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Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 24-25 MARCH 2010

Chairperson: Mr. Ami Levin (Israel)

Note by the Secretariat[1]

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

I. ADOPTION OF THE AGENDA

1. The Committee adopted the agenda contained in WTO/AIR/3518.

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, Guatemala had submitted its Statement (G/TBT/2/Add.102) and Indonesia had submitted a revision to its statement (G/TBT/2/Add.3/Rev.3). In total, since 1995, 119 Members have submitted at least one Statement on implementation under Article 15.2. The latest list of enquiry point contacts is contained in document G/TBT/ENQ/36, issued on 5 February 2010.

B. SPECIFIC TRADE CONCERNS

1. New Concerns

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

3. The representative of Mexico raised concerns about Thailand's proposed health warnings for alcoholic beverages, notified to the TBT Committee under G/TBT/N/THA/332. While she expressed satisfaction about progress in bilateral consultations, concerns remained that the regulation could constitute an unnecessary barrier to trade. It was her delegation's understanding that the notified measure required bottled alcoholic beverages to have a net content volume of no less than 250 millilitres per bottle. Similarly, containers in the form of a can, jar or bag had to have a net content volume of no less than 300 millilitres per container. It was Mexico's view that the requirement to limit the content capacity of containers could effectively impede the marketing of several products on the Thai market, thus creating a barrier to trade under the TBT Agreement. Also, it did not appear to pursue a legitimate objective, as required by Article 2.2 of the TBT Agreement.

4. The representative of Mexico further noted that the obligation to display specific pictorial health warnings on the packaging of alcoholic beverages could convey to the public an erroneous message. She was particularly concerned that the draft labelling requirements could imply that any level of alcohol consumption was dangerous, thus ignoring the fact that risks arise exclusively in the context of an excessive and irresponsible use of alcohol. These requirements also appeared to ignore sound scientific evidence, which showed that moderate consumption of alcohol was compatible with a healthy lifestyle. While Mexico recognized the right of WTO Members to introduce regulations to address public health objectives, according to Article 2.2 of the TBT Agreement, available scientific information needed to be taken into account when regulating. Finally, the Mexican representative noted that the proposed measure also regulated the minimum size of the pictorial labels and warnings. This did not appear to be necessary to fulfil a legitimate objective in accordance with the provisions of the TBT Agreement.

5. The representative of the European Union joined Mexico in expressing concerns regarding Thailand's proposed pictorial health warnings for alcoholic beverages. In this regard, she invited the Thai authorities to take into consideration less trade restrictive measures or to provide clarifications about the evidence that had led Thailand to consider that different, less costly and burdensome alternatives would be insufficient to address the objective pursued. She also argued that the draft labelling requirements appeared to refer to a generic consumption of alcohol, and could therefore be

misleading for the consumer. In this regard, Thailand was invited to provide scientific evidence that the conditions covered by the health warnings were generally caused by any level of alcohol consumption, even moderate consumption. It was the European Union's view that public policies aimed to modify drinking behaviours needed to be approached in a holistic manner; for instance encompassing information or education campaigns to raise the awareness level with regard to specific alcohol-related problems. Thailand was therefore encouraged to indicate whether it was considering undertaking, or whether it already had undertaken, alternatives to mandatory product labelling such as education or information activities. The representative of the European Union also asked Thailand to clarify whether the proposed pictorial health warnings could be placed either on the front or on the back of alcoholic beverage packages. She believed that an obligation to indicate the warnings on the front of the labels without any flexibility would be burdensome and costly for exporters. Finally, she invited Thailand to clarify the relationship between this measure and the draft measure notified in G/TBT/N/THA/282, and particularly whether these new draft requirements on health warnings were intended to replace or add to the requirements set out in the previous notification.

6. The representative of Argentina noted his delegation's concern with Thailand's proposed requirements on health warnings for alcoholic beverages. While Argentina supported the objective of protecting human health, concerns remained that the draft regulation could constitute an unnecessary barrier to trade and was more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. The Argentinean representative also recalled that, according to Article 2.2 of the TBT Agreement, in assessing such risks, relevant factors to consider included: available scientific and technical information, and related processing technology or intended end-uses of products. He also noted that, according to Clause 3 of the proposed regulation, the label should contain the following message: "sale of alcoholic beverages to a person under 20 years is prohibited, violation will entail imprisonment for one year or a fine of Baht 20,000". This requirement, which related to legal obligations and sanctions in case of non-fulfilment, appeared to be costly and should not be imposed on importers. In fact, this information was usually not related to "consumer information"; it was based on national legislation, which tended to differ from country to country. Furthermore, Thailand was asked to provide information about scientific evidence that had been used to justify the strict labelling requirements contained in Clause 4 of its regulation. Argentina looked forward to receiving responses and suggested that Thailand consider an alternative, less restrictive, measure.

7. The representative of New Zealand shared the concerns expressed by previous speakers. While New Zealand was supportive of the right of WTO Members to introduce new regulations to address specific public health issues, concerns remained that the proposed labelling requirements were unnecessarily trade restrictive and that less trade-restrictive approaches were available to achieve the stated objective. The New Zealand representative also argued that the new requirements would impose significant additional costs and administrative burdens on exporters, hence causing trade to be reduced. He informed the Committee that written comments had been sent to Thailand's enquiry point. In particular, New Zealand was interested to know about the reasons and basis for the approach taken to labelling, including information on what alternatives had been considered to achieve the same objective, for example, the consideration of current international practices and the development of public education campaigns.

8. The representative of Switzerland echoed the concerns expressed by other Members and stressed that the proposed labelling requirements appeared to be more trade restrictive than necessary to achieve the specified legitimate objective.

9. The representative of Australia supported the comments made by other delegations and encouraged Thailand to consider an alternative approach to ensuring responsible alcohol consumption, such as requiring wine labels to indicate the alcohol content. This would allow consumers to make better informed purchasing decisions and would be consistent with international

standards, such as those contained in the World Wine Trade Group Agreement on Requirements for Wine Labelling. The representative of Australia looked forward to a satisfactory response to her delegation's concerns and invited Thailand to inform her when an English version of the supporting documentation, including the Alcohol Beverage Control Act BE 2551 (2008), would become available.

10. The representative of the United States thanked the delegation of Thailand for having extended the period for comments for the proposed regulation and noted that further written comments would be sent by his delegation. While the United States shared Thailand's objective of protecting human health and safety, concerns remained that the proposed requirements had the potential to negatively impact exports of alcoholic beverages to Thailand. The US representative noted that Clause 3 of the draft regulation precluded US labels from having: "any word or statement that misleads consumers to understand that alcoholic beverages are safe and good for health or contain lower level of harmful substances compared with other alcoholic beverages or contains words or statements that directly or indirectly advertise the alcoholic beverage". It was his delegation's understanding that, to the extent that a registered trademark contained any such description, this vague provision could result in trademarks being prohibited on alcoholic beverage packaging. While the US delegation supported any prohibition on misleading or deceptive trademarks, he remained concerned that the above-mentioned language could be implemented in such a way as to affect the use of trademarks that had been used on the Thai market for years without evidence of having misled consumers. Thailand was therefore urged to exercise caution in the implementation of this provision.

11. The representative of the United States further recalled that, under Clause 4, all beverage alcohol containers needed to include one of six specific pictorial labels with associated warning statements, which had to be rotated at thousand bottle intervals. Thailand was invited to clarify whether these statements had been developed taking into account available scientific and technical information, and to provide evidence of the scientific basis for the warning statements No. 1, 3, 4, 5 and 6. Moreover, Thailand was asked to explain the need to rotate the six labels at one thousand bottle intervals and how Thailand intended to monitor and enforce this requirement. Concerns also remained that trademark owners importing alcoholic beverages into Thailand would not be allowed to display their existing trademarks and trade dress, because the warning labels potentially restricted the size of the trademarks and required them to be displayed alongside or under pictorial warnings. These restrictions could reduce the ability of trademarks to distinguish one product from another. In this regard, the US representative stressed that trademarks and trade dress conveyed important factual information to consumers about the product. Finally, the representative of the United States noted that Clause 8 provided that the new labelling requirements would enter into force 180 days after their publication in the Royal Gazette. He appreciated the six month delay granted in the implementation of this measure. However, since compliance with the proposed measure would require significant label redesign and reprinting by suppliers, his delegation requested Thailand to ensure that the new requirements would only apply to products placed on the market after the transition period expired, and that Thailand consider extending the transition period to one year.

12. The representative of Thailand said that the comments would be conveyed to the Department Disease Control of the Ministry of Public Health for due consideration. She also informed the Committee that the period for comments had been extended to 21 April 2010, as requested by the European Union.[2]

[2] G/TBT/N/THA/332/Add.1.

(ii) Brazil – Food registration and notification procedures (G/TBT/N/BRA/362)

13. The representative of Mexico noted her delegation's concern with Brazil's draft technical regulation on the list of foods that needs to be registered before marketing. It was Mexico's understanding that the notified draft regulation established the procedures required for food registration, as well as the notification procedures for food products exempt from registration. The regulation seemed to apply to the procedures for the registration and notification of domestic and imported food products, food additives, food processing aids and packaging. However, it was not clear what criteria would be used to determine whether or not a product was subject to registration before ANVISA. Concern was also expressed with regard to the obligation for food products sold in Brazil to be obtained, processed, packaged, transported and stored under conditions that did not produce, develop and/or aggravate physical, chemical or biological substances that endangered consumer health. The representative of Mexico invited Brazil to provide more information on this provision and the scientific evidence that justified its adoption.

14. The representative of Brazil explained that this draft technical regulation was aimed at facilitating trade by removing the obligation to register some products at local and regional offices of Brazilian health authorities. He emphasized that the main objective of this measure was to substitute the previous procedures of registration with a quick, online self-declaring notification. In this regard, the representative of Brazil noted that a notification form for the marketing of such products would be made available on the ANVISA's website. The notification form had to be filled out by any company involved in the supply chain of the products covered by the regulation, for example producers, importers and distributors. The delegate of Brazil explained that one of the criteria considered in selecting the products covered by the new regulation, i.e., products not subject to mandatory registration, was whether they were directed at infant and young child nutrition. Since these population groups were granted special rights by Brazilian legislation, most of these products remained subject to existing regulations. Finally, the representative of Brazil said that food packaging not produced with new technologies would also be covered by the new regulation, and therefore exempt from mandatory registration. His delegation was ready to provide any further clarification to interested Members.

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

15. The representative of New Zealand expressed concerns regarding Italy's new draft regulation on dairy products. On procedure, he noted that written comments had been sent to Italy's enquiry point and that concerns remained on the inadequate timeframe afforded to interested parties to comment on this legislation. Considering that the regulation would enter into force in March 2010, the two-week comment period provided by the Italian authorities did not appear to be adequate. In this regard, the representative of New Zealand recalled that the TBT Committee had recommended that the normal time limit for the presentation of comments should be at least sixty days.[3] On substance, New Zealand was particularly concerned with the proposed ban on the use of protein in cheese making. It was noted that this issue was similar to another issue (compositional requirements for cheese) that had been discussed at length in the Committee. It was New Zealand's view that the proposed ban would run contrary to accepted international practice as embodied in the Codex General Standard for Cheese, which allowed for the use of protein in cheese-making. Italy was therefore invited to clarify why its draft regulation did not appear to adhere to the relevant international standard, as required under Article 2.4 of the TBT Agreement. New Zealand also encouraged Italy to explain the causal link made in the draft legislation between banning the use of protein in cheese-making and preventing fraud in the dairy industry. In the absence of such evidence, it was New Zealand's view that the proposed ban did not appear to be in line with Article 2.2 of the TBT Agreement. The representative of New Zealand also questioned whether the measure adopted by Italy was the least trade restrictive measure that could be chosen to fulfil its objective.

[3] G/TBT/26 para. 40.

16. Furthermore, the representative of New Zealand expressed concerns with the mandatory country of origin labelling (COOL) provisions contained in the draft regulation. He emphasized that, in general terms, New Zealand was opposed to mandatory COOL provisions. It was his delegation's opinion that when consumers did distinguish between goods based on country of origin labelling, strong commercial incentives existed for firms to act without the need for government regulation. In this regard, New Zealand questioned whether this mandatory COOL provision did meet the Article 2.2 test of being the least trade restrictive means of achieving the objective put forward in the legislation. It was also noted that existing consumer protection legislation of the European Union already prohibited misleading consumers about a product's origin.

17. The representative of Australia shared the concerns expressed by New Zealand regarding the proposed ban on milk protein concentrates in cheese making. In particular, she invited the Italian authorities to clarify the basis for this ban.

18. The representative of the European Union informed the Committee that written comments on this measure had been received and that the proposed regulation had been discussed bilaterally with New Zealand. She stressed that Italy had notified this proposal to the European Commission under the internal EU notification procedure and that discussions between the Commission and the Italian authorities were still underway. The European Union delegation would be available to provide further clarification to concerned Members once the internal consultation process had been concluded.

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

19. The representative of Korea raised a concern regarding the proposed amendment of the US Hazardous Materials Regulations (HMR) on the transportation of lithium cells and batteries. It was Korea's view that many incidents related to lithium batteries had to be attributed to the mishandling of the cargo containing batteries, not to the inherent risk of the batteries. In this regard, the representative of Korea pointed out that Korean manufacturers had been transporting lithium ion (Li-Ion) batteries to the United States at a rate of over 4,000 freight flights per year, and no incidents had been reported. Korea's delegation was particularly concerned that the proposed regulation could impede international trade in products that use Li-Ion batteries, by raising the price for the US consumers. Indeed, it had been estimated that the entry into force of this measure would cause an increase of 200 per cent on the total transportation costs of products manufactured in Asia. This additional cost would probably be passed on to US consumers. The delegate of Korea said that the more effective way to secure safer transportation of Li-Ion batteries was to ensure harmonization and compliance with the relevant international standards and regulations, such as those developed by the United Nations (UN), the International Civil Aviation Organization (ICAO) and the International Maritime Organization (IMO). Finally, he noted that the period for comment provided on this regulation was much shorter than the period recommended by the TBT Committee.

20. The representative of Japan shared the concern expressed by Korea with regard to the US measure. While Japan supported the US objective of reducing aerial transportation incidents that occur with lithium batteries, the United States was invited to conduct further technical, economic and practical analyses on its regulation's potential impact. The United States was also encouraged to adopt safety measures that were consistent with the relevant international standards, such as the UN Recommendation on the Transport of Dangerous Goods and the ICAO Technical Instructions. It was emphasized that the adoption of regulatory measures that did not take into account the relevant international standards would impose a heavy burden on the US import supply chain. In particular, this new regulation could have a significant impact on manufactures, battery users, the aerial industry, and consumers. Japan therefore requested the United States to ensure that no less trade-restrictive alternatives existed and that the new regulation would be effective, practical and consistent with international practice.

21. The representative of Israel joined other delegations in expressing concern regarding the US measure on the transportation of lithium cells and batteries and noted that Israel had sent written comments to the United States on 11 March 2010. He reiterated that the proposed regulation would impose new testing and battery design requirements for small lithium cells and batteries, in particular when transported by air. It was Israel's view that the new requirements were inconsistent with the UN Manual of Tests and Criteria, the ICAO Technical Instructions and the IMO International Maritime Dangerous Goods Code, and could constitute an unnecessary barrier to trade. It was also argued that the proposed regulation raised concerns of a discriminatory nature. In fact, while domestic producers usually transported their products by land, importers were in most cases forced to use air transportation, which was the sector most affected by the new requirements. Furthermore, the representative of Israel noted that the US draft regulation had the potential to disrupt and impede importation into the United States of lithium batteries and other products that use these type of batteries, such as: medical devices, gas and water metres, wireless alarm systems and certain communication devices. It was stressed that such products amounted to a significant proportion of the goods exported by Israel to the United States. In particular, the US measure would create burdensome and unnecessary costs for Israeli suppliers, most of which were Small and Medium Enterprises (SMEs), and would impose extensive and costly changes to the packaging, labelling and shipping of their products, rendering them less competitive. The delegate of Israel urged the United States to reconsider the adoption of the proposed regulation and to avoid the implementation of any changes that would be inconsistent with internationally accepted standards and practices, or would lead to the imposition of an unnecessary barrier to international trade.

22. The representative of China shared the concerns raised by other Members and noted that China was one of the major producers of lithium batteries in the world. She was of the opinion that the adoption of the US regulation would significantly increase the transportation costs of lithium batteries. She also noted that the US authorities had provided a comment period of only one month. The representative of China explained that the measure was currently under consideration and asked the United States to extend the comment period for another month, so as to give Chinese authorities the opportunity to provide comments on this notification.

23. The representative of the United States informed the Committee that his delegation had recently held bilateral discussions with Korea and Japan on this issue. First, he explained that the US Pipeline and Hazardous Materials Safety Administration (PHMSA), in coordination with the US Federal Aviation Administration (FAA), had published this proposed measure to comprehensively address the issue of safe transport of lithium cells and batteries. The draft measure was intended to strengthen the existing regulatory framework by imposing more effective safeguards including testing, packaging and hazard communication measures for various types and sizes of lithium batteries in specific transportation contexts. This measure built on regulations that had been published in 2004, 2007 and 2009. The representative of the United States also noted that, in addition to the period for comments provided by the notification of this regulation, PHMSA and the FAA had held a public meeting in Washington DC in March 2010 to offer an additional opportunity for stakeholders to provide comments. He stressed that the meeting was well attended and that companies, trade associations, foreign embassies, other organizations and many individuals had made formal statements. All these statements, other comments received, as well as relevant materials and analyses used in the development of the proposed measure were available on a US Government website.[4] PHMSA and the FAA were evaluating all the comments received and would take them into account when finalizing the regulation. While the period for comments on the draft measure had expired on 12 March 2010, the US representative said that PHMSA would continue to consider additional comments to the extent practicable. The representative of the United States further stressed that lithium batteries represented a hazardous material for transportation, because in certain conditions they could overheat and ignite, and once ignited they could be especially difficult to extinguish. He

[4] http://www.regulations.gov/search/Regs/home.html#home

also gave some examples of incidents that had occurred in this respect. One incident aboard an airplane involved a shipment of 120,000 lithium metal batteries contained in small packages that caught fire; initial attempts to extinguish the fire with water and chemical fire extinguishers were ineffective. Another incident involved a shipment of lithium batteries contained in personal disposable vaporizers also transported by airplane.

24. The US representative explained that under current US regulations lithium batteries were considered as a Class 9 hazardous material, which was the designation provided by ICAO for lithium batteries in general. These rules specified the packaging and testing requirements for transportation of lithium batteries by all modes and provided that lithium batteries of all types and sizes must pass the applicable tests in the UN manual of tests and criteria. These tests were designed to ensure that the batteries could withstand conditions generally encountered in transport and were designed in a manner that precluded a violent rupture. In order to prevent movement that could lead to short circuits, the batteries had to be packaged in combination packaging that conformed to certain specified performance standards. In addition, packages had to be labeled with a Class 9 label and accompanied by shipping papers that described the batteries being transported and the related emergency response information.

