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Committee on Technical Barriers to Trade

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Chairperson: Mr. Amit Yadav (India)

Note by the Secretariat[1]

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

I. ADOPTION OF THE AGENDA

1. The Committee adopted the agenda contained in WTO/AIR/3624.

II. IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

A. STATEMENTS FROM MEMBERS UNDER ARTICLE 15.2

2. The Chairman recalled that the latest list of statements submitted under Article 15.2 of the TBT Agreement is contained in G/TBT/GEN/1/Rev.9, issued on 5 February 2010. He noted that since the previous meeting of the Committee, Belize and Cambodia had submitted their statements (G/TBT/2/Add.103 and G/TBT/2/Add.104). Moreover, Indonesia, Malaysia and Tanzania had submitted a revision to their statements (G/TBT/2/Add.9/Rev.2, G/TBT/2/Add.3/Rev.4 and G/TBT/2/Add.94/Rev.1). The Chairman said that in total, since 1995, 121 Members had submitted at least one Statement on implementation under Article 15.2. He recalled that the latest list of enquiry point contacts is contained in document G/TBT/ENQ/37, issued on 15 June 2010.

B. SPECIFIC TRADE CONCERNS

1. New Concerns

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

3. The representative of India expressed concern about Italy's draft law requiring a label to indicate compliance at each stage of textile, leather and footwear products processing. In particular, he was concerned that these criteria would be difficult to meet for an industry that relied on global and multiple sourcing. The cost of compliance for exporters from developing countries in particular, could make this labelling scheme more trade restrictive than necessary to fulfil its legitimate objectives. In addition, it was India's view that the requirement to have details of employment was a non-product related process and production method (PPM) which was not covered by the TBT Agreement. Furthermore, he noted that non-product related PPMs also altered the conditions of competition to the detriment of the imported goods, which would violate the provisions of the GATT 1994. The representative of India argued that this information requirement was clearly unwarranted as it sought to link labour issues with trade. India was also concerned about compliance with environmental regulations, which would constitute a trade barrier affecting exports from developing countries. According to the Indian representative, linking environment with trade issues was questionable. He queried whether Italy had given due consideration to other less trade restrictive regulatory alternatives to fulfil the intended objectives and concluded by requesting the Italian Government to take the Indian industry's concerns into consideration.

4. The representative of the European Union noted that the new legislation concerning the marketing of textile, leather and footwear products required a compulsory labelling of finished products. Although the law was supposed to enter into force on 1 October 2010, the representative of the European Union noted that Italian authorities had decided to postpone the application of the law due to on-going internal discussion in the European Union. In addition, according to interpretative guidelines issued by the Italian authorities, the provisions on the labelling of finished and semi-finished products and on the use of the "Made in Italy" mark in textiles, leather goods and footwear industries would be considered effective only once an Inter-ministerial Decree pursuant to Article 2 of the law would be adopted. The representative of the European Union mentioned that the implementing measures were also still under internal discussion.

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

5. While the representative of the United States appreciated that Brazil had postponed the implementation of its new labelling requirements for products of animal origin from 1 October 2010 to 1 January 2011, concerns persisted. It was the US delegation's understanding that according to section 2 Field 6.2 of Brazil's Circular Letter, US regulatory authorities would be required to certify to Brazilian market requirements. Although they would have the authority to certify that US food products were produced in accordance with U.S. requirements, US regulatory authorities would not be able to certify products for compliance with Brazil's private market standards, which were outside the scope of US legal authority. As a consequence, the US representative claimed that these requirements would significantly disrupt trade. In addition, the representative of the United States pointed at another concern related to Field 10.1 of the Circular Letter (Field 10 of the Registration: "Composition" and "Ingredients"), which would require suppliers to list all of their ingredients and their respective percentage in the product in order to be registered. The representative of the United States was concerned that this requirement could result in the disclosure of confidential information. Instead, the US delegate proposed to list ingredients in descending order as a less onerous option.

6. The representative of the European Union also expressed appreciation for the postponement of the entry into force of the measure and the granting of a longer comment period. She asked for clarification about the rationale for requesting that all labels of products of animal origin be approved before they could be marketed in Brazil. In addition, she asked for an update on the state of play of the notified measure and looked forward to receiving a written reply to her comments from the Brazilian TBT enquiry point.

7. The representative of Switzerland echoed the concerns raised by the representatives of the United States and the European Union and drew the Committee's attention to three points. First, since product labels already contained an expiry date, she asked if Brazil could provide further clarification for the reasoning behind the requirement to include the date of manufacture. Second, since Swiss companies exporting to Brazil were already subject to Brazilian approval procedures, she requested clarification regarding the separate approval process for these labels. Finally, the Swiss representative was pleased to hear that Brazil had extended period for comment.

8. The representative of Brazil recalled that his delegation had provided several clarifications on the measure at issue during the last meeting of the Committee on Sanitary and Phytosanitary Measures (the "SPS Committee"). He noted that there had been no indication whatsoever of interruptions or difficulties in the flow of exports to Brazil of products covered by the measure. Second, the objective of the measure was to facilitate trade by *simplifying* the formalities for the registration of labels, without adding or changing any substantive requirement, thus facilitating the process of complying with mandatory registration requirements for products of animal origin. Finally, the entry into force of the measure had been postponed to 1 January 2011 and the comment period to 1 November 2010 in order to allow for interested parties to become acquainted with the measure and so as to grant an additional transition period. Regarding the comment of the European Union about the date of adoption, the Brazilian representative explained that April 2010 had been the date on which the public consultation on the draft regulation had started. Therefore, Brazil remained open to comments and would respond to them until January 2011, the date of entry into force.

(iii) India - 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"

9. The representative of the United States expressed concern about the issuance, by India's Department of Telecommunications, of a "template agreement for security and business continuity" in July 2010. He viewed this "template agreement" as a mandatory part of private commercial contracts between telecommunication service providers and vendors of all telecommunications-related equipment, products and services. It was his understanding that the Indian measures contained a series of requirements and conditions as well as burdensome and irrelevant testing and certification requirements. Two particular requirements raised concern: companies had to deposit their source codes in escrow and transfer their technology to Indian companies. According to the US delegation, the fact that companies had to meet all security standards made this measure a technical regulation, while the fact that the "template agreement" contained certification requirements made this legislation a conformity assessment procedure. The representative of the United States raised another concern regarding the fact that, under the terms of the rules issued by India, the same requirements had to be met by all vendors seeking to sell telecom equipment and products to Indian telecom service providers. This obligation was problematic because terms would necessarily vary from contract to contract. The representative of the United States requested an explanation why India had applied these requirements only to imported products and exempted telecom equipment and products manufactured in India. According to letters from global US industry, the issuance of these requirements, particularly the "template agreement" had abruptly halted billions of dollars of US equipment sales in India, while Indian suppliers had not been similarly affected.

10. The representative of the United States also questioned the lack of transparency involved in the adoption process of the measures at issue. He acknowledged the fact that India had announced its willingness to suspend implementation of the "template agreement" and review the security requirements given the concerns raised. However, US exporters would still be hindered by a lack of clarity regarding the specific security requirements currently in effect. Moreover, despite the fact that India had indicated that it was going to consult with stakeholders, the US delegation was still waiting for the announcement of a transparent process of public consultation which would give all stakeholders (including equipment manufacturers) the opportunity to participate in those consultations. Moreover, in the view of the United States, India had failed to notify any of these requirements to the WTO. In fact, all of the measures had been issued as final edicts for immediate implementation without any guidance as to how the telecom service providers were to operationalize these sweeping requirements. This omission caused serious confusion and distress in the market. In addition, repeated requests for information by the US Enquiry Point to the Indian enquiry point had been ignored. While the US delegate supported the objective of telecom security, he considered that open and transparent rulemaking processes consistent with TBT obligations would yield the information critical to formulating effective security policies. Soliciting input from potentially affected parties could therefore increase the effectiveness of the measure and reduce needless and unintended impacts on economic activity. The representative of the United States strongly reminded the Government of India of its obligations under Articles 2.9, 5.6 and 10.1 of the TBT Agreement. He recommended that, once the review of the suspended requirements would be done, any new measures would have to be notified in draft form in order to give trading partners the opportunity to comment on them and take those comments into account. Finally, he urged the Indian delegation to carefully consider the discussions in the TBT Committee on the importance of instituting mechanisms and processes of internal coordination, so that its Enquiry Point would be able to answer all reasonable questions formulated by other Members.

11. The representative of Japan raised similar concerns about India's New Telecommunications related regulations (Amendment to the Unified Access Service License Agreement for security related concerns for expansion of Telecom Services), published in December 2009, March and July 2010. According to the Japanese representative, the requirement for transferring of technology (item (viii) of the March 2010 document) and the mandated escrow of sensitive information such as source codes ((vii)(c) of the July 2010 document) were elements that could have severe effects on the market access of foreign products and the establishment of a fair business environment. It was Japan's view that the requirement of transfer of technology to domestic vendors could be in conflict with the national treatment principle. In addition the mandated disclosure of sensitive information, which was vital to maintain corporate competitiveness, was also a cause of concern from Japan as well as other Members' industries.

12. Moreover, the representative of Japan highlighted the lack of clarity in the formulation of the Indian regulation. First, it was unclear whether the regulation of item (vii)(a) in the July 2010 document (requiring certain security specifications for telecommunication products) could be regarded as a compulsory certification scheme. Second, it was not clear whether item 13 of the "contract agreement" regarding network certification was based on relevant guidelines of an international standardizing body. For these reasons, the Japanese delegate considered the regulation and "contract agreement" associated with the license conditions for telecommunication operators as a measure that substantially affected trade. He also believed that the notification to WTO Members should be conducted based on the TBT Agreement if part of the mandatory regulation consisted of compulsory certification. The Japanese representative called upon the Indian Government to review the regulations in order to make them consistent with international rules, including WTO rules, and appropriately protect intellectual property of industrial firms. In addition, he requested that the scheme at issue be established following a transparent and fair process for all stakeholders. In particular, he asked if the Indian delegation could give information on the current situation of the review and upcoming schedule since the Prime Minister's office of India had instructed the relevant departments to suspend the finalization and review of the scheme in August 2010.

13. The representative of the European Union echoed the concerns raised by the United States and Japan, particularly regarding the unclear and vague content of the measures at issue. It was his delegation's view that the measures appeared to mandate, via the "template agreement" between telecom operators and equipment vendors, compliance with certain standards and testing procedures. The measure further included disclosure of source code which although deposited in escrow would be accessible not only to the telecom operators but also to the Department of Telecoms. The representative of the European Union was interested in the rationale behind this approach which was not based on the principle of least trade restrictiveness; could India consider less trade restrictive alternatives while preserving the legitimate interest of the industry concerning the confidentiality of certain information, like source codes and network design? The representative of the European Union also called for more transparency in the process and an opportunity for stakeholders to provide input. Finally, the European Union delegation appreciated the fact that the measure had been put on hold on request from the Prime Minister's Office. Although the suspension period was – or was going to be extended – the representative of the European Union recommended that the measure be put on hold pending further technical examination and internal coordination within the Indian Government as well as dialogue with interested stakeholders, foreign industry and governments.

14. According to the representative of India, the provisions of the Unified Access Service License Agreement for Telecom Services were not covered by the TBT Agreement. In fact, it was argued that the provisions were in line with the security exceptions under Article XXI of GATT 1994. India was therefore of the view that the TBT Committee was not the correct forum to discuss the measure. Moreover, in the view of India, the measure was in line with the promotion of transfer of technology according to the Working Group on Trade and Transfer of Technology and the mandate in paragraph 37 of the Doha Ministerial Declaration, and subsequent affirmation in paragraph 43 of the Hong Kong

Ministerial Declaration. Finally, the Indian representative informed the Committee that India's Department of Telecommunications was working on simplifying the procedural aspects of the License Agreement.

(iv) Mexico - Mexican Official Standard PROY-NOM-051-SCFI/SSA1-2009: General specifications for the labelling of pre-packaged food and non-alcoholic beverages - Commercial and health information (G/TBT/N/MEX/178)

15. The representative of the United States reminded the Committee that his Government was supportive of nutritional labelling where information could assist consumers in selecting foods that could lead to healthier diets. He thanked Mexico for clarifying that the commercial information contained in the Mexican Technical Regulation (NOM-051) was not subject to certification. He also noted and appreciated the fact that the Secretariat of Economy of Mexico was currently reviewing the implementation of conformity assessment procedures (pre-registration, certification and surveillance) and would publish additional guidance in accordance with NOM-051 requirements with the possibility of public comments for at least 60 days. The US representative inquired when this additional guidance would be issued and asked if Mexico had any plans to extend the exemption for allergen and nutrition labelling to small volume producers.

16. The representative of Mexico said that the modification to the official standard NOM-051-SCFI/SSA1-2010, regarding general labelling specifications for food and non-alcoholic beverages, had been published in the official journal of the Federation on 15 April 2010. A resolution, which modified various aspects of Mexican official standard at issue had been published in the Official Journal of the Federation on 26 October 2010; its entry into force was set for 1 January 2011. This modification had been carried out on the basis of Article 51 of the Federal Law on Metrology and Standardization. According to the Mexican delegate, the general objective of this modification was to establish alternative and optional use of various concepts on nutritional values, tolerance levels, symbols and abbreviations. In particular, the modification allowed substituting the term nutritional information with nutritional data as well as the term calorie and kilocalorie. In addition, on small surfaces, where one could not report this information, a web address had to be included so that consumers could access all this information. It was her delegation's view that these modifications were compatible with the provisions established by the Food and Drug Administration and the Code of Federal Regulations. Therefore, the homologation of the applicable regulations to food, both in Mexico and the United States, was guaranteed without any reduction in the level or degree of protection for the consumer. With regard to the questions raised by the United States, the Mexican representative said she would submit them to her capital in order to obtain a detailed reply.

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

17. The representative of the United States expressed serious concerns about Turkey's new medical device regulation. He noted that although medical devices were already regulated by Turkey's Ministry of Health, a second regulation, the objective of which was quality assurance, had been issued by Turkey's Social Security Institute (SGK) on 15 June 2010. It was his understanding that all producers of medical devices used in spinal, orthopaedic, arthroplasty and traumatology procedures were required to supply additional documentation in order to maintain 100 per cent of current reimbursement levels. In particular, producers were required to document that each group of products was certified by the regulator in the country where the products had been manufactured or imported from, as well as used. The US representative noted that some devices were manufactured in one country and used in another; hence producers would not be able to obtain such certification. In addition, many medical device regulators did not provide documentation on product usage or proof of reimbursement. As a result, obtaining such certification or shipping a device through a country where the producer had obtained a certificate, would be costly, unnecessary and time-consuming. According to the United States, the consequences of not providing such documents were significant. The

reimbursement rate of a device filed after 15 June 2010 dropped to 60 per cent of the current level. Moreover, if a product filing was not made by the end of 2010, SGK would cancel all reimbursement for the device. As a result, the US representative argued that the regulation restricted trade in safe, effective medical devices. He further noted that the regulation had not been notified to the WTO. Consequently, interested stakeholders had not been given notice and were deprived of the opportunity to comment on the draft measure. He also criticized the fact that the measure had been published on 25 March 2010 and went into effect only seven days later on 1 April 2010, with the requirements imposed as of 1 May 2010 (later changed to 15 June 2010). As a consequence, suppliers were denied a reasonable period of time for implementation.

18. The representative of the United States invited Turkey to explain the objective of SGK to require companies to provide these additional documents, given that Turkey's Ministry of Health (MoH) already had requirements to prove the safety and efficacy of medical devices. In particular, the MoH, which was the competent authority in charge of implementing the EU Medical Device Directive in Turkey, required a European CE mark for devices to be marketed in Turkey. He also asked Turkey to explain whether the MoH was of the view that the Medical Device Directive was insufficiently robust. If so, the representative of the United States was interested to know the basis to impose these additional requirements on medical devices. He also questioned the reason why SGK specifically selected medical devices used in spinal, orthopaedic, arthroplasty and traumatology procedures for these additional requirements. The US delegation urged Turkey to suspend the implementation of the SGK measure until it was notified to the WTO for comment; had met with industry stakeholders to hear their concerns and taken these into account so as to eliminate or reduce any unnecessary documentation requirements. Ultimately, suppliers could continue to place their products on Turkey's market provided they were satisfied with the requirements of the Medical Device Directive. Finally, the representative of the United States reiterated Turkey's obligation to notify to the WTO any new extension of these requirements to other devices so that comments could be taken into account and a reasonable interval for compliance be provided.

19. The representative of Turkey explained that medical devices fell under the scope of the Customs Union Decision between Turkey and the European Union. In particular, he informed the Committee that Turkey had fully harmonized the relevant directives of the European Union in its own national legislation. In this context, medical devices had to bear the CE mark before they were introduced to the Turkish market. According to the representative from Turkey, the implementation did not discriminate between domestic and foreign products because domestic producers had to comply with the same legislation. He made clear that customs controls were conducted according to the communiqué on standards legislation that indicated which medical devices had to be checked and how this needed to be done. He highlighted the existence of an exhaustive list attached to the communiqué which included only a small number of medical devices subject to this legislation. The Turkish representative concluded that, in his view, the current legislation and implementation did not create any technical barriers to trade and did not discriminate among third countries.

(vi) United States - Foreign Manufacturers Legal Accountability Act

20. The representative of Mexico expressed concern regarding the HR 4668 law of responsibility of foreign manufacturers, introduced in the US House of Representatives in February 2010 and under consideration for a possible vote in the House. It was her delegation's understanding that this legislation would request foreign producers or manufacturers to establish an authorized representative in the United States in order to accept representation and notifications on their behalf for any civil and regulatory procedure of federal and state courts in the US. The Mexican delegate noted that the bill established that 180 days after the implementation of the regulation, foreign producers or manufacturers would no longer be able to import covered products if they did not have a registered agent in the United States. According to the Mexican delegation, this would correspond to a ban. While Mexico shared the commitment to guarantee product safety and consumer protection, concerns

remained that the requisite for foreign manufacturers to appoint a registered agent in the United States as a condition for the import of its products would contravene US international commitments. In addition, the Mexican representative stressed that the application of this act would be very costly; it would adversely affect producers, importers and exporters. She argued that other countries could decide to implement similar measures, especially in sectors in which the product chains were located locally. She therefore urged the US Government not to adopt these measures given its WTO commitments. She also invited the United States to further inform the Committee of the consequences of this bill in order to comply with all the technical regulations in effect. Based on Annex 1 of the TBT Agreement, which defined procedures for conformity assessment as any procedure used directly or indirectly to determine that the provisions complied with the relevant technical regulation or rules, the Mexican delegate viewed the necessity to comply with the legislation in order to fulfil the technical regulations as a horizontal provision which was part of the technical regulations themselves.

21. The representative of Australia was also concerned about elements of the US Foreign Manufacturers Legal Accountability Act. It was her delegation's view that the draft bill would require exporters of certain products to establish a registered agent in the United States to accept service of processes on their behalf and to consent to the jurisdiction of the state or the federal courts of the United States in which their agents would be located. While the representative of Australia supported the objective of enhanced consumer protection, she encouraged the United States to use less burdensome and less trade restrictive measures to achieve this objective. She believed the draft bill would impose an additional and costly regulatory burden on foreign manufacturers exporting to the United States. In particular, additional costs would make foreign inputs less attractive to US manufacturers; this could impact on competitiveness and costs for the manufacturers relying on foreign imports. Ultimately, some manufacturers could refrain from exporting to the United States. More generally, she highlighted the potential impact of the bill on the disruption of supply chains in the United States, especially the supply of component parts.

22. The representative of Hong Kong, China shared the concerns raised.

23. The representative of the United States explained that the objective of the bill was to ensure that foreign producers, just like domestic ones, could be held accountable in US courts if their products harmed or injured people or property in the United States. He confirmed that the bill was still being discussed in Congress but could expire at the end of the congressional session in November or December 2010 if it remained pending. In any case, the Office of the United States Trade Representative would continue to follow this legislation if it was re-introduced in the next Congress. According to the US representative, this legislation did not appear to fall within the scope of the TBT Agreement's definitions of a technical regulation or conformity assessment procedure. Any discussions on this legislation should therefore continue to be held bilaterally.

(vii) United States – Draft legislation on chemicals – Bill 5820

24. The representative of the European Union expressed interest regarding the introduction of a draft measure entitled "Toxic Chemicals Safety Act of 2010" in the US House of Representatives. It was her delegation's understanding that this bill would amend the existing Toxic Substances Control Act by providing a new framework for the management of chemicals in the United States in order to ensure public and environment protection from chemical exposure risks. She noted that the draft would give the US Environmental Protection Agency (EPA) power to lay down further rules but other parts of the draft already established important requirements for chemical manufacturers, processors or importers. For instance, the draft would provide for a precise time-frame according to which manufactures and processors would have to submit data on chemicals. The EPA would also be given the power to prohibit the production and the placing on the market if the relevant data was not submitted. The representative of the European Union referred to the case of new chemical substances

and mixtures or new uses, which would be subject to a prohibition of production and placing on the market unless a notice to the EPA was submitted 90 days before the manufacturing or processing. This notice would need to attest that the anticipated use of the chemical substance or mixture caused no risk of injury to health or the environment and met the safety standards. Based on these examples, the EU representative concluded that the draft contained technical regulations covered by the TBT Agreement even if, for some aspects, it still needed to be complemented in order to be fully applicable to producers ". While the EU delegation shared the objectives pursued by the draft bill, she asked why it had not been notified to the WTO in order to give third countries the possibility to get acquainted with the draft and comment on it. She also pointed out the existence of a similar draft bill being discussed in the US Senate, which was also supposed to amend the Toxic Substances Control Act. Finally, the representative of the European Union invited the United States to confirm that, in accordance with Article 2.9 of the TBT Agreement, the draft bill would be notified at an early appropriate stage and before its adoption so amendments could still be taken into account

25. The representative of the United States explained that in order to properly protect public health and the environment, the Toxic Substances Control Act (TSCA) of 1976 (TSCA) had to be updated and strengthened. He quoted Lisa Jackson, EPA's Administrator, who had made a statement to this effect in September 2009. The objective was to enable EPA to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals. Relevant "principles" for updating TSCA were made available on a US Government website.[2] The US representative stressed that it was, at this point, premature to discuss the shape of the legislation and its notification because the bill was still being discussed and would expire at the end of the Congressional session in November or December 2010, if it remained pending. In case the bill was re-introduced in the next Congress, the issue would continue to be monitored. In the meantime, the US delegation remained available to address bilaterally any questions raised. He informed Members of the publicly available website reporting all draft legislation.[3]

(viii) Indonesia – Labelling Regulations (Ministry of Trade Regulations 62/2009 and 22/2010)

26. The representative of the European Union raised concerns about the above-mentioned measures. It was her delegation's understanding that these regulations provided for rules on mandatory labelling affecting a wide category of goods. She pointed out that these regulations had not been notified under the TBT notification procedure despite the fact that they contained detailed rules on the labelling of products. In this regard, she drew Indonesia's attention to the fact that this was already the third occurrence in a short period of time that legislation containing important requirements affecting a large number of goods had not been notified to the TBT Committee. The representative of the European Union regretted this omission. It was the European Union's understanding that according to Article 2 of these regulations, the products had to be labelled in Indonesian language at the time when they entered the territory of Indonesia. The EU representative invited Indonesia to clarify whether this provision meant that the products had to be labelled in Indonesian *before* they were shipped to Indonesia. If this was the case, the delegate of the European Union wished to receive a justification from Indonesia on why imported products could not be labelled or re-labelled in Indonesia before they were actually placed on the market. Second, it was the European Union's understanding that according to Article 3 of the Regulations, labels which appeared on goods had to be approved by the Indonesian authorities *before* the goods were imported and labelled. The representative of the European Union noted that a pre-approval of labels for electronics goods, certain construction products, vehicle parts, textiles and other consumer products seemed to be more trade restrictive than necessary. Indonesia was therefore asked to provide the reasons for such a pre-approval procedure. Third, the representative of the European Union asked for clarification about Article 11 of the latest regulation (21 May 2010) which provided for an exemption procedure for

[2] http://www.epa.gov/opptintr/existingchemicals/pubs/principles.html
[3] http://thomas.loc.gov/

producers and importers. In particular, she invited Indonesia to clarify how this procedure was applied and under which conditions producers and importers were exempted from the obligation to label the product in Indonesian language.

