646 upon completion of the study. Members would be informed in due time.

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

226. The representative of the European Union acknowledged the issuing of an amendment on 31 May 2011 by the Indian Government to the rules governing licensing agreements with telecom

[15] http://www.ul.com/.
[16] Korea Management Energy Corporation.

service providers. He noted that the understanding was that the amendment would supersede all previous rules with immediate effect; he requested the Indian delegation to confirm this understanding from a legal perspective and that it would solely be this amendment that governed the licence agreement between the governments and telecom service providers henceforth.

227. He also noted that, in the previous month, the European Union and European industry had had extensive discussions with Indian authorities - he was grateful that the amendment contained several positive elements to address significant substantive concerns raised by the European Union with previous rules. For instance, he referred to the fact that telecom service providers were made responsible for adopting all possible necessary measures to ensure the appropriate level of security for their networks and for creating an organisational policy on security and security management. Since the telecom service provider was best placed to determine the appropriate level of security and the measures that needed to be taken to achieve it this element was very positive. He also noted that there was no longer a mandatory template agreement between telecom service providers and vendors of equipment, which was a positive development since, given the specificities of the telecom network and the equipment operated on it, the content of the agreement was best left to negotiations between the telecom service provider and the equipment vendors. Moreover, there was no longer a requirement for equipment vendors to deposit their source code in an escrow account. That had, for the European Union, been a significant concern from the perspective of protection of intellectual property rights and legitimate commercial interests of equipment vendors. With reference to the liability in case of security breaches, he noted that the amendment removed the unlimited liability provision by providing a ceiling of roughly eight million Euros. He also underscored that there was a reference to relevant international standards on information security.

228. Some further adaptations were, however, necessary. For instance, on the validity period for acceptance of foreign test reports. He noted that the new rules provided for the acceptance of foreign test reports and certificates issued by competent foreign laboratories and certification bodies such as those approved by the contracting parties to the CCRA (Common Criteria Recognition Agreement). He highlighted, however, that the provision was only valid until 31 March 2013 and that, as of 1 April 2013, it was expected that the obligation for in-country testing using Indian labs exclusively would come into force. He requested a clarification on the rationale for the decision with regards to the flexibility afforded to equipment vendors to choose the laboratory in which to have their tests conducted. He requested the Indian authorities to reconsider this decision and to allow for the possibility of using competent, internationally accredited laboratories even after 1 April 2013.

229. The representative of the European Union also raised for discussion the new amendment that foresaw that the equipment vendor would have to provide the licensee details about the software used in the equipment and would have to allow the telecom service provider and/or the Department of Telecommunications of the Indian Ministry of Communications and IT, to inspect the hardware, software, design, development, manufacturing and supply chain, and allow for security checks of the supplies of the equipment at any point. He requested confirmation that such checks would be minimised and restrained to manufacturing facilities only and be therefore conducted in a such a way so as to safeguard the legitimate commercial interests of vendors would be adequately protected. Finally, regarding penalties in case of security breaches, the representative of the European Union welcomed the provision of the upper ceiling, noting however that it might be useful for the purpose of legal certainty and more predictability if more detailed guidelines would be developed as part of the implementation, so as to set clearer criteria allowing full proportionality between the amount of the penalty applied and the gravity of the breach in question.

230. The representative of Japan remained concerned about the security-related amendments to the Unified Access Service Licence Agreement. He noted that on 31 May 2011, India had announced the new rules - as part of this the requirement for foreign vendors of telecom services to transfer their technology within three years and place their source codes in escrow had been deleted. He

acknowledged this development as the old rules violated the principle of national treatment and infringed on intellectual property rights. However, he also raised concerns with the new rules, noting that Japan was currently in the process of determining the impact of these rules on Japanese companies. He cited examples of specific provisions. According to the said new rules, beginning April 2013, network elements would only be permitted if they had been approved by Indian certification agencies. He underscored that the approach might not comply with the CCRA (Common Criteria Recognition Agreement) given that India had accepted the scheme of the CCRA. He reiterated that India should ensure that its telecom regulations did not reduce market access for foreign companies.

231. The representative of the United States reiterated concerns raised with India's telecom licensing amendments and shared the position taken by other Members on the subject. He noted that India had issued new rules to replace previous amendments that had raised issues for Members. The United States welcomed the more open consultative processes, especially those with respect to industry stakeholders, that were considered for developing the new rules. He urged India to notify the new proposal to the TBT Committee for comments.

232. The representative of India said that the provision of 31 May 2011 categorically stated that it superseded all other provisions and was the final amendment on Article 41.6(a) of the Unified Access of the Licensing Agreement. India did not think that security guidelines were technical regulations within the purview of the TBT Agreement and did not see why the issue was being raised in the TBT Committee and why there was a need to notify the measure to the Committee. However, he mentioned that India had displayed the highest level of transparency on a subject with implications for national security and had engaged with all stakeholders at the highest administrative level and taken out clear instructions on the security guidelines, even in the absence of any specific obligations to do so, given their security implications.

233. The representative of India informed the Committee that the Department of Telecommunications (DOT) and the Ministry of Home Affairs had held high level meetings with the telecom service providers on 2 May 2011 to discuss their concerns on the security guidelines. Together the two ministries had developed the revised regulation on 31 May 2011. He also sought to alleviate concerns of Members such as those of Japan and the European Union under paragraphs (vi)(a) and (viii) of the guidelines noting that the provision of software details would not entail the supply of source codes; moreover, origin had been deleted from where it previously was in the guidelines.

(xviii) Brazil - Instructions for Registration for Labels of Imported Products of Animal Origin (G/TBT/N/BRA/385)

234. The representative of the United States appreciated Brazil's willingness to address concerns raised by amending the registration form but noted that there remained some issues on which further clarification was needed.

235. The representative of the European Union continued to be concerned about the requirement to register the labels of products of animal origin, and to have them approved before being marketed in Brazil. The European Union was monitoring the situation to ensure that this requirement would not create unnecessary delays and costs for EU exporters.

236. The representative of Brazil explained that the new measures were aimed at simplifying procedures for the registration of labels of products of animal origin. He recalled that Brazil had extended the consultation period for the measure in light of the concerns expressed by some Members and postponed its entry into force until 2011. Following this extended consultation, the draft regulation had been reformulated to reflect the comments received. Among the points removed

(G/TBT/N/BRA/385/Add.2) was the requirement that an exporting Member authority should state on the registration form that the product in question was in compliance with several aspects of Brazilian regulations. He explained that the date for entry into force of the new measure had again been extended, until April 2011 for new products, and April 2012 for products already registered in Brazil. The delegation of Brazil was of the view that the remaining issues could be dealt with bilaterally and invited interested Parties to engage with Brazil in this regard.

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

237. The representative of the European Union stressed that while her delegation did not question the obligation to label goods in the Indonesian language, she failed to see why labelling of a wide range of goods had to be approved by the Indonesian authorities before import, and why labelling had to be done before goods entered the Indonesian customs areas. She supported the objective of providing consumers with relevant information on goods that they were able to read and understand, but argued that this could also be achieved by importers adding stickers with the relevant information in the appropriate language before the product was placed on the market rather than before entering Indonesian territory. In case there were concerns about insufficient control of such re-labelling through market surveillance, she enquired as to whether a specific area for product re-labelling after entry into the customs area was a feasible proposition. She argued that this would be less burdensome, and would still fulfil the consumer protection objective.

238. The representative of the United States echoed the general concern of the European Union. He requested that Indonesia permit supplementary labels to be applied at importers' warehouses or other approved in-country locations *after* a product had cleared customs, but prior to distribution. To require labelling prior to shipment would prove costly and restrictive given the constraints of supply chains and consolidated shipments. Furthermore, he proposed that Indonesia allow importers to self-declare conformity with labelling requirements rather than having the requirement of a Certificate of Approval following submission of an acceptable sample label to the Indonesian Ministry of Trade.

239. The representative of Australia was concerned about conflicting advice about the labelling regulations. The Indonesian Ministry of Trade officials had confirmed that Regulation 69/1999 allowed labels to be applied to food products in Indonesia, whereas the Indonesian National Agency of Drug and Food Control stated that Regulation 62/2009 and 22/2010 prohibited the use of labelling stickers. This had led to some confusion as to whether the regulations applied to both food and non-food products. Australia sought to co-operate with Indonesia and supported its policy objectives without creating an onerous burden on exporters or disrupting trade. Australia preferred that exporters would be allowed to use labelling stickers, which they considered to be the least trade-restrictive option. Indonesia was encouraged to ensure that its labelling standards were consistent with existing international standards such as those of Codex, which offered guidance on the use of in-country secondary labels in-country.