25. The representative of the United States further explained that the new proposed measure would eliminate the regulatory exemptions for the transport by aircraft, particularly for some of the smaller batteries. In this regard, he emphasized that the US regulators expressed serious concerns about the aggregate risks inherent in the transportation of a large number of packages transported in close proximity to one another, each containing small size batteries. The risks inherent in transporting multiple packages of small size batteries could indeed be more serious than the risks associated with a small number of packages containing large size batteries. Therefore, it was the US view that the elimination of the current exemptions would enhance safety by ensuring that all lithium batteries be designed to withstand normal transport conditions, and be packaged to reduce the possibility of damage that could lead to an incident aboard an aircraft. Lithium batteries would also be accompanied by hazard information that would ensure appropriate and careful handling by air carrier personnel and inform transport workers and emergency response personnel of actions to be taken in the event of an emergency.

26. It was noted that the US proposal would help to further align US requirements with international practice. For instance, the proposed measure would adopt two separate entries into the hazardous materials table for lithium metal batteries and lithium ion batteries. This was consistent with the UN model regulations, the International Maritime Dangerous Goods Code and the ICAO Technical Instructions. The US measure would also incorporate the Fifth revised edition of the UN Manual of Tests and Criteria and would adopt and revise various definitions based on the content of the latter. Finally, the US representative noted that the US Department of Transportation continued to discuss these issues with its counterparts in various international fora. In particular, he informed the Committee that the United States participated in the UN Lithium Battery Working Group, which was composed of lithium battery experts from all over the world. The next meeting of this Working Group was scheduled for 18-20 May 2010 in Washington DC. US authorities would also participate in the next session of the Economic and Social Council (ECOSOC) Sub-Committee of experts on the Transport of Dangerous Goods, to be held in Geneva in June 2010.

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

27. The representative of the European Union raised concerns about Brazil's Ministerial Act No. 327 of 17 September 2009, which established certain criteria for the labelling of beverages as well as the procedures for production and bottling. The European Union was particularly concerned about the possible negative impact that some of the proposed labelling obligations would have on EU economic operators, which would have to redesign their labels for the Brazilian market only. Some of these

requirements appeared to be particularly burdensome for EU exporters, such as: (i) the obligation to indicate the alcohol content on the front main label; (ii) the prohibition to use any abbreviations, including well-established ones, even when the respective information was provided on the label on a voluntary basis; and (iii) the requirement to translate all terms on the label into Portuguese, including those with which Brazilian consumers were accustomed (e.g. "light" or "diet"). The EU representative invited Brazil to explain why a specific registration sign for imported products was considered necessary and to clarify whether this sign had to be part of the permanent label. It was her delegation's view that a registration sign on the permanent label would constitute a considerable burden for importers, which would need to modify their labels to include such a sign. In this regard, Brazil was asked to clarify why this requirement applied to imported goods only and what the nature of the rationale was for departing from the national treatment obligation. Finally, the EU representative noted that written comments had been sent to Brazil in December 2009 and her delegation looked forward to receiving a reply.

28. The representative of Mexico joined the concerns expressed by the European Union. With regard to the prohibition to use any abbreviations, she pointed out that abbreviations were often recognized by the Brazilian consumers. Mexico also expressed concern regarding the obligation contained in Article 8 of the proposed regulation, which required any label including a design, picture or illustration of any ingredients used to make a beverage to include all ingredients of animal or vegetable origin, regardless of their quantity. This requirement appeared to be very burdensome for products made with different ingredients, such as Tequila. In this regard, Brazil was asked to clarify whether it was obligatory to include the pictures of all ingredients or only the main ones. Concerns were also expressed about the requirements contained in Article 13, para. 12 of the draft Brazilian regulation, which prohibited the use of certain expressions associated with a trademark or the commercial name of the beverage, such as "handcraft", "colonial", "home-made", "family", "natural", "reserve", "special reserve" or similar. It was Mexico's view that this provision did not bring any benefits to Brazil and would effectively impede the marketing of internationally recognized trademarks, which traditionally used these terms. The representative of Mexico also noted that Articles 25 and 26 contained an obligation for imported beverages to be labelled with the importer's registration number. She stressed that this label could notably increase costs for industry. Finally, the representative of Mexico noted that the labelling requirements would come into force one day after the publication of the regulation and that a transition period of 180 days had been provided to adapt to these changes. Given that these new requirements did involve important changes in the design and printing of the labels, Brazil was urged to extend the transition period to 365 days and to clarify whether the new requirements would only be applied to beverages labelled after the entry into force of the regulation or also to beverages already on the market at the end of the transition period.

29. The representative of the United States shared some of the concerns raised by the other delegations and informed the Committee that written comments on this measure had been sent to Brazil. He stressed that the proposed requirements had the potential to negatively impact trade in wine, beer and spirits. For example, it appeared that the new requirements could prohibit the use of certain common abbreviations, illustrations and expressions commonly used in the labelling of alcoholic beverages. Concerns were also expressed about the need for mandatory formatting and advisory statements, and about the potentially insufficient transition period provided for suppliers to comply with these requirements. The representative of the United States noted that his delegation looked forward to further discussions with Brazil on this issue.

30. The representative of Brazil thanked the delegations that had sent written comments on Ministerial Act No. 327 and noted that these comments were being processed and a reply would be provided in due time. He explained that the additional labelling requirements for imported products proposed by the new regulation were aimed at harmonizing the requirements imposed on both national and foreign products. He said that there was no intention to differentiate between domestic and foreign producers and stressed that it was in Brazil's interest to bring the new regulation closer to

procedures that were commonly used by other WTO Members. The representative of Brazil also informed the Committee that a deadline for the conclusion of the amending process of this draft regulation had not yet been set. Although the period for comments had expired, the Brazilian authorities would continue to take into account the comments sent on this regulation and its implementation. Finally, with regard to the issue of the pictures to be included on the label, as raised by Mexico, the representative of Brazil explained that the objective of the provision was only to prohibit the display of elements that were not contained in the product.

(vi) Turkey – New conformity assessment procedures for pharmaceuticals

31. The representative of the United States raised concerns regarding Turkey's new conformity assessment procedures for pharmaceutical imports. He noted that in December 2009 the Ministry of Health of Turkey had issued an amendment to the regulation on the pricing of medicinal products for human use, which entered into force on 1 March 2010. As of 1 March 2010, foreign producers were required to have their manufacturing plants inspected by Turkish authorities, who had to issue a good manufacturing certificate unless the country of manufacture was party to a Mutual Recognition Agreement (MRA) with Turkey. While the United States was not opposed to inspection requirements for pharmaceutical manufacturing facilities, concerns remained on several issues.

32. First, the measure had neither been published in Turkey's official gazette in proposed form, nor had it been notified to the WTO. The US industry had also reported that Turkey's Ministry of Health could have instituted an unofficial standstill for new pharmaceutical approvals beginning in August 2009, well before the measure was officially published. Second, Turkey was invited to clarify whether it had identified any health or safety issue with respect to imports from the United States, which had prompted Turkey to discontinue acceptance of Good Manufacturing Practice (GMP) certificates issued by foreign regulatory authorities such as the US Food and Drug Administration (FDA). The representative of the United States noted that his delegation had met bilaterally with Turkey on this issue and, apparently, there existed statistics to support this determination. Turkey was asked to make those statistics available for consultation. This was particularly important in light of a statement that a senior official from Turkey's Ministry of Health had made in the Turkish press in February 2010, noting that the goal of the measure was to encourage domestic production and to make it more difficult to import generic pharmaceuticals into Turkey.

33. Third, the US industry had expressed serious concern that the measure only provided a three month period for suppliers to comply. This inadequate implementation period, coupled with the failure to notify the measure, had disrupted exports of pharmaceutical products to Turkey. The US representative further noted that some of these products were meant to treat diabetes, heart attacks, osteoporosis and other ailments; delaying the import of these products would negatively impact Turkish patients in need of lifesaving and life enhancing medications. Fourth, the US industry had reported that the Turkish authorities did not have sufficient capacity to inspect all of the manufacturing plants that needed to be inspected in the near future. As a consequence, there appeared to be approximately 400 products whose placement on the Turkish market was being delayed as manufacturers waited to have their plants inspected.

34. The US representative urged Turkey to suspend the implementation of its measure and notify it in draft form to the WTO, so as to take the comments of Members and industry stakeholders into account. If the need to conduct inspections was reaffirmed, the United States asked Turkey to allow products that had a GMP certificate issued by foreign regulators to remain on the market, pending completion of the Ministry of Health inspections. It was the US delegation's view that barring such action there would be a de facto ban on imports of such products. Finally, Turkey was urged to immediately start processing the applications for regulatory approval that had not yet been acted upon, so as to allow trade in pharmaceutical products to resume.

35. The representative of Switzerland shared the concerns expressed by the United States. In particular, she stressed that this measure had a significant effect on trade and should have been notified to the TBT Committee at an early appropriate stage. This would have allowed for comments from other WTO Members to be taken into account. Turkey was therefore invited to promptly notify this measure and delay its implementation.

36. The representative of Turkey explained that this regulation had first been published in 2005 and subsequently amended in 2009. Its objective was to protect human health and life by ensuring the effectiveness, safety and quality of pharmaceutical products. The delegate of Turkey further explained that a GMP certificate was required for obtaining a license for pharmaceutical products. She pointed out that under the previous procedures the GMP certificates issued by the authorities of other countries were accepted as equivalent to those provided by the Turkish Ministry of Health. However, the withdrawal of 32 products from the Turkish market in the last three years had convinced the Ministry of Health to take a more active role and improve existing procedures. Under the new regulation the Ministry of Health could either provide the GMP certificates itself or recognize the GMP certificates issued by other countries. In December 2009 Turkish authorities had clarified that the term "recognized" included the authorities of those countries with which the Ministry of Health had concluded Mutual Recognition Agreements (MRAs). The Turkish Ministry of Health was ready to conclude MRAs and information had already been sent to interested parties. The representative of Turkey emphasized that this approach was fully consistent with international practice.

2. Previously raised concerns

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

37. The representative of Canada reiterated his delegation's concerns with regard to REACH. He recalled that at the November 2009 Committee meeting his delegation had submitted a Room Document providing a summary of Canada's outstanding concerns and questions about: (a) the issue of the Only Representative (OR); (b) the authorization and restriction provisions under REACH; (c) the regulation on Classification, Labelling and Packaging of substances and mixtures (CLP); (d) the treatment of nanomaterials under REACH; (e) the relationship between REACH and the directive concerning Restrictions on Hazardous Substances in electrical and electronic equipment (RoHS); and (f) the proposed changes to Article 9 Annex V of the REACH regulation which provided for an exemption for genetically modified organisms (GMOs). While Canada was thankful for the answers that the European Union had provided bilaterally, concerns still remained on several issues. The EU delegation was therefore invited to expand upon its previous answers and provide further clarification on: (a) the issue of peer-review of industry-submitted data; (b) the interaction between distributors and ORs; (c) the relationship between REACH and other EU regulations, such as the RoHS directive.

38. With regard to the treatment of natural vegetable oils sourced from genetically modified soybeans, canola and corn under REACH, it was Canada's understanding that following extensive consultations with EU member States, the European Commission had referred the issue back to the European Chemical Agency (ECHA). The Canadian delegation sought confirmation that ECHA was considering the publication of the guidance documents on Annex V of the REACH regulation without further delay. It was also Canada's understanding that the issue of oils sourced from GMO plants would not be addressed immediately, but at a later stage through the so called "fast track guidance update procedure". The representative of Canada asked the European Union to clarify what this procedure was and how it would affect the treatment of GMO oils.

39. The representative of Japan noted that it continued to have serious concerns about REACH. In particular, concerns remained with regard to the denominator of the threshold for the substances contained in the Substances of Very High Concern (SVHCs) list, included in Annex XIV of the REACH regulation (List of substances subject to authorisation). It was Japan's understanding that the Guidance on Requirements for Substances in Articles was still under review. In this regard, the representative of Japan recalled that six EU member States had expressed disagreement over the 0.1 per cent threshold for the notification and communication obligations with respect to substances on the candidate list. Although the guidance document stated that the 0.1 per cent threshold applied to the article as produced or imported, six EU member States had informed ECHA that, according to their view, the 0.1 per cent threshold should apply to components or homogenous parts of the articles. This situation caused uncertainty and confusion among Japanese exporters. In particular, although the EU delegation had previously stated that the dissenting view of several EU member States was not relevant to the uniform implementation of REACH across the European Union, some EU member States continued to implement REACH in a different manner. The European Union was therefore requested to ensure a uniform interpretation and application of the regulation across all member States.

40. The representative of Argentina reiterated his delegation's concern with regard to REACH. The complexity and lack of transparency of REACH showed that this regulation constituted an unnecessary barrier to trade. This situation was further aggravated by looming implementation deadlines. It was stressed that the complexity and the disproportionate costs associated with REACH, and the lack of technical assistance to developing countries constituted a serious impediment to the continued presence of Argentinean companies in the European market. These difficulties were particularly serious for Small and Medium-sized Enterprises (SMEs), which did not have the expertise to understand and meet the regulation's requirements. In this regard, the representative of Argentina recalled that the text of the REACH regulation was about 1,000 pages long and was accompanied by extensive and complex guidance documents. He also noted that, according to the Fourth meeting of Competent Authorities (CARACAL), some of the updated REACH guidance documents would only be available after the 30 November 2010 first deadline for registration of substances in quantities produced or exported above 1000 tonnes, including carcinogenic, mutagenic and reprotoxic (CMR) substances. Serious concerns also remained on several other issues.

41. The Argentinean delegate pointed out that Annex XIII (Criteria for the identification of persistent, bio accumulative and toxic substances, and very persistent and very bio accumulative substances) and Annex XIV (List of substances subject to authorisation) of the REACH regulation were still under review by the European Commission and no date had been set for their final adoption. This situation increased uncertainty and confusion among Argentinean exporters. The representative of Argentina reiterated his request that appropriate technical assistance be provided to interested Members. While Argentina was thankful to the European Union for the replies provided, it was noted that many of these simply referred to the REACH guidance documents, which were as complex as the regulation itself. As a result of this situation, many companies had pre-registered substances without knowing whether they actually needed to be registered. Argentina therefore invited the European Union to provide technical assistance to the private sector directly involved in the implementation of REACH by sending qualified officials to interested countries. Argentina believed that this type of assistance would be more effective, prompt and precise compared to assistance provided on-line. It was also emphasized that Article 77 of REACH recognized the need to organize technical assistance activities and capacity building in developing countries.

42. The representative of Argentina further highlighted the difficulties and the costs imposed by the registration procedure, especially for SMEs of developing countries, which had to bear additional costs compared to similar European enterprises. While the EU regulation No. 340/2008 granted differential registration rates for SMEs, the criteria used by the European Commission to identify a SME differed from the criteria used in Argentina. For example, the European Union defined an SME

as a company with an annual sale turnover not exceeding EUR10 million, in Argentina, however, an SME was a company with an annual sale turnover not exceeding EUR14 million. This situation created a clear disadvantage for non-EU SMEs *vis-à-vis* EU producers. The European Union was urged to take these concerns into account and modify its legislation accordingly.

43. The representative of the United States shared the EU interest in protecting human health and the environment. However, the United States continued to have trade-related concerns about REACH and its implementation. The US representative noted that concerns were continuously raised by industry. Many of these had been already discussed by the United States and other Members and could be found in the minutes of previous TBT Committee meetings.

44. The representative of the United States stressed that the inadequate transparency and legal uncertainty in the REACH implementation process continued to make compliance planning difficult and limited opportunity for stakeholders to provide input. For example, it was the United States' understanding that some of the REACH guidance documents currently being updated would be finalized too late to help with the first registration deadline. The European Union was requested to clarify whether the remaining guidance documents would be finalized in time for stakeholders to rely on this information in preparation for the registration deadline of 30 November 2010. The United States also reiterated concerns about the different interpretation of REACH provisions across the EU member States. In particular, he echoed the concern already raised by Japan on the disagreement over the 0.1 per cent threshold for the notification and communication obligations with respect to substances on the candidate list, and invited the European Union to clarify what actions were being taken to address this issue. The US delegation also reiterated concerns regarding participation in the Substance Information Exchange Fora (SIEF). Several US companies continued to indicate that the SIEFs were not functioning effectively and that frequently no company wanted to serve as the lead registrant. US industry had also indicated that many SIEFs were non-functional and would not finish their work in time to meet the November 2010 deadline for registration. The US delegation urged the European Union to clarify what actions were being taken to address these issues.

45. The representative of the United States also noted that the European Union had announced the creation of a high level contact group to develop a strategy to meet the first REACH registration deadline. The group included the directors of DG Enterprise and DG Environment, ECHA and six EU trade associations. In this regard, he was particularly concerned that foreign stakeholders, including representatives of SMEs, had not been included in the contact group and would not be able to provide input or learn of developments. Concerns remained also with regard to the obligation for foreign companies, unlike their European competitors, to delegate their participation in the SIEF to their ORs. It was reiterated that this situation could potentially compromise sensitive commercial information and that EU suppliers and downstream users that sourced exclusively from EU suppliers would not be faced with the same confidentiality concerns. Finally, the US delegation reiterated concerns about the impact of REACH on animal testing and noted that concerns on this issue were also raised by EU stakeholders. The European Union was asked to provide an update also on the status of this issue.

46. The representative of Australia shared the concerns raised by previous speakers and reiterated her delegation's concerns about the REACH regulation, which had the potential to disrupt and impede global trade in chemicals. Australia was particularly concerned that REACH would have a disproportionate impact on SMEs and that, as a result, many SMEs would be unable to continue exporting to the EU market. Concerns remained also about the lack of technical assistance provided to Members in the implementation of REACH. It was stressed that non-EU companies continued to require further assistance from EU experts to ensure a correct implementation of REACH. In this regard, the representative of Australia welcomed the development of the REACH guidance documents by the European Union but noted that these were continuously subject to change. She urged the European Commission to take into consideration the concerns expressed by Members about REACH.

47. The representative of Chile supported the comments made by previous speakers and reiterated her delegation's concerns with regard to REACH. Although her delegation had raised most of these issues previously, the response of the European Union had not been satisfactory. She recalled that Chile was particularly concerned about the negative impact of REACH on SMEs, which had to bear disproportionate costs and did not have the expertise to understand and meet the regulation's requirements. In this regard, it was pointed out that ECHA did not appear to be capable of offering the required technical assistance. For example, the REACH guidance documents were only available in English. Other concerns already raised in previous Committee meetings were also reiterated, such as: (i) the lack of clarity on the substances to be included in Annex XIV of the REACH regulation (List of substances subject to authorisation); (ii) the penalties for non-compliance with REACH which had not been notified by several EU member States; and (iii) the protection of confidential business information that non-EU firms were expected to provide. The European Union was urged to provide further clarification on the issues raised by concerned Members.