27. The representative of Australia supported the concerns raised about the implementation of Regulation 62/2009 and 22/2010. In particular, she noted that there was, apparently, conflicting information between two Indonesian authorities. On the one hand, Australia had received confirmation from Ministry of Trade officials that Regulation 69/1999 allowed for labelling stickers to be applied to imported food products in Indonesia. On the other hand, the Indonesian Food and Drug Agency had advised that Regulations 62/2009 and 22/2010 prohibited the use of labelling stickers. The Australian delegate also noted that there was confusion as to whether the regulations applied to both food and non-food products. It was Australia's preference to allow exporters to use labelling stickers which would be the least trade restrictive option to Indonesia's policy objective. Indonesia was encouraged to ensure that any labelling standards adopted were consistent with existing international standards, such as those of the Codex, which would provide guidance in relation to using a second label.

28. The representative of the United States noted that his delegation had been informed by US industry that Indonesia might no longer allow for the use of sticker labels with translations to be applied on imported products. While the representative of the United States appreciated the need for imported food products in Indonesia to bear a label in Bahasa, he asked why sticker labels would not fulfil this need. The US representative invited Indonesia to clarify whether it had in fact changed its requirements. In this regard, he noted that Codex' General Guidelines for the Labeling of Prepackaged Foods (Article 8.2) encouraged the use of supplemental labels to comply with national language label requirements. It was his delegation's view that a supplementary label affixed as a sticker could provide all information required by the pertinent regulations. In addition, a prohibition on applying sticker labels in Bahasa could negatively impact US exports in the form of increased costs. In case this change had indeed been made, the US representative asked Indonesia to suspend implementation while it notified the measure to the WTO for comment and took these comments into account. He urged Indonesia to reconsider the prohibition during the notification process and to accept stickers to be affixed as supplemental Bahasa language labels for imported products as Indonesia had previously allowed (and as was allowed by the United States for exports from Indonesia). He reiterated the European Union's systemic concern about the lack of notifications by Indonesia of TBT measures.

29. The representative of Indonesia noted that the discussion concerned the Regulation of Minister of Trade RI No.62/M-DAG/PER/12/2009 and No. 22/M-DAG/PER/5/2010 on the obligatory label affixing on any goods – which had entered into force on 1 September 2010. He informed the Committee that these regulations were going to be notified to the WTO in due time. He further explained that the said regulations stated that every producer and importer of goods to be traded in the Indonesian market had to affix a label in Indonesia's language. The list of affected products had been included in the attachments of the regulation of the Minister of Trade RI No. 22/M-DAG/PER/5/2010. However, the Indonesian representative mentioned that the following goods were exempted from these regulations: goods sold in bulk and packaged directly in front of the consumers as well as goods listed in Annexes I-IV of the regulation of Minister of Trade RI No. 22/M-DAG/PER/5/2010, if they were used as raw materials in the production process.

30. The Indonesian delegate explained that the procedure for getting the approval for the label was free of charge and listed in the regulation No.22/M-DAG/PER/5/2010. In particular, the label had to be clear and easy to understand. Producers and importers had to submit a sample of the label to the Director of Domestic Business Development and Enterprise Registration, Ministry of Trade. If all requirements had been completed for given goods, the Director of Domestic Business Development and Enterprise Registration would issue the certificate of affixing label in Indonesia language within

five days after receiving the sample. Requirements on how to put the label as well as information contained in the label were stated in the annexes of the Regulation of Minister of Trade No.22/M-DAG/PER/5/2010, whereas sanctions and any other requirements were included in both regulations. In particular, the Indonesian delegate made clear that the certificate would be valid as long as the producers and/or importers produced and/or imported the same goods mentioned in the certificate. If the producers and/or importers were to produce and/or import goods other than goods mentioned in the certificate, the producers and/or importers would have to submit again the sample of the label to the Director of Domestic Business Development and Enterprise Registration, Ministry of Trade. With regard to goods listed in Annexes I, II, III, and IV of the Regulation of Minister of Trade No. 22/M-DAG/PER/5/2010 which were already placed in the market before the date of entry into force of the regulation, the producers and/or importers of the goods had to adjust their label of products to comply with the regulation within 28 months after the date of entry into force of the regulation on 1 September 2010.

(ix) China – National Standard of the P.R.C., Direction for Use and Labels for Carpets (G/TBT/N/CHN/624)

31. The representative of the European Union requested clarification regarding the National Standard of China, Direction for Use and Labels for Carpets, which had been notified in April 2009, and which had been the subject of an extensive bilateral exchange of comments. The representative of the European Union thanked the delegation of China for clarification transmitted through the Chinese TBT Enquiry Point, in particular with regard to which labelling requirements were mandatory and which were voluntary; it was now understood that the mandatory labelling requirements were based on ISO 6347. She sought clarification as to whether the information presented on labels, including dimensions of carpets (point 5.3 of the draft), fibre content (point 5.4 of the draft) and product standard number (point 5.8 of the draft), were also to be verified and tested according to ISO 6347, or another relevant international standard. The representative sought clarification whether ISO 6347 had been adopted in its full integrity, without modification, or if certain aspects had been modified. The representative of the European Union noted that the notified draft provided for the use of international flame resistance pictograms; there appeared, in this regard, to be divergences between Chinese requirements on the test methods of flammability for building materials and relevant ISO standards (ISO 11925-2 and ISO 9239-1). She noted that these pictograms were only permitted for use on products that had been tested in compliance with these ISO standards. Thus, the representative inquired as to whether the relevant Chinese standards were identical to the relevant ISO standards. In addition, she asked whether the notified draft had been adopted, or whether it was still under consideration.

32. The representative of China explained that the Chinese National Standard Direction for Use and Labels for Carpets had been notified to the WTO on 29 April 2009. The standard provided basic principles and requirements for the use and labelling of carpets sold in China. In fact, the European Union had commented on the standard on three different occasions: 31 May 2010, 28 July 2010, and 3 September 2010. The comments had covered a number of different areas, *inter alia*, scope of application, name and address of the manufacturer, product name, dimensions, names and contents of the pile fibre, total thickness, total mass per unit area, mass of pile per unit area, product standard number, product quality grades, issues related to Chapter 7, Annex A and Annex D, flame resistance, and provision of English versions of the two national standards. It was explained that the fifth chapter of the standard was mandatory, while the others were voluntary.

33. The representative noted that China had sought to address EU concerns in four different replies. He reminded the Committee that different levels of technical development between Members led to different technical legislative objectives, and that a Member could not be forced to amend regulations based on comments from other Members. Nevertheless, the TBT Agreement stated that Members shall "without discrimination, allow other members to present their comments in writing,

discuss these comments upon request, and take these written comments and the results of these discussions into account". After full consideration, the competent authority in China had adopted, or was is in the process of adopting, EU comments about flame resistance, Annex A, Annex D, and mass of pile per unit area. In their 3 September 2010 comment, the European Union had welcomed the clarification of Chinese standards regarding fire performance which had followed relevant EU test methods; the European Union also welcomed the clarification that producers could select one of the three label forms described in Chapter 7. The representative hoped that efforts made by China in this respect had been understood and recognized by the EU delegation.

34. With regard to the second and third sets of comments submitted by the European Union, the representative of China expressed concern at repetition of issues already discussed by the two parties. In particular, EU concerns around product size, specifications and flame resistance had been repeated, including in the fourth set of EU comments – and this after several hours after mutual consultation the preceding day. The representative of China affirmed that such comments were the right of a WTO Member, and could be a useful form of technical exchange. However, comments and enquiries on a technical regulation submitted in succession over a period of one year and four months, or even longer, including after the end of the comment period, were not covered by the provisions of the TBT Agreement. The TBT Agreement was implemented to better facilitate international trade, not to influence the regulations of other Members without limitations. In fact, the representative of China noted that when his delegation commented on EU notifications (or those of another Member) they much appreciated receiving careful answers and explanations which could be used for technical reference. He hoped that EU comments could display the same degree of precision as EU replies, and noted that professionals in China put in significant work to respond to EU queries.

35. The representative of China went on to note that, with respect to the EU request for English language versions of GB/T8626 and GB20286, Article 10.5 of TBT Agreement required only developed country Members to provide English, French or Spanish translations if requested from other Members, and hence his delegation would be unable to supply the European Union with English versions. Finally, given that most of the points raised by the European Union concerned detailed technical exchanges, he suggested that further exchanges occur with professionals at the Standardization Administration of China.

(x) Korea - Automobile standards of the efficiency of average energy consumption and allowable emission of greenhouse gases (G/TBT/N/KOR/296)

36. The representative of the European Union welcomed the objective of the draft Korean regulation, notified to the TBT Committee under G/TBT/N/KOR/296, to reduce carbon dioxide emissions and increase motor vehicle fuel efficiency. She believed that it would provide an important contribution to the limitation of emissions of greenhouse gases, alongside measures already adopted by the European Union and other countries. Nevertheless, the representative noted that the draft had raised concerns amongst EU car manufacturers present on the Korean market, in particular with regard to significant potential impacts on imports. She explained that the EU was currently discussing these issues with Korea bilaterally, and understood that Korean authorities were consulting widely with stakeholders in order to achieve a balanced final regulation.

37. The representative of the European Union posed a series of questions in order to improve her delegation's understanding of the notified draft. She first asked whether the measures proposed by Korea had been subject to a comprehensive impact assessment. If such an impact assessment had been completed, she asked if it was publicly available. Secondly, could Korea provide indications, in percentage points, as to the emission cuts to which imported car makers would be subject to on average, as compared to those required of domestic car makers? Her delegation estimated that EU carmakers would be subject to emission cuts more than double those applicable to domestic car makers. Thirdly, what measures were Korean authorities considering to take into account for the

specific situation facing foreign car makers in Korea, so as to avoid negative impacts on imports? Also, she requested information about the envisaged timeline for publication and entry into force of the requirements. In particular, the representative noted that the proposed date of entry into force was 1 January 2012, one year after the envisaged adoption of the draft. She asked whether Korea considered such a short time period sufficient for car manufacturers to adjust their products and production methods to the new requirements.

38. The representative of the European Union noted that EU legislation on automotive emissions had been developed in close consultation with all stakeholders, including domestic and foreign car makers, with a view to setting achievable emission targets. European legislation also offered a considerably longer period for the implementation of the new requirements, and provided for a number of derogations to take into account the specific situations of individual car makers.

39. The representative of the United States was also concerned that the regulation, as currently drafted, would significantly restrict market access for US automobiles. Although the representative recognized positive aspects of the draft regulation aimed at limiting barriers to trade, including relating the standard to the weight of the car, using the 'US combined' fuel economy measurement, and certain flexibility mechanisms, he stated that the draft regulation nevertheless could have a dramatic impact on US and other manufacturers, especially considering the short period (one year) to prepare for its implementation.

40. The representative of the United States explained that imported automobiles sold in Korea were much heavier on average than the fleets sold by domestic Korean manufacturers, and, as a result, his delegation was concerned that the latest draft regulation could place a serious burden on manufacturers producing imports for the Korean market. In addition, the short transition period was insufficient to allow manufacturers to adapt. The new US regulation on auto emissions and fuel economy had been announced three years before implementation, and was being phased in over five years, beginning in 2012. However, Korea was allowing only one year between announcement and the start of implementation, and was phasing in the regulation over a period of four years. The representative of the United States asked how the draft regulation took into account the fact that importers sold a different type of fleet, concentrating on a smaller number of premium models. Finally, his delegation asked whether Korea would consider an exemption for small volume exporters, and derogation for medium volume exporters.

41. The representative of Korea thanked the delegations of the United States and the European Union for their comments. He explained that the Korean Government had set a target of a 30 per cent reduction in greenhouse gas emissions by 2020 under the national vision of low carbon green growth. To this end, the Ministry of the Environment had prepared the regulation at issue and notified it to the TBT Committee (G/TBT/N/KOR/296) on 18 October 2010; it carried explicit references to EU and US legislation. The measure would be applied to passenger automobiles and to automobiles carrying up to 10 passengers and freight; auto-manufacturers had to choose to comply with one of these standards. The measure would be phased in from 2012 to 2015, progressing from 30 per cent to 100 per cent coverage and would be applied in a flexible manner according to the average fleet weight of an auto manufacturer.

42. The representative of Korea highlighted the fact that the draft regulation was less strict than either EU or US regulations. For instance, he noted that the draft regulation targeted average emissions of automobiles of 170 grams CO_2 per km in 2006, falling to 140 grams CO_2 per km between 2012 and 2015. Under the EU regulation the 2006 target was set at 150 grams CO_2 per km, and aimed for 130 grams CO_2 per km between 2012 and 2015. Thus, the representative explained that auto manufacturers in compliance with the European measures should have no problem complying with the Korean regulation. The Ministry of Energy was considering an exemption for small volume manufacturers, and would notify the TBT Committee upon a decision. Moreover, the representative

of Korea noted that the Ministry of Environment had conducted a comprehensive impact assessment on the introduction of the draft regulation; further information could be provided at the request of Members.

43. Regarding the alleged discriminatory treatment of European and American car manufacturers in terms of more stringent emission reduction targets, it was noted that the impact assessment showed no evidence of discrimination against foreign manufacturers. The representative of Korea said that information about a specific manufacturer's required rates of emissions reduction could not be provided since this was related to proprietary business information. On the time-frame for implementation, it was recalled that the Korean Government had informed domestic and foreign manufacturers, including European and American car makers, of this regulation as early as July 2009. Furthermore, European and American car makers would be ready to conform to the Korean regulation by the end of 2011. As the comment period would expire on 17 December 2010, Members were encouraged to submit comments by that date. The Korean ministries of Energy and Environment were evaluating all comments received and would take them into account when finalizing this regulation.

(xi) Canada - Proposed Amendment to the Energy Efficiency Regulations (G/TBT/N/CAN/317 and Add.1)

44. The representative of Korea thanked Canada for the recent decision to postpone implementation of the proposed regulation (G/TBT/N/CAN/317 and Add.1) until April 2011. While the Republic of Korea supported the objective of protecting the environment, his delegation was concerned that costs imposed upon manufacturers would exceed the purported benefits of the regulation. He requested that Natural Resources Canada reconsider the introduction of regulation, due to issues related to accreditation of foreign certification bodies, including Korean bodies. In particular, he cited the requirement of active engagement in national standard-setting and the establishment of working relationships with applicable Canadian regulatory authorities as challenges. The representative invited Canada to explain how the provisions would be implemented with respect to the accreditation procedure of certification bodies. In addition, he stated that a longer transition period would be helpful for foreign certification bodies.

45. The representative of Canada explained that the measure in question had been developed to promote efficient and economic use of energy, and the benefits of this activity in relation to the costs had been analysed, and that this analysis was publicly available, including in supporting documentation that accompanied the notification to the WTO. He expressed appreciation for comments received on this regulation, not only from Korea, but also as a part of the notification process from industry and other stakeholders. He noted the changes made by the regulatory authority, in particular the suspension of the measure until 1 May 2011. The representative encouraged Members with questions to contact his delegation bilaterally even though the comment period had closed. The third party conformity assessment system, and the system for accrediting conformity assessment bodies, had proven to be efficient, open and transparent. Documentation related to the accreditation of certification bodies in Canada was available on the website.[4]

(xii) China - Provisions on the administration of medical device recalls (G/TBT/N/CHN/729)

46. The representative of the European Union expressed concern with regard to China's proposed measures for the administration of medical device recalls. China had replied in July 2010 to comments made by the European Union in May 2010, but its reply had not assuaged EU concerns. While the European Union considered the draft regulation developed by China's State Food and Drug Authority as a significant step towards alignment with international standards, it remained concerned in particular about the requirement to stop selling a medical device and/or suspend its use in case of a

[4] http://www.scc.ca

recall as this was perhaps not the most appropriate response for many medical devices such as, for instance, life supporting devices or implanted devices. In the absence of effective and immediately available alternatives, this requirement could create other risks to the health of patients. Therefore, the European Union urged China to determine the appropriate corrective actions in a documented risk analysis, carried out in cooperation with the medical device manufacturer. Additionally, she remarked that the draft established a multi-layer notification and review structure that could potentially generate conflicting requirements that manufacturers might have difficulties in complying with.

47. The representative of China informed the Committee that its provisions on the recall of medical devices had been notified to the WTO on 3 March 2010. Upon request, China had extended the comment period by 30 additional days, ending on 15 May 2010. She noted that the European Union had submitted its comments on 20 May 2010 and China had responded in writing on 20 July 2010. She also stated that, currently, the relevant Chinese authorities were considering further comments received from the European Union on 26 October 2010.

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

48. The representative of the European Union noted that the above-mentioned notified measure described the requirements that chemicals, chemical ingredients and products containing these chemicals had to comply with if imported into California. She also noted that the final date for comments on this text was 1 November 2010. The European Union recalled that when it had inquired with the US TBT Enquiry Point if there would be an adequate period for comments, as recommended by the TBT Committee, especially considering that the text consisted of 92 pages, the US Enquiry Point had announced that the notification would be withdrawn. Indeed, the United States had indicated by corrigendum (of 29 October 2010) that the text had been notified in error and that the United States wished to withdraw the notification. The European Union asked what reasons had led to the withdrawal of the draft.

49. The representative of the European Union further noted that the draft laid down a complex system for the management of chemicals in relation to consumer products and manufacturing processes and approaches. It was the European Union's view that the draft potentially affected all products placed on the market in California, many of which were produced in third countries. In addition, she noted, the draft provided for an obligation to submit data concerning chemical and products and laid down rules to set up different lists of chemicals. It also set out the precise criteria according to which the lists had to be prepared. It was the EU view that the inclusion of a chemical in one of these lists could have important consequences. For instance, the obligation to carry out alternative assessments for substances that should lead to the redesign or the reformulation of a consumer product; the obligation to remove a product from the market; the obligation to set up end-of-life management programs or the prohibition to sell a product. The European Union also noted that the draft contained requirements for setting up lists of the chemical substances as well as all the details of the procedures that would have to be followed, and all the consequences that resulted from the fact that a substance was included in the list. Hence, the draft appeared to contain technical regulations and aspects of conformity assessment procedures.

50. The European Union's representative stated that her delegation was aware that the government of California had carried out a public consultation on this document that had ended on 1 November 2010. However, she added, the European Union did not know the reasons why the draft had not been submitted for comments under the TBT Agreement. The European Union shared the United States' objective of protecting human health and the environment. However, it expressed its desire to have the possibility to comment on the aforementioned draft, and to share with Californian regulators the experience that the European Union had gained from the application of the Registration,

Evaluation, Authorisation and Restriction of Chemical Substances (REACH) Regulation. Finally, the European Union inquired whether any feasibility and impact assessments had been conducted by California on this matter.

51. The United States' representative recalled that during previous bilateral conversations his delegation had informed the European Union that California's regulators had independently studied this measure and determined that it was neither a technical regulation nor a conformity assessment procedure. Based on this and USTR's assessment, the United States had determined that it was not necessary to notify the measure under the TBT Agreement. Due to an internal miscommunication in processing the European Union's request for notification, the measure had been inadvertently notified – it had subsequently been withdrawn.

52. It was the United States' opinion that the European Union's description of the provisions of the measure was a mischaracterization. For instance, despite the European Union's assertion that companies exporting products to California had to submit data under these regulations, the United States indicated that this proposal did not require stakeholders to take any action. Moreover, the United States indicated that the regulations did not specify particular characteristics or related processes or production methods for any product. According to the United States, they did not require a particular size, shape, design, function or performance for any product. Nor did they impose any specifications on any product or product ingredient. It was the US view that these regulations simply established a process that allowed the California Department of Toxic Substances Control to subsequently request information from stakeholders.

53. In relation to the European Union's request to be able to comment on the measure, the United States noted that all US regulatory measures were subject to a domestic comment process that allowed stakeholders to submit their observations on the proposed measures. This was applicable also to measures that were not covered by the TBT Agreement. According to the United States, this proposal in particular had been developed through many drafts over many years and all stakeholders, including those of the European Union, would have been able to comment on them through the corresponding US domestic process. The United States considered that if any subsequent measures were proposed in connection to these regulations that met the definition of a technical regulation or a conformity assessment procedure, they would be notified to the WTO Secretariat for comment.

54. The representative of the European Union recalled that Annex 1.1 of the TBT Agreement not only applied to documents which laid down product characteristics, but also to their related processes and production methods, including applicable administrative provisions, with which compliance was mandatory. While she acknowledged the US assertion that the proposed regulations did not require any action from the stakeholders at the moment was indeed correct, in her delegation's opinion this was only because the substances which would be included in the list had not yet been identified or qualified. Nevertheless, she noted, this piece of legislation laid down the criteria to create these lists and once the substances had been identified, immediate consequences would follow for the stakeholders. It was the European Union's opinion that the United States' approach concerning these regulations could establish a dangerous precedent. According to the European Union, by laying down a whole framework of technical regulations and conformity assessment procedures, without identifying the covered products, Members could delay the entry into force of these regulations thereby circumventing their notification obligations under the TBT Agreement.

55. The representative of the United States observed that the definition of technical regulation contained in Annex 1.1 of the TBT Agreement was informed by the phrase "with which compliance is mandatory", which in the US view meant that the document in question needed to be mandatory in order to be considered covered. The regulations at issue did not establish a conformity assessment procedure and did not contain a registration requirement either. In relation to the European Union's offer to share its experience with the United States on the application of the REACH Regulation, the

representative of the United States suggested that Californian regulators could provide technical assistance to the European Union on their regulation of chemicals.

56. The representative of the European Union asked for further clarification on the mater of its mandatory application; she noted, in this regard, that once a substance had been identified and included in the list the requirements established by the regulations became mandatory for the manufacturers of those substances or products containing them.

(xiv) 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)

57. The representative of the United States noted that it was his understanding that the European Union's Parliament had recently voted to approve a proposal for a European Parliament and Council Regulation on the indication of the country of origin of certain products imported from third countries. According to the United States, this measure would require that certain consumer products imported from third countries be labelled with their country of origin. In the United States' understanding, the specific products that would be required to be marked included: leather, travel goods, handbags, apparel, textiles and textile articles, ceramics, glassware, jewellery, furniture, bedding, lamps and lighting, brooms and brushes, screws, nuts and bolts, tools and tyres. While the United States recognized that there could be legitimate reasons for requiring country of origin labelling, such requirements should not discriminate based on origin. According to the United States, this measure appeared to *only* require products imported from third countries to be labelled; products of the European Union, as well as of Turkey and members of the EEA Agreement, had been excluded from the application of the requirement.

58. In the US view, any origin labelling requirement for consumer goods needed to apply not only to imported goods or only to imported goods of some countries. The US representative clarified that his government was still reviewing the proposal and could have additional views at a later date. However, he expressed his interest in hearing any clarification from the European Commission on why the new requirements would only apply to imported products but not to domestic products. The US representative also expressed interest in more information as to why imported products from some countries were excluded from the application of this labelling requirement. Moreover, the US representative asked for updated information on the status of this proposal in the European Parliament, and on the process by which the European Union would request input from Members and other stakeholders. He also asked for more information about when the European Council would consider the measure.

59. The representative of Mexico informed the Committee that her delegation was currently analysing the proposal; she reserved her delegation's rights to comment at the next Committee meeting.

60. The representative of the European Union regretted the fact that her delegation had only been informed very late that this issue was going to be included on the agenda. Because of this it had not been possible to consult with its experts. Comments would be transmitted to experts.

(xv) European Union - Directive on eco-design requirements for household dishwashers (G/TBT/N/EEC/321), European Union - Directive on eco-design requirement for fans (G/TBT/N/EEC/323)

61. The representative of China stated that the European Union's Directives on Eco-design Requirements for Household Dishwashers, and on Eco-design Requirement for Fans imposed technical requirements that deviated from international standards. As examples of these deviations, China referred to some indictors that were stricter than those set out in existing international

standards, or other European standards, and to some definitions and calculation methods that, in China's view, were inconsistent with international standards. It was China's opinion that these deviations from international parameters had the effect of significantly increasing production and trade costs for manufacturers and created uncertainty as to what the required specifications were. In China's view, this would affect exports to the European Union from developing countries, including China.

62. The representative of China recalled that during the last TBT Committee meeting, China had enumerated several examples of EU notifications[5] involving eco-design requirements for products such as household, office electrical and electronic equipment, several types of lamps, power supply and household refrigeration equipment that were of concern to China. Other notified measures were also of concern.

63. For instance, China noted that Article 21C of Annex I of the EU Directive on Eco-design Requirements for Household Dishwashers (G/TBT/N/EEC/321), stipulated for all household dishwashers, that the cleaning efficiency index had to be greater than 1.12. This Directive had been notified to the WTO Secretariat one year after its publication in the Official Journal of the European Union. According to China this cleaning efficiency index requirement differed from that used by other developed countries such as Australia and New Zealand, where the stipulated cleaning efficiency index had to be greater 0.9. China encouraged the European Union to harmonize its standard with those of other countries, or at least to use these other standards as reference.