240. The representative of Indonesia said that Members' comments would be considered as input into future reviews of the above-mentioned regulations. She clarified that rules concerning labelling of products *before* entering the customs area (Article 2 paragraph 3 of the Regulation of the Minister of Trade No. 22/M-DAG/PER/5/2010) stated that labels in the Indonesian language were applied to all goods which entered into the customs area of the Republic of Indonesia. Both domestic producers and importers were required to submit a sample label to the Ministry of Trade Directorate of Supply Goods and Service Control in order to obtain certification of labelling in the Indonesia language - this was, in fact, a means of pre-market surveillance used to assist in the control of goods, particularly imported goods, in accordance with the respective regulations applied. She noted that clauses of the Regulation of the Minister of Trade No. 62/2009 and 22/2010 stated that the obligation of affixing labels in the Indonesian language was an important prerequisite that had to be fulfilled by importers

bringing goods into Indonesia. The representative of Indonesia also described the Indonesian National Single Window (INSW) system which enforced compliance with restrictions and prohibitions on imports. Importers were required to submit documents concerning their products, together with a certificate of affixing labels in Bahasa Indonesian, or a duty exemption letter of affixing labels in the Indonesian language.

241. The Indonesian Government view was that Implementation of the Regulation of the Minister of Trade No. 62/M-DAG/PER/12/2009 concerning Obligatory Label Affixing on Any Goods and Regulation of the Minister of Trade RI No. 22/M-DAG/PER/5/2010 was aimed at giving consumers the right to correct and clear information, as stated in Act No. 8/1999 on consumer protection. The procedure was not intended to create barriers to trade. Regarding the content of the label, she stated that type or brand of the good in question was the most common inclusion - but the inclusion of both type and brand was optional; the producer and importer were at liberty to include both the type and brand. For instance, for a leather logo, the inclusion of this logo for goods made from genuine leather was at the discretion of the importer/producer; inclusion would have to be conducted in a responsible manner. With respect to a care label, information on use and care was voluntary (if necessary) - in this context information was to be determined by the producer, given their knowledge of the characteristics of the products. The "Made in" label could include general information on where the product was made. For footwear (printed or stickered), the Regulation of Minister of Trade No. 62/2009 and 22/2010, notably in Article 6, stated that "The label referred to in Article 2, paragraph (1), shall contain information or explanation of the goods and the identity of the producer or importer as set forth in attachment to this Regulation". The attachment to Regulation of Minister of Trade No. 22/2010 contained information on what would need to be printed on the label, and what information could be added by sticker.

242. The representative of Indonesia went on to note that the provisions for exemption of producers and importers from the obligation of labelling in the Indonesian language were available in Article 11 of the Regulation of Minister of Trade RI No. 22/M-DAG/PER/5/2010. This article, particularly paragraph (1), stated that “The obligation of affixing labels in Indonesian language as set forth in this regulation does not apply to goods which are sold in bulk and packaged directly in front of the consumers" - separate procedures were provided for obtaining the exemptions.

243. With respect to food products, the representative of Indonesia explained that her government had been implementing the provisions on labelling in Indonesian language for food products through Act No. 7 Year 1996 for food. The respective provisions were most clearly stated in Article 31 paragraphs (1) and (2) which indicated that: (i) "any person producing or importing into the territory of Indonesia, food which is packed for sale is obligated to place a label on, within and or on the packing of the food" and (ii) "The label as referred to in paragraph (1) shall at least contain information concerning: the name of the product; the list of materials used; net weight or net contents; name and address of the party which produces or imports the food into the territory of Indonesia; information on "halal" (legally permitted) and; the expiry date, month and year. It was noted that the Government Regulation No 69 Year 1996 concerning Food Labelling and Advertising, particularly in Article 15 stated that "Information on the label, written or printed in Indonesian language, in Arabic Numbers and Latin letters".

(xx) European Union - Proposal for a Council Regulation on the Indication of the Country of Origin of Certain Products Imported from Third Countries (SEC(2005)1657)

244. The representative of the United States requested an update from the European Union on developments in the European Parliament and on the process by which the European Commission would solicit input from Members and other stakeholders.

245. The representative of the European Union explained that the European Parliament had introduced a number of significant amendments to the Commission's proposal at its first reading, notably limiting the scope of application of the draft regulation to a list of end consumer goods as well as a review clause. The Council of Ministers was currently examining the Parliament's amendments, but without a set date for the adoption of a Common Position. It was probable that text resulting from the first reading of both institutions would significantly modify the original Commission proposal and any detailed discussion would therefore be premature. She explained that the Commission would examine whether the draft text contained any TBT elements at the time of the adoption of the Common Position by the Council, and in such a case would look into the need to notify the measure to the TBT Committee.

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

246. The representative of the United States expressed continuing concerns about Turkey's medical device reimbursement regulation, *communiqué* SUT 2010, specifically the requirement for producers of medical devices used in certain types of spinal, traumatology and orthopaedic arthroplasty procedures to comply with a second regulation, in addition to the Ministry of Health regulation affecting producers of medical devices. It was noted that no opportunity for comment had been given as the regulation had not been notified to the WTO and the United States was still awaiting clarification from the Turkish Government of the purposes for the second regulation, which was effective almost immediately after its publication. In particular, the United States had asked about the reasoning behind the product selection, if potential broadening of the scope of the second regulation would be likely and if so, whether the addition of products would be notified for comment. The representative of the United States urged Turkey to examine the transparency provisions in the TBT Agreements and to notify the measure, as well as any amendments, to the WTO for comment. He suggested that Turkey discuss the concerns of stakeholders with the industry and eliminate or modify any unnecessary documentation requirements to enable suppliers to continue to place their products on the Turkish market.

247. The representative of Turkey referred to explanations at previous meetings of the Committee and noted that any medical device, imported or domestically produced, would be able to enter the Turkish market if it carried the CE mark. She explained that the aforementioned *Communiqué* enforced by the Turkish Social Security Institute set out the conditions and requirements for reimbursement of medical device payments, along with other products within the social security system. She added that these conditions and requirements only applied to products the payments of which were made by the Social Security Institution for the beneficiaries of the system. The Turkish Social Security Institution covered the health expenditures of a large proportion of the population, and aimed to serve the public interest while protecting public health by ensuring that the most efficient medical devices were provided to patients, but also aiming to keep expenditure within a pre-assessed budgetary target.

248. She noted that the specific product groups to which the documentation requirements applied were those used more frequently in medical operations. These were the products for which patient complaints regarding quality deficiencies were raised most often. She stressed that the documentation requirements of the Institution were neither excessive nor applied in a discriminatory manner for imports. They were essentially required by the originating country authorities for market authorizations. She said the Institution therefore did not effectively create any documentation requirements or conformity assessment procedure, and furthermore, the Social Security Institution had not received, to date, any complaint from the industry regarding difficulties in fulfilling the documentation requirements. She invited US industry to provide more information on any specific problems encountered in the implementation of the Communiqué. Finally, she noted that a draft of the measure had been published on the official Institution website two months prior to enforcement

with interested parties given the opportunity to comment for a period of two months. Nonetheless, notification to the TBT Committee of the communiqué was under consideration.

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

249. The representative of India said that the proposed law required compliance with a large number of regulations and the provision of information at each stage of processing. He argued that an industry premised upon global and multiple sourcing would find it difficult to meet these criteria; particularly the exporters from developing countries. Indeed, the requirements proposed by Italy could be more restrictive than necessary and inconsistent with the requirements of Article 2.2 of the TBT Agreement. Furthermore, the requirements imposed under the Marketing Law modified the condition of competition for imported products from developing country Members and could result in less favourable treatment for imported products as comparable to products from Italy - this was inconsistent with the requirements of Article 2.1 of the TBT Agreement and Article III.4 of the GATT. In addition, the requirement to provide details of employment was a non-product related process and production methods (PPM) that was not covered within the scope of the TBT Agreement. He explained that India believed that this information requirement was clearly unwarranted as it sought to interlink labour issues with trade. Such non-product related PPMs also altered the conditions of competition to the detriment of imported goods and therefore violated the provisions of GATT 1994.

250. The representative of India also raised concerns about the reference to compliance with regulations on the environment and he questioned the inter-linkage between trade and environmental issues, arguing that this would constitute a trade barrier affecting exports from developing countries. He sought clarification as to whether Italy had given due consideration to less trade-restrictive regulatory alternatives in pursuit of its objectives and asked whether the concerns of Indian industry over the proposed regulation had been taken into consideration.

251. The representative of Argentina requested clarification from Italy and the European Union as to whether other European countries applied laws or dispositions or implemented standards with similar characteristics. He asked for information on which International Labour Organization (ILO) and environmental agreements had been referred to by this law and what mechanisms were in place to certify an environmental or labour standard - and how and by whom the certification would be done.

252. The representative of the European Union referred to previous Committee meetings where these concerns had been noted. As explained then, the application of the Italian law concerning the marketing of textile leather and footwear had been postponed until the adoption of an Inter-Ministerial Decree pursuant to Article 2 of the Law. This decree had not been adopted and was not foreseen to be adopted in the near future. It was therefore currently not necessary to discuss the detailed questions put forward by Argentina and India.