48. The representative of El Salvador, speaking on behalf of GRULAC reiterated her delegation's concerns with regard to the REACH regulation and its implementation. While the Members of GRULAC recognized the importance of protecting human health and the environment, concerns remained about the complexity and costs of the regulation, its trade-restrictiveness and the lack of detailed information in Spanish. In particular, it was stressed that REACH had a disproportionate impact on SMEs, which did not have the expertise to understand and meet the regulation's requirements. Therefore, El Salvador reiterated her delegation's request to the European Union to provide appropriate technical assistance to interested Members and consider special and differential treatment provisions for developing countries.

49. The representative of Cuba supported the comments made by Argentina and El Salvador on behalf of GRULAC, and reiterated her delegation's concerns with REACH. Cuba was particularly concerned about: (i) the complexity of the European regulation and the costs associated with its implementation; (ii) the lack of clarity with regard to the OR provision; (iii) the functioning of the Substance Information Exchange For a (SIEF); (iv) the protection of confidential business information; (v) the differential enforcement of the procedure for the confirmation of pre-registration across EU member States; and (vi) the lack of adequate technical assistance to developing country Members. These issues showed that the REACH regulation constituted an unnecessary barrier to trade and a serious impediment to the continued presence of developing countries' companies in the European market. The European Union was urged to take into account the concerns expressed by trading partners and amend its legislation accordingly.

50. Furthermore, the representative of Cuba recalled its serious concern about the negative impact of REACH on the nickel industry and on other industries which used nickel compounds in a broad range of chemical processes, such as the heavy industry and the food processing industry. Again, she remarked that these adverse effects would be particularly severe for the economies of developing countries. In particular, it was noted that the costs to comply with the requirements set out in the proposed regulation were too high for developing countries and that replacing the use of nickel with other substances was unachievable. Cuba was highly dependant on nickel production – nickel represented the main exports of the country.

51. The representative of Thailand shared the concerns expressed by previous speakers about REACH. She was particularly concerned about the impact of REACH on SMEs.

52. The representative of the European Union recalled that several concerns about REACH had already been raised and discussed at previous meetings of the TBT Committee. She referred to previously provided answers recorded in the minutes, and in particular to the explanation provided at the November 2008 meeting of the TBT Committee, when two experts from DG Environment and

DG Enterprise had provided detailed and comprehensive answers to the concerns raised by WTO Members on REACH.[5]

53. On the Substances Information Exchange Fora (SIEF), the EU representative stressed that ECHA and the European Commission continued to effectively assist SIEF and lead registrants. She stressed that since the start of the awareness campaign launched by ECHA the number of lead registrants had steadily increased. It was noted that on 19 March 2010 the number of lead registrants had reached 2,400. The EU representative also confirmed that a high level contact group, consisting of representatives of the European Commission, ECHA and industry associations had been created. This group was working on solutions to practical problems, especially with regard to the functioning of SIEF. She said that, contrary to what had been stated by the United States, SMEs were represented in this group, but that the request of participation of foreign stakeholders made by the United States would be conveyed to capital for due consideration. However, she emphasized that the contact group was already focusing its work on the obligation for importers. The Committee was also informed that ECHA would organize a new Stakeholders Day to help companies meet the 2010 and 2011 registration deadlines, to be held on 19 May 2010.[6] Concerned Members and those requesting technical assistance were invited to participate in this event, which would also be web streamed and afterwards available on the ECHA website.

54. Regarding the concerns on the disclosure of the registration number of chemical substances, the EU representative informed that a solution had been found to this. She explained that the REACH regulation would be amended so as to permit, under certain conditions, the omission of the four last digits numbers of the registration number in the safety data sheet.

55. Regarding penalties for non-compliance to REACH, the representative of the European Union noted that only two EU member States had not yet adopted the relevant sanctions. The European Commission was currently pursuing the infringement proceedings against the two member States who had not notified their enforcement measures. All other EU member States had adopted penalties for non-compliance to REACH and they could be found in the official journals of the member States concerned.

56. On the issue of uniform interpretation across the European Union, the EU representative recalled that the legal instrument adopted for REACH was a Regulation, which was directly applicable in all member States and applied uniformly throughout the European Union. This point was not affected by the dissenting views of some EU member States. It was further noted that only the text of REACH was legally binding and only the European Court of Justice would have the competence to provide a definitive interpretation of its provisions. In case enforcement authorities interpreted REACH in a different way than indicated in the REACH guidelines published by the European Commission, operators concerned could start an action at national courts with a view to seeking the opinion of the European Court of Justice, who would establish which interpretation should prevail throughout the European Union. This was the normal mechanism in the EU, which was not specific to REACH and which ensured a uniform application of REACH.

57. On the treatment of natural vegetable oils sourced from genetically modified plants, the EU representative informed the Committee that the issue had been discussed during the February 2010 meeting of Competent Authorities (CARACAL). In particular, it had been decided that natural vegetable oils sourced from genetically modified plants would be eligible for the exemption contained in Point 9 of Annex V of the REACH regulation, providing that these oils met all other conditions for the exemption. The EU representative also confirmed that the guidance documents on Annex V of the REACH regulation were still under preparation.

[5] See G/TBT/M/46, paras. 179-191.
[6] http://echa.europa.eu/news/events/4rd_stakeholders_day_en.asp

58. On the treatments of SMEs, the EU delegation recalled that REACH provides that the amount of information is lower for lower tonnage ranges and that a special beneficial treatment for SMEs was foreseen with regard to fees. Regarding the issue raised by Argentina on the definition of SMEs, she stressed that it was the EU definition of SMEs that was applied with regard to REACH, that the same definition therefore applied indistinctly to EU and non-EU based companies and that as a consequence there was no discrimination.

59. On the current state of play of the procedure concerning substances subject to authorization, the EU representative informed the Committee that fourteen new Substances of Very High Concern (SVHCs) had been identified by ECHA to be included in the candidate list according to the procedure established by Article 59 of the REACH regulation. She explained that the current candidate list contained twenty nine substances and that eight other new substances proposed for inclusion had been identified on 8 March 2010 by ECHA. The EC delegate informed the TBT Committee that the public consultation procedure on these eight newly identified substances was open and comments could be sent until 22 April 2010.

60. With regard to Canada's question on the issue of peer-review of industry-submitted data, the EU representative asked for more information in order to fully understand the concern. . Regarding the interaction between distributors and Only Representatives (OR), she recalled that the relation between these entities was contractual in nature and subject to private law. Regarding the relationship between REACH and RoHS, the EU representative explained that the REACH Regulation stated that it was without prejudice to other environmental legislation. REACH had a more horizontal scope and therefore vertical legislation that was better adapted to specificities of certain sectors would continue to exist. Certain links existed however between the two measures. For example, the proposal for RoHS called for the application of the REACH methodology and REACH provided that chemical substances already restricted under other EU legislation could not be subject to authorization.

61. With regard to Cuba's intervention on the requirements for nickel compounds set out in the proposed regulation, the representative of the European Union referred to a proposed amendment to the REACH regulation, which had been notified to the TBT Committee on 28 September 2009 (G/TBT/N/EEC/297). It was noted that a period for comments of sixty days had been provided to interested Members. It was further explained that this draft regulation would amend Annex XVII of the REACH regulation, which regulates the restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles. The EU delegate explained that the proposal concerned, among others, borates and nickel substances that had been reclassified through the 30th and 31st Adaptation to Technical Progress (ATP) to the Dangerous Substance Directive 67/548/EEC (DSD) as carcinogenic, mutagenic or toxic for reproduction (CMR). She stressed that the proposal did not lay down restrictions for articles containing these substances, but that it concerned restrictions for the sale of these substances or of mixtures containing them, when they were intended for the supply to the general public and when they exceeded specified concentration limits.

62. With regard to the nickel compounds classified under the EU directive on marketing and use of dangerous substances and covered by the 31st ATP (and the 1st ATP to the Regulation on Classification, Labelling and Packaging of substances and mixtures), it was the EU delegation's understanding that currently there were no nickel compounds or mixtures on the EU market that went beyond the allowed concentration limits and were used by consumers. No disruption of trade was therefore expected. In this regard, the European Union representative invited Members who had information that the newly classified substances or mixtures were on the EU market to inform her delegation about concrete examples. Furthermore, she stressed once again that the above-mentioned classifications and restrictions did not apply to articles, but only to substances or mixtures.

63. With regard to borates, the EU representative recalled that only a few mixtures which were sold in the EU market to the general public contained borates beyond the allowed concentration levels, notably detergents, cleaners and certain photographic mixtures. Since a first risk assessment had concluded that use of borates in these mixtures did not pose a risk to the general public, exemptions to the restrictions had been granted in the proposed regulation. However, the EU delegation informed Members that the ECHA risk assessment Committee had been asked to provide further information on the use of borates acids in photographic applications. In light of this new upcoming opinion and the on-going discussion with EU member States on this issue, the proposed regulation had not been adopted yet. The EU delegation stressed that any revision to the current proposed regulation would be duly notified to the TBT Committee.

(ii) 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)

64. The representative of the United States raised concerns regarding EU measures that restrict the usage of common, descriptive or commercially valuable terms by non-EU wine producers on the grounds that those terms are traditionally associated with European wines. He said that the European Union was apparently trying to claim exclusive rights to the usage of terms commonly included on wine labels in the EU such as "Château", "Vintage" and "Superior", with exceptions for non-EU wine producers limited to the case when the exporting country regulated the use of these terms to the EU's satisfaction. However, he noted that some of the terms did not have a common definition across the European Union and that he was not aware of any efforts undertaken by the European Union to monitor or limit the use of those terms within the European Union. He thus expressed the continued concern with respect to the negative trade impact of this measure.

65. With respect to the EU argument that consumers could be misled by the use of these terms, the United States observed that these terms had been used by US wine producers on the EU market for many years without incident, which suggested there was no risk to consumers. He remarked that the European Court of Justice had furthermore expanded the scope of the measure, and that contrary to the assurances from the representative of the European Union, the traditional terms were now protected in languages other than the one for which protection had originally been identified. He concluded by pointing out that bilateral discussions with the European Union had, to date, failed to resolve the concerns of the United States and that currently, US industry was involved in discussions with the European Commission on the matter.

66. The representative of the European Union noted that the EU wine labelling legislation had been in force since 1 August 2009. She highlighted that the new rules allowed third country wines to use certain traditional terms, provided that they fulfilled the same or equivalent conditions as those required for wines of EU member States in order to ensure that consumers were not misled. She explained that the competent authorities of the European Union, of third countries or representative professional organizations established in third countries could apply to the Commission for protection of traditional terms. She noted that in the past months the Commission had received applications from several WTO Members.

(iii) 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)

67. The representative of Japan noted that the rapporteur at the European Parliament's Environment Committee had suggested seven additional chemical substances in her draft report on the re-cast of the RoHS directive. Japan requested the European Union to avoid the duplication of

procedures and criteria already found in the REACH regulations, and to base their decisions on a scientific assessment of those chemical substances, as well as on an analysis of the social and economic impact of blacklisting them. He explained that the blacklisting of substances without scientific evidence and without an analysis of the socio-economic impact would lead to the removal of products from the market containing those substances even though they carried little risk. As a result, unnecessary costs (for example, development costs for alternative substances) would be imposed on both the suppliers and users of those chemical substances. Japan also requested the European Union to notify the WTO at the appropriate time, if it were to make a major change - such as the addition of new substances.

68. The representative of Korea noted that the draft report of the European Union, which proposed the restriction of seven additional substances such as PVC, DEHP, BBP, DBP etc. had insufficient scientific basis and was an unnecessary and unreasonable measure that would create trade barriers.

69. The representative of the United States highlighted the need for continued transparency in the implementation and operation of the proposed RoHS recast, by taking into account input from all stakeholders including trading partners and industry. He emphasized the importance of providing transparency and adequate legal certainty regarding the scope, the treatment of substances, the exemption process, and the relationship between REACH and RoHS. It was the United States' view that any selection and assessment procedure under RoHS or REACH as well as the development of rules needed to be science-based, taking into account available scientific and technical information science and intended end uses. In this regard, he noted that there were new proposals in the Council and Parliament to open up the scope of RoHS to all electrical and electronic equipment. The United States asked for a status update in this regard, as these proposals were likely to have an impact on many producers who were not aware that their products could be covered by RoHS. Furthermore, he requested information on how the European Union intended to solicit input from stakeholders on the proposed changes.

70. The representative of the United States encouraged the Commission to conduct a thorough impact assessment. He further noted that his delegation had heard concerns about these proposals from several of its industries including home appliances, automobiles and large scale stationary industrial tools; therefore, it would be particularly important for such an assessment to examine the effect of the inclusion of these products under the directive. Moreover, he observed that there were new proposals in the Parliament with respect to additional substance restrictions, criteria for exemptions, and a non-paper on the inter-relationship between RoHS and REACH. Considering that this had come to light after the close of the comment period, the United States requested an update on the status of these issues, including how the European Union would solicit input. It was stressed that the exemption processes for medical devices needed to be transparent and provide legal certainty. These needed to take into account the product development cycle for medical devices in order to ensure the long term investment in new devices and innovations that were critical to hospitals, doctors, and patients in the European Union.

71. The representative of Israel recalled that on 3 December 2008, the European Commission had issued its proposal for the revision of the RoHS Directive and that subsequently the European Union Parliament's rapporteur had suggested extending the scope of chemical substances covered by banning entire families of chemical products (such as Brominated Flame Retardants) and by adding new substances for restriction. He explained that Israel perceived this new position as a breach of WTO obligations under the TBT Agreement, as it was not based on sound scientific findings. Furthermore, the representative of Israel pointed out that Israel regarded the avoidance of duplication and contradictions between REACH and the revised RoHS as important, as REACH was already in place and would be fully operational by the time the revised RoHS directive would enter into force. In this

respect, Israel asked the European Union to precisely identify overlapping elements and clarify the interaction between the two legal instruments.

72. The representative of the European Union stated that at the time of the last TBT Committee meeting the proposal had been in the "first reading" of the legislative process by the Council and the Parliament and that in its revision of the Commission's proposal, the European Parliament had suggested a number of amendments, some of which had been referred to in the statements made by several delegations. She explained that the Environment Committee of the European Parliament, which was the lead committee for this proposal, would vote on several hundreds of amendments that had been tabled by other European Parliament committees in May and that the opinion of the lead committee was to be discussed at the June plenary session of the European Parliament. She expected that during that session, the European Parliament would adopt its opinion on the Commission's proposal. In a subsequent stage there would be a discussion by member States of the text which had been voted upon by the Plenary. In particular, the member States would have to review the European Parliament's amendments. If an agreement were to be found between the Parliament and the Council, and if the Commission were to agree to the proposed amendments, the text would be finalized. If a compromise were not to be reached, the text would be re-submitted to the European Parliament and Council for examination under a "second reading". Thus, due to the uncertainty regarding the amendments that would survive the vote in the Parliament, the representative of the European Union considered it premature for the European Union to give its views on any of the amendments. She emphasized that in its proposal, the Commission had not proposed any changes to the list of banned substances in the RoHS recast proposal – in particular the proposal did not restrict the use of PVC- , nor had it proposed an open scope. The European Union would notify the TBT Committee about the new text should the initial RoHS proposal be substantially amended.

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

73. Regarding the Indian mandatory standards on tyres and tubes for automotive vehicles, the representative of Japan appreciated India's prolongation of the implementation period from 120 days to 180 days, however he noted that Japan considered this period insufficient. In particular, he observed that there seemed to be a limited number of testing laboratories in view of the large amount of distributed tyres and that India had not yet published a detailed and definitive regulation. Therefore, Japan requested India to reconsider a longer suspension period, so that industry would have sufficient time to prepare for the new Indian standards after publication of the detailed regulation. He also noted that Japanese industry had not yet received a reply to questions sent in April 2009.

74. The representative of the European Union stated her delegation's disappointment with the fact that India had published the Order on 19 November, despite India informing Members at the last TBT Committee meeting that it had decided to postpone the implementation of its new legislation and to discuss the issue bilaterally. She noted that the new measure provided a marking obligation for replacement tyres, but did not accept tyres which were marked with an "E-mark" in line with the UNECE regulations, which were widely accepted to be the relevant international standard. The European Union was aware that India had indicated in the past that it deemed it necessary to impose requirements different from those of the UNECE regulations because India had special road and geographical conditions. However, she observed that other countries with comparable road and geographical conditions to India accepted the UNECE Regulations and "E-marking" without any problem. Moreover, India had never provided any evidence why tyres produced according to the UNECE standards would not be safe in India. She noted that the measure exempted tyres imported by Original Equipment Manufacturers, even though replacement tyres met exactly the same quality and safety level. In the EU's view this cast doubt on India's justification that its requirements were imposed due to safety reasons or special geographical conditions. Hence, this raised questions about the measure's compatibility with the TBT Agreement. Furthermore, with regard to the recognition of laboratories, the European Union requested that India also recognize laboratories accredited by the

UNECE and not only those accredited by ILAC. Finally, since not one single EU plant had been audited by Indian authorities, the European Union requested India to further postpone the implementation of the legislation, in order to give importers more time to comply with all the steps of the licensing procedure.

75. The representative of Korea explained that the ISI-marking stated in Article 3(1) involved a considerable amount of time to implement and entailed a large cost increase for both manufacturers and consumers. Furthermore, the information that needed to be disclosed under paragraph 5 would include producers confidential technological information - which was of serious concern to the industry; this requirement needed to be excluded from the order. Korea requested Indian authorities to grant a grace period of 24 months in order for industry to fulfill the requirements of the Order.

76. The representative of India said that in the absence of a universally applicable global technical standard, several countries including India, had prescribed their respective national standards. He said that the decision of the Government of India to notify the new Order was in line with the position prevailing in other countries, where tyres had to comply with both quality and safety parameters determined by the respective governments. He explained that the new Quality Control Order (QC) covered both imported tyres and domestically manufactured tyres that did not fall under any of the categories of tyres which were mentioned under Section 3, Paragraph 1 of the QC Order. He explained that the objective of the QC Order was to ensure the safety of human life as well as the protection of consumer interests. He stressed that the Quality Control Order did not seek to make any distinction between domestic and foreign manufacturers of tyres as could be seen from Clause 3(1) of the Order. Moreover, the measure was applicable only to those tyre sizes which were covered under the Indian Standard as mentioned in the schedule of the QC Order. He noted that India did not know whether laboratories accredited by UNECE approved authorities had test facilities according to the requirements of Indian Standards. Finally, he informed the Committee that the "Pneumatic Tyres and Tubes for Automotive Vehicles (Quality Control) Order, 2009" which has been notified in November 2009, would come into effect in May 2010, which would enable the industry to plan in advance and to obtain a BIS certification of their products in order to continue exporting their material to India without disruption.