64. In relation to the EU Directive on Eco-design Requirements for Fans (G/TBT/N/EEC/323), China considered that the standard for fans was inconsistent with the standard ISO 13349: 2010 Fans – Vocabulary and Definitions of Categories. According to China this created confusion amongst the manufacturers. Moreover, China observed, the calculation formula of the target energy efficiency in the European Directive was inconsistent with ISO 5801: 2007 Industrial Fans – Performance Testing Using Standardized Airways and ISO 5802: 2001 Industrial fans -- Performance testing in situ.

65. China noted that the European Committee on Standardisation and the European Committee for Electrical Technical Standardisation had established a close cooperation relationship with ISO and IEC through the Vienna Agreement on Technical Cooperation and the Dresden Agreement, respectively. Therefore, China hoped that the European Union would be more proactive in preserving the reference-role of international standards. China also encouraged the European Union to conduct a systematic analysis of the consistency of its recently established and revised technical regulations and conformity assessment procedures with the relevant international standards, and to produce statistical information on the rate this standards were adopted as the basis for European Directives.

66. The representative of the European Union observed that the eco-design requirements were set in mandatory performance levels and that those levels were set in accordance with the framework eco-design Directive 2009/125/EC of the European Parliament and of the Council, establishing a framework for the setting of eco-design requirements for energy-related products. She also recalled that eco-design requirements aimed at reducing the environmental impact of energy-related products on the basis on a lifecycle analysis.

67. With regard to the remarks made by China on the use of relevant ISO standards, and on the measurement requirements and test methods, the representative of the European Union stated that the eco-design implementing regulations specified that measurements of the relevant product parameters

[5] Including: G/TBT/N/EEC/208, G/TBT/N/EEC/228, G/TBT/N/EEC/229, G/TBT/N/EEC/234, G/TBT/N/EEC/237 and G/TBT/N/EEC/273). Other notified measures were also of concern: G/TBT/N/EEC/321 (concerning eco-design requirements for household dishwashers) and G/TBT/N/EEC/323 (concerning eco-design requirements for fans).

needed to be performed using reliable, accurate and reproducible measurement methods which took into account the recognized state-of-the-art measurement methods, including, where available, harmonized standards adopted by the European Standardisation bodies. She added that in practice, this meant that the European Commission always issued a mandate to the European Standardisation bodies (CEN, CENELEC and ETSI) for the development of harmonised measurement methods once a new eco-design regulation was adopted. She clarified that the EN standards always used, as a basis, the IEC or the ISO standards, whenever they existed. The measurement requirements set in European standards differed from the IEC and the ISO standards when the latter did not allow for a proper implementation of the eco-design regulations. She also recalled that every time China had posed questions concerning deviations from the ISO standards involving European standards, the European Union had given, in the framework of the TBT Committee, and also in writing, the corresponding explanations why it had been necessary to deviate from the IEC and the ISO standards.

68. In relation to the comments made by China regarding the Directive on Eco-design Requirements for Household Dishwashers (G/TBT/N/EEC/321), the representative of the European Union recalled that a detailed written response from the European Union had been sent to China. She invited China to submit to the EU TBT Enquiry Point any further questions China had in relation to the answers provided.

69. With regard to the European Union Directive on Eco-design Requirements for Fans (G/TBT/N/EEC/323), the representative of the European Union noted that an answer had not yet been provided to China. However, she announced that this answer was going to be delivered in the following days. With respect to this measure, the related ISO standard had not been followed because ISO was developing a new standard in this area. The European legislator had been in close contact with ISO on this matter in order to follow the new standard, which was going to be adopted soon under the number ISO 12759.

(xvi) United States - FCC Rules 96-493 on Broadcast Services; Television Broadcast Stations; TV Transmission Standards

70. The representative of China noted that the US Federal Communications Commission (FCC) had adopted, on 24 December 1996, the FCC 96 – 493 Broadcast Services – Television Broadcast Stations and TV Transmission Standards. These rules had been published in the Federal Register on 25 March 1997. It was China's understanding that the FCC rules had not been notified to the WTO Secretariat. She also noted that the FCC rules incorporated, by reference, ATSC/52, the Digital Audio Compression Standard. Section 73.682 D of the FCC rules provided that transmission of digital broadcast television signals needed to comply with various standards, including the ATSC Digital Audio Compression Standard. China also noted that, since 1 March 2007, all digital televisions bigger than 30 inches had to comply with this mandatory standard. According to China, Chinese export of digital TVs to the US market had, as a consequence, been substantially impaired. China was particularly concerned about the mandatory audio compression standard A/52 incorporated in the FCC rules. China questioned the compliance of the US measure with Article 2 of the TBT Agreement; it was China's view that the measure was creating an unnecessary obstacle to international trade. China reiterated its invitation to the United States to explain the legitimate objectives it pursues by making the audio standard for digital TVs mandatory.

71. The representative of the United States noted that his delegation had only learned the day before that this particular issue was being raised in this TBT Committee meeting. Therefore remarks were of a preliminary nature. As China had noted, this was an "old" measure. He recalled that the FCC had started developing this measure in 1987 and that this process had continued for ten years. In fact, the events predated the TBT Agreement's notification provisions. During this time, he stated, US regulators had entertained comments from numerous stakeholders. They had also looked at many different types of technologies and did consider allowing for the use of competing standards.

72. It was the US opinion that there was no country in the world that did not mandate a single standard for terrestrial free-to-air TV, whether digital or analogue, including China. He explained that that the adoption of the DTV Standard served the public interests and brought many benefits to American consumers by providing certainty to broadcasters, equipment manufacturers and consumers of digital broadcasting. Moreover, he added, adopting a single digital television standard promoted increased choices in video programming with dramatically better visual and audio resolution and, in addition, new and innovative services could be made available by the data transmission capabilities of the digital television standard. Further, in the United States' view, the digital television standard permitted inter-operability with computers and encouraged innovation and competition. The decision had allowed US viewers to receive dozens of different channels with *one* single device. The prospect that viewers would need more than one device to view different channels was an unacceptable alternative for consumers.

73. The representative of the United States invited China to submit its specific concerns. It was the US impression that China was concerned about a particular technical issue in connection to mandatory audio compression standards. China needed to be more precise about this so that his delegation could discuss these concerns with the FCC upon the return to Washington.

2. Previously raised concerns

(i) European Union – Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH) (G/TBT/N/EEC/52 and Adds.1-5; Add.3/Rev.1; G/TBT/N/EEC/295 and Add.1; G/TBT/N/EEC/297; G/TBT/N/EEC/333-6)

74. The representative of Japan drew the Committee's attention to a 27 September 2010 European Commission press release (ECHA/PR/10/19) offering assistance to companies having trouble complying with the deadlines for registration of pre-registered chemicals produced or imported at a rate exceeding 1000t/year. He noted that affected companies which faced exceptional circumstances could be given new registration deadlines on a case-by-case basis. The representative of Japan expressed concern that certain companies might not have knowledge of this recourse and could face difficulties as a result. Japanese industry was of the view that REACH rules required improvements in implementation due to difficulties in compliance and uncertainties in interpretation.

75. The representative of Japan suggested that the European Commission undertake wider consultations on the new draft guidance documents, and take into account responses from affected parties prior to imposing additional REACH related registration deadlines. He stated that the European Commission needed also to consider fundamental improvements to REACH rules to address the issues raised in the aforementioned press release, so as to ensure that REACH achieved high-level protection of human health and the environment while upholding free circulation of chemicals in Europe.

76. He recalled that the Government of Japan had previously requested the abolition of mandatory registration of monomer substances contained in polymers within REACH, and noted that the European Court of Justice had upheld mandatory monomer registration in a July 2009 ruling. The Government of Japan continued to harbour doubts about the necessity of registration of monomers contained in polymers, since i) polymers generated by polymerization did not negatively affect the environment, and ii) mandatory registration was inconsistent with Article 2.2 TBT Agreement, given that this policy was more trade restrictive than necessary. The representative reiterated his delegation's request that mandatory registration of monomers contained in polymers be reconsidered, and that exemption provisions, such as those being implemented by other countries under the OECD system, be established.

77. The representative of Canada inquired as to whether the European Union had taken steps to increase application processing capacity in response to a potential surge in applications leading up to the 30 November 2010 deadline. He wondered whether companies which had submitted documents prior to the deadline, but faced a delay in processing due to high numbers of applications, would be treated as non-compliant. He noted that the EC REACH Committee had proposed changes to Annex XIII criteria for the classification of "persistent, bio-accumulative, and toxic (PBT)" substances, and "very persistent or very bio-accumulative (vPvB)" substances. The representative of Canada asked about the rationale for these changes and how they might affect the identification of 'Substances of Very High Concern', as well as what opportunities existed for non-EU interested parties to comment on proposed changes.

78. The representative of Canada also drew the Committee's attention to the publication of Annex V guidance by the European Chemical Agency (ECHA), which addressed products of modern bio-technology. He questioned how the "fast track guidance update procedure" worked, in particular with respect to impacts on vegetable oils sourced from GM plants. He asked about the objective of a 30 November 2010 review of Annex V guidance by the ECHA, and what progress had been made in this respect.

79. The representative of China questioned the REACH requirement that monomers contained in polymers be registered, and noted that European companies had resorted to court challenges of this requirement - although the challenges had been rejected by the European Court of Justice. Many companies continued to express concern about lack of clarity on this issue, and this uncertainty had hindered preparation of company dossiers and use of International Uniform Chemical Information Database (IUCLID5). She proposed that the European Union and ECHA provide clearer guidance on the registration of polymers.

80. With respect to Substance Information Exchange Forums (SIEFs), she expressed concern about the financial burden imposed on SMEs, and recommended that cost sharing arrangements be set up for SIEFs on the basis of firm size. REACH required registration of the entire tonnage of substances, even if less than 100 per cent of the substance was intended for release. This provision had the effect of increasing the tonnage band for registration which placed increased burden on the registrant.

81. The representative of China also expressed concern about the prohibition on traders registering directly with REACH in light of the financial and human resource capacity limitations faced by SMEs in developing countries like China, and the fact that these SMEs did not trade directly with EU importers. She suggested that the European Union permit traders or associations to appoint an 'Only Representative' to register with REACH on behalf of SMEs.

82. Chinese companies had encountered difficulties while preparing particular dossiers, for example, regarding the analytic spectrum of alloys. REACH required that alloys be registered as every one of their metal components, but she explained that this would lead to challenges since the component analysis of the alloy would not match with data provided by lead registrants of the metal substances. Lack of clarity on this issue from ECHA had prevented Chinese companies from moving forward with the registration process. The representative of China requested an extension of the registration deadline, given the delays caused by this lack of guidance.

83. The representative of Argentina reiterated concerns about the lack of transparency around REACH. He explained that REACH constituted an unnecessary barrier to trade, especially for Argentinian SME exporters due to difficulties in understanding the rules and the disproportionate and needless costs associated with compliance. The representative noted that the text of the regulation was extensive and complex and subject to constant revision, and that the 52 supplementary guidance

documents had not improved this situation, since they were often even more extensive and again subject to multiple revisions.

84. The representative of Argentina requested answers to a number of outstanding questions which continued to cause uncertainty, particularly in light of the upcoming 30 November 2010 registration deadline. He inquired as to whether substances contained in exported articles needed to be registered for REACH compliance. Moreover, he asked how the European Union ascertained that exported articles containing listed substances did so in excess of the one tonne registration threshold. He also wondered whether companies and importers knew about the requirement of registering substances contained in articles.

85. The representative asked what information non-EC companies needed to provide with respect to the registration exemptions for substances present in articles in total annual quantities less than one tonne, or less than 0.1 per cent of weight, or not to be released under normal or predictable circumstances. In particular, he wondered if there was an established means of communicating this information, and when, and to which authorities this information needed to be presented

86. On costs, the representative of Argentina emphasized eight different payments associated with REACH: registering; requests for confidentiality of information; stating of timeframes for tonnage; other updates; notifications; extensions; revision of authorization; and appeals against decisions. Costly sanctions for errors or non-compliance were also noted, as was the possibility of ECHA introducing other fees at any time pursuant to Article 11 of Regulation ECE 340/2010.

87. In the view of Argentina, the costs associated with REACH were disproportionate since they did not provide sufficient reduction rates for SMEs. Regulation ECE 340/2008 gave ECHA full discretion to determine whether a company qualified as an SME, and the representative noted that ECHA could apply a surcharge when a company had not 'sufficiently' demonstrated that it was an SME, even though there existed no explanatory guide for companies to follow in proving that they were an SME. Hence, the representative inquired as to what documentation a company needed to provide to sufficiently demonstrate that it was an SME. In addition, the representative noted that extra-community SMEs bore additional costs relative to European SMEs, since they had to hire an Only Representative or open an office in Europe. The implementation of REACH still works as an unnecessary obstacle to trade and, unless a solution is brought to the indicated concerns, many enterprises will be excluded from the European market.

88. The representative of India shared concerns raised by previous speakers. He questioned the logic of mandatory registration of monomers given that the lifecycle of a monomer ended when it was reacted into a polymer, and monomers themselves did not pose separate risks from those of polymers. He expressed concern about European industry dominating SIEFs and consortia with resultant detrimental impacts on SMEs. High membership fees, penalties for late joining, yearly maintenance fees, non-uniform rules of consortia, high fees for lead registrants, refusal of members to admit participants, and the prohibitive cost of letters of acceptance were cited as challenges particular to SMEs.

89. The representative of India also questioned the rationale for registration of the entire tonnage when less than 100 per cent of the substance was intended for release upon usage, which further increased the burden on registrants. The definition of an SME, which considered annual turnover and number of employees, was flawed and would classify many Indian SMEs as large enterprises, leading to higher registration fees. He also noted the lack of special and differential treatment with respect to the cost of data sharing and the prohibition on new animal testing, rendering associated costs prohibitive, again especially for SMEs. The representative of India stressed the high cost of data sharing in SIEFs and asked the European Union to consider computer simulation of chemical testing as an option.

90. The representative of Kuwait, on behalf of the Gulf Cooperation Council (GCC), expressed concern about the ambiguity of the REACH programme and its potential impacts on trade in chemical substances, in particular petrochemical substances. Referring to his delegation's previous request for information, he asked the European Union to clarify details of the programme, including standards and criteria adopted for the identification of goods covered. REACH was a real and direct threat to the economic interests of developing countries and to the rules and principles of the multilateral trading system.

91. The representative of Colombia noted that her delegation shared concerns raised by previous speakers with respect to REACH. She asked the European Union to re-examine the scope of the measures and provisions contained in REACH in light of the comments made to the Committee. She highlighted the process of registering substances, participation in SIEFs and the lack of legal certainty and security with respect to requirements and deadlines in light of possible changes to guidance documents, all of which disadvantage exporters, especially SMEs. Her delegation would welcome the establishment of a webpage explaining how REACH overlapped with other regulations. The REACH revision process continued to be an obstacle for Colombian industry given that revisions were communicated in English only. The representative requested that progress made in amendments of Annex VII of REACH be notified under G/TBT/N/EEC/297.

92. The representative of the United States explained that his delegation shared the EU concern of protecting human health and the environment, but that his delegation continued to have trade-related concerns with REACH and its implementation. He highlighted several concerns, in particular serious impediments to industry meeting the first registration deadline at the end of November. Given the sheer number of dossiers yet to be submitted (over 30,000) and numerous lead registrants waiting until the last minute to submit registrations, the potential for secondary registrants to miss the deadline appeared to be high. He inquired as to what steps the Commission had taken to ensure that it had the necessary personnel to handle a surge in applications, and to ensure that trade was not disrupted by delays in lead registrations. In addition, he expressed concern that if lead registrants failed their completeness check, notification of which might not occur until 1 March 2011, then all trade from secondary registrants transpiring between 30 November 2010 and 1 March 2011 could be rendered illegal. Given the length and complexity of lead registrations, the representative of the United States did not consider this to be a theoretical concern.

93. The representative of the United States highlighted differences in interpretation of the 0.1 per cent threshold for notification and communication obligations between member States and the Commission. He welcomed the draft guidance from the ECHA on this subject, which was consistent with the Commission's legal position that 0.1 per cent threshold applied to the entire article, but expressed concern about the divergent views of six member States. His delegation viewed efforts by these six member States, and others, to change the Commission's position on this matter as akin to seeking protection from imports. Companies had not undertaken material analysis on the sub-article level, which would be extremely time-consuming and burdensome, and he noted that the ECHA IT tools might be incapable of conducting an inventory at the sub-article level. He emphasized that serious disruption of transatlantic trade would result if the Commission reversed its position on this point.

94. On another matter, it was noted that US stakeholders had concerns about the impact of REACH on animal testing, as it was not clear from the ECHA press release what measures the European Union had taken on the subject. He concluded by noting that the United States intended to participate in the upcoming review of the REACH regulation, and would submit comments by the 1 December 2010 deadline.

95. The representative of Ecuador supported the statements made by other Members to the effect that REACH represented an unnecessary barrier to trade given its complexity and costly nature. He

noted that registration would negatively affect developing country exporters of chemical substances, in particular SMEs. He sought further information on Resolution 210 102/A/15 and the modifications to the REACH regulation published in the daily bulletin of the EU during August 2010.

96. The representative of Cuba supported previous speakers and stated that compliance with the requirements of REACH represented a real challenge for developing countries given the complexity of the system and the high costs imposed on exports. Outstanding issues included different implementation across member States of the EU based on different interpretations, and that technical assistance offered by the European Union to date had been insufficient. She requested that the European Union hold seminars or conferences on REACH. She confirmed that her delegation supported the protection of human health and the environment but that the REACH regulations were more trade restrictive than necessary.

97. The representative of the Bolivarian Republic of Venezuela shared the concerns of other Members with respect to technical aspects of REACH. He noted that the Bolivarian Republic of Venezuela acknowledged the legitimate objective of the European Union to undertake measures to promote human health and the environment. However, the measures adopted by the European Union under REACH contained elements which were obstacles to compliance, in particular since the European Union had not presented sufficient information nor had it sufficiently addressed the requests and concerns expressed by Members. He called on the European Union to provide further clarifications through the publication of verifiable data illustrating classification decisions. The complexity of the regulation would impose significant cost and burden on SMEs in developing countries, which had great difficulty complying with technical requirements given lower staffing levels. The technical assistance aspects of the TBT Agreement and S&D treatment for developing countries needed to be taken into consideration. The fact that the regulations were not available in Spanish – as well as their sheer size – made them very hard to comprehend in this context.

98. The representative of Australia, Bolivia, Chile, the Philippines and Thailand supported the concerns raised by other Members.

99. The representative of the Russian Federation, speaking as an observer, highlighted the negative impacts of REACH on the Russian steel industry. He explained that in 2008, the European Confederation of Steelmakers (EUROFER), with the support of the World Steel Association and Russian steelmakers, had proposed to the ECHA and the European Commission that semi-finished steel products and rolled conversion products, including slabs, be classified within the 'products' category, and not subject to substance registration. This approach had been approved by the ECHA in September 2009, confirming that the substances in these products did not require registration under REACH. Subsequently in March 2010, the German Federal Institute for Safety and Health (BAUA) had decided to categorize slabs within the 'mixtures' category, and thus subject to substance registration, given that the September 2009 decision of the ECHA on requirements for substances in articles (RIP) had no legal force, and member States were allowed to interpret the provisions of REACH as they saw fit. The representative of Russian Federation expressed concern that a precedent had been set whereby a member State of the European Union could diverge from the ECHA position. The result of this was uncertainty for the steel industry regarding registration, potential disruption in deliveries, related disputes between market participants, and additional costs to the Russian steel industry. The competitiveness of the 12 million tons of Russian steel exported annually to the European Union would be greatly reduced by the need to register every input separately in each EU country. The representative concluded that the Russian steel industry could not comply with REACH due to the ambiguity of the methodological guidance on requirements for substances.

100. The representative of the European Union thanked delegations for their comments and noted that many of the issues raised had been discussed at previous Committee meetings. Others were more specific and linked to the fact that the first registration deadline (of 30 November 2010) for certain

classified phased-in substances and for substances manufactured or imported in quantities reaching 1000 tons or more per year was upcoming.. She emphasized the importance of Members reminding all companies concerned to submit their dossiers in time and in full. The Commission and the ECHA were continuing to do all they could to support the industry in this exercise, including establishing a 'directors' contact group'. The group, chaired by the European Commission had found, since its establishment, solutions to 28 issues of concern for industry or Members which were related to the first registration deadline. The solutions had been published on the ECHA website in September.

101. The 'directors' contact group' also identified exceptional situations that were likely to prevent companies from submitting REACH compliant registrations on time. In these specific scenarios, ECHA could offer help if it was alerted on time. She noted that this was the press release Japan had referred to and emphasized that assistance was reserved for exceptional situations only, whereby the registrant was unable to submit full registration dossiers by the 30 November 2010 deadline through no fault of their own. An example of this was the lead registrant going bankrupt two weeks before the deadline thus being unable to submit the registration on time. This flexibility was designed to prevent undue exclusions from the market due to unforeseeable circumstances, which were not in control of companies. It had, however, not been the aim to postpone the existing deadline of 30 November 2010.

102. The representative of the European Union assured Japan, and other concerned Members, that the EU undertook every effort to properly prepare guidance documents. As already explained previously, ECHA had decided not to update existing guidance until after the 30 November 2010 deadline, so as to allow industry to concentrate on the registration process. The efforts that the EU were making in order to help companies, including from third countries, to comply with the REACH regulations showed to be fruitful: as of 27 October 2010, 2,839 lead registrants had been registered and as of 2 November 2010, 9,515 registrants had been registered, which represented more than a doubling of registrants since October 2010.

103. With respect to the completeness check questions (raised by the United States), the representative of the European Union explained that products would not be illegal during the time that ECHA was evaluating a dossier so long as a company had registered on time. However, ECHA could revert to the company if they found that data was missing.

104. In response to concerns expressed by the delegations of Japan, China and India, the representative confirmed that on 3 July 2009 the ECJ ruled that Art. 6 Para. 3 of the REACH regulation providing for the registration of reactive monomers and polymers was valid, since it pursued a legitimate objective of protecting human health and the environment. In particular, registration furthered knowledge of polymers and addressed certain health and environmental risk such as monomer residues. China was referred to detailed guidance on monomers and polymers available on the ECHA website and offered to follow up with regard to the specific questions bilaterally.

105. It was noted that the position of the European Commission had been provided at the March 2010 meeting of the Committee to the Canadian question on exclusion of GMOs, as well as in bilateral meetings and that the position of the European Commission had not changed. Furthermore, the representative of the European Union recalled that the guidance concerning Annex V would not be up-dated until 30 November 2010.

106. With respect to the changes to Annex XIVand Annex XIII, it was noted that all amendments had been notified to the WTO during the summer, and that the EU delegation had not received any comments on them. However, the representative of the European Union offered to accept comments even though the comment period had expired. The Annexes had not yet been adopted – any eventual adopted text would be notified to the WTO. Concerning Ecuador's request on Resolution 210

102/A/15 she stressed that she would need further explanations to understand to what Ecuador was referring to.

107. On enforcement of the registration obligation of substances in articles (the questions raised by Argentina), the representative of the European Union explained that the obligation for registration and notification of substances in articles was an obligation imposed under certain conditions by Article 7 of the REACH regulation. So, the obligation lay with the importer and there were no authorities that would notify the importer as such. Thus it was the responsibility of the importers to prove that the registration had been carried out, if they fell under the Article 7 criteria, or to demonstrate that they did not fall under those criteria, and hence did not have to register or notify under the REACH regulation. Article suppliers needed to consider documenting the results of their compliance checking, especially when they believed that they did not fall under the registration or notification obligation under REACH. Further advice on the obligations and how to prepare such documentation could be obtained on page 20 of the guidance on Articles[6].

108. On discriminatory treatment, in particular in terms of ECHA deciding which companies fell under the SME definition or how SMEs were treated, the representative of the European Union referred to Commission recommendation 2003/361/EC of 6 May 2003 which provided the official definition of an SME, and which was used for the purposes of REACH. Documentation had to be provided according to the criteria laid down in this recommendation.

109. Regarding the sharing of costs between participants in the SIEF (China's question), she explained that the Commission was leaving it up to the industry to organize such cost arrangements in the SIEF. Although the European Commission and ECHA were making efforts to facilitate the SIEF process, the final organization was in the hands of industry. Regarding queries from India and China on changes to Article 7, it was explained that there were no plans to change the criteria laid out in the Article. Regarding China's suggestion that traders and associations should be able to appoint an Only Representative, she reiterated that the appointment of an Only Representative was not mandatory, but a voluntary measure. Also, an Only Representative could represent more than one non-EU manufacturer. With regard to specific questions from China and the Russian Federation on alloys and steel products, it was suggested to contact the ECHA helpdesk and in case the issue was not clarified to inform the EU delegation bilaterally.