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

253. The representative of the European Union supported the objective of protecting human health, which Brazil had indicated as the rationale behind its draft resolution, but referred to previous comments. Specifically, the proposed measure would imply that EU exports of traditionally-blended tobacco products to Brazil and its exports of additives currently used in tobacco would be discontinued. She highlighted that the European Union was itself in the process of revising Directive 2001/37/EC on the approximation of laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products and had identified the

regulation of ingredients as one policy area that could potentially change. She recalled that a number of questions had been raised by the European Union at the previous meeting and, while acknowledging Brazil's helpful responses to several, noted that others remained unanswered. Specifically, she invited Brazil to clarify the grounds justifying a ban on additives over setting limits on use. At the previous meeting, Brazil had indicated that previous attempts to regulate aromas and flavours had been unsuccessful, but had offered no clarifications as to how this justified a complete ban. Furthermore, the European Union was also interested in whether Brazil had conducted an impact assessment, including on the consumption of tobacco products, as well as on growers and employment - particularly if Brazil had considered possible consumption shifts to additive-free cigarettes, such as Virginia tobacco. She requested a copy of any impact assessment, or a summary of its conclusions, if one had been carried out. Additionally, at the previous meeting Brazil had mentioned that its authorities had information indicating that additives enhanced the effect of nicotine, thereby making cigarettes more addictive. She requested more information on those studies, including the references of these studies to enable their evaluation by EU experts. Finally, the representative of the European Union requested an update of the state-of-play and asked Brazil to provide a written reply to its comments on the TBT notification before the adoption of the notified draft.

254. The representative of Mexico endorsed the European Union's concerns and asked for assurance that comments had been taken into account, if a written response to submitted comments would be forthcoming, and details about when Brazil planned to implement the regulation.

255. The representative of Chile requested time to prepare supporting evidence, citing the WHO document on tobacco control which supported governments giving consideration to scientific and any other kind of technical evidence. He supported the aim of reducing consumption to protect the health of young people but argued that these objectives could be achieved through less-restrictive barriers to trade.

256. The representative of Honduras was of the view that the Resolution would prohibit practically all types of additives, including menthol, representing a *de facto* ban on the marketing and sales of products containing certain types of tobacco, such as Burley and Oriental tobacco. Honduras remained concerned as Burley tobacco represented a significant proportion of its production and the draft Resolution would ban its use in Brazil, decreasing Honduran exports and national production. He argued that even though additives did not necessarily produce a specific flavour, the majority would be banned without supporting scientific or technical evidence; he added that no scientific evidence suggested that specific flavours would create a consumption pattern or make smoking more attractive. Honduras was concerned about the negative impact on its economy in the long-term.

257. The representative of Turkey questioned the definition of additives listed for prohibition in all tobacco-related products, specifically the inclusion of any substance or compound other than tobacco or water used to process, manufacture or pack tobacco-based products, including flavourings. The extensive list of prohibited additives and lack of supporting scientific evidence of any increased risk to human health concerned Turkey as the draft resolution would prohibit Burley and Oriental tobacco used in traditional blended products. Turkey had submitted comments and urged Brazil to consider them and amend the draft resolution to comply with its TBT obligations.

258. The representative of Colombia asked how Brazil would make use of the comments and queries received, suggesting they would prove a useful basis for a resolution more in-line with the TBT Agreement. He asked Brazil to provide updates on progress and reiterated concern that the draft would be set out and implemented as notified under G/TBT/N/BRA/407. He also asked for access to the scientific evidence used to justify the prohibition of the additives in question and any studies demonstrating the ineffectiveness of less-restrictive measures.

259. The representative of the Philippines was of the view that the draft resolution was arbitrary and unjustified discrimination, which would potentially result in a total ban of traditional blended cigarettes.

260. The representative of Brazil informed the Committee that the draft regulation and the comments received were still under consideration, that responses would be forthcoming and that he was unable to indicate when the final regulation would be published. He stressed that the objective was the legitimate protection of public health, with particular attention given to Article 1.2.1.1 of the partial guidelines to the implementation of Articles 9 and 10 of the WHO's Framework Convention on Tobacco Control. He recalled that the name "partial guidelines" only indicated that some parts of the instrument were pending further discussion while others were already fully approved. Article 1.2.1.1 was one of the provisions that had been unanimously approved by WHO and stated that, from a public health perspective, there is no justification for permitting ingredients such as flavouring agents, which made tobacco products more attractive. He observed that Articles 3.1.2.1 and 3.1.2.2 of these guidelines were similarly unanimously approved, and stated that regulation of ingredients aimed at reducing product attractiveness could contribute to reducing the prevalence of tobacco use and dependence among new and continuing users. Those articles also stated that attractiveness and its impact upon dependence should be considered when designing regulatory measures; and that the harsh and irritating character of tobacco smoke provides a significant barrier to experimentation and initial use. He referred to tobacco industry documents describing significant efforts to mitigate those negative characteristics of tobacco smoke. He cited a survey conducted by the Brazilian National Institute on Cancer (INCA) that had found that 45 per cent of people aged 13-15 consumed flavoured tobacco products.

261. For Brazil the measure was necessary given the failure of previous efforts to prohibit flavoured products rather than additives, due to the subjectivity of assessing flavouring and smells of products. Furthermore, according to information received by the Brazilian Government, the processing of Burley tobacco without additives was technologically feasible since 1996. He explained that evidence existed that some additives (including acetaldehyde, levulinic acid, gamma-valerolactone and ammonia) strengthened the effect of nicotine. In addition, some studies indicated that, besides increasing the addictiveness of tobacco products, some additives, when burnt, could augment the carcinogenic properties of cigarettes. He informed Members that Brazil had compiled scientific references related to the properties and effects of additives and offered to share them with interested Parties. Finally, he referred to Brazil's production of Burley tobacco, highlighting that the measure did not differentiate between domestic and foreign producers and was thus non-discriminatory.

(xxiv) 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)

262. The representative of the European Union referred to previous statements on the issue and requested an update on the timeline of the revision process of the Regulation on commercial encryption products managed by OSCCA, which at the previous meeting China had confirmed to be part of the 2011 State Council legislative agenda. In particular he enquired as to how transparency would be ensured, and specifically how consultation of interested parties would take place in accordance with China's domestic regulations and when a TBT notification would be made. In this regard, he highlighted the need for that consultation and the TBT notification to take place at an early appropriate stage, in order to provide stakeholders with a meaningful opportunity to provide input. On the implementation of the MLPS, he noted that China had previously clarified that the MLPS was a regulation that classified information security systems according to the level of their sensitivity for national security, and had confirmed that not only governmental bodies but also the financial and banking sectors as well as public utilities were impacted by the classification as critical infrastructure.

In the European Union's view, this confirmed the potential of the MLPS to impact upon areas not generally considered to be sensitive for national security in other jurisdictions, including commercial sectors such as banks and financial institutions. He explained that, in the European Union, for instance, banks and financial institutions were responsible for ensuring the security of their transactions and taking all appropriate measures to that effect. He called for greater transparency in the implementation of the MLPS, including the notification of relevant implementing rules. Finally, he thanked China for keeping a channel of communication open, and reiterated the European Union's commitment to reinforcing bilateral cooperation and having fruitful discussions with the Chinese authorities on these issues with all relevant actors on the Chinese side.

263. The representative of the United States said that his delegation was monitoring the development of this regulation given the potential impact of changes to information security requirements in China if the scope of covered products was to expand. He requested an update on proposed changes to the Office of State Commercial Cryptography Administration (OSCCA) regulations, including any indication of an eventual notification of the measure to the WTO TBT Committee. With respect to the MLPS, he explained that the United States had two concerns if the currently drafts were fully enforced or the product scope was to be expanded.

264. First, all information technology security products used in IT systems classified at level 3 or above under the MLPS would need to contain indigenous intellectual property. In addition to discriminating against foreign products, he argued that the measure would lower national security: security of products was not related to nationality of producer or origin of intellectual property, but to the quality of the specific system, the use of international standards and other objective criteria. Limiting the use of foreign products would also reduce the number of available information security technologies, ensuring that many of the most innovative security solutions would be excluded from China. Second, any products listed in the certification directory of information security products would need to acquire a certificate issued by a national information security product authentication organization. Having to provide confidential business information to a government-affiliated laboratory where there was no protection of confidentiality would be a disincentive for foreign companies to supply IT products to the Chinese market for fear that intellectual property and product security could be put at risk. He urged China to adopt and participate in development of international standards for product assurance in the information security area, including the common criteria.

265. The representative of Japan supported other concerned delegations and said that the Chinese schemes and regulations on information security would pose problems for future trade in information security products. He argued that these schemes were not in line with global standards and practices, and that Japan was paying particular attention to how these measures could negatively affect trade in information security products; the most recent issues being the OSCCA regulations on encryption and the MLPS. He recalled that other delegations had expressed desire for China to be prudent in introducing additional measures regarding information security and looked forward to being informed of how China intended to proceed.

266. The representative of China informed the Committee that bilateral discussions were held with the European Union, the United States and Japan. He informed the Committee that the Commercial Cryptography Administrative Regulation by OSCCA was still on the agenda of the Legislation Plan of the State Council (2011). As its draft was not ready, he did not think it was proper to discuss it in the TBT arena now. As for the Regulation on Classified Protection of Information Security, he argued that systems covered by Level III and above only took a small percentage of IT systems among major industries. As for the concerns of the US delegation, he invited the US to provide concrete examples. As for the global norm mentioned by the Japanese delegation, he invited the Japanese delegation to explain what was global norm in the field of information security.