(v) European Union – Regulation on Classification, Labelling and Packaging of Substances and Mixtures (ATPs and CLP) (G/TBT/N/EEC/297; 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)

77. The representative of Canada reiterated his delegation's concerns regarding the EU classification of over 130 nickel-containing substances as carcinogenic and dangerous under the 1st ATP to the regulation on Classification, Labelling and Packaging of substances and mixtures (CLP). He recalled that the EU classification could have a significant impact on the economy of his country and that exports of nickel containing substances to the EU market were worth about CAD5.4 billion per year. Given the potential of negatively impacting nickel producers and exporters, it was essential that any classification of substances was transparent and based on sound science, regardless of what legislation or regulation they were made under. The Canadian representative further stressed that, in order to avoid unnecessary obstacles to trade, Article 2.2 of the TBT Agreement prescribed that Members consider available scientific and technical information as elements relevant to the risk assessment of a technical regulation.

78. The representative of Canada drew the attention of the TBT Committee to the proposed amendment to the REACH regulation, notified under G/TBT/N/EEC/297. He noted that the new EU proposal would prohibit the sale to the general public – or the use in mixtures above a certain concentration limit – of a number of nickel substances classified as category 1 or 2 carcinogenic, mutagenic or toxic to reproduction (CMR) under the 1st ATP. Such substances and mixtures needed to be labelled as “Restricted to Professional Users”. He further noted that written comments

regarding this notified draft regulation had been sent to the EU delegation on 15 March 2010. Canada sought assurances that the European Union would give serious consideration to the comments provided by trading partners and would take them into account before proceeding towards the amendment of Annex XVII of REACH. Furthermore, Canada urged the European Union to explain what procedure had been used to reclassify nickel compounds under the 1st ATP to the CLP regulation, for example, provide the water solubility data of the nickel compounds classified under the 1st ATP. In Canada's understanding, industry had provided data which demonstrated that for substances within the same water solubility grouping, classifications varied across compounds. The European Union was urged to clarify whether, in light of this new data, the approach to the classification of nickel compounds and the classifications themselves would be revised. The European Union was further urged to ensure that any measures taken did not create unnecessary obstacles to international trade.

79. The representative of Canada was also concerned about the proposed classification of boric acid as a substance of very high concern (SVHC). He emphasized the systemic concern of his delegation in ensuring that the assessment and management of substances was scientifically based, conducted in an appropriate and transparent manner and proportionate to the risk that substances posed. His delegation encouraged the European Union to clarify whether the proposed classification of borates, including boric acid, was based on perceived risks associated with inhalation exposure in the workplace, and what other risk management options had been considered in this case.

80. The representative of Canada then referred to a Room Document providing a summary of its outstanding concerns, many of which had previously been raised. With respect to the classification of nickel-containing substances, it was reiterated that the Canadian industry continued to have significant concerns regarding the scientific validity of the classifications of the nickel compounds that had been adopted by the 1st ATP to the CLP regulation. Recent data from the industry appeared to put in question the EU assumption that a wide range of toxicological effects in the human body could be accurately predicted by grouping nickel containing substances on the basis of water solubility alone. This assumption had provided the basis upon which the European Union had applied the read-across methodology to reclassify the majority of nickel compounds. Canada sought assurances that the European Union would give serious consideration to the research data that industry was producing as part of the REACH registration process, as well as other relevant scientific information. Canada sought further assurances that, in light of this information, the European Union would consider reviewing its classifications of nickel in a transparent and objective manner. To this end, the delegation of Canada asked the European Union to provide information on the transparency, oversight and peer review measures that would be put in place to ensure data submitted by industry under REACH was adequately considered.

81. Canada recalled that, despite the EU's characterization of nickel classifications as "mere labelling requirements", concerns on downstream impacts remained. For example, the representative of Canada reminded the Committee that nickel substances had been added to the so-called "Substitute It Now" (SIN) list drawn up by a coalition of environmental campaign groups, which was aimed at speeding up the implementation of REACH. The representative of Canada also recalled the challenges faced by industry as a result of the reference to these classifications in the EU Toy Safety Directive. However, he welcomed the fact that the European Commission had considered the risk associated with the use of nickel in stainless steel and created an exception for its use in toys.

82. With regard to the proposed amendments to Annex XVII of the REACH regulation, it was Canadian industry's view that the European Commission had not properly assessed the addition of new nickel compounds to Annex XVII against the legal requirements of REACH. In particular, it was noted that the legal basis for the proposed amendment was Article 68 para. 2 of REACH, which allowed a substance that “meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, and [that] could be used by consumers and for which restrictions to

consumer use are proposed by the Commission" to be added to Annex XVII of REACH. While the legal text of REACH suggested that the European Commission had to show that the nickel compounds could be used by consumers in a way that could create a risk in order for them to be added to Annex XVII, Canadian industry's had reported that very few of the nickel substances contained in the 1st ATP to the CLP were used by consumers. While Canada supported the objectives of protecting human health and the environment, as well as the principle of restricting consumer exposure to products containing carcinogenic, mutagenic or toxic to reproduction (CMR) substances, concerns remained that imposing a ban on the sale of the nickel compounds without first assessing the risks encountered by consumers was more trade restrictive than necessary, therefore not in line with Article 2.2 of the TBT Agreement. It was further pointed out that the European Commission appeared to have made considerable efforts to understand the consumer uses and potential risks posed by other substances included in the proposed amendment, including borates. However, industry stakeholders indicated that the same work had not been done with regard to nickel substances.

83. Finally, Canada asked the European Union to provide further clarification on the following issues: (i) what information the European Union had on how nickel compounds in the proposal "could be used by consumers"; (ii) what steps had been taken to assess the potential risks to consumers from the use of these nickel compounds; and (iii) whether an impact assessment on the effect of the proposed classification of nickel substances had been conducted.

84. The representative of Japan continued to have concerns with regard to the regulation on Classification, Labelling and Packaging of substances and mixtures (CLP). He noted that the deadline for the notification of hazardous substances or mixtures under the CLP regulation was 3 January 2011 for substances that had been placed on the market before 1 December 2010. For substances placed on the market on or after 1 December 2010, the deadline for notification was within one month after their entry into the EU market. In this context, the representative of Japan explained that importers could experience serious difficulties in obtaining information on the constituent components of certain mixtures, particularly with regard to substances that were present in mixtures only in small quantities. He further noted that importers could face other difficulties, such as lengthy communication channels in supply chains located outside the European Union, or the possibility that certain confidential information would be disclosed. For the above-mentioned reasons, the representative of Japan believed that the EU measure imposed an excessive burden on non-EU companies, which would not be able to submit the necessary notification by the deadlines set. The European Union was requested to take these concerns into account when implementing the regulation and allow importers sufficient time to obtain the necessary information through their supply chains.

85. The representative of Brazil reiterated his concerns with regard to the EU classification of nickel compounds under the 1st ATP to the CLP regulation, which incorporated the results of the 30th and 31st ATP to the Dangerous Substance Directive (DSD) 67/548/EEC. His delegation continued to believe that the EU process of classification was based on questionable scientific and procedural grounds.

86. On substance, Brazil was particularly concerned about the flawed application of the OECD read-across methodology by the European Commission, which simply assumed that several toxicological effects in humans could be derived from grouping substances based on the sole criterion of water solubility. Concerns were also reiterated about the disregard of other more important criteria such as bioavailability, about the absence of justification for skipping some important read-across steps, especially those related to the need for validating results through testing, and about the fact that the European Commission had failed to demonstrate that the classification decisions were based on any data at all. It was also Brazil's understanding that the water solubility of the grouped substances was inferred from a report that had never been published nor peer reviewed. In view of that, the European Union was invited to provide specific data for water solubility of each nickel compound

classified under the 1st ATP, and explain on what data relied the "expert judgment" that the OECD recommendations related to "validation through testing" could be disregarded.

87. On procedure, Brazil recalled that the 30th and 31st ATP to the DSD regulation had been incorporated into the 1st ATP to the CLP regulation, which constituted a different regulatory framework from the Dangerous Substances Directive. However, the European Union had not notified the incorporation of the previous ATP into the CLP regulation, as required by the TBT Agreement, and had not allowed for consultations with Members at an early stage, when comments could still be taken into account. The delegation of Brazil continued to believe that that the 1st ATP was not based on sound science and that it would cause disruptions in the global supply chain of nickel compounds. Finally, Brazil recalled that in statements provided at previous meetings of the TBT Committee, the European Union had assured Members that the new classification of nickel compounds only related to labelling and would not result in bans or restrictions on the use of chemical substances in consumer products. However, it was Brazil's understanding that these classifications could lead to further restrictions under other EU regulations and could have a significant market impact. The European Union was urged to take into account the scientific data produced by industry in the context of REACH and to review the nickel classifications contained in the 1st ATP.

88. The representative of the United States noted that, in light of the most recent risk assessment commissioned by the European Commission, borate usage in the cases examined either did not pose a risk to the general public, or the risk was negligible. He welcomed that, as a result of this study, it had been proposed that the placing on the market and use of borates-containing substances in household cleaners, detergents and certain photographic mixtures should not be restricted. However, the US delegation had been informed that a second risk assessment was currently being conducted because some EU member States objected to the conclusions of the first study. The European Union was invited to explain on what basis some EU member States objected to the conclusions of the first risk assessment. With regard to nickel and certain nickel compounds, the US representative reiterated his delegation's concern that the relevant competent authority appeared to have disregarded certain steps when applying the OECD read-across methodology, which raised questions as to whether the European Union adequately took into account available scientific and technical information and intended end-uses of the relevant nickel compounds. He noted that the European Union had previously stated that certain steps of the read-across methodology had been skipped in order to avoid human testing. However, the OECD methodology did not foresee the carrying out of CMR testing on humans, nor was the United States aware of any EU legislation that would prevent the EU from following all the steps of the read across methodology. The US delegation would continue to monitor the potential adverse trade impacts of the nickel and borates classifications and the potential methodological issues raised.

89. The representative of the Dominican Republic reiterated its concerns with regard to the reclassification of nickel carbonates and other nickel compounds under the 30th and 31st ATPs to the DSD and the transposition of the results of these ATPs into the 1st ATP to the CLP regulation, which his delegation considered to lack sufficient scientific evidence. He also noted that the many comments expressed by various delegations at the TBT Committee meetings held in 2008 and 2009 had not been taken into account by the European Union. The Dominican Republic representative recalled that written comments regarding the 31st ATP had been sent to the EU delegation on 18 November 2008, and were subsequently circulated to all WTO Members in document G/TBT/W/302. He regretted that his delegation had not received any response from the European Union. Again, he also expressed regret that the Technical Progress Committee (TPC) approved the 31st ATP on 19 November 2008, within only 24 hours of the end of the notification comment period. It was his delegation's view that, having been adopted in these circumstances, the 31st ATP did not satisfy the requirements set by Article 2.9 of the TBT Agreement.

90. Furthermore, the Dominican Republic objected to the manner in which the European Union applied the read-across methodology in the reclassification of nickel substances. In this regard, the representative of the Dominican Republic believed that the European Union violated Article 2.2 of the TBT Agreement which stipulated that "Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade". He recalled that nickel exports represented, in 2007, more than 50 per cent of the total exports of the Dominican Republic, with a total value of USD1,153 million, and that the 31st ATP would have serious harmful effects for both producers and exporters of nickel substances. Moreover, he stressed that the EU measure would have a devastating effect on the industry and economy of the country as a whole, also considering the serious drop in nickel prices that had occurred in 2008, which had reduced the total value of Dominican Republic's nickel exports to USD492 million.

91. The implementation of the 1st ATP to the CLP regulation was likely to further aggravate conditions in a very economically depressed area of the Dominican Republic, where the population's income relied only on nickel extractions, as well as causing increased production, transport and insurance costs and worsening conditions in a industry already severely affected by the world economic crisis. The Dominican Republic representative further stressed that the European Union did not notify the 1st ATP as required by Article 2.9 of the TBT Agreement, so as to allow reasonable time for Members to comment. The EU delegation was urged to take into account the comments made by Members and to comply with the obligations of TBT Agreement.

92. The representative of Colombia echoed the concerns already expressed about the adoption of the 1st ATP by other speakers and regretted that the European Union had failed to take into account the comments previously made by WTO Members. Her delegation raised a systemic concern on transparency and emphasized the importance of ensuring transparency in the regulatory process that led to the development and enforcement of regulations. In this regard, Colombia invited the European Union to provide the scientific data on which the reclassification of nickel compounds was based and to explain the reasons why the European Commission automatically transferred classifications under the DSD to the CLP, instead of following the new procedure for harmonized classification and labelling of substances specified under Articles 36 and 37 of the CLP regulation. The European Union was also asked to provide available data on the carcinogenicity of nickel substances and the use of the OECD read-across methodology. Finally, the representative of Colombia stressed that in statements provided at previous meetings of the TBT Committee, the European Union had assured Members that the new classification of nickel compounds only related to labelling and would not result in bans or restrictions on the use of chemical substances in consumer products.

93. The representative of Australia recognized the importance of ensuring a high standard of protection for human health and for the environment and supported the development of regulatory strategies to insure such protection. However, concerns remained that the EU's decision to reclassify nickel compounds was based on questionable scientific and procedural grounds and had been adopted while the concerns of WTO Members remained outstanding. In particular, the representative of Australia recalled that the Australian assessment authority, the National Industrial Chemical Notification and Assessment Scheme (NICNAS), had reviewed the scientific literature available on the issue in late 2008, including EU and OECD documentation, and had disputed the robustness of the European Union's scientific basis for its classification decisions. She also noted that the proposed amendment to Annex XVII of the REACH regulation would further prohibit the sale of nickel substances to the general public and would require these substances and mixtures to be labelled as "restricted to professional users". It was Australia's understanding that the consequences of this amendment for nickel producers and users were far reaching; she recalled concerns that the reclassification of nickel compounds as category 1 and 2 CMR substances could trigger a series of downstream regulatory requirements which would impose additional restrictions and prohibitions on the use of nickel substances.

94. Furthermore, the representative of Australia noted that in previous TBT Committee meetings the EU delegation had assured Members that a risk assessment needed to be carried out before any type of marketing restrictions were imposed, or maximum exposure levels or bans considered. It was also noted that a risk assessment had been conducted for borates, resulting in the exemption of some borates for certain end uses from the proposed prohibition on sale to consumers. However, a similar risk assessment did not appear to have been conducted for nickel substances. Concerns had also been expressed about the fact that industry had reported that only three of the numerous nickel substances proposed to be included in Annex XVII were currently used by consumers. The European Union was urged to provide more information on these substances and to clarify what steps had been taken to determine whether the nickel substances included in the proposed amendment to Annex XVII of REACH would be used by consumers. The European Union was also invited to clarify how the potential risks to consumers resulting from the use of these nickel substances had been assessed.

95. The representative of Cuba reiterated her delegation's concerns regarding the adoption of the 31st Adaptation to Technical Progress (ATP) to the Dangerous Substance Directive 67/548/EEC (DSD) and its incorporation into the 1st ATP to the regulation on Classification, Labelling and Packaging of substances and mixtures (CLP). She stressed that several concerns which had been raised at previous Committee meetings had not received a satisfactory response. Cuba recalled the recommendation adopted by the TBT Committee at the Third Triennial Review that encouraged developed Members to provide more than 60 days for comments on notified technical regulations and procedures for assessment of conformity.[7] The European Union did not appear to have taken this recommendation into account: she recalled that the 31st ATP had been approved within 24 hours of the end of the notification comment period. The European Commission could not have had time to take into account the comments provided by other WTO Members. In this regard, Cuba expressed further concerns about the absence of a notification and consultation on the 1st ATP to the CLP regulation. It was pointed out that new criteria for assessment had been included in this regulation, which therefore constituted a new regulatory framework.

96. As had been stated previously, Cuba's main concerns were related to the incorrect application of the OECD read-across methodology, which the European Union had disregarded without providing any scientific justification. The European Union was invited to provide the data which was used as a basis for the "expert judgment" that some of the OECD steps could be disregarded. The representative of Cuba also believed that the EU's reliance on a single data point, water solubility, as the primary basis for categorizing nickel compounds stood to be challenged. She further disputed the validity of the theory that the mere presence of nickel ion generated toxic effects. In Cuba's view, the potential trade impacts of the measures flowing from these classifications remained to be seen. However, it was expected that the reclassification of various nickel compounds would give rise to stigmatization of nickel and would reduce access to this market and to other major ones through domino effects of other standards and classifications. The Cuban representative noted that, despite the EU's delegation assurances that the nickel classifications were merely "labelling requirements", the European Union had notified a draft proposal which would prohibit the sale to the general public of all substances classified as Category 1 or 2 CMR under the 1st ATP, and all mixtures containing them at above certain concentrations. In conclusion, while Cuba supported the objectives of protecting human health and the environment, concerns remained that the EU's regulatory regime for nickel substances created unnecessary obstacles to international trade. The EU delegation was requested to take the comments expressed by Members into account and revise the 1st ATP to the CLP regulation accordingly.

97. The representative of Indonesia joined other delegations in expressing concern about the classification of nickel substances in the 30th and 31st ATP and their incorporation in the 1st ATP to the CLP regulation.

[7] G/TBT/1/Rev.9 page 18.

98. The representative of Turkey continued to have serious concerns about the 30th and 31st ATPs and the transposition of their results into the 1st ATP to the CLP regulation, particularly with regard to the classification of borates. She stated that in previous TBT Committee meetings, her delegation had outlined their main concerns regarding this issue, and referred to the minutes of those meetings for a detailed outline of these concerns. Turkey encouraged the European Union to take into account Members' comments and bring its regulation in line with the TBT Agreement.

99. The representative of Thailand shared the concerns expressed by previous speakers and stressed the importance of having regulations based on solid scientific justification and procedural thoroughness.

100. The representative of Venezuela supported the comments made by other Members and reiterated the importance of having regulations based on clear scientific evidence. In this regard, the European Union was asked to provide the scientific data on which the classifications were based, and to take into account the impact that its measures could have on WTO Members, particularly developing countries and small economies.

101. The representative of the Russian Federation, speaking as an observer, supported the comments of previous delegations with regard to the nickel classification and stressed that technical regulations needed to be based on clear scientific evidence. He noted that such scientific evidence had not been provided by the European Union. Russia also believed that the erroneous application of the OECD read-across methodology could create a dangerous precedent for the manner in which other groups of chemical substances would be classified under REACH. In this context, attention was further drawn to the consequences of the EU decision on the nickel market. The European Union was requested to reconsider its classification or provide to interested Members the relevant scientific data on which the European Commission had based its decision.