110. In response to the request from Cuba for conferences on REACH, the representative of the European Union noted that her delegation had notified the Committee on several occasions of stakeholder meetings and conferences organized by ECHA, which could be accessed through the internet, including streaming of archived events.

111. The representative the European Union noted that the candidate list totalled 38 substances and that ECHA had published on 30 August 2010 a proposal to identify 11 chemicals as Substances of Very High Concern and possible candidates for authorisation. A public consultation had been held, and comments were possible up to the 14 October 2010. The first proposals to include substances in Annex XIV of REACH had been notified to the WTO on 30 June 2010 (G/TBT/N/EEC/337); no comments had been received to date on this.

112. Regarding developments on the draft Commission regulation amending Annex XVII, it was recalled that this proposal covered, *inter alia*, borate and nickel substances that had been reclassified through the 30th and 31st Adaptations to Technical Progress (ATP). This proposal was still under discussion and there were no new developments. She drew the attention to the fact that despite the invitation to Members having indicated in the Committee that they were aware of the availability on

[6] http://guidance.echa.europa.eu/docs/guidance_document/articles_en.pdf

the market of substances or mixtures for the use of consumers containing borates or nickel compounds above the concentration levels to provide this information to the EU, no such information had been received.

(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 and G/TBT/Notif.00/310, Corr.1)

113. The representative of Japan expressed concern about proposals to regulate nanomaterials (especially carbon nanotubes (CNT) and Nanosilver) under EU RoHS rules adopted by the European Parliament on 2 June 2010. The proposals prohibited CNT and Nanosilver use, and would require enterprises to notify the Commission of the use of MNOs (Manufactured Nano Objects) and PCMNOs (Products Containing Manufactured Nano Objects) in addition to related labelling for products that could lead to consumer exposure. Should the European Union desire to prohibit the use of CNT and Nanosilver, scientific evidence needed first be presented, including data that documented danger to human health and the environment.

114. Japan was also concerned about EU RoHS requirements for nano labelling, which would obstruct the development of nanotechnology, and create standardization barriers to innovation and dissemination. He noted that economic operations of products affected by the implementation of these regulations were distributed broadly over many industrial fields, and huge costs and immense work would be required to ensure the conformity of nanotechnology. He hoped that the European Union would proceed cautiously when imposing restrictions on nanomaterials within EU RoHS and inquired as to the current status of the discussion on these regulations.

115. The representative of Japan also asked about the relationship between REACH and the RoHS Directive in particular with respect to the application of the threshold value which appeared to differ between the two regulations. Under REACH, the entire article was the denominator in the calculation, while in the RoHS Directive, the homogeneous material in the article was the denominator. These differences could give rise to confusion. He requested that the threshold value for concentrations subject to control be calculated using the same standard in both sets of regulations.

116. The representative of the United States expressed support for the RoHS directive's objective of protecting health, safety, and the environment. However, he stated that the Council and Parliament proposals for an open scope with certain exclusions would likely have an impact on many producers. He noted that US industry was concerned about proposals for an open scope and additional substance restrictions, and hoped that the European Union would take these concerns into account. He asked about the steps the Commission was taking to defend its proposal for a closed scope and limited substances restrictions based on a scientific approach within the trialogue process (negotiations between the Commission, Council and Parliament).

117. The United States was also concerned about the relationship between RoHS and REACH and suggested that the Commission's proposal for the RoHS recast could benefit from greater clarity. Should the same substances be evaluated under two separate measures, and by two separate agencies using different criteria, and having different objectives, different conclusions seemed likely. He asked for more information from the Commission on: how such conflicts would be handled; and whether there would be a transparent exemption process with fixed timeframes for decisions, a meaningful opportunity for all interested parties to comment and have those comments taken into account, and an explanation setting out the basis for decisions that would improve the operation of the Directive.

118. The representative of Korea noted that it was his delegation's understanding that Belgium had proposed the abandonment of the Priority List (Annex III) in September 2010. He invited the

European Union to explain the Belgian proposal and to clarify the status of the RoHS recast. Finally, he reiterated his delegation's request that a scientific risk analysis be undertaken prior to any substances being added to the lists.

119. The representative of the European Union explained that the proposal was currently being discussed by the European Parliament in the 'first reading' of the legislative process. The European Parliament Committee on Environment, Public Health, and Food Safety (ENVI Committee), which was the lead committee on the proposal, had adopted, on 2 June 2010, its report on the Commission's proposal. This report retained 103 amendments out of over 300 amendments that had been tabled in several parliamentary committees. The ENVI committee had proposed extending the scope of RoHS to all electrical and electronic equipment, including cables, consumables and accessories as of 1 July 2014, as well as adding 29 substances to a list of candidates for future restrictions under Annex III. The ban on the use of carbon nanotubes and nanosilver and the notification requirements for nanomaterials had also been proposed by the ENVI committee – no such proposal had figured in the Commission's original proposal.

120. The European Parliament would vote on the report of the ENVI committee during the 22 November 2010 plenary session. In the meantime, member States were considering the Commission's draft text and had initiated discussions with the European Parliament to assess the potential of reaching a first reading agreement. Clearly, at this stage there were broad differences between the proposals of the three institutions, in terms of scope, substances and restrictions, and that it was therefore not possible to determine whether a compromise might be achieved in the first reading. Should an agreement be found between the European Parliament and the Council, and if the Commission agreed to the proposed amendments, the text and legislation would be finalised. However, if a compromise was not reached, the text would be resubmitted to the European Parliament and Council for examination under a 'second reading'.

121. Given the uncertainty about which amendments might survive the vote in the Plenary session of the European Parliament, and as to the positions that member States and the Commission would take on these amendments, her delegation considered that it was premature to express any views on the matter. She assured Members that all of their concerns would be conveyed to the European Parliament and to the Presidency of the Council of the European Union. Should the Commission's initial proposal be substantially amended, the new text would be notified to TBT Committee. The EU delegation would update Members on developments in the legislative process at the next TBT Committee meeting.

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

122. The representative of the United States noted that despite continued discussions between US industry and the Commission, serious concerns remained with respect to the above-mentioned notified measures. The United States was of the view that the EU measure would severely restrict the ability of non-EU wine producers to use common or descriptive and commercially valuable terms (many of them adjectives) to describe their products on the grounds that those terms were traditionally associated with European wines. In particular, the European Union was still trying to obtain exclusive rights to use terms commonly included on the labels of wines such as chateau, vintage and superior – except under certain limited circumstances. While the European Union attempted to justify limitations on the use of traditional terms by indicating that consumers could be misled by their use, the fact remained that these terms had been used without incident on US wines in the EU market for many years.

123. In addition, the European Union had not indicated how it intended to enforce limitations with respect to imported wines. For example, he asked whether the European Union or its member States would take action to block importation of US wines bearing a traditional expression. The European Court of Justice had expanded the scope of the measures that protected these so-called terms in languages other than the one for which protection was identified. To illustrate his point, he gave the example of the recent case in Cyprus where protection was requested for the term "special reserve" in English as a traditional term in Cyprus. He also expressed on-going concerns with non-TBT related aspects of the protection of trademarks and intellectual property, concerns that had also been raised within the European Union in other fora.

124. The representative of New Zealand was particularly concerned about the discussion between the Commission and Cyprus with respect to the application for the "special reserve". She reminded the Committee that New Zealand had raised issues on the matter of traditional terms use for some time. Regarding the special reserve application, New Zealand had been assured by the Commission that it expected to resolve the matter in the near future. She requested an update on the matter.

125. The representative of the European Union confirmed bilateral discussions with US authorities on the issue of traditional terms in the context of bilateral wine talks. Furthermore, she informed the Committee that in June 2010, two US wine associations had filed several applications to the Commission for the use of certain traditional terms. In October 2010, the objection procedure had been launched with the publication of the application forms in the Official Journal of the European Union and Commission services would shortly send its first observations to the applicants regarding the admissibility of the applications. The representative explained that Cyprus had made an application for the use of the "special reserve" term, and that the Commission was reviewing the application in light of oppositions received from the United States and several member States.

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

126. The representative of Japan reported that the Government of India had postponed the entry into force of this regulatory act for an additional 180 days, now scheduled for 14 November 2010. Yet the number of tyres to be certified had increased and additional factories needed to be accredited, in particular since the certification system had been modified in mid-course. Thus, he requested further postponement of at least one additional year in order to give companies adequate time to prepare. He explained that 360 days was insufficient time to complete factory accreditation and lab tests. Regardless of India's claims that this regulation had been first notified in 2006, his delegation emphasized that the scope of the regulation had in fact been determined in May 2010.

127. The representative of Japan further noted that Article 3(1), reported in the Official Gazette in November 2009, stipulated that tyres without India Statistical Institute (ISI) certification marks were prohibited from being manufactured, imported, stored for sale, sold, or distributed in India. Japan was concerned about the time lag between time of manufacture and the time of sale or distribution, and requested that the time of manufacture serve as the point of enforcement, following other international regulations for automotive tyres.

128. While Paragraph 6.3 prohibited foreign manufactures from exporting tyres bearing the ISI certification mark to destinations other than India, the same requirement was not imposed on domestic manufacturers – which were able to use the same mould to manufacture tyres for both domestic and export markets. Foreign manufacturers, on the other hand, were required to use two separate moulds. This provision was unreasonable and amounted to an unnecessary restriction on trade since it competitively disadvantaged foreign manufactures; he requested that this provision be deleted.

129. The representative of Japan also expressed concern about a series of fees associated with the *BIS* certification mark, pursuant to Paragraph 2 of the agreement for the use of the certification mark. This included: a minimum marking fee, renewal application fees; annual license fees; and marking fees. He categorized these fees as unprecedented and unacceptable by any international measure, since they were based on tyre unit production – they needed to be be modified or eliminated.

130. The representative of Korea reported that Korean tyre manufacturers that had applied for *BIS* certification had been faced with delays due to the new certification requirements and had found it extremely difficult to obtain the necessary certification by 19 November 2010. He cited factory inspection and sample testing requirements as particularly burdensome, and requested that India accelerate the process. Given the delays, his delegation believed that a longer transition period would be beneficial for both foreign manufacturers and Indian authorities; he requested that the entry into force of the new requirements be delayed by an additional year. Furthermore, he noted that Korean tyre manufacturers were having difficulties crafting appropriate moulds and determining appropriate production and sales plans due to the lack of detailed information regarding: sampling, ISI marking, and the terms of validity of *BIS* certification under the new requirements.

131. The representative of the European Union reiterated concerns discussed at several past TBT Committee meetings, in particular regarding the additional marking introduced by the new Order. In the EU view, tyres produced according to United Nations Economic Commission for Europe (UNECE) regulations would in principle not have difficulties to comply with the Indian requirement, but would need to be produced–with different moulds, which increases production costs and creates an unnecessary barrier to trade. The European Union regretted that India had decided to move forward with entry into force on 14 November 2010, and urged India to resolve certain issues in advance of this date, or postpone entry into force. The representative of the European Union notably urged India to apply the royalty fees to the total value of actual imports to India rather than to total production.

132. Similar to the point raised by Japan, the European Union was concerned about the provisions of the *BIS* license agreement that prevented foreign manufactures from exporting tyres with the ISI Mark to destinations other than India, while exempting Indian manufacturers from this requirement. This requirement appeared to be discriminatory and entailed an unnecessary barrier to trade since foreign producers had to produce tyres specifically for the Indian market. She sought clarification as to whether the ISI Mark could be dyed or affixed as a non-permanent label, as had been discussed bilaterally, or if it had to be embossed on the tyre. Furthermore, she asked if the number of the standard and the plant specification designation had to be embossed in addition to the ISI Mark. The representative of the European Union also asked why detailed information concerning raw materials, manufacturing machinery, the name of the maker, the number of installed machines, and test equipment had to be provided in the certification procedure.

133. The European Union was also concerned about the lack of laboratories operated by Indian authorities, since there appeared to be only two laboratories in India able to conduct the required testing. She invited India to accept tyres tested in International Laboratory Accreditation Cooperation (ILAC) laboratories, or to reduce the varieties of tyres requiring testing in Indian laboratories. She reported that one application had been rejected by *BIS* due to lack of in-house testing facilities – she asked India to clarify whether in-house testing facilities were a requirement.

134. The representative of the European Union requested that manufactures be allowed additional time to comply with the requirements, given the narrowing of the certification procedure exemption notified by India in June 2010. Moreover, producers needed to be permitted a transition period of at least six months following the finalization of the list of tyres covered by the requirements of the Order by the local technical Committee. The European Union delegation was, in addition, still awaiting a response to written comments submitted on 11 May 2010 regarding G/TBT/N/IND/40.

135. The representative of India noted that although he appreciated the concerns regarding further postponement of implementation, he reminded the Committee that this regulation had been first notified in July 2006 and that industry had been made aware of plans to create a certification system. In November 2009, the revised certification scheme had been notified and the 360 day period before entry into force was more than reasonable, and beyond the time period mandated by the TBT Agreement. Nonetheless, he assured Members that he would convey the request for postponement to relevant regulatory authorities.

136. In response to points raised, the representative of India noted that the stipulation in the *BIS* agreement that ISI marking could only be used for exports to India did not restrict trade, nor did it bar exports to other markets. On fees, in some cases foreign manufacturers could pay *less* in fees overall as compared to domestic producers – hence fees were equitable in terms of unit cost of tyres. Regarding the rejection of applications due to lack of in-house testing facilities, the representative of India would confer with authorities and provide a detailed reply at the next meeting.

137. The representative of India reminded Members that India was not a signatory to the 1958 UNECE Agreement and therefore India was not required to follow UNECE regulations for the automotive sector. Nonetheless, *BIS* had considered UNECE and other standards, such as those of ISO, in designing a standard specific to India's geographic context and road conditions. For example, the *BIS* standard included the tyre strength test, the endurance test, and the bead unseating resistance test, but had adapted these tests and the standard to differences in the climatic conditions, geographical terrain and road conditions.

(v) 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.1-2, Add.1/Corr.1)

138. The representative of Japan expressed concern about the upcoming notification deadlines under the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP) for hazardous substances (in pure and mixed forms). Products on the market prior to 1 December 2010 were required to be notified by 3 January 2010, while products on the market on or after 1 December 2010 were required to be notified within one month. He noted obstacles to importers gathering information on the constituent components of mixed substances, due to lengthy supply chains, and stated that importers might not be able to meet the deadline as a result. The delegation of Japan requested an extension to the CLP notification deadline for mixed substances, similar to that under REACH.

139. The representative of the United States reiterated concerns regarding the initial classification of certain borate and nickel compounds under the Dangerous Substances Directive (DSD), and their translation to the CLP. He noted that the most recent EU commissioned risk assessment had found that borates usage in the cases examined posed no or negligible risk to the general public. On the basis of this finding, the European Union had proposed that there should be no restrictions on market access and use of borates-containing substances in household cleaners, detergents, and certain photographic mixtures. However, the European Union had not adopted this exemption due to disagreements between member States, and had instead referred the issue back to the ECHA's Risk Assessment Committee, which once again had found that "normal use" of photographic compounds was indeed safe. He requested an update on the status of this exemption.

140. The United States emphasized that available scientific and technical information should be considered with respect to the decision to place borate compounds on the Substances of Very High Concern list. He reiterated his delegation's concerns about the 'knock on' effects of the initial borates classification under other EU measures, which appeared to have been confirmed by this decision. It was worrying that the Danish competent authority appeared not to have completed all of the necessary

steps of the OECD read-across methodology. Namely steps 5 through 8 of the methodology had been excluded, which raised concerns that not all available scientific and technical information had been taken into account, including with regard to intended end-uses. His delegation had been unable to detect any legislative reasons that would prevent the European Union from fully following the read-across methodology; hence the United States urged the European Union to revisit its analysis so as to include the steps omitted in the initial analysis. The United States would continue to monitor potential adverse trade impacts of the nickel and borates classifications, and the on-going litigation on these classifications, as well as the potential methodological issues related to this measure and other EU measures.

141. The representative of Canada expressed concern about the precedent that the process had set for future classification exercises, as well as the downstream effects and possible unintended consequences of classification. For example, he noted that while the EU Raw Materials initiative had identified six platinum group metals and cobalt as being critical to the EU's economic well-being, the EU classification of nickel and nickel substances under CLP could adversely affect the provision of these critical metals since they arose principally as by-products of nickel mining.

142. The representative of Brazil shared the concerns of other delegations regarding the classification of nickel compounds under the 1st Adaptation to Technical Progress (ATP) to the CLP Regulation. This classification was based upon inadequate use of the OECD read-across methodology, and thus potentially more trade restrictive than necessary to achieve health and environmental objectives. Several steps of the methodology relating to scientific validation tests had been omitted by the European Union, and, although this omission had been justified by the European Union on the basis of legal obstacles, his delegation believed that this was not reasonable grounds for classification.

143. In addition, Brazil was concern that water solubility appeared to be the only criteria taken into account by the European Union to classify nickel compounds in the context of the 1st ATP, and that consideration of other criteria including biological effects could lead to a more scientifically sound classification. Industry was concerned about wrong assumptions made in the water solubility testing of nickel compounds, given that this testing was based on a report that was neither published nor peer reviewed. He asked the European Union to provide a list of nickel compounds for which water solubility data was available for the 1st ATP and asked whether the European Union had considered criteria other than water solubility.

144. In addition, it was noted that the trade and regulatory impacts of the measure would not be limited to labelling, since the EU rules on prevention of major accidents involving dangerous substances would also apply following the chronic toxicant classification under the 1st ATP. This additional regulation implied higher costs related to transport and storage of nickel compounds, as well as costs related to emergency plans and procedures adopted by companies. He noted that the proposed amendment to the CLP regulation envisaged a specific label for mixtures containing a sensitizer, even when the mixture was not a sensitizer. His delegation considered this requirement to be unjustifiable and in need of revision. In addition, he asked whether the highest sensitization categories would be used as criteria for the determination of Substances of Very High Concern under REACH.

145. The representative of the Dominican Republic reiterated his delegation's serious concerns regarding the EU decision to adopt the draft of the 30th and 31st modification of Directive 67/548/CEE on the reclassification of nickel carbonates and other nickel compounds, and the inclusion of those substances in the new CLP regulation. He noted that the 1st ATP had been in force since 26 September 2009; his delegation maintained that insufficient scientific evidence had been taken into account. He expressed regret that the European Union had not considered comments on this matter, including written comments. In particular, like other delegations, the Dominican Republic objected to

the way in which the European Union had applied the OECD read-across methodology; this constituted, in the view of the Dominican Republic, a violation of Article 2.2 of the TBT Agreement.

146. For the Dominican Republic, the labelling requirements for nickel compounds or substances would impose very prejudicial effects on producers and exporters of nickel substances. In particular, he cited an increase in the cost of production, transport and insurance for ferrous nickel, which would compound the detrimental impacts of the economic crisis, especially harming developing and small vulnerable countries which produced these substances. He appealed to the European Union to reconsider their position on these regulations, and ensure that they complied with the provisions of the TBT Agreement.

147. The representative of Turkey noted that this was the 10th TBT Committee meeting at which this issue had been on the agenda, and because his delegation's comments had been reflected in the minutes of these previous meetings – these points remained valid as there had been no improvement to date.

148. Turkey was particularly concerned that the classification of borates did not have a sound legal and scientific basis, and that subsequent downstream impacts of this classification posed significant barriers to trade. Turkey had in fact notified the European Union of recent published scientific research undertaken in China, providing a different perspective on the issue, to which his delegation had yet to receive a response. In addition, another study, conducted in Turkey, would be shared with the European Union following publication. He hoped that this scientific research would be seriously considered and that a mutually satisfactory solution would be reached.

149. The representative of Cuba reiterated concerns about the classification of nickel substances under CLP, since it was based on inadequate consideration of evidence and scientific data, and incomplete application of the OECD read-across methodology. The European Union had arbitrarily decided that it was not obliged to notify the 1st ATP of the regulation to the Committee since it related to classifications adopted in the 31st ATP of the Directive 67/548, even though the former concerned distinctive issues, within a different framework. Despite EU assurances that this regulation affected only labelling, and not trade in nickel products, Cuba was of the view that the inclusion of these classifications within REACH would impose onerous additional registration burdens on these products and could lead to the prohibition of these products on European markets. Furthermore, these classification decisions could lead to stigmatization of nickel products thereby hindering trade. The delegation of Cuba appealed to the EU to re-evaluate its nickel product classifications.

150. The representative of Colombia said that a number of outstanding concerns remained, in particular with regard to the accelerated approval process of the regulation, which called into question the transparency with which Member's comments were addressed. Furthermore, she questioned the scientific basis of the regulation, as well the incomplete application of the OECD read-across methodology, which had led to the reversal of the burden of proof; substances were classified on the basis of their water solubility until such a time as proof to the contrary was provided. Evidence supporting the reclassification of nickel compounds, and the associated risk assessment, suggested that this regulation did not conform with good practice as established by Members. In practice, the scope of the measure extended well beyond labelling, and could in fact lead to the prohibition of nickel substances, since they were classified as Category 1 carcinogens. Colombia wished to have further information regarding progress on the modification of Annex 17 of REACH, G/TBT/N/EEC/297, since this seemed to be a clear example of the prohibitive effect of the classification of nickel compounds.

151. The representative of Australia reiterated concerns about the EU decision to reclassify nickel compounds, in particular in terms of the scientific validity of the exercise. She noted that concerns raised by her delegation at a number of previous TBT Committee meetings remained unaddressed.

Her delegation had welcomed assurances that the decision to reclassify nickel substances would result only in additional labelling requirements, yet she believed that the measure extended beyond such requirements, to the point that there was likely to be a significant impact on trade in nickel compounds.

152. The representatives of China, Ecuador, the Philippines, Thailand and Venezuela shared the concerns raised by other Members.

153. The representative of the European Union noted the concerns raised by Members about the classification of borates and several nickel compounds in the 30th and 31st APT. She regretted that concerns remained, despite the explanations provided at previous meetings. Indeed, she cited lengthy replies on all issues, both written and oral, provided over a number of TBT Committee meetings, including a 20 page reply circulated to address all Member comments. Furthermore, two experts had provided over two hours' worth of extensive and detailed replies to questions raised by WTO delegates. For this reason, her delegation failed to see what additional information could now be provided in reply to these same issues.

154. The representative of the European Union strongly urged delegations to review previous TBT Committee meeting minutes which summarize these exchanges. Any new information that challenged the Commission's conclusion on classification and labelling of nickel compounds could be submitted by industry to a member State, which could then be submitted in a dossier to ECHA for review of the classification and labelling decision as listed in the 1st ATP of the CLP Regulation. With respect to industry comments that the classification had been based on wrong assumptions, raised by Brazil, she requested that further detailed information be provided. In response to the US question about the impact assessment for borates, and the question posed by Colombia on Annex 17 of REACH, these issues had been addressed earlier in the meeting under the REACH discussion.

155. It was suggested that the issue of the revision of CLP regulation, noted by Brazil, be addressed bilaterally – as it was not clear which revision had been referred to. Regarding the study conducted in China (mentioned by Turkey), the representative of the European Union would confer with European experts and convey any information to Turkey bilaterally.

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

156. The representative of New Zealand remained concerned with Canada's compositional cheese standards that limited the protein sourced from dairy ingredients, even though such ingredients were widely used and accepted in cheese production worldwide. Canada's standards appeared to be inconsistent with the relevant international standards as the Codex standards did not prescribe limitations on the sourcing of milk proteins. Therefore, New Zealand questioned the compliance of Canada's regulation with the TBT Agreement. She asked for an update on developments regarding the appeal process following the initial court ruling on the cheese standards and also asked whether the standards were being enforced pending the outcome of the appeal. She also requested information about whether Canada's dairy producers were actively lobbying the government to introduce similar standards for other dairy products such as yoghurt, and what had been the government's response to such proposals.

157. The representatives of Australia and the European Union supported New Zealand's concerns and asked for an update.

158. The representative of Canada confirmed that its federal court decision had been appealed. However, no date for a ruling had been scheduled yet, so his delegation was unable to provide an update to the Committee. The Government of Canada was not currently working on regulatory processes for any other dairy products and, to date, all imported cheeses had been deemed to be in

compliance with the revised standards by the regulatory agency responsible. Therefore, no shipments had to be returned due to non-compliance and no complaints had been received to date.