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

267. The representative of Korea reiterated concerns that new technical guidance had not been released and Korean steel manufacturers were therefore unable to adequately prepare and apply for SNI certification for tin-plated electrolyzed thin steel bars. He asked for information on the establishment process of the draft Decree and detailed technical guidance as soon as it became available.

268. The representative of the European Union referred to past comments on mandatory third party certification for certain steel products. She noted that Indonesia had previously stated that it could accept certification from other countries and sought details of the criteria for such an acceptance - specifically whether EU Suppliers' Declarations of Conformity (SDoC) would be accepted. Finally, she requested a response to the concerns and requests for clarification that had been submitted to the Indonesian Enquiry Point in writing on 23 March 2011.

269. The representative of Japan supported the preceding interventions, expressing concern over possible further expansion of the mandatory standards. He noted that Japanese steel mills already implemented strict quality management systems certified by ISO9001 and this expansion would increase the time and cost required to obtain and maintain certifications, likely impacting negatively on foreign trade by increasing distribution costs and delaying supply to major Indonesian industries and therefore causing Indonesian industries to be less competitive in the global market.

270. The representative of Indonesia informed the Committee that the draft Decree was still being finalized, and would enter into force six months after the day of publication. During the six month period, technical guidance would be prepared by the Indonesian Ministry of Industry and adopted prior to the date of entry into force. She added that SNI would not be implemented before entry into force, thus importation procedure would refer to the previous regulation until that date. She explained that certain steel products, which had different technical specifications but fell under the same HS numbers were not covered by the mandatory implementation of SNI. Elaborating, she said that imports of these products should be accompanied by a letter of technical consideration issued by the Indonesian Ministry of Industry, and no rule or regulation on quotas that applied to these products was currently in place.

271. The representative of Indonesia said that her government would design the regulation based on the following considerations: consumer protection, improvement of product quality, and fostering fair trade competition. With regard to the latter, Indonesia intended to use the regulation to ensure that electrolysis tin-plated thin steel sheets complied with the requirements in SNI, thereby ensuring consumer safety. She explained that SNIs for steel products which would be implemented as mandatory requirements referred to standards of some WTO Members; SNI had been developed by consensus through stakeholder engagement, taking into consideration the development of technology and the capacity of manufacturers. Product certification bodies designated by the Indonesian Ministry of Industry could outsource product testing to the respective laboratories outside Indonesia; laboratories could only be appointed if the country in question had signed a bilateral or multilateral agreement with the Government of Indonesia. She said that an agreement could be made by considering a Mutual Recognition Agreement (MRA) between KAN and the accreditation body of another country. She would keep Members up to date on the timeline for implementation once the regulation and technical guidance had been finalized.

(xxvi) Colombia - Alcoholic Beverages (G/TBT/N/COL/121 and Adds.1-3)

272. The representative of the United States appreciated the cooperation from Colombia thus far and said that some additional issues had been raised for discussion. These included the recognition of

distinctive products, formulating positive lists of food additives, as well as certain parameters on alcohol content.

273. The representative of the European Union explained that the European Union continued to have several concerns which would be submitted in writing. In particular she referred to the definitions of alcoholic beverages, which continued to cause a number of concerns - including the upper alcohol limit for fruit spirits, the definition of liqueurs, brandy and vodka, and the requirement of oak containers for rum production. She asked for clarification of the sanitary interest of requiring labels to be affixed at origin, emphasizing that this could prove problematic, particularly for low-volume imports. She also asked whether the requirement of presentation of a quality certificate at the time of importation was also applicable to locally-produced goods. Finally, she enquired as to how goods legally-imported into Colombia before the legislation came into force would be treated, and whether they would be subject to the new requirements.

274. The representative of Colombia reiterated previous comments made informing Members that the draft decree had been published on 5 November 2010, amending G/TBT/N/COL/121/Add.2. This document set a deadline for comments of 4 February 2011. This deadline was subsequently extended for a further three months at the request of Members and notified in G/TBT/N/COL/121/Add.3. He noted that Colombia had dealt with concerns raised by Argentina, Guatemala, Chile and the European Union, integrating several of their recommendations and comments.

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

275. The representative of the European Union sought an update on the status of the catalogue of products required to comply with pollution control, recalling that in the previous Committee meeting China had explained that such catalogue was still under development, and would be notified to the WTO in due course. She also recalled China's statement that mandatory, voluntary or other kinds of certification could be chosen for the purpose of certification. The European Union understood from that statement that Article 21 of the notified draft did not automatically impose mandatory third party certification and the means of compliance assessment were still to be decided. The representative of the European Union sought confirmation that this understanding was correct, and asked China to elaborate on how the catalogue and certification procedures were linked. Finally, she expressed doubts over the necessity of a third party certification for controlling a risk that only manifested once products became waste, and not when the product was being used by the consumer.

276. The representative of Korea noted an information exchange on the issue in a bilateral meeting. He voiced the concerns of the Korean industry on this regulation and explained that the State Recommendation Voluntary Certification System (SRVC) was viewed as *de facto* mandatory certification because of government procurement and tax benefits. Only Chinese certification bodies designated by the Chinese Ministry of Industry and Information Technology (MIIT) and Certification and Accreditation Administration (CNCA) would provide acceptable tests, and he urged acceptance of results from third countries which would also test according to international standards. He asked for more detailed information on test methods and the requirements of certification bodies.

277. The representative of Japan sought clarification in response to its comments. He asked which type of certification system could be applied, as Japan was unsure if the "national certification system for the control of pollution caused by electronic products" could be a mandatory third-party conformity assessment, or a Voluntary Supplier's Declaration of Conformity Certification (SDoC), which Japan advocated. He referred to Article 3(1), concerning electrical and electronic products. The Chinese Government had explained that an exempted products list was under consideration and he emphasized that automobiles, batteries, any parts and materials incorporated in "equipment and attached products", and any jig, tool and material used in the production of "equipment and attached

products", were to be exempted from the definition of electrical and electronic products. He also asked for an update on the status of the exempted products list for Article 3(1).

278. The representative of the United States raised concerns with respect to the administration and control of pollution caused by electrical and electronic products, specifically the implementation rules for voluntary certification issued earlier in 2011. He urged China to notify those procedures and postpone implementation until comments had been received and taken into account. He also asked China to indicate the objective and rationale of these certification procedures and requested clarification as to whether any incentives were linked to compliance with certification procedures. The United States understood that producers could receive incentives for compliance, including acceptance of certification results for CCC certification purposes, tax relief for companies whose products were certified, and government procurement opportunities; such linkages could make even a voluntary scheme *de facto* mandatory. The US representative sought confirmation of notification if and when voluntary measures would be made mandatory.

279. The representative of China appreciated the opportunity to clarify some points bilaterally with the EU, Canada, Japan, South Korea, and the United States. He stated that China has replied in writing to comments from the US, Japan, and the EU, and for the EU, there had been a second reply. He recalled previous statements at the last meeting that the draft "Catalogue for Standard-reaching Management" contained a list of product categories, and mandatory, voluntary, or other kinds of certification could be employed for conformity assessment. He said that China would fulfill its notification obligation under the TBT Agreement.

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

280. The representative of the European Union asked whether the current practice of allowing labelling in customs warehouses would be maintained, as opposed to in the country of origin. In addition, she sought clarification about the scope of the regulation with respect to alcoholic beverages, *inter alia*, if labelling requirements applied to all types of alcoholic beverages or only to "toddy"; only the latter was explicitly mentioned in point 5.9.5 of the regulation. If labelling requirements were to be extended to all alcoholic beverages, the European Union would seek an exemption for the indication of food additives, date of manufacture and vegetarian/non-vegetarian declaration, and the acceptance of “single ingredient status” for the list of ingredients (e.g. “contains scotch whiskey” would avoid listing all ingredients). She said that India was deviating from Codex Alimentarius in certain areas, such as the obligation to label certain aspects in capital letters, which went beyond what would be necessary to safeguard a legitimate objective.

281. The representative of the United States was concerned about the lack of a notification. He appreciated the delay in enforcement of the revised labelling provisions and India’s response to questions concerning the applicability of certain sections of the requirements to the distillation of spirits. He expressed concern over India’s application of date of production labelling to distilled spirits and suggested that lot identification numbers would prove more effective in the event of a product recall. He urged India to remove this requirement and also to reconsider the listing of ingredients for alcohol, given international practice of not requiring an ingredient list for non-nutritive products. He asked India to follow international practice with respect to requiring labelling of flavour declarations on the part of the label covering the back of the package, not the label on the front of the package as currently required.

282. The representative of India stated that the measure had only been notified to the SPS Committee as it related to consumer safety and protection; it was intended to protect human health, which, he argued, was clearly covered by Annex A1(b) of the SPS Agreement. He was unable to

offer specific replies to the concerns raised but pledged to refer them to the Indian Food Safety Authority, who would respond in due course.