102. The representative of the European Union noted that several concerns raised by a number of delegations were reiterations of concerns previously expressed and to which her delegation had already adequately replied orally and in writing. The answers to these concerns were reflected in the minutes of previous Committee meetings and the representative of the European Union did not intend to repeat arguments already made. Regarding the issue of compliance with the OECD guidelines on read-across methodology, the EU delegate reiterated that, when confirmatory testing was required to confirm that a classification was necessary, the European Commission had chosen the approach of not classifying the given compound at all. In particular, she noted that Article 4.3 of the Dangerous Substance Directive (DSD) 67/548/EEC did not allow the European Commission to ask for additional testing for the purposes of adopting a harmonised classification. However, if new arguments or scientific evidence – i.e., epidemiological studies, animal testing and alternative methods – were to challenge the European Commission's conclusions on the classification and labelling of substances, industry could provide this information and ask to EU member States to submit a dossier to the European Chemicals Agency (ECHA) in order to be examined. With regard to the issues raised about the proposed amendment to the REACH regulation (G/TBT/N/EEC/297), the representative of the European Union referred to the explanation given by her delegation in the context of REACH.

103. On the comments from Japan about the notification obligations laid down in Articles 39 and 40 of the CLP regulation, the representative of the European Union recalled that the CLP regulation had been notified to the TBT Committee in 2007 (G/TBT/N/EEC/163) and no comments had been received by WTO Members. She noted that this requirement to notify certain substances already applied under Articles 112 and 113 of the REACH regulation. In other words, industry was well aware that this notification deadline was approaching. The European Union delegate also noted that the deadline had been extended compared to the one originally foreseen under REACH, and that most of the information required for notification had been provided as part of the safety data sheets submitted under REACH procedures. Finally, the EU delegation stressed that the notification

procedure applied equally to EU and non-EU manufactures and that it was aimed at protecting human health and the environment. It could therefore not be postponed.

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

104. The representative of New Zealand reiterated concerns about Canada's compositional standards for cheese and continued to question their consistency with the principles of the TBT Agreement. He noted that the standards were overly restrictive in nature in terms of both the thresholds imposed for the use of dairy ingredients as well as their impact on trade. The standards limited the use of protein sourced from dairy ingredients even though such ingredients were widely used and accepted in cheese production, and he argued that Codex did not prescribe any limitations on their use. The representative of New Zealand requested that Canada provide the Committee with an update on the appeal of the federal ruling on these cheese standards. He also asked whether Canada intended to also introduce similar standards for yoghurt in the future.

105. The representative of Australia echoed the concerns raised by New Zealand and noted that his delegation remained concerned about Canada's consideration to make domestic milk proteins for cheese available at prices lower than those applied to imported milk proteins.

106. The representative of the European Union joined New Zealand and Australia in reiterating concerns regarding Canada's compositional standards for cheese. She noted that her delegation continued to have significant concerns with this measure, which had already begun to have negative impacts on EU manufacturers and exporters.

107. The representative of Canada noted that the revised regulations clarified and harmonized the federal compositional standards for cheese. These revised regulations came into force on 14 December 2008, and applied to cheese manufactured after that date. He stated that when developing these regulations, Canada had taken into account international standards, other countries' regulations, and comments received during the WTO notification period. The Canadian representative anticipated that most imported cheese would meet the revised standards.

108. On the issue raised regarding yoghurt, the Canadian representative informed the Committee that his Government had not initiated any regulatory process for establishing compositional standards for other dairy products. With respect to the judicial review, the hearing had been held on 31 March and 1 April 2009. On 7 October 2009, the federal court had ruled that the application for judicial review be dismissed. However, the federal court decision was currently being appealed. Lastly, the representative of Canada stated that there was no evidence that the regulations constrained the overall usage of milk ingredients such as milk protein concentrates.

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

109. The representative of the European Union reiterated concerns regarding India's order laying down a registration procedure for imported cosmetics products. She noted that her delegation had sent written comments regarding the issue and had not received a written reply, despite commitments made at the last Committee meeting. She asked India whether the planned registration procedure was still under consideration, and whether the text would be revised, as had been indicated by an expert from the Ministry of Health in September 2009.

110. The representative of India informed the Committee that the procedure for the restriction of cosmetics had not been notified and that there was no change in the procedure for the import of cosmetics. He also noted that India's position remained unchanged.

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

111. The representative of Japan reiterated his delegation's concern regarding the proposed compulsory certification of IT security products from China. He expressed his country's appreciation for China's efforts in bilateral consultations; as a result the scheme had been clarified to a certain extent. He noted, however, that China had not shared these clarifications with other concerned countries and therefore he believed it would be appropriate for the Chinese delegation to do so. The Japanese representative stated that regardless of such clarification, it remained a concern that the scheme was not consistent with international standards regarding IT security products and, as a result, Japan wished to pursue consultations.

112. The representative of the European Union joined Japan in thanking China for keeping an open channel of communication. Nevertheless, the European Union remained concerned with three separate issues: (i) the entry into force of the China Compulsory Certification (CCC) scheme on 1 May 2010; (ii) the continued application of the OSCCA (Office of State Commercial Cryptography Administration) 1999 Regulations of Commercial Encryption Codes ("the 1999 OSCCA Regulation") – which contained discriminatory elements against foreign companies *vis a vis* domestic companies; and (iii) the full implementation of the Multi-Level Protection Scheme (MLPS) in the near future. These three sets of rules jointly considered would introduce significant restrictions on access to the Chinese market for a wide range of information security products, even regarding purely commercial applications which were not sensitive to national security protection.

113. The EU representative proceeded in elaborating on these three concerns. Regarding the first point on CCC Regulations, he thanked the CNCA for the explanations and clarifications provided so far. One important outstanding issue was whether state-owned enterprises (SOEs) were covered by the scheme. If not, the European Union was seeking an official written confirmation that SOEs are not within the scope of application of these rules. Furthermore, he noted that any clarification as to the type of government organizations covered by the concept of "government procurement" in China would be appreciated. The European Union remained concerned that the proposed CCC procedures were not aligned to the Common Criteria international standard (ISO/IEC 15408:2005 on the Common Criteria for Information Technology Security Evaluation) and related conformity assessment practices.

114. The EU representative further highlighted that EU companies would not be able to participate in the conformity assessment system as it was currently set up. In particular, he noted that the substantive concerns raised with respect to the requirement to disclose highly confidential information such as encryption and product source codes or very sensitive product design information, had not yet been addressed. He underlined that it was absolutely vital for global information and communication technologies (ICT) companies to maintain full control of their Intellectual Property Rights and essential design information of their products throughout the evaluation process. The current disclosure requirements effectively prevented EU companies from applying for certification. In addition, he noted that it was the EU's understanding that not all of the final implementing measures and related evaluation procedures that CNCA's approved laboratories would use had been published for review and comments. Under these conditions, it was not surprising that no EU company to date – and, to the EU's knowledge, no other foreign company either – had applied for CCC certification.

115. The representative of the European Union noted that the discussion with the Chinese authorities, both bilaterally and in the TBT Committee, had shown the complexity of these issues and the need for further bilateral and perhaps plurilateral consultations with all affected trading partners and stakeholders. He therefore invited China to consider the suspension of the implementation of the CCC rules pending further discussions. The aim of this dialogue should be to achieve a balance between the two legitimate interests at stake: on the one hand the Chinese Government authorities'

legitimate aim to protect national security, and on the other, the industry's equally legitimate expectation that these regulations would not introduce unnecessary obstacles to trade.

116. The representative of the European Union explained that EU industry had considerable experience to share regarding its work with evaluators of information security products around the world which were usually based on the Common Criteria international standard (ISO/IEC 15408:2005). He noted that the European Union would continue to work with the Chinese authorities on this issue with a view to finding a satisfactory solution.

117. Regarding the OSCCA Regulation, the EU representative noted that, at the last TBT Committee meeting, China had indicated that the 1999 Regulation of commercial encryption codes was being revised and that OSCCA would be open to an exchange of experiences with foreign governments. The European Union welcomed this statement and confirmed its interest in working with OSCCA on the revision of the 1999 Regulation with a view to ensuring a level-playing field for the marketing of commercial encryption products by: (i) removing the current discriminatory provisions that effectively prevent foreign manufacturers from applying for certification from OSCCA; and (ii) aligning the relevant testing and evaluation procedures with the ISO/IEC Standard 15408:2005 on the Common Criteria for Information Technology Security Evaluation.

118. The EU representative observed that the application of the current OSCCA Regulation was severely affecting the ability of European manufacturers, including foreign investment companies operating in China, to market their products in China. Following direct advice from OSCCA, it was the EU's understanding that major customers of encryption products falling within the scope of the 1999 Regulation were now requiring their European suppliers to produce the OSCCA certificate or - in anticipation of the entry into force of the CCC scheme for information security products - the corresponding CCC certificate as a purchasing condition. Furthermore, he stated telling examples of this practice could be found in the latest calls for tender issued by important users of encryption products such as the Bank of China or China Mobile, the largest mobile telephone network operator in China, both of which are state-owned enterprises. Given the urgency of the problem, the EU requested China to indicate the expected time frame for the revision of the 1999 Regulation and whether there would be an opportunity for foreign interested parties to participate in the revision process.

119. Concerning the Multi-Level Protection Scheme, the EU representative requested China to provide an update on the expected time frame for implementation. The MLPS required that IT systems classified as critical infrastructure use only products having obtained CCC certification, if listed in the CCC catalogue, or approved by OSCCA. In addition, he asked if China could confirm that state-owned enterprises would not only be excluded from the scope of the CCC requirements, but also from the definition of critical infrastructure under the MLPS. If the latter was not ensured, he said that there would be a risk of backdoor applications of the CCC requirements via the MLPS.

120. The EU representative underlined again the need for coordinated dialogue with the Chinese authorities on this matter. Given the pivotal role of the MLPS in this system, he suggested that perhaps the MIIT could take up this role of coordinating the dialogue on the Chinese side. Lastly, the EU representative urged China to reconsider whether, in the present climate, it would make sense and would be beneficial for China to enforce rules which foreign companies unanimously consider not being workable for them.

121. The representative of the United States supported many of the issues raised by the European Union and Japan regarding China's 13 implementing rules for compulsory certification for various IT products in relation to information security requirements as well as related information security measures. He requested clarification on whether the 13 implementing rules applied to products purchased by Chinese state-owned enterprises and products purchased by semi-public entities like

public schools and hospitals. He stated that if the measures did not apply to such entities, it would be useful to have this clarified in a public document. Furthermore, China was asked to clarify whether it planned to increase the scope of the compulsory certification rules, for example, with expanded product coverage.

122. The US representative noted that his country was also concerned with how the implementing rules relate to the MLPS, a separate measure coordinated by the Ministry of Public Security and the Ministry of Industry and Information Technology. The MLPS appeared to require business entities in certain areas of Chinese infrastructure only to acquire equipment certified under the information security regulations. Given these remaining questions on the scope and interaction with other measures, the US representative reiterated his country's primary concern that these measures could expand the CCC mark product scope to the area of information security which under international practice, is not normally subject to conformity assessment procedures for private sector use. As a result, the US representative supported the EU's view that China should reconsider the 1 May 2010 deadline for implementation for the 13 implementing regulations.

123. The representative of China thanked Japan, the European Union and the United States for their continued interest in this issue. He recalled that since the mentioned regulation had been notified to the WTO in 2007, China had received comments from Members and that the Chinese authorities had responded positively to them on a bilateral basis, and had agreed to postpone relevant measures by almost two years. A one year transitional period had been agreed on the basis of taking into account the comments from stakeholders and the applicable scope adopted was limited to government procurement. He stated that the government procurement law did not apply to state-owned enterprises; the law only referred to procurement activities of government departments, institutions and public organizations at all levels. His delegation encouraged concerned Members to continue following this issue on a bilateral basis. He noted that China did not think it was appropriate to discuss commercial procurement of state-owned enterprises under the TBT Agreement.

124. With respect to the concern regarding the use of relevant international standards raised by Japan and the European Union, the representative of China noted that his delegation had informed the Committee at previous meetings that the regulation had been established based on the relevant international standards such as the Common Criteria (ISO/IEC 15408:2005).

(ix) United States – Consumer Product Safety Improvement Act (G/TBT/N/USA/421 and Add.1)

125. The representative of China reiterated his delegation's concerns with the US Consumer Product Safety Improvement Act (CPSIA). He noted that in previous meetings China had expressed its serious concerns on the non-transparency of the Act, as well as its unnecessarily stringent requirements. While his delegation appreciated the continuing bilateral discussions with US counterparts, China nevertheless wished to highlight some of the key concerns that remained.

126. It was China's understanding that there was a difference in treatment given to Chinese governmental laboratories by the US Consumer Products Safety Committee (CPSC). The United States had replied to China's concern during the last Committee meeting by stating that China's relevant governmental labs were not recognized because they failed to meet the requirements of the CPSIA. The Chinese representative pointed out that the reason China's governmental labs had failed to meet the criteria, as determined by CPSC, was not because the labs were not technically competent, but because the criteria set for them in the CPSIA were more stringent than those applied to third party labs. He argued that the Chinese Government had put a lot of resources into these labs to ensure their technical capability and as proof of this, they now had ILAC recognition. He invited the United States to once again consider China's concern, apply the same recognition criteria to Chinese governmental labs as those applied to third party labs, and recognize CIQ laboratories as well as the test reports and certificates issued by CIQ laboratories.

127. In addition, the representative of China noted that his delegation had received several complaints from industry regarding the approval procedure for all-terrain vehicles by CPSC under its "Safety Action Plan" within the scope of CPSIA. According to these complaints, the approval procedure was time consuming and lacked transparency causing major barriers to international trade. Some importers had to wait for more than seven months and had made five or six revisions before being approved – some had even had to wait 2-3 months to receive a response for correcting certain mistakes. He asked the United States to simplify the examination and approval procedures and make them more transparent, and to stipulate regular audit cycles and develop mechanisms of communication with businesses to reduce unnecessary barriers to trade.

128. On the point raised regarding the alleged lack of transparency with respect to CPSIA implementation, the representative of the United States stated that his authorities had notified at least twelve CPSC measures that implement the CPSIA. It was important to note that these covered all aspects of CPSC implementation of the CPSIA. He stated that the CPSC website provided: additional key guidance documents on test procedures, test methods and accreditation, a list of accredited laboratories, advisory opinions from the general counsel, and specific guidance for small businesses. He added that there was also a section of the website that provided information in Chinese.

129. With respect to the issue of accreditation of Chinese government labs, the US representative stated that to date, CPSC had accredited 56 laboratories based in China, meaning that an additional nine labs had been accredited since the last TBT Committee meeting. Furthermore, 14 Chinese government joint venture labs were included in that number. As had been previously discussed, China's CIQ labs had not been accepted because they did not meet the relevant conditions. The representative of the United States noted that US agencies had adopted a highly trade facilitative approach in their testing regime for children's articles; it was based on relevant international standards and acceptance of test results from labs, including those outside of the United States that have been accredited by ILAC MRA signatories. The United States remained convinced that CPSC's approach was a model for other countries, including China, that require third party testing for certain regulatory schemes. He noted that China still did not recognize test results from any labs in the United States that had been accredited by ILAC MRAs signatories with respect to CCC system and other Chinese regulatory schemes.

130. With respect to all-terrain vehicles, the US delegate noted that after the conclusion of the last TBT Committee meeting, he had asked China for additional information on which particular applications were encountering difficulties. To date, the United States had not received this information. He therefore asked whether China could provide those examples following the meeting in order to make it possible for the US representative to follow up with US regulators and get back to China in advance of the next meeting.

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

131. The representative of Japan reiterated his delegation's concern regarding the conformity assessment procedure for India's mandatory certification for steel products. He noted that the Indian Government had announced through its Official Gazette to omit seven items from the list of the Second Order, dated 9 September 2008. However, a remaining item – the standard for galvanized steel sheets – had been implemented on 12 February 2010. As Japan had already explained at the last TBT Committee meeting, his delegation believed that there was no use in imposing mandatory certification regulations on intermediate products such as steel products, even when its objective was to secure human safety. He noted that at the last meeting, India had argued that there was no requirement in the TBT Agreement to limit covered items for mandatory certification regulations to final products. However, Japan's was of the view that Members needed to take the least trade restrictive measures, even when the objective was to ensure human safety.

132. While Japan appreciated India's efforts in reducing the number of items that were subject to the mandatory certification regulations; the Japanese representative regretted that the mandatory standard for galvanized steel sheet had been implemented. He reminded India that the technical regulation should be implemented in a way that was consistent with Article 2.2 of the TBT Agreement. The representative of Japan requested India to review the necessity of the current technical regulations on iron and steel products from the point of view of legitimate objectives and actual economic effects.

133. The representative of the European Union joined Japan in raising concerns about India's mandatory certification requirements for steel. India had informed the Committee in March 2009 that the new certification requirements, which had not been notified to the WTO, would be postponed for one year. As had also been pointed out by Japan, it seemed that before the end of this postponement period, India had recently exempted certain steel products from the certification requirements. She noted that as with the initial order imposing certification requirements, this new measure had not been notified to the TBT Committee and was therefore causing confusion among economic operators exporting steel to India.

134. The EU representative requested a confirmation from India on whether such an exemption had indeed been provided, and whether it would be applied on a permanent basis. If this was the case, the European Union would also like to know why certain steel products had been exempted, whereas others would still be subject to the requirements. She invited India to reconsider the need for the Indian national standards, and the requirement for compulsory certification proving compliance with such standards in an area where widely accepted international standards existed and were being applied by steel manufacturers in the European Union and around the world. Furthermore, she urged India, in accordance with TBT transparency obligations, to notify any new draft legislation imposing mandatory requirements in this sector so as to give other Members the possibility to comment before the adoption of new legislation.

135. The representative of India responded by highlighting that his country had notified the mandatory certification of steel products under G/TBT/N/IND/32 dated 5 February 2007. He noted that the implementation of the Quality Control Order had been deferred until 12 February 2010 and that had been communicated to the Committee in March 2009. By an Official Gazette notification dated 10 February 2010, items had been deleted from the list covered under the Order that had been revised on 9 September 2008. Regarding the issue of notification, the Indian representative took note of the concern but said that since it was a continuation of an earlier notification with some items being dropped off the list, there should not be any confusion. He noted that India had complied with the TBT Agreement provisions in that there was no provision in the TBT Agreement to limit covered items for mandatory certification regulations to final products.