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

159. The representative of the European Union reiterated concerns regarding the Indian notified order laying down a registration procedure for imported cosmetics products. She noted that subsequently India had published a new order in its official Gazette on 19 May 2010 and new requirements would enter into force on 1 April 2011. The European Union asked India to notify the new order to the TBT Committee to allow WTO Members to provide comments. When the initial order for cosmetics was notified to the WTO in 2008, the European Union provided extensive comments and had suggested India implement a notification system rather than a registration system, as registration did not provide improvement in consumer safety.

160. The representative of the European Union observed that the notification system used in Europe since 1976 was one used in most international markets. The system had proved sufficient to provide European Union national authorities with necessary information while at the same time allowing manufacturers to launch products without unnecessary or costly delays. The European Union invited India to replace its registration system for cosmetic products with a notification system.

161. If, nevertheless, registration requirements continued to be imposed, the European Union urged Indian authorities to postpone implementation until January 2012 and to take steps to ensure that economic operators, in particular foreign manufacturers, were not faced with overly burdensome requirements. The representative proposed, for instance, that the registration certificate and import license validity period be raised from three to five years, similar to local manufacturing licenses; that the registration certificate should be provided within a maximum period of two months and be given for a product line and not for single products within the same line; that tests conducted in the country of origin attesting compliance with international cosmetic standards should be accepted; and that labelling and packaging should be allowed to be carried out in India by importers or local agents.

162. The representative of India reminded the Committee that the draft rules pertaining to the registration of cosmetics had been circulated to the TBT Committee for comments in February 2007 and a system of registration of imports of drugs had already been in practice since 2003. The amendment to the drugs and cosmetic rules for introducing a system of registration of imports of cosmetics into the country had been published on 19 May 2010 with a subsequent amendment dated 19 July 2010. The rules would come into effect on 1 April 2011 and thus met the TBT Agreement stipulation of providing a reasonable interval between publication and entry into force. The representative explained that the measure was based purely on public health concerns of consumers. The provisions of the amendment did not discriminate between exporters to India and similar provisions were already in existence for domestic manufacturers. Concerns of the European Union and other WTO Members had been taken into consideration before finalising the amendment, which led to the deletion of an objected clause relating to inspections and visits to manufacturer premises by the licensing authority of India. India therefore felt concerns already had been taken onboard. Nevertheless, new suggestions would be forwarded to India's regulators for consideration.

(viii) China – Proposed Regulations on Information Security (G/TBT/N/CHN/278-290)

163. The representative of the European Union raised concerns about the revision of the 1999 regulation on commercial encryption by the Office of State Commercial Cryptography Administration (OSCCA) and implementation of the Multi-Layer Protection Scheme (MLPS) under the leadership of the Ministry of Public Security. Regarding the OSCCA regulation, the representative asked China for an update and expected timeline on the revision process carried out by the State Council Legislative Affairs Office as well as confirmation that a public consultation would be held and the draft measure

would be notified to the TBT Committee at the earliest appropriate stage, when amendments could still be introduced so that comments could be taken into account in accordance with Article 2.9.2 of the TBT Agreement.

164. Regarding the MLPS, the representative of the European Union noted that the measure had been developed in the absence of a process allowing stakeholders to provide input. Furthermore, no clear implementation guidelines were given, thus creating an uncertain and unpredictable environment for foreign manufacturers of ICT equipment operating in the Chinese market. He recalled that the MLPS mandated classification of IT systems into five different levels depending on the importance of the information handled in relation to national security. If a system was classified as "critical infrastructure" (level 3 or above), only products incorporating indigenous core technology and key components and having obtained certification under the OSCCA regulation and under the Compulsory Certification for Information Security (CC-IS) scheme as applied to information security products would be allowed to be used in such a system. Thus, these product requirements effectively barred foreign products from entering the Chinese market, firstly by mandating the use of indigenous technology, and secondly because the OSCCA procedures were not open to foreign or foreign invested companies. Therefore, even if a foreign company were to incorporate Chinese technologies into its product, it would still not be allowed to obtain the required OSCCA certification. Also, while the OSCCA regulation currently applied only to products with encryption as a core function, it was not clear whether, for the purposes of the MLPS, products with encryption but without such facility as a core function would be required to be approved by the OSCCA. Additionally, the representative noted that product requirements for critical infrastructure would mandate a backdoor application of the CC-IS in the sense that the current CC-IS was limited to government procurement but the MLPS extended into the commercial area.

165. The representative of Japan supported the concerns of the European Union. The representative said China's regulations were not in conformity with global norms and approaches and thus could negatively affect the trade of information security products. Japan hoped China would exercise prudence in introducing additional measures and would engage in a dialogue with stakeholders should such be deemed necessary.

166. The representative said the European Union was increasingly worried about MLPS implementation in sectors such as banking, energy transportation, and education where large state-owned enterprises with no obvious relevance to national security were active. This concern was especially relevant given that the latest calls for tenders only solicited offers from vendors who could demonstrate compliance with the product requirements set by the MLPS for critical infrastructure. Thus, *de facto* implementation of the MLPS prevented foreign and foreign-invested ICT manufacturers from accessing significant sectors of the Chinese economy. The European Union proposed to explore whether alternative but equally effective approaches could assist in achieving the legitimate goals of national security protection that the Chinese authorities were pursuing. They requested an update on the implementation timeline of the MLPS.

167. The representative of the United States noted that an expansion of the scope of China’s core function test to more information technology products could create trade disruptions similar to those that had occurred in 1999, when China introduced the first version of its encryption regulations. The United States reiterated its request that China notify any draft revisions of these measures to the WTO so interested parties may comment.

168. The representative of China said that, as could be seen from the title of this specific trade concern, China's proposed regulations on information security involving 13 Chinese TBT notifications were limited to government procurement. Therefore it was not appropriate to continue discussion in the TBT Committee on the issue.

169. The representative of the European Union said his delegation would re-formulate the title of the specific trade concern to ensure it explicitly reflected the scope of the European Union's concerns.

170. The representative of China said regardless of the title of the specific trade concern, her delegation remained to be convinced that the OSCCA and MLPS issues fell under the governance of the TBT Agreement.

(ix) India – Mandatory Certification for Steel Products (G/TBT/N/IND/32 and Add.1)

171. The representative of the European Union enquired whether India's envisaged deletion of certain steel items in its list of products needing to be certified was intended to be permanent or whether the deletion was limited to a period of 6 months. The European Union sought justification as to why galvanized steel was not deleted from the list.

172. The representative of Japan supported the comments of the European Union. In Japan's view, finished products, not intermediate materials, were entirely responsible for ensuring human health and safety. Consequently, safety regulations should be restricted to finished products; there was no need to impose mandatory standards on intermediate materials such as steel products. Japan understood that the Government of India had taken into account this position and India would not establish any further mandatory standards for intermediate products. The representative sought an update on the development of India's draft measure since the last TBT Committee meeting.

173. The representative of India said its regulating authority, BIS, considered intermediate products such as ingots and billets to be critical for the safety of final buildings, which was why it was important to have standards to ensure these products conformed to specific composition and property design requirements relating to the safety of the final building *per se.* The representative noted that following a review carried out by the BIS, some items had been deleted from the list. However, the standard IS 277 for Galvanized Steel Sheets had been retained keeping in view the objective of safety specifically of consumers in rural areas who did not have access to very high quality housing. Also, concerning items deleted from the list, India had not entirely dropped the development of standards for such items. Instead, the standards for deleted items were under review, while products remaining on the list had been prioritized and notified in terms of in terms of mandatory certification. In general, Indian standards for steel were reviewed every five years and at each review a comparison was drawn to international standards. Wherever appropriate, elements of international standards were adopted, in line with specific needs and requirements of India.

(x) European Union – Seal products (G/TBT/N/EEC/249 and Adds.1-2;G/TBT/N/EEC/325)

174. The representative of Norway noted that both the European Union regulation on trade in seal products 1007/2009/EC (notified as G/TBT/N/EEC/249), and the related implementing regulation 737/2010/EU (notified as G/TBT/N/EEC/325), had entered into force since the last meeting. The implementing regulation raised new questions particularly with regard to the conformity assessment of the attestation bodies required for the documentation of seal products conforming to the exceptions of the seal regulation. Norway had asked for supplementary consultations with the EU under the Dispute Settlement Understanding. It was Norway's view that the seal regulation and its implementing regulation were inconsistent with both the TBT Agreement and GATT 1994.

175. The representative of Canada supported Norway's concerns.

176. The representative of the European Union referred to ongoing WTO consultations on the basic regulation. The representative said the adopted regulation did not fall within the scope of the TBT Agreement and it was not appropriate to discuss the matter further in the TBT Committee.

(xi) Colombia – Draft Decree Establishing Provisions to Promote the Use of Biofuels (G/TBT/N/COL/96 and Adds.1-3)

177. The representative of the European Union welcomed Columbia's intention to make requirements relating to the ability of vehicles to run on biofuel more flexible and observed that Colombia currently was undertaking studies on this. The European Union also welcomed the launching of a public consultation on a new draft measure providing for a lower percentage of ethanol in the fuel mixture and implementation in a gradual manner. The representative sought an update on the consultation procedure and indication of when a new draft text would be notified to WTO Members.

178. The representative of Colombia said that on 29 July 2010, the Ministry of Mines and Energy had published proposed changes to its decree 1135 of 2009, inviting comments from the general public. Proposed modifications included removal of a minimum market share of flex-fuel-automobiles and establishment of prescribed mixtures between regular gasoline and bio-ethanol. It was further proposed to allow the Ministry for Mines and Energy to adjust proportions of prescribed mixtures with a view to improving the performance of vehicles that would use the new fuels. Comments received continued to be analyzed. Once the process had progressed further, a document would be made available to the WTO and a timeframe set for comments on the amended measure.

(xii) France – Unique Requirements for Ride-on Lawn Mowers

179. The representative of the United States reiterated concerns on the French Ministry of Agriculture's "skirt" requirement to cover transmission moving parts for ride-on lawnmowers. This had disrupted U.S. lawnmower exports to France. The representative noted that in the preceding week, the CEN TC144 WG7 Working Group had discussed the Ministry of Agriculture's proposal. After hearing arguments for and against the proposal, the CEN consultant who is advising TC144 on the revision of EN 836 as it relates to the Machinery Directive mandatory requirements compliance review process had concluded that the total enclosure of all transmission moving parts was unnecessary. This was a direct rejection of the Ministry of Agriculture's position on total coverage. The consultant had further confirmed that the risk of fire from total enclosure was significant, as had been noted previously by both European and U.S. producers. The consultant had suggested shifting attention in the revision process to pinch points only, instead of concentrating on all transmission moving parts. The United States believed this was a compromise position industry could accept.

180. The representative of the United States observed that WG7 accordingly would advise CEN TC144 to request the Ministry of Agriculture to withdraw its appeal against the original proposal and ask WG7 to address the issues of hazards to bystanders during the revision process of EN 836 and ISO 5395. The scope of the bystander access issue, however, as it related to the revision process would be limited to pinch points only under the WG7 recommendation.

181. Despite the outcome of the working group, the French Ministry of Agriculture had not altered its position regarding total coverage and as a result all companies were now being forced to comply or face recalls, despite TC144's repeated rejections of the French proposal. The United States was of the view that the issue of bystander access to transmission moving parts of ride-on lawnmowers needed to be addressed as part of the CEN/ISO revision process. Therefore France should refrain from unilaterally enforcing its total coverage position. Instead, the European Commission should direct France to allow the standards revision process to proceed. The representative said the United States was especially concerned that France may again seek to delay the revision process by filing another appeal on the latest WG7 recommendation. United States companies were interested in reaching a compromise solution; the United States urged the Ministry of Agriculture to stop blocking the standards revision process through continued appeals within the CEN.

182. The representative noted that even though the Technical Committees of the European Commission issued *de facto* mandatory requirements for the European Union, these were not notified to the WTO for comments. Non-European Union member States could not vote in these committees and observers were small in number and at the discretion of the respective chairs. Additionally, France had neither published nor notified its skirt measure that deviates from the CEN standard and which it has continued to enforce.

183. The representative of the European Union thanked the United States for the update, but indicated that it could not comment on the substance of the United States' intervention related to the standardization process, as the European Commission was not directly involved. While sharing the objective to achieve the best technical solution for all stakeholders, the European Commission's role was limited to assessing the adequacy of the harmonised standard against the relevant essential requirements of EU legislation (in this case, the Machinery Directive) when the standards would transmitted to it with a request for publication of its references in the Official Journal of the European Union. The meeting of the Working Group set up under the Machinery Directive in December 2010 would be a good opportunity to take stock of the situation and ask CEN for an update. Finally, the EU recalled that US manufacturers were providing extensive input in the standardization process through their European subsidiaries, and also to the parallel ISO standard being developed under CEN lead in accordance with the ISO-CEN Vienna Agreement.

(xiii) Korea – Regulation for Food Industry Promotion Act (G/TBT/N/KOR/204 and Suppl.1)

184. The representative of the European Union thanked Korea for further postponing the entry into force of new requirements for organic products until 31 December 2012. The European Union hoped the upcoming revision of the Korean legislation would introduce an equivalence mechanism in its regulatory framework as foreseen in the Codex guidelines on organic products.

185. The representatives of New Zealand, Canada, Australia, Chile, Switzerland, United States, and Mexico supported the European Union and requested introduction of a mechanism to provide the requisite legal authority to negotiate equivalence arrangements into Korea's legislation in view of avoiding unnecessary barriers to trade. The representatives of Canada and Switzerland suggested Korea re-notify its draft measure upon completion of the revision process.

186. The representative of Korea informed that the MIFAFF had decided to unify two previously separate certification systems for processed organic food and raw organic food ingredients under the Environmentally Friendly Agriculture and Forestry Act. In the combined system, accreditation procedures for primary products and processed products would be identical, which would help in preparing provisions for equivalence agreements. The proposed regulations were expected to be adopted by the National Assembly in the first half of 2011, after having received comments from stakeholders and worked through the necessary administrative procedures within government. MIFAFF intended to notify the amendment to the WTO as well.

187. The representative of Korea said current labelling requirements under the Food Sanitary Act would stay in place until 31 December 2012. With regard to the accreditation procedure, it had previously been required that no fewer than two inspectors conduct on-site assessments. However, as of 17 June 2010, the amended Designation and Operation of Food Quality Certification Authorities for Organic Processed Food did not specify a number of inspectors for on-site assessments. The representative noted that starting from 1 January 2013, organic producers and operators who wanted to export organic food to Korea should be certified by certification bodies based in Korea or bodies outside Korea accredited to Korean standards. Otherwise, equivalence agreements should be reached between Korea and the country concerned. Given the considerable amount of time required for equivalence agreements to be concluded, Korea encouraged certification bodies to obtain recognition as a qualified certification body in accordance with Korean regulations.

(xiv) Brazil – Health products registration (G/TBT/N/BRA/328)

188. The representative of the United States reiterated concerns on Resolution 25 requiring Good Manufacturing Practice (GMP) inspections of medical devices before re-registration and new registration of medical devices. Concerning re-registration of medical devices, the representative welcomed reports from United States industry that ANVISA was demonstrating flexibility to enable products to remain on the market pending inspection. However, United States industry was also reporting lengthy delays for registration of new medical devices and was concerned it could take two years to clear the current backlog. The delays for United States medical devices exports to Brazil had resulted in patients being denied access to innovative medical technologies. The United States was disappointed by this development given assurances from Brazil at the last TBT Committee meeting of not intending to disrupt the entry of medical devices into Brazil due to their essential nature. The United States requested Brazil to provide sufficient resources for both its inspection and registration programs in order that new applications could be processed as efficiently as possible so as to ensure trade in these new medical device products could resume. The United States would continue to monitor the situation closely.

189. The representative of the European Union noted that at the previous TBT Committee meeting Brazil had provided assurances that there would be no disruption of imports of medical devices into Brazil. However, according to the Technical Note 1/2010 of ANVISA of 5 October 2010, any company wishing to register a new medical device would have to present a GMP certificate as part of the application process for registration. If the GMP certification had been requested after the deadline of 21 May 2010, a receipt of the request for a GMP inspection would not be accepted. The European Union's understanding was that in the case of applications for renewals of registration and in the absence of a new GMP certificate, companies would be able to submit the receipt of the request for a GMP inspection in order to advance the application process. If this understanding was correct, the European Union expressed concerns that this might potentially lead to restrictions of new medical devices not previously registered into the Brazilian market, with a possible negative effect not only on trade, but also on access of Brazilian consumers to the best and most advanced medical care.

190. The representative of Switzerland said Switzerland supported the intention behind ANVISA resolution number 25/09 which aimed at guaranteeing the quality of medical devices sold in Brazil in order to protect human health. However, Switzerland remained concerned about the change in Brazil's regulation regarding market access for medical devices classified in Brazil under risk categories 3 and 4. He reiterated particular concern that Brazil no longer recognized quality inspection results based on the International Standard ISO 13485 for medical devices. At the last TBT Committee meeting, Brazil had informed Members that inspections necessary for granting certificates of good manufacturing practices had been carried out in a timely and orderly manner by ANVISA. In addition, Brazil had stressed that the sanitary authorities of Brazil had not received any complaints related to the importation or commercialization of medical devices. In this regard, the representative informed Brazil that the Swiss medical device industry continued sharing with the Swiss Government difficulties related to the Brazilian inspection regime, which Switzerland would like to discuss with Brazil on a bilateral basis.

191. The representative of Brazil said that since Resolution RDC 25 of ANVISA had entered into force in May 2010, there had not been any reports of trade disruptions related to the implementation of the measure. Imports of health products into Brazil had not been affected and companies had managed to comply with requirements of the resolution. The representative added that ANVISA had been able to respond to all requests of inspection in a timely and orderly manner.

192. Regarding the United States' comment of an alleged backlog of two years for inspections to be concluded on new registrations, the representative of Brazil said Brazil would talk to the United States bilaterally in order to find out what data the United States had used, given that the

regulation was in force for only around six months. The representative shared with Members some statistics regarding the pace of inspections that had been conducted by ANVISA. He said ANVISA had performed 171 inspections so far and 50 more inspections were to be concluded by the end of 2010. Moreover, 397 inspections were expected to be performed in 2011, of which 40 were already scheduled.

193. Regarding Switzerland's comment on non-acceptance of ISO 13485 certifications, the representative said Brazil had already provided extensive explanations on this issue and he invited Switzerland to consult the minutes of the last TBT Committee meeting. He emphasized that it was essential that companies revalidate their existing registration and request the necessary inspection from ANVISA well in advance. This request should be submitted six months before the expiration of the existing registration. The representative recalled that Resolution 66 of 2007 of ANVISA ensured that if a company requested a GMP inspection at least 120 days before the expiration of its existing certificate, the latter could remain valid if no problem had occurred with the current certification.

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

194. The representative of the United States reiterated concerns regarding the European Union's new accreditation framework set out in Regulation 765/2008. Recalling concerns raised in the previous TBT Committee meeting, the representative said the United States was particularly concerned at the potential impact on recognition of non-EU accreditation bodies under the ILAC MRA and the IAF MLA and acceptance of conformity assessments performed by bodies that were accredited under those two agreements.

195. The representative of the United States recalled that at a previous TBT Committee meeting, the European Commission had indicated a lack of scientific and technical basis for the Regulation 765 requirements which was confirmed by the fact that the Regulation did not prevent competition between member State accreditors in other markets. Given this acknowledged lack of scientific and technical basis, the United States continued to have concerns with the European Union's stated intention to promote EU accreditation policy, including in the recent Framework Partnership Agreement with EA (European Co-operation for Accreditation), and wondered how that would be consistent with the IAF/ILAC requirements.

196. The United States requested clarification as to how implementation of Regulation 765/2008 would be consistent with two requirements under ILAC/IAF: first, that a Regional Group needed to make its services concerning its Arrangements accessible to all accreditation bodies whose activities fell within its declared field of operation and geographic area; and second, that the Regional Group needed to confine its requirements, evaluations and decisions on accreditors wishing to join its Arrangement to those set out in ISO/IEC 17011, other normative documents relevant to the function performed and supplementary requirements and guidance where appropriate. The representative said the United States was aware of ongoing discussions between EA and ILAC concerning these issues. He requested the European Union provide background on the Framework Partnership Agreement and whether it had considered issuing further written clarification regarding how EA would cooperate with non-EU accreditation bodies through ILAC and IAF, as the European Union had noted it would do at the last TBT Committee meeting.

197. The representative of Australia said Australia was also concerned that Regulation 765/2008 could potentially impede the recognition of conformity assessment results from bodies accredited by non-EU accreditation bodies that were members of ILAC and IAF. Australia provided detail at the last TBT Committee meeting which could be seen in the Committee minutes.

198. The representative of Thailand shared the concerns raised by the United States and Australia.

199. The representative of the European Union referred to previous explanations by the European Union on the fact that the new accreditation framework did not change the way both accreditation certificates issued by non-EU accreditation bodies and conformity assessment results from conformity assessment bodies in a non-EU country would be accepted in the European Union. Concerning the issue of non-competition between the national accreditation bodies in the European Union, the representative said the European Union never stated that there had been a lack of scientific and technical basis. The European Union had stated that it was a policy choice which was based on the conviction that an activity which was performed as a public interest activity should be performed in an environment which was immune from commercial pressures and commercial interests.

200. On the relationship between EA and ILAC, the representative of the European Union recalled that the EA had replied in early 2010 to a very elaborate set of questions raised by ILAC Members with respect to the EA framework. In the reply, the EA had explained to all ILAC Members how the EA framework met all ILAC requirements. It was the understanding of the European Union that all issues had been addressed in a satisfactory way and it was not necessary to duplicate in the TBT Committee a discussion which had already taken place at ILAC and IAF level.

201. On the Framework Partnership Agreement, the representative said the agreement was necessary to formalize the role of the EA as the body responsible for overseeing the European Accreditation Framework and providing the required support infrastructure and also for enabling the necessary financing operations for the European Union. In light of discussions in TBT Committee, the European Union agreed that communication of policies could always be improved. The European Union was convinced that the EA, rather than the Commission, was best placed to explain to its peer accreditors in other countries the meaning and facts of its external policy.

202. The representative of the United States recalled that in reply to the question posed by the US at the March 2010 TBT Committee meeting, on whether there was a scientific and technical basis behind the requirements, the representative of the European Union stated that there was none and that it had been a political decision.

(xvi) Canada – Bill C-32 amendment to Tobacco Act

203. The representative of Mexico said her delegation shared Canada's commitment to protect human health and recognized the impact of smoking in this regard. Mexico was making efforts to discourage smoking among its population. The representative said Mexico was concerned at Canada's non-compliance with Articles 2.2, 2.9 and 2.9.4 of the TBT Agreement. Specifically, Canada had not notified Bill C-32 to the Committee and therefore had not provided WTO Members opportunity to make comments. The representative recalled that Mexico's concerns were shared by many other Members.

204. The representative of Mexico reiterated that the measure was unnecessarily restrictive as there existed other ways to meet the objective without prohibiting the use of taste enhancers. In other countries where additives to tobacco had been regulated, only the quantity had been limited. Mexico noted Canada's commitment to reduce tobacco consumption among its population, especially among youth, but claimed the measure was restrictive and contrary to Canada's obligations under the TBT Agreement. Mexico requested information on the status of the Bill and asked if Canada intended a revision to take into account comments made by Mexico and others.

205. The representative of the European Union requested further clarification from Canada on the scientific rationale behind Bill C-32, in particular given the European Union's own work in investigating the link between additives and addictiveness and attractiveness of tobacco products. At the June 2010 TBT Committee meeting, Canada had made available a room document with selected references that had been considered in the development of the amendment of Canada's Tobacco Act -

some 170 publications and other information providing "evidence that additives are used to make tobacco products more appealing to youth and novice users". However, the selected references offered no details with regard to the content of the studies therein, or their conclusions. In this context, the European Union asked Canada to provide information as to which studies from the list specifically dealt with the impact of additives on addictiveness and/or attractiveness, in particular in children and youngsters, and also provide the TBT Committee with a short summary of their conclusions.

206. The representative of the European Union noted that the Schedule of the Bill provided for an exemption of certain additives including benzoic acid, citric acid, guar gum and menthol from the prohibition. The European Union asked Canada to provide more details as to the scientific rationale for the exemptions since, in particular in the case of menthol, several scientific studies had postulated that menthol could act as an indirect enhancer of nicotine addictiveness and could also help boost tobacco products' attractiveness, by providing tobacco with a more pleasant, cooling taste.

207. The representative noted that the 2008 *Report to Health Canada on Tobacco Product Attractiveness as a Contributor to Tobacco Addiction and Disease* by Ferris Wayne G. & Henningfield J. E., had been included in Canada's room document as an important source of scientific reference, used in the analysis for Bill C-32. The representative invited Canada to make this report available to the TBT Committee so WTO Members could become familiar with the scientific information therein. The European Union enquired whether an impact assessment had been carried out prior to the introduction of the Bill, and if yes, whether this impact assessment or, alternatively, a summary of its conclusions, could be shared with the Committee.