(xxix) Korea - PCV flooring material and Wallpaper and paper linoleum (G/TBT/N/KOR/303 and Add.1 and G/TBT/N/KOR/304 and Add.1)

283. The representative of the United States reiterated concerns about the proposed content limits of 0.1 per cent for the three phthalates DEHP (Di-Ethyl Hexyl Phthalate), DBP (Di-butyl Phthalate) and BBP (Butyl benzyl Phthalate) in certain uses, particularly for PVC flooring and wallpaper. He sought more information from Korea on the proposed content restrictions which he argued would effectively prohibit the use of these substances in two applications (flooring and wallpaper). He noted that effect of under-floor heating had been offered as justification, but the United States was unaware of evidence that this would cause the release of such substances in PVC flooring material. In addition, no explanation was given with respect to wallpaper. Korea had since explained that a study on the release of hazardous substances in construction materials was the basis of their proposal, and he restated his request for a copy of the study.

284. He added that US regulators had expressed general concern regarding DEHP because of their toxicity, the United States Environmental Protection Agency (EPA) had published a plan outlining a number of actions to better assess exposure and potential safety concerns with DEHP, and the US and other countries had imposed restrictions on children's toys and childcare articles, though as far as he was aware, this would be the first instance of restrictions on DEHP in flooring and wall coverings.

285. The representative of Japan supported the position of the United States, restating serious concern over the restriction of specific plasticisers such as DEHP, DBP and BBP in PVC flooring material and wallpaper. In response to Korea's citation of similar restrictions in other countries, he noted that Japan limited the content of DEHP in infants' toys to a maximum of 0.1 per cent, based upon the possibility of these toys being held in children's mouths for extended periods. He argued that no other economy imposed similar regulations on housing materials and found the regulation to be excessive.

286. The representative of Korea noted that bilateral discussions had taken place with the Japanese delegation that had provided specific information on long-term monitoring of phthalates indoors. He reiterated that Korean houses employed Ondol, a unique, centuries-old under-floor heating system which meant most of these houses used PVC flooring materials and wallpaper. The Korean Agency for Technology and Standards (KATS) conducted safety assessments for PVC wallpaper and flooring materials; they tested the phthalate-content of 46 PVC flooring materials and found it to range from 16.4 to 20.8 per cent. The second type test, rubbing flooring materials with fabric, resulted in detection of a transferral of 0.13-0.71 $\mu g/cm^2$ phthalates. These results were positively correlated with higher floor temperature and formed the basis for the safety regulation. KATS had gathered input on the proposed measure from industry and experts and had received very positive feedback. Industry had not only agreed with the phthalate limit but regarded the measure as a positive regulation, which could encourage the development of alternatives and enhance competitiveness. He added that Korea had informed the EPA of plans to regulate the level of phthalates in wallpaper and flooring and asked the United States to share the results of any work on phthalate regulation.

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

287. The representative of the European Union noted China's efforts to implement an efficient and comprehensive regulatory system for the approval of cosmetics and efforts to clarify and streamline new requirements. She also welcomed recent progress by the SFDA in dealing with a backlog of applications for products without new ingredients. She said that some issues remained, most notably

those tied to the registration of products containing new ingredients which had been impeded until recently by a lack of guidelines on the definition of a "new ingredient". On 8 June 2011, China had notified a set of such guidelines to the TBT Committee (as notification G/TBT/N/CHN/821), which had been already adopted on 12 May 2011 and would be implemented on 1 July 2011. The European Union was in the process of analysing these guidelines and would revert with more detailed questions in writing or bilaterally, but expressed hope that they would eliminate the existing difficulties in the registration of products with new ingredients.

288. The representative of the European Union also informed Members that this issue was under discussion bilaterally under the framework of the Working Group on cosmetics set up by the State Food and Drug Administration of China (SFDA) and the European Commission's Directorate General for Health and Consumers (DG SANCO), whose next meeting on 21 June 2011 would allow these issues to be tackled at expert level. She hoped discussions would prove fruitful, and thanked the SFDA for its openness and constructive approach. She urged the SFDA to follow good regulatory practice when developing mandatory requirements – particularly in allowing for sufficient stakeholder consultation and thorough impact assessment, notification to the TBT Committee at an early draft stage to enable comments from interested Members, and giving sufficient time between adoption and implementation for economic actors to adapt.

289. The representative of China explained that the short comment period provided in the notification was due to detailed consultations with enterprises, including those from the European Union. He said that a clear definition on new ingredients for cosmetics was given in the Cosmetic Hygiene Supervision Regulation, and specific regulations on safety assessment of new ingredients for cosmetics were also formulated in Implementing Rules of Cosmetic Hygiene Supervision Regulation and Cosmetic Hygiene Standard. He stated in order to strengthen the supervision on new ingredients for cosmetics, Application and Evaluation Guideline of New Raw Materials for Cosmetics was drafted and notified to the WTO, and the list of the first batch of raw materials used was being sorted out. He confirmed that SFDA would attend the third Session of Sino-EU Cosmetics Working Group Meeting in Brussels on 21 June, and in-depth discussions and exchanges were expected with EU counterparts on safety management of cosmetic raw materials, risk assessment evaluation, and testing methods for prohibited and restricted cosmetic substances.

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

290. The representative of the European Union reiterated concerns about the above-mentioned measure, in particular on the provision for certain facilities for cosmetics manufacturers, such as an exemption from the requirement of batch testing and from conducting quality management by lot number. She referred to Korea's confirmation that only domestic manufacturers would benefit from these derogations, and to its assertion that foreign manufacturers received similar preferential treatment, such as exemption from quality inspection under Article 9 of the Enforcement Regulation of the Cosmetics Act. She argued, however, that while this Order indeed provided for the possibility of a waiver from quality control inspection in the territory of Korea, it did not allow for the other derogations foreseen in the Good Manufacturing Practice Requirements for cosmetics (KCGMP). The European Union therefore believed that the 'preferential treatment' provided by the two acts were not equivalent and reiterated its request for Korea to ensure fair competition between domestic and foreign manufacturers. She informed the Committee that the issue was under discussion bilaterally. The representative of the European Union also enquired as to whether Korea's responsible authority, the Korea Food and Drug Administration (KFDA) would recognize assessments performed, or certificates issued, by testing laboratories and governmental agencies of third countries proving compliance with ISO 22716 as equivalent to those proving compliance with the KCGMP - in particular since Korea had provided assurances at the last meeting that KCGMP had been developed to harmonize Korean requirements with the aforementioned international standard.

291. The representative of the United States referred to the potential for the measure to provide preferential treatment for companies in compliance with GMP standards, which offered significant cost advantages. He urged Korea to ensure that rules would be applied consistently to both foreign and domestic producers and asked if foreign producers would be eligible for this certification. If not, he stated that the measure would appear to discriminate against foreign producers. In addition, the United States believed the GMP standard to be based on ISO 22716 and was currently comparing the two documents. He expressed concern that the trade group for the Korean Cosmetics Association (KCA) would control certification of compliance, creating a potential conflict of interest. Given that GMP and ISO standards appeared very similar, if not identical, he argued that Korea could accept certification to the ISO standard from an independent third party. He also asked for clarification of the exact role of the KCA and for confirmation that submission of foreign cosmetic producers' formulae was no longer a requirement for pre-market approval. He believed the latter issue had been resolved in 2008, but said that the issue had been raised again by US industry

292. The representative of Korea confirmed that KCGMP formed part of efforts to harmonize with the ISO 22716 to improve the quality of cosmetics and to protect public health from hazardous cosmetics. He added that KCGMP was voluntary, with no mandatory standard foreseen. Regarding the exemption from the requirement of conducting batch tests and conducting quality management by lot number, he explained that the exemption would offer preferential treatment to domestic manufacturers sufficiently in compliance with the requirements. Similarly, importers of non-Korean cosmetics products could enjoy preferential treatment, for instance the exemption from quality inspection upon passing on-site inspection, under Article 9 of the Department Ordinance of Cosmetics. This had been adopted in 1999 and 23 importers of foreign cosmetics manufacturers had since benefitted from it. In response to concerns about the impartiality and neutrality of KCA, he clarified that the organization merely supported implementation and the body responsible for certification was the KFDA; he pledged to bring the other points raised to the attention of the KFDA. He noted that the European Union planned to introduce a Cosmetics Regulation, which would enter into force in 2013; he asked for more information on the EU's good manufacturing practice, particularly the date of notification and any deviation from ISO 22716.

(xxxii) Ukraine – Draft Technical Regulation on the labelling of foodstuff (G/TBT/N/UKR/52)

293. The representative of the European Union requested clarification of the state of play of Ukraine's GMO legislation, including confirmation that only foodstuffs containing more than 0.9 per cent of GMOs would require labelling as "with GMO" and that the statement "GMO free" would remain voluntary for foodstuffs with GMO content of less than 0.1 per cent. She urged Ukraine to align its legislation with international practices and not to prohibit health claims in food labelling, for which guidelines were given in the Codex Alimentarius and which were generally permitted under EU legislation. She recommended that information on storage conditions only be required if necessary and not systematically for all products.

294. The representative of Ukraine said that there were internal discussion on-going on possible modifications and amendments of the technical regulation to more adequately reflect domestic objectives and international commitments. She clarified that the corresponding reference to standard DSTU4518 implied a recommended and voluntary measure which was under revision. Ukraine's Safe Standards Committee prepared a second set of clarifications on issues including conditions for the identification of nutritional value recommendations to avoid misleading consumers. She added that the regulation allowed for proper indication of dietary functional characteristics and dietary supplements, following Ukrainian Health Authority approval. She acknowledged European Union input on specific shelf life conditions to be indicated on a label and invited further comments from Members.