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

136. The representative of Norway informed the Committee that the issue remained unresolved.

137. The representative of Canada noted that this issue was currently being dealt with under the dispute settlement understanding; however, Canada looked forward to the European Union notifying the implementing rules for the seal regulation prior to their formal adoption.

138. The representative of the European Union took note of the brief comments raised by Norway and Canada. In light of the challenge brought by Norway and Canada before the Dispute Settlement Body, she noted that the European Union did not consider it opportune to continue discussing the measure in the TBT Committee. She also recalled that in previous Committee meetings the European Union had indicated that the adopted regulation did not fall within the scope of the TBT Agreement. For these two reasons, the European Union maintained that it was not appropriate to discuss this

matter within the framework of the TBT Committee. Nevertheless, the European Union remained available to discuss this matter bilaterally.

(xii) Thailand – Mandatory Certification for Steel Products (G/TBT/N/THA/306 and Add.1)

139. The representative of Japan reiterated his country's concerns regarding Thailand's conformity assessment procedure for the mandatory certification requirements for steel products and other products. He noted that Thailand had implemented this technical regulation since 1985. It was Japan's understanding that under this regulation, an importer had to apply to the Thai Industrial Standards Institute (TISI) to acquire an "import license" of the conformity assessment on the specific product. He noted that the "import license" should be applied importer by importer, producer by producer, size by size, etc. Moreover, sampling tests would be conducted for every shipment at customs, even though the importer had the "import license".

140. The Japanese representative emphasized that the procedure for conformity assessment should be fully consistent with the TBT Agreement and other WTO agreements, including Article 5 of the TBT Agreement and the general principle of national treatment. He stated that Japan was concerned that Thailand's conformity assessment procedure was very complicated and created unnecessary obstacles in the distribution of steel products. He noted that discussions between Japanese steel importers and TISI for clarifying the procedure had been conducted in Bangkok. However, it was Japan's understanding that work had not been sufficiently developed.

141. The representative of Thailand specified that TISI's new criteria for certification was effective from 1 May 2009, and respected both ISO 4001 and ISO/IEC guides 65 and 67. Compared to the older criteria, the difference was that the requirements which had been applied with greater stringency to local manufacturers in the past, would now apply equally to both local products and imports alike. As Thailand had mentioned at the previous meeting of the Committee, compliance difficulties had been reported only during transition and were mostly in terms of quality control document requirements, resulting in some unnecessary delays. Currently, Thailand had a good understanding of all the importers and had received no further complaints on compliance difficulties. Thailand remained, of course, open for further comments and would consider a review when necessary.

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

142. The representative of the European Union reiterated her delegation's concern regarding the Colombian legislation that mandated that all gasoline-engine motor vehicles be flexible-fuel vehicles in the future. She thanked Colombia for the constructive bilateral discussions that had been held on this issue. Her delegation had been informed that Colombia was working on a revision of the legislation and therefore invited Colombia to give an up-date of the situation.

143. The representative of Colombia noted that her country's aim was to implement a regulation that promoted the sustainable use and production of biofuels at a national level. In this regard, her country was committed to advance measures aimed at increasing the flexibility of the regulation. This flexibility related to the reduction in the content of alcohol based fuel in the fuel mixture, which would follow countries such as Brazil that make use of 25 per cent mixtures while also taking into account the development of automotive technology to respond to these requirements. At this stage Colombia had not set out in detail the percentages for the mix of flex fuel but the intersectoral body responsible for this issue was working on the matter.

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

144. The representative of the United States reiterated his delegation's concerns with the French Ministry of Agriculture's skirt requirement for ride-on lawnmowers, a measure that was never published as part of an official law or decree in France, never notified to the WTO, and that had disrupted US lawnmower exports to France. He noted that the United States had raised concerns on this issue in previous meetings of the Committee, including questions regarding the technical basis for this skirt requirement, the deviation of this requirement from other member States' requirements and international standards, lack of transparency and related implications for the New Approach. It was the US understanding that there were on-going discussions involving the US and European industry, the French Ministry of Agriculture, the Commission and other stakeholders to attempt to resolve this issue. These efforts included finding appropriate language for the CEN ride-on lawnmowers standards that would differentiate the skirt requirement based on evidence of fire risk. The US representative was encouraged by these discussions and hoped that they would lead to a resolution.

145. The representative of the European Union referred to his delegation's previous interventions explaining the rationale for the measure and the basis of the market surveillance action by the French authorities. Concerning the latest developments, he noted that work was being undertaken on the amendment of the European Standard EN 836 on safety of lawnmowers. Work was also being undertaken on the development of a new standard EN/ISO 5395, parts 1 to 3 on the safety of lawnmowers which would be intended to replace and supersede the European standard if and when adopted. This new standard was being prepared under the lead of the European Committee for Standardization (CEN), in accordance with the CEN-ISO Vienna Agreement.

146. The EU delegate also recalled recent meetings between the European Commission services and the EU and US industry to discuss a workable technical solution via standardization to the problem identified by the French authorities. He noted that the French Association of Distributors and Manufacturers of Garden Machinery was working towards a compromise solution, acceptable to both the regulatory authorities and the manufacturers, which would address the issue of compliance with the requirement to protect bystanders against the risk of exposure to moving transmission parts through technical specifications to be inserted in the relevant standards. He stated that the European Commission was not directly participating in this work but was encouraging all interested parties to take an active role in this process. He expressed his delegation's confidence that this joint effort would lead to the development of a technical solution that was robust and capable of meeting the requirements in light of the existing technology in the lawnmower industry. The aim was to reach a solution that would not impose disproportionate burdens on manufacturers, while meeting a high level of safety as specified in the EU Machinery Directive.

(xv) India – Restriction on Toys

147. The representative of China stated that India had notified its new regulation No. 27 in January 2010 which had been a replacement for the former restrictions on Chinese toys. She expressed China's appreciation for India's efforts and noted that according to the new regulation, imports of toys had to meet two requirements: (i) to comply with either of four standards, prescribed in American standard ASTM 8963, ISO standard 8124, Indian standard IS 9873, or EU standard EN71; and (ii) to provide the certification of conformance from manufacturers from an independent laboratory accredited under ILAC. The representative of China asked India to accept as equivalent the Chinese standard for toys GB 6675 which was in accordance with the relevant ISO Standard 8124.

148. The representative of India noted that the notification number 27/2009/14, dated 27 January 2010, specified allowing toy imports subject to conformance with stipulated technical and safety standards. The Indian representative confirmed that there were two requirements consisting of prescribed standards and various labs that could be accredited for certification. He added that

regarding the safety and other aspects of toys, the Indian Bureau of Standards had notified that there would be three standards for toys in India, which would relate to mechanical and physical properties, flame resistance requirements and migration of certain elements that prescribe maximum acceptable element migration for various chemical substances in toy materials. The Indian representative noted China's concern regarding Chinese standard GB 6675 and its relationship to ISO 8124.

(xvi) Chile – Cosmetics (G/TBT/N/CHL/81 and Add.1)

149. The representative of the European Union once again raised concerns regarding Chile's notification on cosmetics (G/TBT/N/CHL/81). She noted that her delegation had recently received Chile's answers to the comments as well as a copy of the legislation. The European Union was therefore currently analyzing these documents and would perhaps revert to the Chilean authorities at a later stage with comments, either in the Committee or bilaterally.

150. The representative of Chile responded by noting that on 4 March 2010, a modification to the Decree 239 on cosmetics had been published in the Official Bulletin. This publishing included the responses from the Ministry of Health to the parties who had asked questions about the Decree. The representative of Chile noted her country's willingness to engage in further consultations after analyzing the answers they had received.

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

151. The representative of New Zealand welcomed the official confirmation from Korea dated 31 December 2009 that it had postponed implementation of the new requirements for certification of processed organic food products until 1 January 2011. He noted that while New Zealand welcomed this delay, his delegation remained concerned about several aspects of the new regulation. The requirement for all ingredients of processed foods to also be certified under the Environment Friendly Agriculture Promotion Act was of particular concern. In its current form, this aspect of the regulation was unworkable and, due to the nature of global supply chains, would effectively make many processed products economically non-viable for export to the Republic of Korea. The New Zealand representative considered that there were less trade restrictive ways of meeting Korea's objective. For instance, Korea could amend its regulations to provide for recognition of equivalence and also consider equivalence agreements with the International Organic Certification Agency and/or foreign governments before the new regulation took effect.

152. The representative of the European Union reiterated her delegation's concerns regarding Korea's enforcement regulation for the Food Industry Promotion Act. She noted that the European Union was concerned about the negative impact this regulation would have, once fully implemented, on exports of organic foods to Korea. This issue had been raised during the last TBT Committee meeting in November 2009 and during recent bilateral discussions. She stated that the European Union valued the good working relations that had been established between the Korean and the European Union organic experts and welcomed Korea's constructive approach to addressing the EU's concerns. In particular, the EU representative thanked Korea for granting a transitional period of one year until 1 January 2011 for the existing system to be phased out. Nevertheless, a number of concerns remained. In particular, as expressed by New Zealand, the notified Korean legislation did not foresee equivalence with regulations applied by other WTO Members. She noted that it was the EU's understanding that Korea was considering favourable the introduction of equivalence in its law – the EU representative welcomed this and inquired about the timeframe.

153. With regard to the approval procedure of EU certification bodies, the representative of the European Union welcomed Korea's efforts to facilitate this process. However, she feared that the approval procedure represented a technical and economic challenge for many EU certification bodies, especially in those cases where the volume of trade involved was small. According to EU information,

out of more than 100 EU certification bodies that were approved under the old system, only two had now been approved under the new system. Therefore, the EU representative reiterated her delegation's request for Korea to take international standards such as ISO 65 into account during the approval process and to process the applications for approval expeditiously.

154. The representative of the European Union also expressed concerns with regards to the certification of ingredients. The fact that ingredients of agricultural origin must be certified according to the "Environmentally Friendly Agriculture Promotion Act" and processing must be certified according to the "Food Industry Promotion Act" posed significant problems for imported processed products. In the case of processed products composed of multiple ingredients coming from different locations, this requirement was nearly impossible to comply with. Therefore, the EU representative reiterated her delegation's request for Korea to grant a derogation from the requirement to certify ingredients in case of imported products, at least until equivalence was introduced. Moreover, she asked Korea to further extend the transitional period in order to allow for a sufficient number of EU certification bodies to be approved.

155. The representative of Switzerland fully supported the concerns expressed by the European Union and New Zealand. She argued that the revised regulation, once fully implemented, would have a negative effect on Switzerland's exports of organic products. She appreciated Korea's openness to discuss the issue bilaterally and to extend the transitional period to resolve open questions; however, the regulations remained very strict and would result in heavy financial burdens, especially in view of the small quantities of goods traded. The fact that Korea still did not foresee any possibility of recognizing foreign regulations as equivalent, would have serious effects on Switzerland's exporting companies. The Swiss representative highlighted that currently, only a limited number of certification bodies in Europe had been approved under the new system, with none in Switzerland. She therefore urged Korea to introduce the possibility of accepting equivalence in its regulation and to further extend the transitional period in order to avoid trade interruptions.

156. The representative of Australia welcomed the decision by Korea's Ministry for Food, Agriculture, Forestry and Fisheries to allow the revised regulations governing the import of organic food products into Korea (the Food Industry Promotion Act and its supporting Environment-Friendly Promotion Act) to run in parallel with the Korean Food and Drug Administration's labelling requirements until 31 December 2010. She also welcomed the fact that the issues her delegation had previously raised such as education requirements and auditor numbers had been addressed through minor amendments which were to be formally announced in March 2010. It was Australia's understanding that, before equivalence recognition of foreign government systems could be permitted, legislative changes to both the Food Industry Promotion Act and the Environment-Friendly Promotion Act were required.

157. The representative of the United States thanked Korea for extending the implementation date for its processed organic products measure for one year in order to permit trade in these products to continue. However, the United States supported the concern raised by other Members that Korea's regulation did not contain procedures for recognizing a foreign government's conformity assessment body to accredit certifiers nor for determining equivalence. The US representative encouraged Korea to work as quickly as possible to amend the regulation to incorporate language allowing for such agreements to be negotiated. He looked forward to continuing bilateral discussions on this matter.

158. The representative of Korea explained that the Korea's Organic Processed Foods Certification System had been introduced to enhance the quality of processed organic foods, to promote the production of the organic foods, and to protect consumer's health and safety. The programme was based on the Food Industry Promotion Act which had been introduced on 26 June 2008. He said that the Act prescribed the certification system, certifying bodies, subject of certification, certification procedures, certification standards, management practices, and related penalties. He further noted, that

as of 1 January 2010, all organic product had to comply with the requirements of the above Processed Organic Foods Certification Program. The Program applied not only to domestic products but also to imported products. Therefore, if foreign producers wanted to export their processed organic foods to the Korean market, those products would have to be certified by either domestic or foreign certifying bodies, which were accredited by the Korean Government.

159. With regard to the equivalency issue, the Korean delegate explained that the Ministry for Food, Agriculture, Forestry and Fisheries did not currently have an appropriate system to implement a measure that was based on equivalency. However, the Ministry was conducting studies on how to install such a system.

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

160. The representative of the European Union once again raised the issue of Brazil's new Good Manufacturing Practice (GMP) requirements for health products. In particular, she returned to the issue of Brazil's non-acceptance of certificates proving conformity with ISO Standard 13485 as evidence of compliance with its GMP requirements. In bilateral exchanges on this issue, Brazil had indicated that it could no longer accept ISO certification, due to the fact that ISO Standard 13485 only focused on the quality of the manufacturer, and not on risk control and product quality, which were the main objectives of the Brazilian GMP requirements. The EU representative highlighted that this answer did not provide adequate justification with regard to Brazil's refusal to continue to accept certificates proving conformity with the international standard. According to the EU's assessment, the scope and objectives of ISO standard 13485 were exactly the same as those of the Brazilian requirements for the manufacture of medical devices. Furthermore, many of the new Brazilian requirements did not go further than those provided for by ISO Standard 13485 and therefore did not aspire to a higher level of protection of public health.

161. She stated that the European Union found it difficult to understand why an international standard that had been developed specifically for medical devices, and whose objective was to protect public health through the use of an appropriate quality management system was considered by Brazil as ineffective or inappropriate in order to achieve the legitimate objectives pursued. She therefore, requested Brazil, in accordance with Article 2.4 of the TBT Agreement, to base its new GMP requirements on the international standard and to continue to recognize this standard as equivalent to its own requirements on GMP. The EU representative welcomed Brazil's continued willingness to discuss this issue with its trading partners, and reiterated her delegation's interest to bilaterally discuss possible solutions for the recognition of certification carried out by EU notified bodies.

162. The representative of Switzerland shared the concerns expressed by the European Union. She noted that her country remained concerned about whether Brazil would continue to recognize quality inspection results based on the internationally used quality standard, ISO 13485. She stated that if Brazil no longer accepted ISO 13485 certification as evidence of compliance with the Brazilian requirements, Switzerland would encourage Brazil to explain to the Committee the reasons for such a refusal.

163. The representative of Canada expressed his country's concern with resolution RDC 25 and its implementation. He appreciated the opportunity to discuss Canada's concerns with Brazil on a bilateral basis.

164. The representative of the United States thanked Brazil for the steps it had taken thus far to provide additional details to industry on the inspection process. He requested Brazil for a status update on further steps it was taking to ensure that trade in medical devices would not be disrupted after the 22 May 2010 deadline. The United States would continue to closely monitor the situation.

165. Concerning the point raised by the United States, the representative of Brazil underlined that trade flows would not be negatively affected by this measure. She noted that the Brazilian authorities had confirmed that Anvisa would be able to inspect all the companies once they were required to do so, preventing in this way an undesirable interruption of trade flows. The Brazilian representative reminded the Committee that the inspections had been scheduled while taking into account the date in which the existing registrations would expire, and not the date of entry into force of the new regulation. In that sense, it was important to remember that companies which would register new products or products where registration was about to expire were encouraged to apply for their certification within a reasonable period of time. Furthermore, Anvisa had received 115 requests for certification and, until now, all of them had been processed. She highlighted that 45 inspection visits had taken place successfully and that 70 requests for inspection visits were already scheduled.

166. Concerning the points raised by the European Union and Switzerland, the representative of Brazil stressed that regulation RDC 25 of 2009 only applied to products under classification of higher risks for human health. As a result, Brazil did base its procedures on ISO standards but developed further procedures for these specific products. She said that Anvisa's Regulation 59/00 provided for the classification of products in four different types of risk to human health; Regulation 25/09 only applied to those products classified under risk 3 and 4. For the remaining products, she noted that companies were required to only fill out an electronic form which was available at Anvisa's website. The representative of Brazil said that additional clarifications were available at Anvisa's website and stressed that Brazil was open to holding bilateral meetings with Members.

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

167. The representative of the United States reiterated his delegation's concerns regarding the EU's new accreditation framework set out in Regulation (EC) 765/2008. He explained that the new regulation required each EU member State to appoint a single national accreditation body and thus prohibited competition among EU member States' national accreditation bodies. He noted that the new regulation further specified that national accreditation bodies should operate as public, not for profit entities and independently of any conformity assessment bodies. This meant that only a single government entity in each member State should be permitted to accredit conformity assessment bodies in the European Union. The United States continued to be concerned in particular about the regulation's impact on recognition of non-EU accreditation bodies under the International Laboratory Accreditation Cooperation Mutual Recognition Arrangements (ILAC MRA) and the International Accreditation Forum Multilateral Recognition Arrangements (IAF MLA) and the acceptance of conformity assessment performed by the ILAC MRA and the IAF MLA accredited bodies. In particular, the United States' understanding was that the regulation left to member States the discretion of whether or not to recognize non-European accreditation bodies as well as the discretion on whether or not to accept conformity assessments issued by ILAC MRA and IAF MLA accredited bodies. The United States was concerned that without clear guidance from the Commission, member States might refuse to recognize non-European accreditation bodies and conformity assessments issued by non-European testing and certification bodies, which would both undermine the international accreditation system under ILAC and IAF and impede US exports to the European Union.

168. The United States had several questions about how the EU accreditation framework would operate in practice after hearing a number of reports from industry in this regard. The questions were about the rationale behind the system, how attestations of conformity assessment results issued by bodies that had been accredited by foreign accreditation bodies that were signatories of ILAC or IAF, but that did not necessarily comply with EU's accreditation requirements would be treated in Europe, and the potential impact on the European Union's new system on the international accreditation framework.

169. The representative of Thailand supported the concerns raised by the United States.

170. The representative of the European Union stated that as the matter was of general interest as part of the TBT Committee's discussion on conformity assessment policy, the European Union planned to share their experience on shaping a common accreditation system for the European Union (see page 56, below). He stressed the fact that the European Union remained available, if there was a need for further follow up at expert level, to continue the discussions bilaterally after this TBT Committee meeting.