208. The representative informed the Committee that, as part of its own work on attractiveness and addictiveness of tobacco additives, the European Union had asked the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to provide an opinion on this issue. The preliminary opinion of the Committee was published on 12 July 2010 and was available on the website of the Directorate General for Health and Consumers Products of the European Commission.[7]

209. The representative of Turkey reiterated his country's concern with Canada's Cracking Down on Tobacco Marketing Aimed at Youth Act. Turkey supported Canada's objective of deterring youth from tobacco use, but was seriously concerned at the way Canada sought to achieve this objective. The representative reiterated concerns that the Canadian measure was more trade restrictive than necessary as it prohibited the production, sale and distribution of tobacco products containing additives that not only provided a characterising flavour to the product, but that were also used during the blending process of burley and oriental tobacco. He noted that some of these additives were vital and indispensable components for blending Burley and Oriental tobacco (American blend), that these additives did not give a characterising flavour to the end product that could result in attraction, and there was no scientific evidence confirming that Burley and Oriental blends were more appealing than non-blended tobacco. The representative said blended and non-blended tobacco products were like products and were substitutes; any measures resulting in the prohibition of one would favour the other. Turkey asked Canada to reconsider the Act based on its TBT Agreement commitments and requested further information on the exclusion of traditional flavours such as menthol from the coverage of the Act.

210. The representative of Chile stated her delegation's support for the initiative of Canada towards preventing consumption of tobacco products which may be attractive to young people. She reiterated concern that the coverage of the measure was broad since it imposed a *de facto* prohibition on the import, manufacturing and marketing of American blended tobacco in cigarettes. Chile supported concerns raised by other Members in this regard, reiterating that the measure prohibited additives and

[7] http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_029.pdf

taste enhancers in specific tobacco products such as cigarettes and cigars, and as a consequence the measure would inhibit traditional tobacco products. Chile was of the opinion that the measure would close the Canadian market to these products but not to other types of tobacco which did not use these types of ingredients, creating discrimination. The representative cited examples of alternative regulations seeking the same objective in the United States and France. She reiterated that the Canadian measure had not been notified to the WTO and was more trade restrictive than necessary to achieve its objective. Article 2.8 of the TBT Agreement stated that Members should base their technical regulations on the use of products instead of their descriptive characteristics. In this regard, Canada could adopt an approach based on performance.

211. The representative of Zambia reiterated its concerns that the Canadian measure created an unnecessary obstacle to trade and Canada had failed to notify it to the TBT Committee. Article 2.9 of the TBT Agreement required Members to publish, at an early, appropriate stage, the proposed technical regulation, whenever such technical regulation was not in accordance with the technical content of relevant international standards, and if it had a significant effect on trade. Notification was to enable interested Members to become acquainted with the regulation and submit comments in writing, and for the notifying Member to take into account the results of such consultation. Zambia was concerned that Canada had introduced its measure without due regard to its notification obligations.

212. The representative of Zambia said that for many sub-Saharan African countries tobacco production and trade accounted for a large proportion of rural income. The measure introduced by Canada would have a direct impact on the lives of these rural communities whose livelihood revolved around tobacco production. The tobacco industry accounted for 20 per cent of Zambia agricultural exports. In the light of the trade impact of the measure, Zambia urged Canada to reconsider its position and take into account concerns raised.

213. The representative of Ecuador repeated his country's concerns with respect to the Canadian law. In the view of his delegation, the measure would result in a *de facto* prohibition against the importing and marketing of American blend cigarettes, which Ecuador exported. While Ecuador did not object to the legitimate policy objective behind Canada's measure, they did question the process and measures Canada adopted; these had established standards which did not comply with Articles 2.2, 2.8 and 2.9 of the TBT Agreement. The representative observed that any measure seeking to promote a legitimate policy objective, such as protection of human health, should be reasonable and proportionate of the objective and should not create unnecessary technical barriers to trade. Also, the Canadian measure did not give due consideration of the TBT Agreement provision that technical requirements be based on performance rather than the product's design or descriptive characteristics.

214. The representative of Jordan reiterated his delegation's support for the objective of Bill C-32 amending the Tobacco Act. However, in the view of his delegation, the measure was more trade restrictive than necessary.

215. The representative of the Dominican Republic explained that, in her delegation's view, the Canadian law to discourage tobacco marketing directed at youth would effectively prohibit the manufacture and sale of traditional blended tobacco. Canada should have provided notification, as required by Article 2.9 of the TBT Agreement, so WTO Members could have debated and commented on the law. The representative recalled her country's previous statements that the law could have important effects on the market for cigars and cigarettes, especially with respect to the Burley tobacco market. As a result, the Bill could have serious adverse effects on tobacco production and the national economy in the Dominican Republic, resulting in social problems due to job losses amongst tobacco harvesters.

216. The representative of the Dominican Republic observed that the law was aimed at prohibiting the manufacture and sale of tobacco products, including cigars and cigarettes, with characteristic flavours such as sweeteners or fruit. While the Dominican Republic shared the objective of protecting human health, the way the Canadian law was drafted was too broad and disproportionate.

217. The representative of the Philippines reiterated that Bill C-32 appeared to be more trade restrictive than necessary as it banned many additives regardless of whether or not they imparted a characterizing flavour to the finished tobacco product.

218. The representative of Uganda said his delegation was still awaiting a response from Canada to questions raised by Uganda at the June 2010 meeting of the TBT Committee concerning Bill-32 amending the Tobacco Act.

219. The representative of Kenya said her delegation shared concerns raised by other Members. The regulation appeared to be more trade restrictive than necessary to fulfill a legitimate objective, contrary to Article 2.2 of the TBT Agreement. Nor had the measure been notified to the TBT Committee as required by Article 2.9 of the TBT Agreement. Pursuant to Article 12.3 of the TBT Agreement, which required WTO Members to ensure their technical regulations did not create unnecessary obstacles to exports from developing country Members, and given Kenya's developing country status and heavy dependence on tobacco growing, manufacture and export, the representative requested Canada consider adopting a less trade restrictive approach.

220. The representative of Croatia supported the purpose of the Canadian law, but reiterated his delegation's concern that the law was too restrictive.

221. The representative of Cuba supported the objective of protecting human health, particularly the health of young people. As a country producing and exporting cigarettes and tobacco, Cuba was concerned at how the measure would prevent the marketing of certain tobacco products and cigarettes. She asked Canada to provide more information on this Law.

222. The representative of Canada recalled that the TBT Agreement required that regulations be notified if they may have a significant trade impact. Consideration was given to the commercial impact of the Canadian measure as it was being developed and analysis of the market for consumption of tobacco products in Canada showed that less than one per cent of the market consumed the type of tobacco product that Members had characterized as being American style or American blend. As a result, less than one per cent of the total Canadian market for cigarettes was expected to be impacted. Given the interest in the measure expressed at past TBT Committee meetings, Canada had been carefully following the impact of the measure. To date, Canada was not aware of any American style brands which had been withdrawn from the Canadian market since the measure had come into force.

223. The representative of Canada said the measure became law on 9 October 2009 and that the final additive prohibition came into force on 5 July 2010. Since then, there had been no impact on the cigarette market in Canada. Canada was of the view that because less than one per cent of the market was affected and because there had been no initial impact after introduction of the measure, it did not appear the measure was likely to have a large impact. Canada understood the interest of tobacco exporting Members in the impact of this type of measure if implemented in various markets. But its implementation in the Canadian market did not look like it would have a significant impact.

224. The representative noted from trade figures that many delegations that had intervened in the present or past TBT Committee meetings had either no trade or no recent trade with Canada. This meant WTO Members were looking at the measure as a systematic concern. The representative said Canada was willing to engage with Members bilaterally. He suggested as well that in some cases

Members' concerns were not of a TBT nature but were more of a general policy nature. Canada would pay close attention to the concerns of Members and was taking note of their interventions.

225. The representative spoke to the context in which the measure was developed and its health policy objective. He noted that each year 37,000 premature deaths occurred in Canada as a result of the consumption of tobacco products. Tobacco use was estimated to be responsible for nearly four and a half billion dollars in direct healthcare costs in Canada. This represented a very serious situation. The Canadian approach had been deemed to be the best fit to address the public health problem Canada was facing. The representative reminded the Committee that more information on this subject had been provided by Canada at the March 2010 session of the TBT Committee.

226. The representative commented on studies and scientific documentation that had been examined in the development of the Canadian measure, noting that Canada was of the view that there was sound evidence that certain additives, including flavours, increased product attractiveness of tobacco products. The references included documentation from the tobacco industry itself, which had become available as a result of various litigation exercises, showing that the use of additives help to make tobacco products more appealing to young people. The representative noted that Canada had previously made reference documents available. By showing a sample of some of the documents that had been looked at, Canada hoped to raise awareness of the information available on the topic. Canada was open to further bilateral discussions on concerns in this area.

227. Regarding concerns that the measure established a *de facto* ban of certain types of tobacco products, including reference made to cigarettes that contain Oriental and Burley tobaccos, the representative said analysis carried out prior to the implementation of the measure showed the market in Canada was already next to non-existent for this product. Over a long period of time, consumer taste had not flavoured that particular product.

228. The representative emphasised that the measure had been developed for the Canadian context, where consumers had particular tastes and habits, and that Canada was not suggesting other Members adopt precisely the same model should they choose to address the same public health objective. Canada did not believe all of the concerns raised by Members actually played out when the trade data was looked at. Should Members have further questions or seek further information, Canada was ready to discuss bilaterally

(xvii) Indonesia – Regulation of BPOM No. HK.00.05.1.23.3516 relating to distribution license requirements for certain drug products, cosmetics, food supplements, and food

229. The representative of the European Union welcomed Indonesia's revised regulation on distribution license requirements which had replaced a previous prohibition on the use of substances deemed not "halal" with a labelling requirement. She noted that the regulation had come into force on 5 July 2010 and sought clarification on what would happen to products for which registration had been requested under the old regime, but which were still awaiting approval at the time of the revision. She also asked Indonesia to notify the revised regulation to the TBT Committee.

230. The representative of Indonesia informed the Committee that Regulation of BPOM No. 3516 had been withdrawn and replaced with Declaration BPOM No. 5166 covering the inclusion of information on certain sources, alcohol contained and expiry dates on the marking or labelling of drugs, traditional medicines, food supplements and food. The representative was of the view that, because the previous Regulation had been revoked, the issue of the halal distribution license was no longer valid. Notification would be made in due time.

(xviii) Indonesia – Decree No. Kep-99/MUI/III/2009 relating to Halal certification

231. The representative of the United States said the United States respected Indonesia's right to regulate trade in halal products. But he reiterated concerns that the regulations should have been developed in a transparent manner. Basic concerns of the United States were: (i) the lack of notice that a new list of certifiers would be posted and (ii) uncertainty over the criteria for becoming accredited by Indonesia. The representative said this left United States certifiers with many questions as well as uncertainties, including whether the relevant authority, MUI, would need to approve US production facilities or the certifiers of the production facilities.

232. The representative said the United States was of the understanding that various halal certifiers in the United States had contacted Majelis Ulama Indonesia (MUI) regarding inspection visits. The United States would appreciate being notified by MUI of any trips it might make to the United States to inspect halal certifiers, requesting transparency in the inspection process to ensure that no halal certifiers would be excluded from an inspection visit. The representative noted that it was not too late for Indonesia to notify to the WTO the draft criteria for accrediting certifiers.

233. The representative of Indonesia noted that the Indonesia Council MUI had had bilateral discussions with the United States in April 2010 in Jakarta. At that time, the United States had encouraged Indonesia to recognise not only halal certifiers and agencies for cattle slaughtering, but also for poultry and lamb. MUI had informed that Indonesia could not recognize halal certification agencies for poultry and lamb slaughtering because the slaughtering had been done by machines. However, MUI would conduct a visit to the US certification agencies to see how poultry and lamb slaughtering was done. MUI had communicated to the US council the criteria and requirements for halal certification agencies in foreign countries, as contained in the attachment 2 of the Decree of the Indonesia Council of Ulama No. D410 number 2009.

(xix) Thailand – Health Warnings for Alcoholic Beverages

234. The representative of New Zealand thanked Thailand for hosting a plurilateral meeting which allowed Members an opportunity to ask questions regarding Thailand's labelling requirements for alcoholic beverages, including the basis on which they had been developed. New Zealand understood Thailand was reviewing the measure, taking into account concerns raised by Members.

235. The representative said New Zealand supported the right of Thailand to regulate to prevent alcohol-related harm, but there were less trade restricted means of pursuing the objective. New Zealand was concerned about significant additional costs the measure would impose on exporters and how much of that cost would arise from differences in Thailand's requirements *vis-à-vis* requirements in the rest of the world. The representative noted that the World Health Assembly's "Strategy on the Harmful Use of Alcohol" provided guidance, indicating that there should be a proper balance between policy goals in relation to the harmful use of alcohol and other policy goals.

236. The representative of the United States reiterated his delegation's concerns with Thailand's proposed warning label requirements for alcoholic beverages. He hoped Thailand would favourably consider the United States' comments submitted with respect to the notification and the supporting study. While the United States appreciated Thailand's efforts to substantiate its proposed alcohol regulation with the technical report provided in June 2010, it still had many unanswered questions.

237. The representative of the United States raised concerns regarding the size of the warning label in proportion to the bottle, and its potential to interfere with legitimate trademarks on the bottle and the ability to display useful information on product labels, such as information necessary to distinguish one product from another. The representative repeated a previously raised concern that the requirement that warning statements be rotated every 1,000 bottles would present a very onerous

problem for industry. He requested that the implementation period be extended to allow for the major modifications proposed.

238. The representative also noted that in October 2008, Thailand notified changes to its alcoholic beverage warning statement requirements, which indicated that the Ministry of Public Health would issue a proposal to modify the warning statements on alcoholic beverage containers to reflect the change in the legal drinking age in Thailand from 18 to 20 years of age. He asked for clarification as to whether requirements to change the drinking age would be incorporated into the new labelling requirements.

239. The representative of the European Union appreciated Thailand's transparency on this issue, and its willingness to discuss with trade partners. The EU invited Thailand to provide an update on the foreseen revision of the requirement which had been announced by the Thai delegation in the previous weeks. The European Union recalled its concerns that had been expressed in previous meetings, and indicated that it would continue to follow this matter with interest.

240. The representative of Chile thanked Thailand for meeting with her delegation and was appreciative that the Thai authorities were taking their comments into account. Chile supported the objective Thailand was seeking to achieve with the measure but, according to Chilean experts, it was not the consumption of alcohol *per se*, but rather excessive consumption which could trigger the effects mentioned in point 6 of the document delivered by Thailand.

241. The representative of Chile said regular and moderate consumption of wine could be beneficial for consumers and she suggested a label on alcoholic beverages reflecting this could be a very useful measure. Similarly, a whole range of food products could be dangerous for health if consumed excessively. The representative noted that the measures proposed by Thailand would be very costly for many Members.

242. The representative of Canada reiterated Canada's concerns that the proposed measure had been constructed in a way that could be more costly than necessary to achieve the objective, noting also that Canada did not have difficulty with the objective itself.

243. The representative of Australia welcomed information that Thailand was undertaking a review of the measure. The representative requested an update on the review process, timeframes, and whether the updated measure would be made available to WTO Members for consideration.

244. The representative of Mexico sought an update from Thailand on progress of the revision and its implications.

245. The representative of Thailand informed the Committee that concerns raised by Members would be taken into account by the Department of Disease Control during the review of the proposed measure. She explained that alcohol is a non-ordinary commodity in Thailand, where drinking is not part of the culture. The two religions practiced by 99 per cent of Thais discouraged alcohol consumption among followers. Although increasing significantly, only 30 per cent of Thai adults could be classified as current drinkers. However, the average consumption volume per Thai drinker was double the figure from Western countries. Alcohol consumption had directly and indirectly led to extensive impacts on Thai society in addition to public health impacts. As a result, at the aggregate level, the cost of alcohol consumption that society had to bear was much higher than its public benefits. As such, comprehensive measures, including the pictorial warning label were of the greatest need to control the impacts of alcohol consumption.

246. The representative of Thailand said protection of human health, safety and life, and not trade obstruction, had been the sole objective of the measure. She stressed that because drinking patterns

and drinking mentality differed from country to country, tackling the problem required adjustment. While all countries faced alcohol advertising, Thai drinkers had been bombarded with subtle marketing strategies. Marketing, including advertising through beverage packaging, had been the most important vector for the alcohol epidemic in Thailand. The representative said miseries of life, disabilities and death, all depicted on the pictorial warnings, were not exaggerating the real impacts of alcohol consumption in Thai society. The frequency of which these impacts made front page news meant that the government could not ignore these incidences.

247. The representative said the pictorial warning label was expected to have three levels of impact. First, it would provide correct information and understanding concerning health risks and potential dangers at the time of purchase. Second, it would increase knowledge, attention and awareness. Third, the pictorial warning label was expected to spell out the non-ordinary characteristics of alcohol and caution people not to underestimate its impacts. Thailand was of the view that even though the pictorial warning label of alcohol packages had not been a popular initiative, research evidence from tobacco control experiences had proved the success of pictorial warning labels.

248. The representative reminded the Committee that alcohol drinking had been a national problem in Thailand, and tackling it required comprehensive and consistent action. Thailand planned to adopt and continue informative and educative measures and campaigns in parallel to the labelling requirement. The representative reconfirmed that all concerns raised by Members would be taken into account, and the outcome of the review would be notified to Members as soon as it became available.

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

249. The representative of Japan said the United States' proposed restrictions on the transportation of lithium batteries were inconsistent with the UN Recommendation on the Transport of Dangerous Goods and the International Civil Aviation Organization (ICAO) Technical Instructions and would negatively impact trade. He noted that on 8 October 2010 the Federal Aviation Administration had issued a Safety Alert for Operators (SAFO) that advised air carriers to pay special attention to the handling of Class 9 hazardous materials, including lithium batteries, in view of complying with existing regulations. The representative said Japanese industry was concerned that this SAFO may be an indicative step towards a strict final rule. Japan requested that the United States regulation be made consistent with the UN Recommendations and the ICAO Instructions. Additionally, Japan asked the United States to exempt lithium batteries with less than 50 per cent "state of charge", since in the draft measure itself, the United States had made reference to studies indicating that such low-charged batteries could be considered to fulfil existing air transportation safety standards.

250. The representative of Korea proposed that the United States ensure harmonization and compliance with the UN and ICAO requirements. Despite the non-alignment of the procedures of these bodies with the TBT Committee's 2000 decision mentioned by the United States, in particular the failure to follow openness and consensus principles during the standards development process, Korea believed these requirements were an effective way to secure safer transportation of Li-Ion batteries.

251. The representative of Korea said if the Pipeline and Hazardous Materials Safety Administration (PHMSA) chose not to adopt the existing UN and ICAO regulations, Korea urged the United States to include an exemption for lithium based secondary cells (lithium-ion, lithium-polymer, etc.) that were shipped at no more than 50 per cent of charge. According to reports referred to in the United States' draft measure, the severity of the hazard arising from an internal short circuit was strongly affected by the state of charge. Fires had been shown to have a minimal effect on bulk packaged lithium ion cells with less than 50 per cent state of charge.

252. The representative of the European Union said the draft measure of the United States would lead to unnecessary burdens for producers with regard to the production and packaging of a wide range of products, and would require costly changes within the logistic chain. She noted that the United States' claimed that the respective UN recommendations and ICAO technical instructions could not be considered as an international standard in the sense of the TBT Agreement and that the respective bodies were dominated by EU Member States. But this did not explain why the United States was opting for a unilateral approach while issues of relevance to the draft measure were being discussed within the framework of these specialized international organizations. The representative pointed out that in its draft measure, the United States had maintained that its proposal was meant to be largely consistent with the existing UN and ICAO regulations, which the European Union believed was not the case. Should the United States opt for a unilateral approach, the European Union requested the implementation period be extended to 18 months.

253. The representative of China said her delegation submitted comments to the United States in May 2010 and continued to await a written reply. The United States' draft measure would impose stricter restrictions on the handling of lithium cells and batteries which would significantly impact international trade. China requested scientific justification for the elimination of the currently existing exceptions to handling certain types of lithium batteries. The representative further commented that the envisaged implementation period of 75 days would cause difficulties for manufacturers especially of developing country Members to adapt their production to the new requirements of the United States. China asked the United States to extend the transitional period to at least six months.

254. The representative of the United States reiterated that the safe transportation of lithium batteries aboard aircraft was a serious issue for its regulators, who wished to minimize the risk of catastrophic accidents. Currently, United States regulators were reviewing all comments received and were taking them into account as a final measure was developed. The draft measure was subject to a formal review process of the US Office of Information and Regulatory Affairs (OIRA) pursuant to Executive Order 12866, under which any interested stakeholder was entitled to request a meeting with the OIRA, which would also be attended by US regulators and USTR. Several of these meetings had been held over past weeks with various stakeholder groups including battery manufacturers, transportation companies and retailers. A list of all meetings, including the names of participants and the materials provided, could be found in the United States' online electronic docket. Regarding written replies to submissions, as requested by China, the representative noted that the United States was legally required to publish a detailed reply to all significant comments alongside the final regulation, which would explain whether the United States' regulator agreed or disagreed with comments made, and indicate any changes that had been made to the final regulation as result of these comments. As the United States was still in the process of considering comments, no answers could be provided at the moment, yet potentially the EO 12866 meetings could serve as a forum to solicit additional comments.

255. The representative of the United States confirmed that US regulators were actively participating in the work of the ICAO and UNECE and sought to use their documentation wherever possible. However, in this case, they had expressed concerns that their views were not actually being taken into account, in part also because European Union member States had a majority in the Committees and formed set positions prior to meetings. Furthermore, these bodies were not open in a non-discriminatory fashion to all WTO Members. The United States believed that these procedural issues had systemically led to a situation where existing standards did not cover certain batteries that did pose serious safety concerns according to the United States' regulatory authorities who had analysed them. The United States expressed hope that the ICAO and UNECE would take steps to try to resolve these procedural issues.

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

256. The representative of the United States noted that Brazil had issued a proposed revision to this regulation in September and several matters the United States had earlier raised had been addressed. However, a number of issues remained unresolved. The representative noted the proposed revision omitted a previously included requirement prohibiting the use of abbreviations for common terms. He requested confirmation from Brazil as to whether abbreviations for common terms would be allowed.

257. The representative said the United States agreed with the intent behind Brazil's plan to prohibit illustrations on labels which could mislead consumers. He referred to Article 8 of the measure stating that labels that displayed a drawing, figure or illustration of any ingredient used to prepare the beverage must indicate all of the ingredients of animal or plant origin, regardless of quantity. The representative requested clarification as to whether the proposed revision to the regulation retained the prohibition against illustrations or statements on the label of ingredients that were not present in the composition.

258. The representative further sought confirmation that the provision concerning illustrations would not apply to fanciful drawings and illustrations which were well-established elements of trademarks and which did not purport to represent ingredients. Examples included the Grey Goose logo which pictured flying geese, the "striding figure" portrayed in the Johnnie Walker logo, and the Bacardi bats, which represented the fruit bats that inhabited the distillery where the rum had been first produced.

259. The representative sought explanation of the requirement that cans bear the statement "This container must be washed prior to consumption". Specifically, did this requirement address a health or safety concern? Also, the representative expressed concern that the requirement in Article 13(II) of the draft proposal would effectively bar the use of the trademarks of certain internationally-traded spirits brands, including spirits produced in the United States. Even where such terms had not been incorporated expressly into a registered trademark, some of them have been used for years without incident on the labels of internationally-traded distilled spirits. The representative requested Brazil to explain the rationale for its decision to restrict the use of such terms.

260. The representatives of Mexico and the European Union requested an update from Brazil on the revision of the proposal.

261. The representative of Brazil informed the Committee that Brazilian authorities were still examining comments received on the draft regulation on beverage labelling. Members comments would be taken into account before publication of the final measure. The representative said although the deadline for submitting comments on the draft proposal had expired, Brazilian authorities remained available for questions concerning the proposal's content. Authorities in the Ministry of Agriculture had received visits from representatives of other countries and remained open to dialogue.

262. The representative of Brazil said the draft measure had the legitimate objective of guaranteeing an adequate level of protection and information to consumers, without creating an unnecessary obstacle to the regular flow of beverage exports to Brazil. Requirements in the draft regulation would apply equally to domestic and imported alcoholic beverages.