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

295. The representative of the European Union noted that, contrary to what Ecuador had indicated at the previous meeting, the Resolution 18 had not been notified according to Article 2.9.2 of the TBT Agreement. She asked why supplier's declarations of conformity (SDoC) from enterprises certified according to ISO 9001 and issued by bodies recognized by Ecuador's Accreditation Body were suddenly no longer accepted and whether ISO 13006 certificates issued by similarly-accredited bodies would be recognized. Imports had been seriously impeded by the fact that only one laboratory had been accredited in Ecuador to carry out the necessary tests and the drastically shortened validity of existing certificates, from one year to 90 days. She added that requests for clarification following the last TBT Committee meeting addressed to Ecuador's Enquiry Point had met with no response; she urged Ecuador to reply.

296. The representative of Ecuador explained that Resolution 18 followed ISO 13006 requirements. And, although there was no obligation to notify it under Article 2.9.2 it did fall under the notification contained in document G/TBT/N/ECU/44/Add.1. In general, Ecuador was of the view that ISO 9001 certification was not the most appropriate tool for gauging technical qualities of products, and that ISO 9001 was intended to ensure conformity and *management* of a product, rather than its quality. This meant that although certain products complied with ISO 9001, they were not in line with Ecuador's technical requirements.

297. The representative of Ecuador explained that ISO 13006 had been used as a basis for study of its technical regulations on ceramic tiles and the requirements of this standard had been incorporated. Thus these certificates of conformity were recognized when in line with N003 or other standards, or when they state that they are in line with ISO 13006. With respect to certification he explained that both Articles 1 and 2 of Resolution 018 of CONCAL offered three options for conformity certification: country of origin, country of shipment or country of destination. He said that a single certified laboratory did not necessarily constitute a technical barrier to trade, as the laboratory would have the capacity to handle the demand. Nonetheless, Ecuador had started to increase the number of laboratories and certification bodies. He reiterated that products with only ISO 9001 certification would no longer be accepted once the provisional measure had expired. He clarified that new certificates were based upon Resolution 18 of CONCAL would maintain their one-year validity as in the past.

(xxxiv) European Communities – Regulation on Certain Wine Sector Products (G/TBT/N/EEC/15 and Corr.1-2; G/TBT/N/EEC/57; G/TBT/N/EEC/252 and Add.1; G/TBT/N/EEC/264 and Add.1)

298. The representative of the United States expressed concern about measures which severely restricted the ability of non-EU wine producers to use common descriptive or commercially-valuable terms to describe their products – on the grounds that these terms were traditionally associated with European wines. He noted that discussions were on-going but the European Union still claimed exclusive rights to terms commonly included on wine labels worldwide. The United States was unaware of any basis upon which these terms could mislead consumers and was also concerned that protection of these terms had been extended to languages other than the one for which protection was identified. He added that the United States had raised intellectual property concerns on this issue in other for a as well.

299. The representative of the European Union observed that bilateral discussions with the United States were on-going and that applications filed by US wine associations for the aforementioned traditional terms were under review.

(xxxv) Norway – Proposed regulation concerning specific hazardous substances in consumer products (G/TBT/N/NOR/17)

300. The representative of Japan requested an explanation of Norway's risk assessment for the specified hazardous substances and stated that a publically-available risk assessment should be conducted for newly-specified substances, in this case: lead, pentaclorofino, medium-chain chlorinated paraffin (MCCP) and perfluoro octanic acid (PFOA). He asked for an update on the possible new regulation of specific hazardous substances and urged Norway to notify the regulation to the TBT Committee should it be modified.

301. The representative of Norway explained that the draft had been thoroughly reviewed, with eight substances of the 18 in the original notification removed following a second review. A subsequent review concluded that the four (referred to by Japan) of the remaining 10 substances were to be prioritized for regulation; she explained that comments from earlier reviews had been considered when undertaking impact assessments for these four substances and they were available through the Norwegian Climate and Pollution Agency website. English language versions had been forwarded to the Japanese delegation. She informed Members that the Norwegian environmental authorities were in the process of reviewing the proposals in light of new comments received but there was no schedule for completion of this task or implementation of the regulation.

(xxxvi) Brazil - Canned Sardines - Ministerial Act Nº 406 of 10 August 2010

302. The representative of Peru informed the Committee that bilateral consultations with Brazil would soon begin on the labelling requirements for canned and tinned sardines, the results of which would be conveyed to the Committee in due course.

303. The representative of the European Union also expressed interest in the issue.

304. The representative of Brazil confirmed Brazil's willingness to hold a bilateral dialogue with Peru on this issue.

C. EXCHANGE OF EXPERIENCES

1. Good Regulatory Practice

305. The Secretariat introduced two background notes. One on regulatory cooperation between Members (JOB/TBT/10) and the other on a list of Sources on Good Regulatory Practice (JOB/TBT/11). The attention of Members was also drawn to the draft outline of the programme for the Workshop on Regulatory Cooperation between Members, contained in JOB/TBT/7/Rev.1.

306. The representative of India offered some preliminary comments. He suggested adding the word "technological" in the parenthesis of paragraph 3; the deletion to the reference made to "different levels of development" in para 6(d); and, the need for some clarification in 14(e) in terms of the link between the Committee's work and regulatory co-operation.

307. The representative of El Salvador reiterated the importance of developing country participation in regulatory cooperation activities.

308. The Chairperson invited Members to comment on the papers (the above-mentioned JOB documents), including the programme for the Workshop, by 15 July 2011.[17]

[17] This deadline was later extended to 15 August 2011.

309. The representative of the United States updated the Committee on GRP developments in the United States. These on-going activities included an agreement on terms of reference with Canada and Mexico in two bilateral regulatory cooperation councils where there had also been much stakeholder interest in providing input on regulatory cooperation projects. A similar exercise was also under way between the United States and the European Union. Further information on US regulatory activities would be provided at the Workshop on Regulatory Cooperation between Members.

310. The representative drew the Committee's attention to a memorandum circulated to US Agencies by the US Trade Representative (USTR) and the Office of Management and Budget (OMB) on the transparency obligations involved in GRP and their relationship with preventing unnecessary obstacles to trade.[18] This memorandum, he said, showed how Good Regulatory Practice was good for business and also good for the protection of the environment, health and safety.

311. The representative also informed the Committee about the US policy principles for US Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials.[19] This was an area that would be used in many different sectors and across many jurisdictions, both within the US and internationally. The United States' aim was to have a coordinated US Government approach to regulating nanotechnology. This memorandum, he said, specifically encouraged coordination with the international community. Cooperation with the European Union was already underway and his delegation looked forward to discussing this issue with other delegations.

2. Standards

312. Concerning standards, the Chairperson reminded the Committee that during the Fifth Triennial Review the Committee had considered in depth the issue of standards. In particular the Committee had looked at the issue of the development and use of standards in line with paragraph 25 of the Triennial Review report. The Committee had recognized the need for international standards to be relevant and that they effectively respond to regulatory and market needs and scientific and technological developments while not creating unnecessary obstacles to international trade. Among other things, the Committee had recommended the circulation of key studies or other research on the impact of standards on economic development and international trade.

313. She recalled that Members had also been invited to share their experiences related to the implementation of the TBT Agreement, including the Code of Good Practice as outlined in paragraph 26 of the Triennial Review report - and that the Committee had stressed the importance of participation in the work of international standardizing bodies. In paragraph 27(a) of other Triennial Review report the Committee had encouraged Members, Observers, Organizations and other relevant bodies involved in the development of standards, to exchange information on initiatives implemented successfully achieved and obstacles encountered. She invited Members to begin an exchange of experiences in this respect.

[18] http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-23.pdf.
[19] http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf.

3. Conformity Assessment

314. Representatives of the ILAC and IAF made a joint presentation of their organizations.[20] The following are a few of the key messages delivered. The full presentation was circulated as document G/TBT/GEN/17.[21]

(a) ILAC is the global authority for laboratory and inspection body accreditation.[22] IAF oversees accreditation in the fields of the certification of management systems, personnel and products. The objective of both organizations is the same: one test accepted everywhere, one conformity assessment result accepted in every market place.

(b) IAF and ILAC determine the competence of accreditation bodies by peer evaluation based on an ISO/IEC standard (ISO/IEC 17040) on how peer evaluation should be conducted. Most of the peer evaluations are coordinated and conducted at the regional level. The ISO/IEC 17000 series is the international standard used for conformity assessment and accreditation.

(c) The main tool used by the two organizations is multilateral, mutual-recognition arrangements among accreditation bodies (for ILAC it is called an MRA and for IAF an MLA). The vision is to have a single world-wide programme of conformity assessment which reduces risks for business, regulators and the consumer by ensuring that accredited services can be relied upon.