(xx) European Union – Poultry Meat (G/TBT/N/EEC/267 and Add.1)

171. The representative from Brazil reaffirmed Brazil's concerns regarding the EU regulation 1047/2009 on marketing standards for poultry meat, notified under G/TBT/N/EEC/267 and addendum. As Brazil had explained on previous occasions, Brazil feared that the regulation was likely to have a significant impacts on Brazil's exports of poultry meat to the European Union market, since it would have the practical effect of prohibiting frozen poultry meat use in poultry meat preparations. Brazil was of the opinion that there was no justification for this prohibition, since there was no sanitary or hygienic impediment to using frozen poultry meat in poultry meat preparations. She emphasized that this argument was corroborated by the definitions of fresh poultry meat contained in international standards such as the Terrestrial Animal Health Code of the World Organization for Animal Health (OIE) and even in the EU hygiene regulation.

172. The representative of Brazil recalled that the only justification that the European Union had presented for this prohibition was the need to inform consumers about the characteristics of the product. Brazil continued to believe that the objective of informing consumers could be better attained by a less trade restrictive labelling requirement. During the consultation period of this regulation, Brazil had suggested that the phrase “previously frozen” could be used in the label of poultry meat preparations made from frozen poultry meat. The European Union had replied that it could not accept this suggestion because when consumers bought preparations labelled as fresh they expected it to be indeed fresh and not one which contained defrosted poultry meat. The Brazilian representative clarified that Brazil was not asking the European Union to allow that poultry meat preparations made from frozen poultry meat be sold as fresh, but that they could be marketed as “previously frozen”. Brazil requested that the European Union provide an answer as to why it was not possible to accept Brazil's suggestion, which, in Brazil's view, would be less trade restrictive and would allow consumers to choose from a wider range of options, in a better informed way.

173. Furthermore, Brazil raised the concern that the prohibition of using frozen poultry meat in poultry meat preparations would represent *de facto* discrimination against foreign producers that had to freeze poultry meat so as to export it to the European Union, given the distance that separated them from that market. She argued that while local producers in the European Union would continue to be able to supply the European industry of preparations, foreign producers based in countries such as Brazil would not. In Brazil's view this prohibition might represent a violation of Article 2.1 of the TBT Agreement, and she therefore urged the EU to review its regulation with a view to making it consistent with the European Union's commitments under the TBT Agreement.

174. The representative from Australia echoed the concerns raised by Brazil and asked the European Union to inform the TBT Committee on whether they considered alternatives to the current marketing standard, such as including in the label a reference to “previously frozen or chilled” product.

175. The representative of the European Union noted that since the last TBT Committee meeting in November 2009, several bilateral meetings had been held with the Brazilian authorities and industry. She found it regrettable that despite the very useful and constructive discussions, Brazil

continued to have concerns about the impact of the new marketing standards on their exports to the European Union. She reiterated that the EU marketing standards were an extrapolation of the measures that already applied to poultry products. She emphasized that the European Union had studied Brazilian exports to the European Union and had concluded that there should not be a substantial impact since the vast majority of the products which were at stake were either poultry products or preparations, for which the marketing standards did not introduce any new requirements. The only goods that might be affected by the new standards were frozen filets that were currently used for preparations sold as "fresh". These, however, represented a very small fraction of Brazil's exports of poultry meat into the European Union and could still be exported and sold on the EU market, but not labelled as "fresh".

176. On the possible discriminatory impact of the measure raised by Brazil, she explained that there were many domestic suppliers in the European Union which supplied their products in a frozen state to which the measures applied. She announced that the new marketing standards would be enforceable as of 1 May 2010, and as had been previously outlined, the European Union did not expect to see, as of that date, any substantial changes in trade flows from Brazil to the European Union.

(xxi) European Union – Implementing Measures of the Directive on eco-design of energy-using products (G/TBT/N/EEC/208 and Add.1; 228 and Add.1; 229 and Adds. 1-2; 234 and Add.1; 237 and Add.1; 273 and Add.1)

177. The representative of China reiterated concerns on several measures by the European Union aimed at implementing the Directive on eco-design of energy-using products ("Eco-design Directive"). He explained that since August 2008, the European Union had developed several implementing measures regarding the EuP Framework Directive (G/TBT/N/EEC/208, 228, 229, 234, 237, and 273). These implementing measures covered a wide scope of energy using products, ranging from electrical and electronic equipment, various lamps, to household refrigerating appliances. China fully supported the objective of the European Union to save energy and natural resources by increasing energy efficiency. However, China was concerned about the potential adverse impact of these measures on international trade. China had submitted written comments on all these measures and had also raised concerns during previous TBT Committee meetings. China's concerns were mainly about the non-use of relevant international standards, the stringency of the energy efficiency requirements and the lack of consideration of the needs of developing country Members.

178. China highlighted its concerns about the latest EU notification G/TBT/N/EEC/273 with regard to eco-design requirements for household refrigerating appliances. China had studied the new requirements for wine storage compartments added to the directive, and found that the new requirements were all technical references and indices specifying wine storage compartments' performance and function. The Chinese delegate recalled that according to Article 2.8 of TBT Agreement, technical regulations should be based on product requirements in terms of performance rather than design or descriptive characteristics. China therefore considered that the requirements for wine storage compartments would cause unnecessary barriers to trade as they specified reference and indices to make the product fulfil its expected performance.

179. He stressed that the appendix of the proposed Directive specified that the measured value of energy consumption should not be less than the rated value by more than 10 per cent, while the tolerance value of the relevant international standard IEC 62552 (2007) was 15 per cent. Referring to Article 2.4 of TBT Agreement, the representative of China urged the European Union to develop technical regulations in conformity with international standards so as to reduce unnecessary barriers to trade. Finally, he noted that China was still waiting for EU's reply to their written comments. China was hoping that the European Union would take into account China's comments, as well as the special needs and difficulties of developing country members, as provided in Article 12 of the Agreement.

180. The representative of the European Union recalled that the objectives of the Eco-design Directive and of the corresponding implementing measures was to render more efficient the electricity consumption of the regulated products and to make a substantial contribution to environmental protection and to climate change mitigation efforts. She explained that the requirements were set in view of this legitimate objective which was of great importance for the European Union, but also for the whole world. She added that the requirements did not create excessive costs for industry and that the European Union had paid particular attention to this aspect. She further noted that the requirements were based on in-depth studies on existing available technologies and that the studies had been developed together with stakeholders and interested parties, including from third countries – the results of which were available on the internet.[8]

181. The representative of the European Union further highlighted that all the requirements were introduced in a staggered manner meaning that they became more stringent over the years, in order to provide manufactures with sufficient time to adapt their products. In addition, all the implementing measures included transitional periods. The European Union was of the opinion that a good balance between the requirements and the objective of environmental protection had been struck and therefore the European Union considered the measure to be in compliance with the TBT Agreement. With regard to the specific comments on the notification 273 and on the Annex 4 of this measure, she pointed out that the European Union had sent a written response to China on 5 November 2009. She added that the European Union had also given an extensive reply in the TBT Committee meeting of November 2009 explaining why the deviation from the international standard for the measure was necessary.

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

182. The representative from Mexico explained that in October 2009 Canada had adopted a new act to ban tobacco marketing aimed at youth. This act prohibited the manufacture and sale of American blend cigarettes which would give rise to a reduction in imports of burley and oriental tobacco which was used to produce these cigarettes. While the new legislation was aimed at tobacco products with sweet or fruit flavours, the law had proved to be much broader because it prohibited the manufacturing and sale of traditional cigarettes of the so-called American blend which had the taste of tobacco and were not of fruit or sweet in flavours.

183. In Mexico's view, the principle problem of this law was that it focused on specific ingredients which were used in the manufacture of American blend cigarettes, but did not focus on the flavour of the cigarette as a final product. The American blend contained additives and sweeteners, but did not have a sweet flavour. Despite the fact that the Canadian Government had agreed with this statement, it would still ban cigarettes containing these additives. The representative of Mexico argued that for these reasons the new measure was inconsistent with Canada's obligations under the TBT Agreement, specifically, with Article 2.2 which provided that technical regulations should not restrict trade more than necessary to comply with the legitimate public health objective. The representative from Mexico argued that the Canadian law was more restrictive than necessary to ensure compliance with the objective of prohibiting fruit sweet flavoured tobacco products aimed at attracting young smokers. The law prohibited American blend cigarettes even though they did not contain these flavours and Canada had not provided any evidence that would suggest that American blend cigarettes were particularly attractive to young people.

184. In Mexico's view, alternatives existed which were less trade restrictive. Other countries, such as the United States, France and Australia could serve as a model for Canada, as they simply banned products with fruit flavours or sweet in flavour. Referring to Art. 2.8 of the TBT Agreement, the representative of Mexico recommended that Canada base its technical regulations on the properties of

[8] www.ecocold-domestic.org/

the use of products rather than their design and descriptive characteristics and that Canada simply ban the products with fruit flavours or sweet in flavour. The representative from Mexico argued that Canada had not provided any evidence that the performance based approach, as recommended in Article 2.8 of the TBT Agreement, was not appropriate to address the issue.

185. In addition, the representative of Mexico said that Canada had not complied with its obligations in terms of transparency as set down in Article 2.9 of the TBT Agreement which provides that WTO Members should notify at an early appropriate stage. During the TBT Committee meeting on 6 November 2009, various delegations, including Mexico, had put several questions to Canada, including questions concerning the consistency of this measure with the TBT Agreement, and requested Canada to notify these measures to the TBT Committee. However, Canada had not provided answers to these concerns raised. Mexico was of the opinion that Canada could solve this problem without amending the legislation, as the law allowed the lists of additives and products subject to a ban to be corrected or modified at an administrative level without any need for additional legislation.

186. Mexico was also interested in knowing how the list of banned additives and sweeteners had been established. Mexico asked which scientific evidence had been taken into account by Canada to justify that more than 5000 additives referred to in the list were particularly attractive to young people, regardless of the quantity used in the cigarettes and also regardless whether in part a fruity or sweet flavoured was present in the final product. More specifically, Mexico requested more information whether there was any scientific or technical information used by Canada which justified the ban of sweeteners in the American blend and which showed that American blended cigarettes were particularly attractive to young people.

187. The representative from Argentina shared Canada's public health objective to reduce incentives for young people to start smoking. Nevertheless, the representative reiterated his country's concerns about the new Canadian law approved on 8 October 2009 amending the tobacco act since it imposed a ban on a long list of sweeteners for cigarettes, small cigarillos and small cigarette papers, or blunt wraps. He noted that despite the observations made by Argentina at the last TBT Committee meeting in November 2009, Canada had still not notified the act, thereby failing to comply with the principle of transparency. Furthermore, he indicated that Canada should not only notify the act to the TBT Committee, but also make reference to possible proposals for amendment and draft regulations for implementation. In Argentina's view, Canada had failed to explain before the TBT Committee why it had decided to adopt a measure that was more restrictive than necessary to ensure its objectives as it imposed a complete ban on a list of additives of which probably most did not give a sweet or chocolate flavour to cigarettes. Argentina echoed the questions asked by Mexico and encouraged Canada to notify the legislation as soon as possible.

188. The representative of Colombia supported the statements made by Mexico and Argentina. She urged Canada to notify its law which, in Colombia's view, contained elements that were contrary to what Canada had committed itself to under Article 2.2. and other articles of the TBT Agreement. Colombia was of the opinion that protection of public health could be achieved through other measures, as other countries had successfully tackled the problem of an increase in cigarettes with flavours interesting to young people. She recalled that these countries had taken action against particular products which had those flavourings. Canada's approach appeared to be excessively broad as it included a large range of cigarettes which were not attractive to young people or those beginning to smoke. The representative from Colombia argued that Canada had included ingredients which were used in traditional blend cigarettes which had no particular link to the youth population. She emphasized that the possible consequence was a fall in Colombian exports of these products to Canada and a job losses. She invited Canada to submit to the Members the corresponding scientific evidence that justified taking these measures.

189. The representative of Malawi introduced a submission on "The effects of Canada's Tobacco Act on Malawi" (G/TBT/W/329). He expressed his country's deep concern regarding the consequences that the ban on tobacco marketing aimed at youth would have on the economy of Malawi. He explained that Malawi was the largest producer of Burley tobacco in the world with about 700,000 farmers depending on it for a living. Any trade measure that unfairly restricted the manufacture of cigarettes that used Burley tobacco would have a detrimental affect on Malawi's exports and hence very negative consequences on the entire economy of Malawi. Malawi was deeply concerned that the law was inconsistent with Canada's obligations under the TBT Agreement. Malawi's understanding of the purpose of the law was to reduce youth smoking by prohibiting the manufacture and sale of confectionary and fruit flavoured products that were designed to appeal to youth. While the representative of Malawi fully subscribed to this objective, he was deeply concerned that the law was much more trade restrictive than necessary to achieve this objective, in particular, because the law would effectively ban traditional blends of cigarettes. He stated that traditional blended cigarettes were one of the major categories of cigarettes in the world and that they were produced with three types of tobacco, including Burley tobacco, and included certain additives that the law would prohibit. He therefore urged Canada to treat differently additives which were an essential in traditional blend cigarettes.

190. Malawi noted that there existed a less trade restrictive way to deal with the problem, namely to ban only those products with characterizing confectionary or fruit flavours, following other WTO Members, such as France, Australia and the United States. Malawi also had concerns that the regulation would spread to other markets which would have disastrous consequences for economies that were highly dependent on tobacco. Based on the information available, Malawi failed to see how Canada had sought to ensure that the law was not more trade restrictive than necessary to fulfil the legitimate public health objective. He stressed the point that in the current version, the law risked to affect the livelihood of thousands of tobacco farmers in Malawi.

191. The representative of Brazil noted that bilateral discussions with the Canadian delegation on the issue had taken place prior to the meeting. He stated that Brazil would continue to monitor the implementation of the measure and would seek clarification on some outstanding issues.

192. The representative of Switzerland expressed concern about the fact that the measure had not been notified. She appreciated the statement by Canada at the last TBT Committee meeting in November 2009 assuring that a notification of the implementing measures would be submitted. The representative of Switzerland reiterated that notifications should take place at an early appropriate stage when it was still possible to introduce amendments and to take comments into account.

193. The representative of the Dominican Republic echoed other delegations that had expressed concerns about the measure at issue. He noted that Canada had not yet notified the measure to the TBT Committee despite the possibly significant trade affects in terms of manufactured cigarettes, particularly comprising Burley tobacco. He explained that the Dominican Republic produced various varieties of tobacco including traditional blended types. The ban would therefore affect the tobacco production in the Dominican Republic and affect the national economy. Tobacco by its nature involved many small producers who were able to distribute income and improve the national economy. He stressed the fact that Canada should have notified this law prior to adoption as provided for in Article 2.9 of the TBT Agreement in order to ensure sufficient time to take into account comments by Members. The Dominican Republic urged Canada to take into account these comments before moving to adoption.

194. The representative from the Dominican Republic also noted that the legislation was intended to prohibit the manufacture and sale of tobacco products including cigarettes, cigarillos and other tobacco products with specific flavours such as confectionary or fruits with the understanding that these were being aimed at young people. The representative of the Dominican Republic agreed with

the objective of this legislation, however, found that the way in which the new legislation had been drafted was excessively broad and disproportionate. Rather than prohibiting products with a specific flavour, it prohibited those containing at least one ingredient from a list of more than 5000 ingredients used in the manufacture of various types of cigarettes. As a result, traditional blended cigarettes of various kinds containing additives but without a particular flavour also became prohibited. He noted that in Canada the traditional blended cigarettes accounted for only 1 per cent of the cigarette market. He therefore concluded that the prohibition was not being imposed for public health objectives, but that it constituted an unnecessary technical barrier to trade in violation of a number of provisions of the TBT Agreement, including Articles 2.2 and 2.8. With this in mind the Dominican Republic urged the Canadian authorities to review and amend the above-mentioned law to ensure compliance with its obligations under the WTO TBT Agreement.

195. The representative of the Philippines supported Canada's objective to address public health concerns by reducing the incentives for young people to smoke. In his view, Bill C-32, however, appeared to be more trade restrictive than necessary to achieve Canada's public health objective, as it banned thousands of additives in any amount, regardless of whether or not they imparted a characterizing flavour to finished tobacco products. He emphasized that Canada had not provided any direct evidence that each of those items that were used for advice purposes were specifically utilized to attract the youth and were not related to preference of adult users. In addition, he argued that Article 2.8 of the TBT Agreement also encouraged WTO Members to base technical regulations on performance standards rather than design or descriptive characteristics – it appeared, however, that Canada - through Bill C-32 - sought to regulate the design of the product. The Philippines therefore recommended that Canada adopt a performance based approach by prohibiting tobacco products that existed with characterising fruit or confectionary flavours that were directed to the youth, but allowing those that catered for adult preferences. He noted that Canada had provided no evidence why a performance based approach was not appropriate in this regard. Finally, the Philippines requested Canada to provide the scientific and technical basis for the ban on the ingredients.

196. The representative of Turkey reiterated concerns regarding the Canadian measure at issue. While Turkey supported deterring youth from tobacco use, Turkey had serious concerns about the way in which Canada was attempting to achieve this objective. He argued that by the new measure Canada prohibited the use of various additives in certain tobacco products, including in blended tobacco products. These additives, however, were essential components of blended products and did not give a characterizing flavour, such as chocolate or other fruits aroma, to the product. As a consequence any restriction on these additives would in practice imply a prohibition of all blended products. Moreover, as these types of tobacco products either blended or non-blended would be considered like products, any measure that would result in prohibiting blended tobacco products would be discriminatory. He explained that as 98 per cent of the Canadian market was covered by non-blended tobacco products, any measure targeting to protect youth from tobacco use only including blended tobacco products would be discriminatory.

197. The representative of Turkey reiterated that additives did not give any characterizing flavours to the tobacco product implying that the end-products, either blended or not, had similar tastes. Turkey's concern was that Canada based its decision on the ingredients contained in the product without considering the effects of such ingredients on the final products. Furthermore, for Turkey, there existed no scientific evidence that the additives attracted youth or that blended tobacco products were more attractive to youth then the non-blended ones. Moreover, he argued that when taking into account that the share of blended tobacco products in the Canadian market was only 1 per cent, the taste preferences of Canadian users was clear. She concluded by noting that as the measure would result in prohibiting blended tobacco products from the market, it was obvious that the measure was not proportionate with its objective. She recalled that the TBT Agreement stated that technical regulations should not be more trade-restrictive than necessary to fulfil a legitimate objective. Turkey

was of the opinion that there were several other ways to protect youth from tobacco and therefore requested the Canadian authorities to reconsider their decision and amend the measure accordingly.