263. The representative explained that because comments from Members were still being processed, it was not possible to provide definitive answers on most topics. However, he provided some preliminary remarks. On the abbreviations provision, the objective was to avoid consumers being misled. On illustrations, the objective was to avoid illustrations leading to confusion among consumers. The representative assured the United States there was no intention to prohibit well-established pictures associated with trademarks, such as the striding Johnnie Walker figure.

Regarding expressions such as "hand-crafted", "colonial" or "home-made", the draft regulation aimed to prevent their indiscriminate use. Such expressions could sometimes mislead and confuse consumers, giving the wrong idea of superior product quality.

264. The representative reiterated that comments received would be taken into account and Brazil would try not to make the provision restrictive of trade. As soon as the revised proposal was published, it would be notified to the Committee.

(xxii) Turkey – New Conformity Assessment Procedures for Pharmaceuticals

265. The representative of the United States said his delegation continued to find problematic certain aspects of Turkey's decree regarding conformity assessment procedures for pharmaceuticals. He urged Turkey to take immediate steps to restore market access for safe, high quality pharmaceuticals.

266. The representative of the United States noted that the current measure had never been published in Turkey's Official Gazette and had not been notified to the WTO. Other recent measures relating to medical devices, biotechnology labelling, and inspection procedures for IT products had also been published in final form without WTO notification and without opportunity given for Members to comment. The United States was concerned at the trend and hoped Turkey would take steps to rethink its notification procedures.

267. The representative informed the Committee that Turkey had provided the United States with a list of recalled pharmaceutical products which it claimed had been the impetus for the decree on good manufacturing practices. The United States was still examining the list. However, the United States was of the view that product recalls were a critical aspect of ensuring prompt and effective responses to concerns raised over the safety of a pharmaceutical product. The fact some US products had been the subject of recalls should be viewed as a sign that the system to safeguard public health was working.

268. The representative said the US Food and Drug Administration could be alerted to problems with particular products in several ways, for example: a company could discover a problem and contact FDA as required by law; an FDA inspection of a manufacturing facility may determine if there was a problem that may warrant a recall; or FDA could receive reports of health problems through various reporting systems and from foreign counterparts.

269. The representative urged Turkey to consider the following measures to alleviate the current blockage of pharmaceutical exports: first, process registration applications (as filed) that were submitted prior to March 2010 and not apply the GMP decree retroactively; and second, give priority in the inspection and registration process to innovative drug applications that provide new medicinal therapies to patients in Turkey. The representative further proposed to hold technical discussions with Turkey to discuss and quickly resolve these issues.

270. The representative of the European Union reiterated his delegation's concern with Turkey's Good Manufacturing Practices requirements for pharmaceuticals which came into force on 1 March 2010. European GMP certificates for medicines for human use had been accepted by Turkey for many years. However, EU manufacturers were now requested to submit extensive additional documentation related to manufacturing sites and also had been subject of on-site inspections by Turkish Authorities.

271. The representative of the European Union explained that, in order to obtain EU GMP certificates, EU manufacturers had to be inspected by the competent authorities in EU member States. Turkey had not provided any indication as to whether any problems were encountered with EU GMP-

certified products on its market. This caused the European Union to question the need for a second on-site inspection and need for the extensive documentation to be submitted before an inspection. The European Union was of the opinion that those additional administrative requirements would not provide any further protection of public health in Turkey and could delay the placing on the market of pharmaceutical products potentially important for the health of Turkish patients.

272. The representative urged Turkey to revert to its previous practice and recognize EU GMP standards and certificates without additional administrative requirements. The representative explained that, according to information received from EU economic operators, the introduction of the present measure on such short notice had already led to significant delays in the registration of new pharmaceutical products in Turkey, in particular since the Turkish authorities did not appear to have the necessary capacity to carry out all the necessary inspections and deliver the required GMP certificates in a reasonable time.

273. The representative said if Turkey continued to impose the requirements, the European Union would urge Turkey to take steps to ensure economic operators were not faced with overly burdensome requirements. In particular, the European Union encouraged Turkey to: align the requested GMP inspection and documentation requirements with international practices; improve GMP inspection capacity; provide market authorizations within a defined and shorter timeframe; and give priority to innovative drugs in the GMP inspection process.

274. The representative expressed disappointment that the measure was not notified to the Committee despite being a technical regulation. Furthermore, the three month period between publication and entry into force had been too short for economic operators to be able to comply with the requirements.

275. The representative of Switzerland reiterating previously raised concerns. He requested Turkey inform Members on the outcome of the survey, announced by Turkey in previous Committee meetings, supporting the new policy. In particular, Switzerland sought information on quality problems with pharmaceuticals manufactured according to international principles. The representative said in general the competent Swiss authorities accepted GMP-certificates from Members of the Pharmaceutical Inspection Cooperation Scheme as proof of GMP-conformity. Switzerland encouraged Turkey to adopt a similar solution.

276. The representative of Turkey said the relevant regulation had been introduced with the aim of protecting public health and human life by ensuring the effectiveness, safety and quality of pharmaceutical products. The announcement by the Ministry of Health had been made well before entry into force of the implementation change, to provide sufficient time for interested parties to adjust to the new situation. Furthermore, on 31 December 2009, the Ministry of Health clarified through a notification in its official website that GMP certificates accepted by the Ministry would either be ones provided by the Ministry through its own inspections, or those provided by the Health Authorities of other countries with which a Mutual Recognition Agreement existed. The representative said all countries were treated equally, with the GMP inspection requirement being applied to all pharmaceutical plants, whether domestic or foreign. The representative added that the Turkish Ministry of Health had sufficient capacity and personnel to conduct GMP inspections. As encouraged by the TBT Agreement, the Ministry of Health was open to conclude Mutual Recognition Agreements with interested parties.

(xxiii) Italy – Dairy products (G/TBT/N/ITA/13)

277. The representative of New Zealand reiterated her delegation's concern with the proposed Italian law on dairy products notified to the Committee in February 2010, including provisions providing for a ban on the use of protein in cheese making and the proposal to introduce mandatory

country of origin labelling for milk and dairy ingredients. The proposal was not consistent with relevant international standards, including the CODEX General Standard for cheese. Nor would the proposal be the least trade-restrictive means to achieve its stated objective, including fraud prevention. The representative understood the draft law remained subject of discussions between the Commission and Italy and she encouraged the Commission's continued engagement on the issue. She requested an update from the European Commission and asked that ongoing deliberations take Members' concerns into account.

278. The representative of Australia supported the concerns raised by New Zealand and requested an update.

279. The representative of the European Union said the Commission and Italian authorities were discussing the measure within the framework of internal notification procedures. Since the discussions were still underway, she could not provide further information on the measure. The European Union would be available to provide clarification once the internal consultation process was concluded.

(xxiv) Viet Nam – Alcoholic Beverages (G/TBT/N/VNM/10)

280. The representative of the European Union raised the issue of Viet Nam's new proposal on the National Technical Regulation on Food Safety for Alcoholic Beverages. Viet Nam had sent a detailed reply to comments submitted by the European Union in June 2010, indicating Viet Nam's willingness to take into account most of the European Union's concerns, notably to eliminate the maximum limit for aldehydes in distilled and mixed spirits. The European Union was grateful for the constructive stance of the Vietnamese authorities. In addition, the representative requested an update on the state of play of the draft Regulation and asked when a revised text would be made available to the TBT Committee.

281. The representative of the European Union also sought clarification on the administrative requirements in the draft Regulation. For example, what would the "compliance announcement" entail? How would certification be obtained? Which products would require certification stamps? What test would be used to attest compliance? The representative said these questions were particularly relevant for the European Union since, upon entering Viet Nam some shipments of European wines had been required to present an analysis certificate on allowable heavy metal limits, the legal basis of which was unclear.

282. The representative of Australia confirmed Australia's interest in Viet Nam's proposed regulation on food safety for alcoholic beverages. Australia welcomed the response received from Viet Nam in June 2010 in which Viet Nam undertook to reconsider areas of concern in the draft regulation in order to bring them in line with international standards. The representative requested information on the redrafting of the proposed regulation and asked whether it would be notified to the TBT Committee for comment.

283. The representative of Chile stressed the importance of Viet Nam's conformity with international requirements and regulations. Chile requested information on the current state of play and asked when the final version of the regulation would be ready and if comments would be taken into account.

284. The representative of Viet Nam said his country was in the process of examining comments from Members and incorporating them into a new draft. Viet Nam would update the Committee on further developments in due course. No specific deadline had been set.

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

285. The representative of India reiterated concerns on the European Union's 2001 and 2004 amended Directives on Traditional Herbal Medicinal Products. The European Union's failure to notify either of the Directives to the WTO was a systemic concern.

286. The representative of India said his delegation was concerned over a provision in the Directives concerning extensive documentary evidence to be provided on physico-chemical, biological, micro-biological and pharmacological tests as well as onerous data requirements on quality and safety for the purposes of obtaining marketing authorization or registration. India considered the provision constituted an unnecessary obstacle to trade and may not have been based on scientific principles. Moreover, the Directive requirement was excessive and not limited to what was reasonable and necessary. In effect, it denied market access to India's ayurvedic products.

287. The representative informed the Committee that a proposal was being debated in the European Union for an inspection regime on traditional herbal medicinal products. Such a regime would create an obstacle to exports of active pharmaceutical ingredients (APIs) and may affect their availability in the European market.

288. A further concern raised by the representative of India was that suppliers were required to show 30 years of traditional use, including 15 years of traditional use in the European Union, in order to establish the efficacy of the medicinal product. Such requirements were difficult to fulfil and could result in a *de facto* ban on imports of Traditional Herbal Medicinal Products.

289. The representative said the Common Technical Document (CTD) format under the Directive appeared to be acceptable for single herbs, but may not be appropriate for multi-component traditional medicinal formulations. It would be almost impossible to provide information with respect to multi-component traditional medicinal formulations in the CTD format, even if the products had otherwise been eligible as a traditional herbal medicinal product.

290. The representative said a large number of suppliers of traditional herbal medicinal products were small and medium sized enterprises (SMEs), for whom the cost of registration under the Directive had been prohibitively high and would have created market access barriers. If registration-related costs were broken down into the various components such as analytical development, galenical development, stability testing, dossier compilation and dossier submission, it was estimated they would amount to more than €150,000 for a single ingredient product.

291. The representative observed that the Directive had not recognised ayurvedic products that complied with provisions of the Ayurveda Pharmacoepia of India and which had been certified by bodies accredited by Members of ILAC/IAF mutual recognition agreements or arrangements. The scope of the Directive had been limited to purely herbal products and many of the Ayurveda, Siddha and Unani products, or "ASU" products, which contained a combination of ingredients which were of mineral and animal origin, were denied registration under the Directive.

292. The representative said India was of the view that quality and stability guidelines for herbs under the Directive were inappropriate for multi-component traditional herbal products. Insistence on quantitative determination, or Bio Assays, in poly herbal compounds was technically not feasible for any poly herbal formulations having more than three to four ingredients.

293. The representative said Article 16c(4) of the 2004 Directive prescribed an alternate process, of a Committee referral, for seeking registration of traditional herbal medicinal products when the product has been in use in the European Union for less than 15 years. However, the guidelines and parameters on how the Committee would assess the product had not been detailed. In India's view,

the derogation from the requirement of showing 15 years prior use in the European Union to establish efficacy of a product indicated that the 15 years prior use requirement was itself not sacrosanct and may not have been based on sufficient scientific evidence. The representative asked if the European Union had considered any alternate methods or procedures for ascertaining the safety, quality and efficacy of traditional medicinal products when formulating procedures under the Directive. Noting that the 2004 Directive provided for registration of over-the-counter products, the representative sought clarity on the status of other herbal medicinal products which may fall under the category of prescription products.

294. The representative of China reiterated concerns on the European Union's Directive on Traditional Herbal Medicinal Products. China was concerned at the short transitional period and requested an extension of the transitional period for simplified registration to the year 2019, to give Chinese companies adequate time to fulfil registration requirements. Only one Chinese enterprise had so far registered its products through the simplified procedure; this illustrated the complexity of the requirements.

295. The representative recalled that in previous meetings, the European Union had informed the Committee that once the transitional period finished in March 2011, no unauthorized herbal medicines could be sold on the European market as medicinal products, though they could continue to be sold as standard products. Chinese enterprises had learned from authorities of some European member States that most Chinese traditional medicine products were not in the list of standard products like foodstuffs. Therefore, they would have to apply as new resource foodstuff and would have to go through a complex procedure, taking quite some time. To avoid interruption of normal trade, China requested the European Union reconsider China's request to extend the transitional period to 2019 and also provide detailed guidance for Chinese enterprises to follow.

296. The representative of Ecuador noted that his country exported traditional herbal medicinal products. He encouraged the European Union to provide more information about the Directive and its scope. Ecuador was particularly interested in rules and/or restrictions which the measure would impose on importation or commercialisation of traditional herbal medicinal products. Ecuador was also interested in the list of medicines to be covered by the measure. In Ecuador's view, the measure appeared to be in contravention of Articles 2.1, 2.9.1 and 2.9.2 of the TBT Agreement, and thus potentially was an unnecessary barrier to trade.

297. The representative of the European Union said bilateral discussions with India and China had helped the European Union better understand Members' concerns.

298. The representative of the European Union provided background on Directive 2004/24/EC amending the standard authorisation procedure (as regards traditional herbal medicinal products) first laid out in 2001 for medical products. The Directive provided a simplified registration procedure for traditional herbal medicinal products where the manufacturer was exempted from providing a number of tests and clinical trials which had been required under the standard authorisation procedure.

299. The representative said Article 16 set out criteria that products had to fulfil in order to be eligible for the simplified procedure. This included, *inter alia*, evidence that the product had been in use throughout a period of at least 30 years, including at least 15 years within the Community. If the 15 year requirement was not met but the product had otherwise been eligible for the simplified registration, the product would be referred to the Committee for Herbal Medicinal Products. The Committee would then verify if the other eligibility criteria had been fulfilled and in that case, it would establish a Community Herbal Monograph to be taken into account by the member States when evaluating requests for registration. The Directive also foresaw the establishment of a list of herbal medicinal products by the Commission, on the basis of a recommendation of the Committee for Herbal Medicinal Products (HMPC). This list, in practice, meant the manufacturer would not have to

justify the 15 years use requirement anymore, nor would it have to submit safety data. It would only have to demonstrate the quality aspects of the product. The European Union was of the view that the 15 year requirement did not constitute an obstacle for manufacturers to benefit from the simplified procedure.

300. The representative recalled that the 2004 Directive gave manufacturers seven years to submit to the relevant authorities a registration request for their products. As of March 2011, herbal medicines which had not yet been authorised or registered would no longer be sold as medicinal products in the European Union. Products not fulfilling the definition of medicinal products, and not containing medical claims, could be marketed as standard products.

301. The representative said the European Commission in 2008 started an internal reflection process on the registration of traditional herbal medicines; this concluded with the drafting of a report. In the report, the Commission stated that it was prepared to consider extending the simplified registration procedure to products containing substances other than herbal substances and that more experience with the requirement for at least 15 years use in the Community would be gathered with a view to assessing its necessity. Any changes would require legislative action.

302. Regarding non-notification of the Directive, the representative explained that the proposal had escaped their radar screen and had not been notified to the Committee. Nevertheless, both India and China had learnt about the Directive through other channels which had enabled both parties to have exchanges with EU authorities for several years already. The European Union said lack of notification of the measure did not amount to a systemic problem.

(xxvi) China – Textiles (G/TBT/N/CHN/20 Rev.1)

303. The representative of the European Union reiterated her delegation's concerns with China's new national General Safety Technical Code for Textile Products. The draft laid down a limit PH value as well as a level for colourfastness and required that textiles could not have a peculiar odour. In the view of the European Union, the mandatory requirements, which did not impact consumer's health or safety, were more trade restrictive than necessary.

304. The representative of the European Union informed the Committee that, in a written reply of 29 September, China claimed that PH values of textiles differing from the one in the draft would make the skin more susceptible to suffering from pathogens, that bad colourfastness would permit the entering of carcinogenic and allergenous dyestuffs into the body, and that the odour requirement was necessary to avoid excessive chemical residues or risk of mildew. While appreciative of the explanations provided by the Chinese authorities, the European Union's view was that the stated risks should be confirmed by scientific evidence. The representative invited China to provide supporting scientific evidence. She further sought information on whether the measure already been adopted or was still under discussion.

305. The representative of China recalled that China notified its National General Safety Technical Code for Textile Products to the WTO in February 2010 and provided a 60 day comment period in line with TBT Agreement transparency requirements. China also replied to comments submitted by the European Union. As well, the European Union had raised questions as a specific trade concern during the June 2010 TBT Committee meeting and had talked extensively with China on this issue in bilateral discussions. China was of the view that it had already provided clear, scientific-based answers to the European Union on concerns raised over PH value, colourfastness, odour, and prohibition of carcinogenic enzymes. For example, regarding aromatic enzymes, China's reply of 29 June cited animal test results from international cancer research institutes to demonstrate a scientific basis for such prohibition. China understood the concerns of the European Union related to

technical issues; the representative suggested such issues be left to professionals and departments in charge.

306. The representative of the European Union clarified that she had not asked for scientific evidence on the aromatic enzymes question but had instead focused her intervention on the PH value, odour and the colourfastness. The European Union would appreciate receiving the scientific evidence China mentioned.

(xxvii) United States - Conditions and Criteria for Recognition of Certification Bodies for the Energy Star Program

307. The representative of Korea expressed appreciation that many of Korea's comments and suggestions on the Conditions and Criteria for Recognition of Certification Bodies for the Energy Star Program were taken into account by the United States. He welcomed removal of the requirement that certification bodies have a substantial North American presence. However, Korean certification bodies were still concerned that the requirement relating to availability of personnel to the agency and provision of information would still necessitate that certification bodies or personnel have a presence in North America. The representative invited the United States to clarify the requirement.

308. The representative of the European Union said her delegation was following up on this issue bilaterally with the United States. She expressed disappointment that the United States had moved away from a self-declaration system to third party certification.

309. The representative of the United States noted bilateral discussions with Korea and said many changes had been made to the accreditation and other conformity assessment procedures in response to Korea's comments and requests. He requested Korea be specific as to their additional concerns. The United States was of the view that the requirement to have personnel available to answer questions was a reasonable one. He confirmed that the provision for a North American presence had been deleted from the proposal.

310. In response to comments from the European Union, the representative of the United States noted that the system was voluntary. Producers could still test outside the United States, whether in their own facilities or in third party laboratories, in accordance with the procedures, and goods could continue to be shipped to the United States regardless of whether they had met the Energy Star criteria.

311. To illustrate, the representative noted that the United States had had several investigations that identified vulnerabilities and potential for fraud in the current qualification process of the Energy Star Program. As well, there had been numerous consent decrees that US regulators had signed with producers who had been found to be selling products in the market with an Energy Star label that did not meet the criteria. Under the terms of the consent decrees, which could be found online, companies had agreed voluntarily to stop using the labels.

312. The representative said based on what had happened in the market place and the potential for fraud, US regulators were of the view that they had little choice but to add these new procedures to ensure products being purchased by consumers actually met the criteria. It was important to uphold the value of the Energy Star brand in the United States, which had been very successful and showed that voluntary approaches could be taken to achieve legitimate objectives - sometimes even better than through the use of mandatory measures.

(xxviii) Colombia – Shelf life Requirements for Milk Powder

313. The representative of the European Union reiterated concerns expressed in previous meetings relating to a Colombian Decree, dated 13 May 2010, requiring imported milk powder to have a minimum shelf-life of 12 months. This was a six month increase over the previous requirement. The representative observed that the decree had already entered into force, without being notified to the TBT Committee.

314. The representative said the European Union was concerned that the extension of the shelf-life period could impair European exports of milk powder to Colombia. According to the European Union, the normal shelf-life of whole milk powder was 12 months from the date of production. Quarantine time and shipping period usually took up to two months. This meant that if the length of the shelf-life started from the date of commercialisation, as established in the Colombian decree, it would become impossible to export the product without incurring additional costs to extend the shelf-life of the milk powder through specific and costly treatments.

315. The representative recalled that at the previous TBT Committee meeting her delegation asked Colombia to clarify several aspects of the decree. The European Union also submitted a request to the Colombian TBT Enquiry Point seeking an update. Colombian authorities were still to respond. The representative asked Colombia to identify the legitimate objective being pursued through the measure and to clarify if domestically produced milk powder was also subject to the minimum shelf-life requirement.

316. The representative of Colombia informed the Committee that the Colombian Ministry of Social Welfare was working on a draft resolution in which a number of measures would be adopted. As soon as the relevant decision was taken, Members would be advised.

317. The representative said Colombia had not adopted any decree related to powdered milk. The draft notified for comments (G/SPS/N/COL/126/Add.6 and G/TBT/N/COL/83/Add.6) was a draft resolution to modify Resolution 2997 of 2007. The representative said Resolution 2997 establishes technical requirements for powdered dairy products as foodstuffs for human consumption. The draft resolution was notified through the Colombian TBT Enquiry Point on 11 June 2010 and a deadline for comments was fixed on 10 September 2010.

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

318. The representative of the United States reiterated a longstanding concern that China was not permitting US suppliers to use competent conformity assessment bodies, for example, testing laboratories or product certifiers located outside the territory of China, to demonstrate that US products comply with Chinese technical regulations, including the China Compulsory Certification (CCC) scheme. According to US estimations, at least 20 per cent of US exports to China must obtain the CCC mark prior to entering the Chinese market. However, there is typically only one designated certification body in China authorized to perform testing, inspection and certification activities for any given product within the scope of the CCC system. Article 32 of Decree No. 390 required at least two certification bodies designated for each field of products listed in the CCC catalogue. However, in reality there was only one certification body per field of products. This had led to additional costs, burdens and delays for US exporters and was especially prejudicial to small and medium-sized enterprises.

319. The representative of the United States noted that since Chinese conformity assessment bodies did not generally have a presence outside China, US companies exporting to China had to arrange and fund the trip of a Chinese agent to the manufacturer's location for pre-market inspections.

Moreover, after receiving the CCC mark, US exporters also needed to comply with the requirement of subsequent annual inspections and pay for the certification and testing of their products for a second time in China. The representative referred also to US industry complaints that Chinese certification bodies often introduce or change implementing requirements without advanced notice and without providing opportunity for others to comment on such requirements. This occurred even after US products had obtained market access. As well, according to US industry, there were inconsistent post-market surveillance requirements implemented by provincial authorities due to differing interpretations of CCC labelling requirements.

320. The representative recalled that only one US conformity assessment body had entered into an MOU with China. This allowed the body to conduct follow-up factory inspections (but not primary inspections) of manufacturing facilities that make products for export to China and which require the CCC mark. However, the representative understood China was not willing to grant rights to other US-based conformity assessment bodies, under the argument that the Chinese Government entered into only one MOU per country. The United States urged China to take positive, trade-facilitating steps, whether through the reinterpretation or the modification of Decree No. 390 or through the use of some other legal instrument, to liberalize its approach to recognizing competent conformity assessment bodies - regardless of their location. One step in this direction would be the use of ILAC and IAF accreditation as the basis for recognition of facilities.

321. The representative acknowledged positive bilateral discussions in which China had invited the United States to request a technical discussion with the Certification and Accreditation Administration of China (CNCA). The United States intended to submit such a request.

322. The representative of China observed that this was a recurrent issue. China had on previous occasions explained its views to the United States including in bilateral discussions and in the TBT Committee. The representative re-emphasized a number of points. First, in China's view the Regulation of the PRC on Certification and Accreditation was consistent with principles of the TBT Agreement. Second, China had concluded a total of forty bilateral and multilateral cooperative documents with twenty three countries. Moreover, China had identified ILAC and MRA as a key technical base for mutual recognition between China and other countries. The representative said his government recognised 168 conformity assessment bodies, including foreign certification bodies. In addition, in recent years the Chinese Government had taken a series of measures to simplify the CCC certification process and had reduced applicable fees. These actions were taken to promote China's trade with WTO partners.

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

323. The representative of the United States recalled that in the previous TBT Committee meeting, the US delegation raised issues concerning Korea's requirements for the certification of solar panels. Since July 2008, Korea had required that solar panels to be sold in Korea be certified by the Korea Management Energy Corporation (KEMCO). Korea's standard KS 61646 for the design qualification and type approval of thin-film solar panels appeared to draw from international standard IEC 61646. However, the United States was concerned that Korea modified the standard so that it only applied to a certain type of thin-film solar panels, i.e. amorphous silicon (A-Si) solar panels, and not to other types of thin-film solar panels. There were many other types of thin-film solar panels currently being traded globally as well as others under development. Since the KS 61646 standard applied only to one type of solar panel, other types of solar panels were not allowed to be tested or certified. As a result, these other types of solar panels could not gain the necessary certification to be placed on the Korean market. The United States was not aware of any other country that applied the IEC standard in such a narrow way.