(d) The ILAC and IAF arrangements consist of ILAC and IAF accreditation body members that are deemed competent through a peer evaluation process to confirm conformance to ISO/IEC 17011 and the IAF-ILAC A series documents. Accreditation bodies are then allowed to sign the ILAC MRA or IAF MLA. Signatories must recognize certificates, reports, and results issued by organisations accredited by all other members of the arrangements. These arrangements provide businesses with assurance that equivalent overseas conformity assessment bodies operate to the same standard as those in their own country. This recognition contributes to removing unnecessary barriers to trade by eliminating redundant conformity assessment procedures. The idea is that an organization can be accredited once and then have that accreditation recognized anywhere in the world.

(e) There are 72 ILAC MRA Signatories representing 59 economies and there are 49 IAF MLA Signatories, representing 47 economies.

(f) Both ILAC and IAF provide assistance to developing countries to help them develop their conformity assessment and accreditation infrastructures.

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[20] The presentation was jointly made by Mr Randy Dougherty and Mr Peter Unger. Mr Dougherty is the Vice President of the ANSI ASQ National Accreditation Board which is the United States' recognized national accreditation body for management system certification bodies. He is currently Chair of the IAF and the IAF Executive Committee. Mr Peter Unger is President and CEO of the American Association for Laboratory Accreditation, a non-profit membership organization administering a comprehensive laboratory accreditation systems.

[21] More information can be obtained at www.ilac.org and www.iaf.nu.

[22] Accreditation is defined as: "Independent evaluation of conformity assessment bodies against recognized standards to ensure their impartiality and competence to carry out specific activities, such as tests, calibrations, inspections and certifications".

315. The representative of Egypt asked for some clarification about the proportion of "regulators" (77 per cent) that accepted results from accredited organizations: what did the remaining percentage consist of? Were these non-signatories?

316. The representative of China asked whether the CPSC[23] (a US body) automatically accepted test results issued by testing laboratories of exporting Members as long as they had fulfilled the criteria under ILAC, for instance with respect to toys - an issue that had been raised as a specific trade concern in the Committee. In China's understanding, it was primarily the technical competence of testing laboratories that needed to be taken into account for regulators to decide whether (or not) to accept the test results of laboratories. Yet, the CPSIA[24] set additional and unreasonable requirements for governmental laboratories and this was a primary reason for the CPSC to refuse to accept Chinese governmental laboratories. Is it justifiable for a laboratory to be denied recognition by regulators solely because of the governmental background of it?

317. The representative of Pakistan asked if MRAs and MLAs were covered under international treaties (or international law), governable under the Vienna Treaty of Conventions. He also asked for some clarification about the membership of ILAC. He also asked about public sector involvement in certification activities.

318. The representative of New Zealand noted that several slides in the presentation had mentioned the growing acceptance by regulators of the value of accreditation. She asked if this was because regulators themselves had seen value in accreditation and had therefore provided for this in their regulatory frameworks. Or was it because accreditation had grown through government to government MRAs, or were there other reasons? This was important because the Committee was involved in work on guidelines for trade facilitation mechanisms and insights from the ILAC and/or IAF could be useful.

319. The representative of ILAC explained, with respect to the question from Egypt, that the 77 per cent figure was based on self-declaration among ILAC members (when reporting on the degree of acceptance by the regulators of accreditation). This was not necessarily directly related to the ILAC MRA but was about the degree that regulators were using the national accreditation body. Although the majority had declared that, indeed, there were regulatory agencies in their country that were using accreditation, a smaller share (the remaining 23 per cent) had not succeeded in convincing regulators to use accreditation. He noted that communication with regulators had been on the increase over the years.

320. On the question regarding the CPSC (from China) the representative of the ILAC said that he could not speak officially for the CPSC. He noted, nevertheless, that with respect to government laboratories impartiality and accuracy was important: it was important that laboratories had the equivalent to what was required in ISO 17,025 with regard to being impartial. Testing needed to be unbiased. The conformity assessment standards of ISO and IEC, he said, focused very heavily on the impartiality of the body, i.e. to have confidence that conformity assessment results could be relied upon. The conformity assessment body has to be able to demonstrate that it was not influenced by outside forces.

321. On the issues of international law (question from Pakistan), the representative of IAF noted that this was precisely one of the reasons that ILAC and IAF did not refer to multilateral mutual-recognition *agreements* - because an "agreement" was considered to pertain to governments. Hence the word "arrangements" was used - but it was still about mutual recognition. This was not necessarily government-to-government recognition, he explained. It was recognition between

[23] http://www.cpsc.gov/.
[24] http://www.cpsc.gov/about/cpsia/cpsia.html.

conformity assessment practitioners: primarily accreditation bodies - the mutual recognition of results that were produced by the accredited laboratories, or accredited conformity assessment bodies. In other words, this was a private sector activity and not government-to-government mutual recognition *agreements* or multilateral agreements.

322. With respect to membership, the representative of IAF noted that while membership in ILAC was limited to accreditation bodies, the IAF had decided some time ago that it was important to give voice to the stakeholders: the bodies that were actually being accredited, the industry that had being served. Hence, while individual companies could not become IAF members, industry associations could - and the same was valid for conformity assessment bodies. Individual conformity assessment bodies could not become members of IAF, but they could become associate members. On public sector involvement, it was noted that most certification bodies were actually private-sector organizations. Normally, certification was done in the private sector although there could be some government bodies or certification bodies that were government-based.

323. The representative of ILAC stressed that his organization relied on international standards: most activities related to harmonization were done through ISO and IEC. In his view this was one of the drivers for the growing acceptance by regulators of accreditation (New Zealand's question). There was, in his view, a desire by regulators to play within the global community and international standards provided a mechanism better than any other kind of relative mechanism. The ILAC and IAF provided a mechanism through which the private sector could work in close cooperation with official regulators to provide confidence in the safety of products. A good example of how this worked effectively and in a highly regulated area was the Canadian Medical Device Conformity Assessment System. This system, developed several years ago, allowed for the private sector to have responsibility for overseeing lower-risk medical device products whereas the Canadian Government had kept responsibility for regulating the very high risk medical devices. So the government had been able to focus their resources on the higher risk and work closely with the private sector conformity assessment area to handle some of the lower risk products. This was also an example of how the efficient use or resources was also a significant driver for governments.

324. The representative of India asked, with respect to the issue of membership, about the proportion of accreditation bodies from developing countries compared to developed countries. He asked what types of bodies that were members (inspection, certification and testing bodies). He also asked about the concept of international standards and asked whether there was any specific definition used for international standards in the IAF and ILAC context.

325. The representative of the United States asked about the obligation of signatories to promote the use of IAF and ILAC within their countries: what were those obligations? And what was the level of implementation of such obligations? He also asked about support provided by ILAC and IAF to developing countries to develop accreditation infrastructure. Sometimes, in discussions, a reason given for *not* using ILAC and IAF was a perceived need to protect the development of their emerging infrastructure.

326. The representative of Australia asked for clarification about the relationship between ILAC and IAF: was there an MoU? Also, how often was the competency of accreditation bodies reviewed?

327. The representative of Canada asked for clarification about the challenges that ILAC and IAF faced in convincing regulatory authorities to use accreditation. What were the reasons that accreditation was perhaps not more widespread? In addition he wondered if some work was being undertaken on some form of guidelines.

328. The representative of the European Union asked whether there had been any attempts to merge the two organizations. He also asked for clarification on how ILAC and IAF cooperated with

regulators in order to ensure that the results of accreditation served all the regulators' needs in different countries. In addition, the representative of the European Union asked whether sectoral schemes existed in order to better link accreditation to the needs of specific product areas. With respect to peer evaluation, he asked about the training of "lead assessors" and how ILAC and IAF ensured uniformity in assessment.

329. The representative of China asked for some more detail about the issue of impartiality and technical competence of laboratories. While he understood the importance of accreditation to ensure the impartiality and technical competence of testing laboratories, he also noted there was an international standard (ISO/IEC 17,025) for laboratory accreditation. It was his understanding that gaining accreditation under ILAC in accordance with this standard means the testing laboratories had demonstrated impartiality and technical competence regardless of the nature of the technical laboratory; that is regardless of whether it was a governmental laboratory or a private one. In this sense the regulators had the obligation to treat government laboratories and private laboratories in the same manner as long as the testing laboratory was accredited under ILAC in accordance with the relevant international standard. Nevertheless, China was faced with a situation where some regulatory authorities of some Members did not automatically accept the testing results issued by testing laboratories accredited under ILAC but rather imposed additional and WTO-inconsistent requirements on government laboratories.

330. The representative from ILAC noted that indeed there existed sector-specific requirements in certain areas and these could come from many different standardization bodies. On the use of the ILAC MRA, he noted that there were some agencies that were unwilling to use accreditation in particular regulated fields - it was sometimes difficult to convince certain sectors of the market place, consumers in particular, that were sceptical of private sector solutions. Consumers did not always believe that the private sector could be as impartial as a government regulator, government inspector or a government laboratory. With respect to developing countries, ILAC did have a modest budget to help developing countries; it was currently partnering with donor agencies to develop national accreditation bodies or to join a multi-economy accreditation system. Indeed ILAC was encouraging and did have rules to accept multi-economy accreditation bodies: some countries were very small and would not necessarily have their own national system for accreditation but their conformity assessment bodies could then be accredited by a neighbouring accreditation body. Such cross-frontier accreditation was accepted. Also, there existed an IAF/ILAC/UNIDO MoU that set out cooperation with UNIDO in support and promotion of development of accreditation infrastructure in developing countries.