324. The representative of the United States said his delegation was also concerned that the one type of thin-film solar panel to which standard KS 61646 applied was the type of solar panel that Korean producers make. He added that his government was not aware of any scientific or technical evidence indicating that there were risks associated with the use of the other types of solar panels. The United States was of the view that Korea should adopt the IEC standard without limiting its application to only the type of solar panels produced by its own industry. This would be more trade-facilitating than the current system and would also allow Korean producers and consumers to benefit from emerging technologies in the area of energy conservation.

325. The representative noted bilateral discussions with Korea in which Korea had expressed concern that some of the other solar panels contain certain types of cadmium. The United States shared Korea's concerns on potential environmental dangers linked to cadmium and had established legal requirements on its safe and effective use. However, according to US solar panel producers, the residual level of cadmium in solar panels was extremely low since the use of cadmium constituted a minor step in the production process and the cadmium remaining in the panels was minimal. The representative referred to a specific instance of a company producing cadmium telluride panels with residual cadmium content of only 2 per cent of a gram per watt basis. Another example was the case of a company producing 200W panels where the amount of cadmium contained in the final product was only $1/8^{th}$ of the amount of cadmium found in a single NiCad AA battery. Another US firm whose products were not allowed to be tested and certified for the Korean market produced eight foot telluride thin-film solar panels containing, per unit, less cadmium than one size-C NiCd flashlight battery. Since the amounts of residual cadmium were well below most regulatory levels, the United States considered there was no sufficient basis for excluding these products from the application scope of standard KS 61646.

326. The representative recalled Korea's stated intention not to allow testing and certification of other types of solar panels and to conduct a feasibility study on the use of such panels. This decision raised two issues: first, if Korea needed to conduct a feasibility study before allowing testing and certification of these products, it would confirm that compliance with the standard was mandatory. This would contradict Korea's position that the standard is voluntary. Second, the feasibility study could take several years, which would substantially delay market entry for non-Korean solar panels. In the view of the United States, the appropriate way to address this issue would be to allow foreign producers of solar panels to test and certify their products, following which Korea could analyse the evidence produced (instead of conducting a feasibility study which could take much longer).

327. The representative recalled Korea's stated intention not to allow testing and certification of other types of solar panels and to conduct a feasibility study on the use of such panels. This decision raised two issues: first, if Korea needed to conduct a feasibility study before allowing testing and certification of these products, it would confirm that the standard was mandatory. This would contradict Korea's initial position that the standard is voluntary. Second, the feasibility study could take several years which would substantially delay market entry for non-Korean solar panels. In the view of the United States, the appropriate way to address this issue would be to allow foreign producers of solar panels to test and certify their products, following which Korea could analyze the evidence produced (instead of conducting a feasibility study which could take much longer).

328. The representative of Korea noted bilateral discussions had been held with the United States on several occasions. Neither Korean standards applicable to solar panels nor their related certification were mandatory. Even without KS 61646 certification, companies can sell their solar panels in Korea. Moreover, Korea's standard for thin-film solar panels and thin-film terrestrial photovoltaic modules design qualification and type approval was largely based on IEC 61646.

329. The representative of Korea noted that Korea's standard departed from the international standard in matters involving use of cadmium telluride and copper indium selenide. He said there

were valid scientific and environmental justifications for this departure, relating to the use of toxic substances like cadmium in the manufacturing process of certain solar panels or in the solar panels themselves.

330. The representative said that in June 2010, KEMCO commenced a feasibility study aimed at reviewing technologies other than the amorphous silicon (A-Si) solar panels. The study is due by June 2012. Korea invited the United States to provide KEMCO with all information the United States deemed relevant during the conduct of the study. Following completion of the study, KEMCO will be able to decide on inclusion of other types of solar panels within the scope of application of standard KS 61646. The representative undertook to deliver to KEMCO all concerns raised by the United States in the meeting.

C. EXCHANGE OF EXPERIENCES

1. Good Regulatory Practice

(i) Workshop on Regulatory Cooperation between Members

331. The Chairman drew the Committee's attention to the draft outline of the Programme for the Committee's Workshop on Regulatory Cooperation, circulated on 19 October 2010 as JOB/TBT/7.

332. The representative of Mexico reiterated her delegation's interest to give a presentation during the workshop. Sharing experiences can help identify areas for useful cooperation around regulatory measures and methods. Her delegation viewed regulatory cooperation as a catalyst for further integration into markets.

333. The Chairman thanked Mexico for the offer of a presentation and invited the delegation to forward details of the presentation at the earliest convenience.

334. The representative of New Zealand observed that several of the presentations were being organized as joint presentations which underlined the message of cooperation. She appreciated Mexico's offer of a presentation as it would shed light on regulatory cooperation in the NAFTA region. The representative observed that developing countries and certain regions, for example the Caribbean Community, Southern African Development Community and Gulf Cooperation Community, were underrepresented in the workshop presentations and she wondered if Members from these groups could volunteer to present their experiences and challenges with respect to regulatory cooperation. Hopefully, Members would present both positive and negative experiences. New Zealand was enthusiastic about the workshop and the guidance it may provide for choice and design of trade facilitating mechanisms.

335. The Chairman encouraged developing country Members to volunteer to give presentations at the workshop.

336. The representative of Chile enquired whether they could make their presentation on the APEC Agreement on Electronic Products on a joint basis with other Members party to the agreement, for example Singapore. She also encouraged presentations from Central American Members.

337. The representative of South Africa said colleagues in the Southern African Development Community intended to make a presentation at the workshop, but had yet to decide who would give the presentation.

338. The representative of the European Union expressed appreciation for the updates on the program. He highlighted the importance of other regional groups (in Africa and the Middle East)

making presentations on regulatory cooperation initiatives, and in particular developing countries. He requested that Members make the links between regulatory harmonization efforts and more ambitious regional economic integration efforts.

339. He suggested that experiences in international organisations, such as OECD and the UNECE be included in the programme, to the extent that their work is relevant for fostering regulatory cooperation. The representative proposed that the Chairman or the Secretariat contact these organisations to explore their availability and interest in making presentations. Bilateral exchanges between his delegation and those organizations indicated that was such an interest, and he asked observers present from those organisations to provide initial feedback on potential topics of presentation. Finally, he supported the idea, already reflected in the revised programme, of a closing Session in the form of a Panel and suggested allowing sufficient time for discussions among panellists and with participants on the lessons learned.

340. The representative of the United States thanked the Secretariat for the draft programme, and explained that it strongly supports work to advance regulatory cooperation. He stated that the Workshop would be a timely and relevant contribution in the context of discussions in the TBT Committee, which could strengthen regulatory outcomes and reduce unnecessary barriers to trade. He hoped that Part D of the Workshop could help regulators overcome impediments to international engagement, such as resource constraints and narrow mandates. The representative noted that outcomes of regulatory cooperation to date have been uneven, and that his delegation would welcome Member suggestions on how to identify successful outcomes, and the factors that produce such outcomes. The point made by Brazil that internal coordination enhances relationships with other countries was highlighted, and Brazil's call for increasing developing country participation in the Workshop was echoed. In response to New Zealand's comment about his delegation's participation in a NAFTA presentation, he stated that he would discuss with NAFTA partners, but that his delegation was already making two presentations at the Workshop.

341. The representative of the OECD welcomed the suggestion of OECD participation in the workshop. She would share the draft programme with colleagues to determine how OECD might contribute, and then contact the WTO Secretariat.

342. The representative of UNECE suggested UNECE might present on ongoing regulatory cooperation initiatives under the Working Party on Regulatory Cooperation and Standardization Policies, regarding development of common regulatory systems and common regulations, and common methods of assessing conformity with regulations. She indicated she would consult with colleagues on potential areas for presentation, such as on regulatory cooperation in the automotive sector, and provide details to the WTO Secretariat.

343. The Chairman encouraged Members to finalize their plans and submit information including details of their participation to the Secretariat by 30 November 2010. He noted the Committee's interest in broadening the programme to include presentations from developing countries, regional organizations, and other organizations.

2. Conformity Assessment Procedures

344. The representative of New Zealand drew attention to a document circulated by her delegation on 17 September 2010 entitled "Trade Facilitation Mechanisms: Guidelines on Choice and Design" (JOB/TBT/5). The document reflected her delegation's ongoing interest in developing guidance on the choice and design of mechanisms to facilitate trade. It compiled a non-exhaustive list of existing materials on trade facilitation mechanisms, which could be augmented with further papers and information from Members.

345. The representative of New Zealand said that based on materials available, her delegation had prepared a draft outline of guidelines covering context, purpose, typology overview, and key considerations. She hoped the draft could be a starting point for discussion and invited feedback from Members so the document might be further refined. Questions listed on the first page regarding order of the discussion and possible need for additional sections may help the feedback process. The representative invited Members to contribute case studies from which lessons might be drawn as well as any other inputs to help flesh out the paper. She observed that the Workshop on Regulatory Cooperation would be a valuable source of information.

346. The representative observed that the present meeting marked one year since the Fifth Triennial Review was held. Few Member experiences had been shared and coverage of all regions and mechanisms was lacking. In the view of her delegation, it would be beneficial to ensure implementation of the Fifth Triennial Review recommendations before the next Triennial Review, leaving only three more TBT meetings to advance the matter. She suggested an initial comment period of ninety days for Members to offer input and views, which would be valuable as a first step.

347. Various delegations expressed appreciation to New Zealand for its document and initiative in follow up the Fifth Triennial Review including Hong Kong China, Egypt, Mexico, Chinese Taipei, United States, European Union, China and Singapore.

348. The representative of Hong Kong China said the New Zealand document could be the basis for further discussion. His delegation broadly agreed with the document and with the fundamental principle that the guidelines should not advocate particular mechanisms.

349. The representative of Egypt agreed the New Zealand document could be the basis for future discussion. Section C could mention interregional undertakings. There could be an additional section addressing regional or multilateral undertakings.

350. The representative of Mexico said her delegation generally supported the New Zealand document and would be pleased to provide more specific comments on the proposal. Mexico attached importance to guidelines on conformity assessment, which should cover *inter alia* technical assistance in this area. Guidelines could help Members develop infrastructure and properly engage in different conformity assessment schemes.

351. The representative of Chinese Taipei said New Zealand's proposal provided a good basis for further discussion in follow up to Paragraph 19(c) of the Fifth Triennial Review. Choices on conformity assessment reflect Member's risk management frameworks and therefore the inclusion of guiding principles for risk management framework establishment and operation would be valuable. Language reflecting S&D provisions in Article 12 of the TBT Agreement should be included in the introduction or elsewhere in the draft guidelines. Concerning the typology overview section, the representative noted that the document had captured most of the common practices employed by Members for facilitating conformity assessment. However, multilateral and regional cooperation efforts, such as those under APEC, and accreditation regimes under the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF), could usefully be included into the document.

352. The representative of the United States thanked New Zealand for the document, which provided useful background for Members to inform and stimulate exchange of information as per the recommendation of the Fifth Triennial Review. He commented that the document correctly noted that domestic regulations will differ around the world according to risk profiles. He noted that Supplier's Declaration of Conformity is recognized as the most trade facilitative conformity assessment procedure, but it may be inappropriate in particular contexts. The representative offered to share US experiences with selecting conformity assessment procedures.

353. He inquired as to whether some of the options listed for trade facilitation were more advanced than others, in the sense that Members would need to undertake certain options prior to moving onto other more advanced options. Given his delegation's experience he believed that this was the case. For example, while the TBT Agreement does call for accepting other technical regulations as equivalent, he explained this may not be possible due to differences in physical infrastructure and the long time frames required for developing relationships between regulatory agencies in different countries. Once a relationship is established, the agencies may begin to share non-public information, with the confidence that it will not be disclosed. His delegation viewed these preliminary steps as necessary prior to moving onto more advanced options, such as mutual recognition and equivalency arrangements. He cited experience in developing a six sector mutual recognition agreement (MRA) between the United States and the European Union, which was very challenging and complex, bearing a heavy resource burden, and stretched over several years, even for two jurisdictions at similar stages of development, and has not been fully implemented. Hence the representative suggested that it could be instructive for Members to share experiences about the building blocks for enabling greater regulatory cooperation between Members.

354. The representative also questioned the value of Members focusing on MRAs and more advanced forms of cooperation in every context. He noted that in certain contexts, MRAs may not be appropriate, and may in fact create additional barriers to trade. An MRA may not be possible if one Member does not regulate the sector of interest, if two Members have different ways of regulating the same product, and additionally, an MRA may not be cost effective when the volume of trade is low, or if trade flows are unidirectional. Should a Member insist on an MRA, it could become a barrier to trade if there were other more effective ways of achieving the same result, for example, conformity assessment through the use of international accreditation regimes.

355. The representative hoped Members would take a common sense approach to trade facilitation, applying appropriate approaches in different contexts. He emphasized that small steps were better than no steps. Also, putting in place necessary building blocks between regulators takes time. Advanced forms of cooperation should be used only when necessary, feasible and appropriate. The representative suggested Members focus on the goal of facilitating trade, rather than emphasizing the mechanisms for doing so.

356. The representative of the European Union thanked New Zealand for taking leadership on implementing the recommendations of the Fifth Triennial Review, and Members for their useful comments. He brought to the Committee's attention his delegation's proposal to add two additional sections to the extensive outline of issues already provided by New Zealand. First, under "Unilateral trade facilitation" in Section III of the New Zealand paper, the EU was interested to address the question of granting trade facilitation unilaterally, through least restrictive conformity assessment procedures, and to share experiences on the criteria informing the choice of conformity assessment procedures in a given regulatory context. These procedures should be based on the relevant risk management framework, and he noted that this could help implement the recommendations of Paragraph 19B of the Fifth Triennial Review. The representative offered to share EU experience with good regulatory practice tools, and in particular impact assessments for conformity assessment. He reminded that Supplier's Declaration of Conformity was indeed one of the mechanisms listed in the Illustrative List of Approaches to Facilitate the Acceptance of the Results of Conformity Assessment as adopted by the TBT Committee at the end of the Third Triennial Review

357. Second, the EU representative suggested considering relevant initiatives at regional or international level aimed at facilitating the acceptance conformity assessment results by establishing or referring to common principles for regulation. He highlighted initiatives within APEC (e.g. MRA for telecom equipment), the UNECE Conventions on motor vehicles, OECD (test guidelines and principles for good laboratory practice), as well as international accreditation schemes under ILAC and IAF. In addition, he cited international voluntary cooperation arrangements between conformity

assessment bodies, such as the International Electrotechnical Commission System for Conformity Testing and Certification of Electrical Equipment (IECEE CB Scheme), and the International Electrotechnical Commission System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx System).

358. He agreed with the point made by the United States regarding the need to determine prerequisites for different forms of regulatory cooperation. The representative noted that the use of certain mechanisms depends, *inter alia*, on the policy context, the regulatory context, the level of economic development of partners, existence of sufficient confidence between regulators, comparability of regulatory frameworks and infrastructure for conformity assessment. When placed within this context, certain instruments like MRAs may in the long term appear to reduce incentives for further convergence, and remove an incentive for approximation. The US-EU MRA, which has largely not been implemented, has been an important lesson for his delegation and for the United States about the challenges of these approaches, and he hoped other Members could learn from this experience.

359. The representative of China emphasized the importance of considering a range of factors when discussing conformity assessment procedures including diversity of conformity assessment measures, differing levels of development between Members, and differences between Member's rules and regulations for conformity assessment. With respect to MRAs, important preconditions for such agreements may include a sufficiently high trade volume, well-suited trade structures, and compatibility of the conformity assessment regulations. The representative noted that considerable human resources and financial support were required for an MRA negotiation. She emphasized practicality of guidelines for conformity assessment, as mentioned in the Fifth Triennial Review, in order to pursue the target of efficient and effective trade facilitation mechanisms.

360. The representative of Singapore welcomed the New Zealand document as a good basis for discussion. She concurred with New Zealand's suggestion for further experience-sharing which could help identify ways to facilitate conformity assessment and assist with the development of practical guidelines.

361. The Chairman noted the lead taken by New Zealand and recalled that one year had already passed since the Fifth Triennial Review. He welcomed the constructive suggestions of Members and the experiences shared, in particular with respect to MRAs. The Chairman invited Members to prepare their papers and help flesh out the skeleton prepared by New Zealand.

3. Standards

362. The representative of the OECD referred to an OECD study entitled "The Use of International Standards in Technical Regulations".[8] The study assessed technical regulations in three sectors of several OECD countries and the extent to which they follow international standards. The study took a pragmatic approach in defining an international standard as any non-national standard. The representative reported that in all cases countries under analysis implemented TBT Agreement provisions on the use of international standards and followed a broad range of non-national standards, many of which were not produced by typical international standard-setting bodies.

363. The representative of the OECD noted a lack of transparency with regard to which non-national standards were being followed in any particular regulation. This lack of transparency severely impeded analysis of whether standards were the basis of technical regulations. For example,

[8] Fliess, B. et al. (2010), "The Use of International Standards in Technical Regulation", *OECD Trade Policy Working Papers*, No. 102, OECD Publishing - http://www.oecd-ilibrary.org/trade/the-use-of-international-standards-in-technical-regulation_5kmbjgkz1tzp-en.

in some cases different regulatory bodies within a country employed standards in different ways: standards might be included as a reference; standards might be directly included into a text; or standards might be included as references to other standards. There were difficulties in tracing the exact origin of standards in this context.

364. Furthermore, in some cases non-national standards were incorporated into technical regulations without acknowledgement. While there existed national databases of standards linked to national technical regulations, often these were not comprehensive and did not specify regulatory objectives. The representative expressed concern about the lack of publicly available information in this context and explained that serious research and direct contact with regulators were typically required to ascertain whether and how non-national standards were being used.

365. The representative said the lack of transparency was significant because it impeded analysis of the use and uptake of standards over time, or analysis of the impact of standards on international trade, such as in the case of technical regulations following international standards. She noted that interested stakeholders would likely have difficulty identifying when and where international standards were being followed.

366. The Chairman noted the importance of the points raised in the OECD study and invited Members, observer organizations and relevant bodies to share experiences and cases studies in forthcoming meetings.

4. Transparency

367. The representative of the European Union recalled the importance of the TBT Information Management System and its development to Members. She explained that her delegation would very much like to work with Members to further develop the existing TBT Information Management System to become a common WTO website for notifications, which could help further enhance transparency. Reiterating previous comments, she explained that a common website could even enable Members to carry out notifications directly. This would increase the time available for comments. The representative inquired as to the development of a similar initiative in the SPS Committee, and wondered whether there had yet been pilot programs implemented. She asked if Members would support the development of such a system, and whether the Secretariat was working towards this end.

368. She explained that the EU had recently completed an internal database for EU Member State notifications, with a direct notification function, which had demonstrated the feasibility of her delegation's proposal. Finally, she offered to share the IT expertise used in the development of this website with any Member or the Secretariat.

369. The Chairman noted the proposal could be valuable and that he believed there was some work occurring to this end in the SPS Committee. He asked the Secretariat to look into these developments and report back to the Committee in the next meeting.

D. OTHER MATTERS

370. The Chairman noted that the particular trade concern on REACH had been raised at 24 TBT Committee meetings, including the current meeting – the first discussion had taken place on 20 March 2003. Over 35 Members had engaged in the discussion at various points in time. Given the extent of the discussion, and given that the European Union had stated that they had replied to many questions at previous meetings and did not wish to repeat what had already been said, the Chair suggested that the Secretariat compile the questions and answers raised on REACH since 2003, for

guidance purposes only – and for the sake of making discussions more efficient. The Chair invited comments and views from Members on this proposal.

371. The representative of Argentina said that the Chairman's idea was interesting. Given the importance of the issue to Argentina, and given that his delegation had engaged extensively on this issue in the TBT Committee and bilaterally, he considered it to be a positive initiative. However, structuring such a paper was a challenge not to be underestimated. He suggested that the European Union could perhaps contribute to the process by to ensuring that information contained therein was as accurate and useful as possible.

372. The representative of India supported the suggestion of developing such a paper and highlighted the importance of clear categorization of issues. He believed that such a paper would represent value-added for his delegation's capital-based regulators and negotiators.

373. The representative of Cuba gave her delegation's support to the Chairman's idea of compiling questions and answers on REACH, and stated that it should emphasize EU responses.

374. The representative of the European Union agreed with Argentina that aspects of the proposal would need to be clarified, but that it was an interesting suggestion. With respect to the EU contribution, she explained that she would have to consult with experts in Brussels on the extent of potential contributions. She emphasized that her delegation had taken a very transparent approach on this issue and had tried to answer all questions, even when questions fell outside of the purview of the TBT Agreement.

375. The Chairman invited the Secretariat to look into the feasibility of the proposal.

III. TECHNICAL COOPERATION ACTIVITIES

376. The representative of Thailand updated the Committee on various technical cooperation activities. In August 2010, the Thai Industrial Standards Institute provided training to the National Agency of Science and Technology of Lao People's Democratic Republic on the TBT Agreement. In 2009, the TBT Enquiry Point and notification authority welcomed study tours from a Bangladeshi standards organization and the Tunisian National Institute for Standardization and Industrial Property. In 2008, Bhutan's Standard and Quality Control Authority (SQCA) visited the Thai Industrial Standards Institute.

377. The representative of El Salvador thanked the WTO Secretariat for organizing a National Workshop on the TBT Agreement and SPS measures, two topics which were of great importance to El Salvador. This event would take place on 25-26 November.

378. The representative of the International Trade Centre updated the Committee on its technical cooperation activities.[9]

379. The Chairman drew the Committee's attention to a document containing the Secretariat's technical assistance activities.[10]

[9] G/TBT/GEN/106.
[10] G/TBT/GEN/102.

IV. UPDATING BY OBSERVERS

A. INFORMATION FROM OBSERVERS

380. The representative from the International Telecommunications Union (ITU) thanked the Committee for granting the ITU ad hoc observership status and made a presentation on the ITU and Standards.[11]

381. The representative of Codex provided the Committee with an update on its recent events and on-going work related to the TBT Agreement.[12]

382. The representative of UNECE informed the Committee that the 20th session of the Working Party on Regulatory Cooperation and Standardization Policies had taken place in November.[13] At the session, a new group of experts on risk management and regulatory systems was established. The group would develop best practices and recommendations on how risk management tools could be used to mitigate risks that might hamper economic development within the UNECE's mandate of technical regulation and standardization policies. The representative updated the Committee on other aspects of work at the 20th session including conformity assessment and on-going secretariat initiatives in sectors such as telecoms and earth moving equipment. She highlighted the development of a skeleton database of market surveillance authorities and invited delegations to visit the UNECE website[14] for further information.

383. The representative of the IEC provided the Committee with an update on its recent activities in developing countries.[15]

B. APPLICATIONS FOR OBSERVER STATUS IN THE TBT COMMITTEE

384. The Chairman brought the Committee's attention to the document G/TBT/GEN/2/Rev.2 containing the list of bodies applying for observer status in the Committee.

385. The delegate from South Africa supported the Southern African Development Community's (SADC) request for observer status in the TBT Committee. SADC was comprised of 15 countries, of which 14 were WTO Members. Facilitation of inter-regional trade and development of regional standards were goals of SADC and the Community had an extensive programme on standardisation, quality assurance accreditation and methodology (SADC–SQAAM) within the Southern African region. Observership status in the Committee would complement this programme and contribute to integration efforts in the region. It would also assist the region's wider integration into the global family of trading nations and would assist implementation of the WTO TBT Agreement in the region.

386. The delegations of Zambia and Namibia supported the request for observer status by SADC and associated themselves with the statement of South Africa.

387. The Committee agreed to grant ad hoc observership status to the Southern Africa Development Community (SADC).

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[11] G/TBT/GEN/109.
[12] G/TBT/GEN/107.
[13] Presentations from this meeting are available on http://www.unece.org/trade/wp6/documents/2010/2010_DocsList.html.
[14] http://www.unece.org/trade/wp6/AreasOfWork/MarketSurveillance/Contacts.html.
[15] G/TBT/GEN/110.

V. REPORT (2010) OF THE COMMITTEE ON TECHNICAL BARRIERS TO TRADE

388. The Committee adopted its 2010 Report to the Council for Trade in Goods (G/L/940).

VI. OTHER BUSINESS

389. The Chairman brought the Committee's attention to a letter from the Chairman of the Working Group on Trade and Transfer of Technology and his reply to that letter.

VII. DATE OF THE NEXT MEETING

390. The next regular meeting of the TBT Committee will take place on 24-25 March 2011.