331. The representative of ILAC also confirmed that the MoU between IAF and ILAC committed both organizations to close cooperation on common issues. This was evident through joint peer evaluation, for example. Regarding the issue of merging the two organizations, a formal vote had been taken in 2010 on a merger and although the majority of participants in each organization had been in favour of merger, a three-fourths vote in ILAC and two-thirds in IAF was needed to proceed and neither threshold had been met. Therefore a merger had not been undertaken.

332. The representative of IAF explained that for both IAF and ILAC the MLAs and MRAs had moved quicker with developed countries because they had accreditation bodies that had been established and had been working for a longer period of time. Nevertheless, numerically the predominant members were from developing economies (in both ILAC and IAF). He stressed that all members that joined the bodies had to work actively to becoming an MLA signatory and progress was checked.

333. The Chairperson thanked the representative from ILAC and IAF for their very informative presentations

334. The representative from Thailand informed the Committee that Thailand would host the annual joint meeting of the international accreditation forum and international laboratory accreditation co-operation. IAF/ILAC 2011 Joint Annual Meeting. This meeting would take place during on 2-11 November 2011 in Bangkok. She invited Members of the TBT Committee to attend this meeting.

4. Transparency

335. The representative from the United States thanked the Secretariat for providing an update of the document containing Decisions and Recommendations of the Committee since 1995 (G/TBT/1/Rev.10).

5. Technical Assistance

336. The representatives from Sweden and Kenya[25] presented the results of the Swedish Mentorship Programme which had been launched in November 2008. The following are a few of the key messages delivered; the full presentation is contained in document G/TBT/GEN/16.

(a) The Programme, which is managed by the Swedish National Board of Trade (SNBT) and financed by the Swedish International Development Co-operation Agency (SIDA), is between Sweden and six sub-Saharan East African Countries: Burundi, Kenya, Rwanda, Tanzania, Uganda and Zambia.

(b) It emphasizes, *inter alia*: attendance to the TBT Committee meetings; building national infrastructure for transparency (notification) and provision of comments on other WTO Members' notifications (of draft measures); building a network of civil servants among participating countries; building a network between private and public sectors and interested parties (e.g. regional trade groupings and chambers of commerce).

(c) From the mentee's perspective an important starting point was the identification of the root causes for lack of implementation of the TBT Agreement in their countries: These included: poor feedback on notifications; inadequate physical infrastructure and regulatory framework; unclear definition of institutional roles with overlap of mandates between various institutions; poor national co-ordination mechanisms between various regulatory authorities; inadequate financial resources; low capacity of personnel to undertake implementation tasks; and, ineffective mechanisms for collecting information about regulations (lack of databases).

(d) There were a number of tangible results. For instance, between 2008 and 2010 there had been an increase in the number of notifications made to the TBT Committee: in 2008 there were 37; by 2010 combined notifications from the six countries were 226; national enquiry pods had been established (where none existed before); improved engagement in TBT Committee meetings and enhanced understanding of the TBT Agreement among stakeholders; improved national coordination (mechanisms had been developed) both at the domestic level and between capital-based experts and missions in Geneva; and, enhanced regional co-operation between countries involved in the programme.

[25] Presentation by Mr. Christer Arvius from the Swedish National Board of Trade and Ms Lucy Wanjiru Ikonya, Manager of Trade Affairs at the Kenya Bureau of Standards (KEBS), Nairobi (on behalf of the mentees).

(e) The mentees thanked SIDA and the Swedish National Board of Trade (SNBT) for their support and called for follow-up with respect to work under way.

D. OTHER MATTERS

1. Sixth Triennial Review of the TBT Agreement (2012)

337. The Chairperson noted that there had been, since November 2009, a robust discussion on issues falling under the Agenda Item 2.C. (Exchange of Experiences). She reminded the Committee of the upcoming Sixth Triennial Review and the need to start preparations. She therefore suggested that the Committee hold an informal meeting after the summer to discuss matters arising under Agenda Item 2.C. She suggested that this opportunity also be used to finalize the programme for the Workshop on Regulatory Cooperation between Members. The date for the informal meeting was subsequently set for the morning of 23 September 2011.[26]

2. The Great East Japan Earthquake and Tsunami Disaster

338. The representative of Japan expressed his country's gratitude for various kinds of support by WTO Members after the Great East Japan Earthquake and Tsunami Disaster. He reaffirmed Japan's strong commitment to international trade. Regarding the safety of industrial products exported from Japan, he said that these products were manufactured in factories outside of the no-entry zone and remained under strict quality control. It was therefore unlikely that such products would be affected by radioactive material. Safety was ensured. In addition to monitoring the level of radiation across the country, Japan published data on radiation levels in ports and airports. Moreover, a guideline on radiation measurements for export containers and ocean going ships had been developed and published, and an attestation of measurement results had begun at some ports including Yokohama since 28 April 2011. Japan would continue to provide the international community with prompt and accurate information on its response to the nuclear accident and would ensure the highest level of transparency. Japan would like to request WTO Members to respond to this situation on scientific grounds.

III. TECHNICAL COOPERATION ACTIVITIES

339. The Chairperson drew the Committee's attention to a document containing the Secretariat's technical assistance activities (G/TBT/GEN/122).

IV. OBSERVERS

A. UPDATE FROM OBSERVERS

340. The representative of ISO highlighted the importance that ISO placed on technical assistance and training in supporting its developing country members which, he said constituted three-quarters of its current membership. Recent activities in this area included the brochure "Developing Talent"[27] containing an overview of all technical assistance and training activities provided by ISO to its members. While these activities were mainly directed at ISO members, the representative highlighted the support that had also been given to sub-regional and regional organizations in training activities. Such organizations needed training in standardization as their members dealt directly with regional trade of products and services and therefore harmonization of standards and conformity assessment procedures were critical. He drew the Committee's attention to a new activity launched in 2011, to help identify gaps in best practices. These gaps, he said, would be addressed through targeted actions

[26] Chairperson's fax to WTO Members of 15 July 2011.
[27] Available on the ISO website at http://www.iso.org/iso/publications_and_e-products/about_iso.htm.

over the course of a year. Initially, work was being undertaken with 13 standard bodies, but the programme would be extended to other ISO members - in particular developing country members. He also highlighted the ISO guide on engaging stakeholders and building consensus published in December 2010.[28]

341. The representative of the IEC drew the Committee's attention to the IEC report to the TBT Committee.[29] She highlighted new developments in IEC international standardization such as the new IEC Technical Committee 117 on Solar Thermal Electric Plan. Another development was the intention to reduce the time line in the delivery of final standards. A decision would be taken on this at the IEC Standardization Management Board in 2012. With regard to capacity building, she highlighted the IEC's participation in an event organized by the African Electrotechnical Standardization Commission to be held in Nairobi in September 2011. On conformity assessment activities, the representative informed the Committee that the IEC Conformity Assessment Board (CAB) had circulated a survey on conformity assessment aspects on electrical energy efficiency in developing countries and had received feedback from forty-two affiliate countries. It was also noted that the IEC had nominated Phuntsho Wangdi from the newly formed Bhutan Standards Bureau, as the new Affiliate Leader and informed the Committee that the IEC would hold its 75th Annual Meeting in Melbourne, Australia from 24-28 October 2011.

342. The representative of the UNECE invited the Committee to attend the 21st session of the Working Party on Regulatory Cooperation and Standardization Policies (WP6) which would take place on 25-27 October 2011 and would include a workshop on traceability.[30] This session, she said, would also look at new recommendations on market surveillance policies, risk management in regulatory systems, and contingency planning in regulatory policies. The representative also highlighted the formal launch a database of market surveillance authorities. In addition, she informed the Committee on progress made in the promotion of regulatory convergence in specific sectors, in particular the initiative on equipment used in environments with an explosive atmosphere. A meeting of regulators in this sector would take place in Croatia in September 2011 where regulators would present their different regulatory approaches and discuss how the UNECE proposal could be used to promote regulatory convergence.

343. The representatives of the ITC, Codex and the OIML[31] provided updates to the Committee on their on-going activities in developing countries and other work relevant to the TBT Committee.

B. REQUESTS FOR OBSERVER STATUS IN THE TBT COMMITTEE

344. The Chairperson drew the Committee's attention to the document G/TBT/GEN/2/Rev.3 containing the list of bodies applying for observer status in the Committee. She invited Members to consult with relevant authorities regarding the list of pending requests so that the Committee could take a decision on these.

[28] http://www.iso.org/iso/publications_and_e-products/standards_development_publications.htm).
[29] G/TBT/GEN/118.
[30] http://live.unece.org/trade/wp6/documents/2011/2011_docslist.html.
[31] G/TBT/GEN/119, G/TBT/GEN/120, G/TBT/GEN/121.

V. DATE OF NEXT MEETING

345. The next regular meeting of the TBT Committee will take place on 10-11 November 2011. It will be preceded by the Workshop on Regulatory Cooperation Between Members on 8-9 November 2011. The following dates have been preliminarily agreed for meetings in 2012: 21-22 March, 14-15 June and 7-8 November.