198. The representative of the European Union strongly supported Canada's objective of protecting human health and, in particular, deterring youngsters from smoking, which was in line with the WHO Framework Convention on Tobacco Control. However, the European Union reiterated its disappointment about Canada's lack of regard for its transparency obligations under the TBT Agreement. As the measure was a technical regulation within the meaning of the TBT Agreement, the European Union considered that it should have been notified to the TBT Committee. Furthermore, in order to ensure that Canada's measures could be accommodated and fully understood, taking account also of Canada's trade obligations, she asked Canada to provide more details on its approach to prevent smoking among youngsters, and to update the TBT Committee with regard to any other measures envisaged in this regard. The European Union requested more information with regard to Canada's approach to ban a comprehensive list of additives, including certain flavours which might be perceived as appealing to youngsters. The European Union also asked Canada to make available the scientific studies or other such information that established a link between the prohibited additives and attractiveness to youngsters. The European Union also asked Canada to provide assurances to the Committee that the measures envisaged achieved uniform levels of protection in relation to all forms of tobacco, regardless of whether it was imported or domestically produced. Finally, the European Union wanted to know which other policy initiatives (such as information and education campaigns) Canada had introduced, or was planning to introduce, in conjunction with Bill C-32 in order to deter smoking among youngsters and increase awareness of tobacco-related risks in this particular population group.

199. The representative of the Former Yugoslav Republic of Macedonia fully supported the statements made by the European Union and other delegations.

200. The representative of the United States hoped to hear from Canada its responses to the questions that his delegation had raised on the subject during the November 2009 TBT Committee meeting. He announced that the US would take account of those answers as well as Canada's responses to comments and questions that other Members had raised in reflecting further on this matter.

201. The representative of Japan echoed other members' concerns.

202. The representative of Zimbabwe supported other Members who had raised concerns on this issue and emphasised that Zimbabwe's situation was similar to the one of Malawi.

203. The representative of Canada said that his Government took seriously its responsibility to regulate tobacco products and to develop and implement initiatives preventing the harm associated with tobacco use. He recalled that tobacco use was a contributing factor to serious chronic diseases such as cancer, respiratory ailments and heart disease that accounted for approximately CAD4.4 billion in direct health care costs each year in Canada. He emphasized that there was sound evidence that certain additives, including flavours, increased tobacco product attractiveness. He explained that the tobacco industry's own documents, made public as a result of litigation, had shown that the use of additives help to make tobacco products more appealing to young people. He stated that the Cracking Down on Tobacco Marketing Aimed at Youth Act responded to an important public health objective of the Government of Canada and applied to cigarettes, little cigars and blunt wraps manufactured or sold in Canada, regardless of their origin.

204. Canada was aware of the fact that tobacco manufacturers in Canada and those located in other countries might be required to reformulate little cigars, blunt wraps and cigarettes in order to continue to sell them in Canada. He stressed that although the Act did ban the use of certain additives, such as

flavours that were appealing to children and youth, in little cigars, cigarettes and blunt wraps sold in Canada, he clarified that it did not ban any type of tobacco product or types of tobacco. He assured Members that Canada's obligations under WTO Agreements, including the TBT Agreement, were taken into account during the Bill's development and that Canada was committed to respecting its international trade obligations in meeting its policy objectives. For Canada, the objective pursued by the amended law was important and legitimate. The views expressed by Members during the TBT Committee meeting concurred with this objective. He noted that some Members had concerns on how this new act had been designed to respond to this objective. Canada therefore decided to provide detailed responses to questions posed by the United States at the last TBT Committee Meeting in November 2009. Canada hoped that these responses would answer some of the concerns that had been raised earlier during the meeting.

205. The representative of Canada confirmed that Section 4 (manufacture) of the amended Tobacco Act would come into force on 6 April 2010, while Section 5 (sale) would come into force on 5 July 2010. Second, he clarified that pursuant to Section 9 of the amended Tobacco Act, the Governor in Council had the authority to amend the Schedule by Order. Third, he informed the Committee that no amendments to the schedule of additives were under consideration at this time. Fourth, concerning the information on the criteria used to develop the list of prohibited additives, he explained that the list of prohibited additives comprised additives that either had flavouring properties or enhanced flavour as well as other additives that contributed to reduce the harshness of tobacco smoke or increased the attractiveness of cigarettes, little cigars and blunt wraps, particularly to young people and other first-time smokers. Canada had reviewed a variety of sources, including published literature, industry reports to Health Canada as well as internal industry documents, made public as a result of litigation in the United States.

206. He noted that the flavouring additives were those already identified by the Joint FAO/WHO Expert Committee on Food Additives and those identified by the Flavour and Extract Manufacturers Association (FEMA) Expert Panel. He added that some flavouring additives, such as menthol and citric acid, had been excluded from the list, while other additives that contributed to increasing the attractiveness of cigarettes, little cigars and blunt wraps were added, e.g. caffeine, probiotics, vitamins and spices as well as certain colouring agents. Specifying the list of additives that were banned, added clarity and predictability to the legislative measure, which in turn enabled a more effective and consistent compliance monitoring approach.

207. In response to the question about specific efforts to identify the relationship in general between prohibited additives and products marketed to – or that were innately attractive to – youth he replied that the objective of the amended Act was to protect from inducements to use tobacco products, by addressing in particular tobacco marketing tactics that targeted youth. He recalled that the harm caused by tobacco use was well documented in the medical and scientific literature. There was sound evidence that certain additives, including flavours, increased tobacco product attractiveness. He explained that the tobacco industry's own documents, made public as a result of litigation, had shown the use of additives helped to make tobacco products more appealing to young people. Other government health agency departments, including the US FDA, also shared the same concerns with respect to the use of flavours.

208. In response to Colombia and Mexico's concern on the list of additives being unnecessarily broad, he recalled that the amended Tobacco Act introduced a Schedule of Prohibited Additives that included not only additives with flavouring properties, but other additives such as sweeteners, vitamins, mineral nutrients and colouring agents, as all scheduled additives either had been used or might be used to make tobacco products more appealing to youth and first-time smokers. He clarified that the new legislation was not intended to prevent the use of additives required for manufacturing cigarettes, little cigars and blunt wraps, and that the Act did not ban any type of tobacco products or types of tobacco leaf. He emphasized that the amended Tobacco Act's legislative approach provided

for precision and certainty in the market place as to what chemicals would not be permitted for use in the manufacture of cigarettes, little cigars and blunt wraps. This approach was adopted as it was deemed to best fit the Canadian tobacco product market and reflected the Government's policy intent to curb product development and marketing aimed at youth.

209. He noted that some Members had expressed concern on the lack of a notification to the WTO of the new legislation. Without prejudging the status of the new tobacco legislation under the TBT Agreement, he explained that it had been already too late to notify under Article 2.9.2 when Members had raised the issue in the fall of 2009. However, he assured Members that it never had been the intention of Canada to hide the legislation from other WTO Members. Canada had a very transparent legislative process. He underscored that Canada was very mindful of the comments that had been made by WTO Members at TBT Committee meetings. In addition, Canada assured Members that if any implementing regulations were to be considered, these would be notified to the WTO at an early stage.

210. The representative of Canada acknowledged that the new legislation provided for more precision and certainty: it banned a list of precisely identified additives, including additives that had been identified by the FAO, the WHO or other organizations as flavouring agents. Regarding claims that Canada was pushing for a similar ban within the WHO Framework Convention on Tobacco Control (FCTC) working groups, he replied that these issues were better addressed within the FCTC Conference of the Parties. Canada was one of a number of countries involved in working groups to develop guidelines for the implementation of the FCTC. Activities to further the implementation of the FCTC took into account best practices and scientific and medical literature from around the world.

(xxiii) 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

211. The representative of the United States expressed concern about Indonesia's requirement for producers of food, food supplements, drugs and cosmetics to obtain distribution licenses from the National Agency of Drug and Food Control of Indonesia under a measure that had been announced on 31 August 2009. He explained that the United States respected the right of Indonesia to regulate halal requirements with respect to products in its markets, however, the United States believed that this objective could be achieved in a way that did not disrupt trade. He noted that Indonesia had not provided any notice of the new decree that had became effective the same date it was published. Furthermore, he argued that the new requirements were unclear in several respects and could restrict exports of certain food and food supplements, drugs such as gelatine capsules, vaccines and cough syrups and cosmetic products to Indonesia. The representative of the United States urged Indonesia as a first step to suspend the implementation of the decree, while taking comments into account in revising the measure. It remained unclear to the United States how the halal licensing process worked, as the requirements and process for obtaining a distribution licence were vague and unclear. He mentioned the example of pharmaceutical products and drugs sourced from, containing, or manufactured using certain animal substances, which were only awarded a distribution licence in case of an emergency.

212. The representative of the United States noted that the description in the decree raised a number of important questions, including who determined an emergency for the purposes of the decree, how this was determined, the timetable for the decision and what standards for safety, use and quality would be used to evaluate whether a license would be granted. The United States was concerned that because little clarifying information had been included in the decree, it might disrupt trade in critical medicines, such as vaccines. He noted that vaccines that were developed to address a pandemic could contain porcine and thus could be banned in Indonesia because of the decree. Moreover, because swine sourced or derived products and products containing swine in the food and beverage sectors were also subject to similar emergency provisions, failure to clarify how these

provisions operated could block exports of certain foods and beverages to Indonesia. He added that the decree indicated that the use of traditional drug products, food supplements and cosmetics were not an emergency and thus it appeared that products sourced from, containing or derived from certain animal substances would presumptively not be given a distribution licence. A number of other questions could be raised regarding this provision: for example, what was the scientific and technical information that Indonesia had considered when determining that such products were not an emergency? In sum, the United States believed that additional transparency and clarification of Indonesia's distribution licensing regime was needed to ensure that Indonesia could meet its regulatory objectives while ensuring trade in critical products, such as medicines, was not impeded, which was to the detriment of Indonesian consumers as well as traders and suppliers.

213. The representative of the European Union supported the United States in its concerns with regards to Indonesia's new regulation. While the European Union respected Indonesia's right to regulate the trade in halal products, in order to ensure an adequate level of consumer information, the European Union recommended that such regulations be adopted in a transparent and participatory manner, involving all stakeholders, in order to ensure that measures adopted achieved the legitimate objectives pursued without being more trade restrictive than necessary. Furthermore, the European Union had concerns with regards to the potential negative effects of the measures on Indonesian consumers, in particular with regards to access to pharmaceuticals vital for either preventing or curing diseases. Finally, she mentioned the constructive bilateral discussions between the European Union and Indonesian authorities, and in particular the Ministry of Health and the National Agency of Drug and Food Control. In this regard, the European Union noted that, according to information at its disposal, Indonesia was in the process of reviewing the regulation on distribution licenses. The European Union hoped that such a revision would take into account the concerns of trade partners and urged Indonesia to provide an update of the revision process and to notify the draft revised measures to the TBT Committee in due time.

214. The representative of Indonesia informed the Members that the regulation was aimed at protecting consumers from the use of traditional medicine, cosmetics, food supplement and food which did not fulfil the condition of food safety. In response to EU and US concerns, Indonesia had organized consultations with the National Agency of Drug and Food Control who had issued this regulation. The halal issues were the portfolio of the MUI - Indonesian Ulema Council and not of the National Agency of Drug and Food Control (BPOM). The new food and drug regulation only sought to protect human health and not to create unnecessary obstacles to trade. Therefore the agency was currently reviewing the regulation. He announced that Indonesia would share the results of the review during the next TBT Committee meeting. Regarding the notification issue, he said that the National Standardization Agency had informed the BPOM about the obligations to notify the new measure to the WTO.

(xxiv) Chinese Taipei – Organic Products (G/TBT/N/TPKM/65 and 69)

215. The representative of the European Union asked Chinese Taipei to cease making a distinction between the requirements inferred upon older and newer EU member States in its new management system of imported organic products without delay. She mentioned that the European Union had submitted TBT comments on this issue in February, May, and in October 2009, and had also outlined its concerns at the previous TBT Committee meeting. The reply given by Chinese Taipei, while providing useful clarifications, had failed to address the EU's most significant concern, namely the different application of the requirements between EU member States. Notwithstanding this request, the EU invited Chinese Taipei to process information and provide feedback without delay to the new EU member States that had decided to submit the additional information requested by Chinese Taipei, in order to facilitate recognition of equivalence.

216. The representative of Chinese Taipei pointed out that in order to protect the rights and interests of consumers, Chinese Taipei's review of organic equivalency not only covered regulations and technical specifications of organic agricultural products and organic agricultural processed products adopted in foreign countries, but also the development of the organic agriculture sector, as well as the implementation and enforcement of organic management systems in foreign countries. She said that Chinese Taipei had determined the EU regulations and technical specifications concerning organic agricultural products and organic agricultural processed products as being equivalent to those of Chinese Taipei. However, for the 12 countries that became new EU member States in 2004 and 2007, she noted an apparent lack of necessary information with respect to the organic agriculture sector and/or an effective implementation of the EU's organic management system. Therefore, Chinese Taipei considered the declaration of these countries as having an equivalent organic system as pending until further information was provided for review. She mentioned that in the interest of a better mutual understanding, Chinese Taipei had communicated its concerns to the European Economic and Trade Office in Taipei on 29 October 2009, as well as to the WTO Members attending the last TBT Committee Meeting on 3 November 2009. Moreover, on 2 February 2010, Chinese Taipei had received information from Hungary, which now was in the process of being reviewed - Hungary would be informed of the results in a timely manner. The representative of Chinese Taipei strongly encouraged the remaining new EU members to provide the relevant information, as Hungary had done, in order to facilitate recognition of equivalence.

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

217. The representative of the United States expressed continued concerns regarding Indonesia's procedures for approving halal certifiers. He highlighted that the United States respected Indonesia's right to regulate trade in halal products. However, the United States believed that the regulations should be developed in a manner that was transparent and not trade disrupting. Indonesia's development of a halal certification system could not be considered transparent, as many traders and certifiers were caught by surprise when the measure was implemented, and some found themselves shut out of the market. Furthermore, the representative of the United States argued that the rules by which Indonesia accredited halal certifiers were unclear, and would act to restrict or eliminate exports of certain foods to Indonesia. As a first step in addressing the situation, the United States urged Indonesia to allow previously recognized halal certifiers to continue to certify halal products while Indonesia addressed the concerns of trading partners in revising the measures. He further stressed the importance of continuing to accept and review applications from certifiers that had not yet been approved.

218. With respect to the current measures, including the Decree No. Kep-99/MUI/III/2009 relating to Halal certification and the final certifiers list from 22 October 2009, the United States had several concerns. For example, the process to apply for and gain MUI's approval was not set out in the decree and had not been publicly announced. As a consequence, many certifiers did not know that they were required to re-apply and were not aware of the current rules for halal accreditation. The United States encouraged Indonesia to explain and to make available the criteria used to recognize halal certifiers and to allow stakeholders to provide comments. He noted that the United States had submitted questions on these points at the last meeting without receiving a reply.

219. He noted, with respect to transparency, that it was important that suppliers and certifiers were made aware of the new requirements and that they were given the ability to review and comment on the requirements in draft form and have their comments taken into account by the relevant authorities. They should also be provided with a reasonable time period to comply with new requirements. In addition, he was worried about the fact that the new list of halal certifiers from 22 October 2009 did not include any certifiers for poultry or lamb. Since 1 October 2009, eight US poultry certifiers which had been previously accredited were no longer recognized. The United States requested some

clarification for the rationale behind this measure. He recalled that the omission of any US poultry certifiers from the recognized halal certifiers list blocked US exports of poultry to Indonesia.

220. Furthermore, he explained that an attachment to the certifiers list indicated that the certifiers set out therein could only certify raw materials, which raised questions as to how finished or retail level goods, including processed foods, could be certified as meeting the halal requirements. He announced that the United States continued to seek bilateral discussions on this issue in order to help ensure that legitimate trade in halal products was not disrupted, for the benefit of Indonesian consumers as well as traders, suppliers and certifiers.

221. The representative of Indonesia informed the TBT Committee that the halal certification process was not mandatory, in principle. He clarified that the Indonesian Ulema Council (MUI) had stipulated several decrees related to halal issues, one of them the Decree MUI No. 410/MUI/X/2009 concerning the list of approved foreign halal certification bodies. This decree was stipulated on 15 October 2009 and would be effectively valid for two years after the date of stipulation. He explained that this list contained several approved US certification bodies: six approved US certification bodies for cattle slaughtering; five approved US certification bodies for processed food; and four approved US certification bodies for the flavour industry.

222. The representative of Indonesia further elucidated that the decree stipulated that every foreign halal certification body should fulfil the criteria and requirements of the MUI (covered in Attachment 2 of the decree) and follow the operational procedure for foreign approved halal certification bodies (covered in Attachment 3 of the decree). He emphasized that the National TBT Enquiry Point in Indonesia had sent a letter to the US TBT Enquiry Point on 23 December 2009 (reference No. 2534/BSN/D3-d3/12/2009) in order to respond to the concerns raised by the United States. He announced that the MUI would respond to the United States on the issue of the removal of eight US poultry certifiers accreditations from the list. Finally, regarding the transparency issue, he stated that the BSN as Notification Body and Enquiry Point had informed the MUI about the obligation to notify the WTO Secretariat.

(xxvi) Indonesia – Mandatory Certification for Steel Products (G/TBT/N/IDN/33)

223. The representative of Japan reiterated concerns about conformity assessment procedures related to Indonesia's mandatory certification regulations. Japan noted that in February, Indonesia had notified to the WTO Secretariat the introduction of mandatory certifications for cold-rolled steel sheets and strips, in addition to current mandatory certification regulations for hot-rolled steel coils and zinc-aluminium-coated steel plates. While Japan appreciated Indonesia's efforts to ensure safety, they continued to have questions about the necessity of mandatory certification standards for intermediate products.

224. The representative of Japan highlighted differences that existed in the market structure of hot-rolled steel and cold-rolled steel in Indonesia. He mentioned the example of Japanese hot-rolled steel that was used by a limited number of industries in Indonesia, in contrast to the large number of sectors requiring Japanese cold-rolled steel. The distribution flows of cold-rolled steel in Indonesia were also more complicated compared to hot-rolled steel. Japan requested Indonesia to take into account those differences in case Indonesia decided to design and implement technical regulations on cold-rolled steel.

225. The representative of Indonesia informed the Committee that Indonesia and Japan had held fruitful bilateral discussions. Concerning Japan's question about the technical regulation on the hot-rolled steel and strips, he informed Japan that the Ministry of Industry from Indonesia had drafted the technical guidance on mandatory standards for hot-rolled steel and coiled steel (SMI-07-0609-2006) which had been previously notified, and which was only available in Bahasa.

Regarding Japan's concerns about the differences in the market structure of hot-rolled steel and cold-rolled steel, he announced that the government authority responsible for this regulation would be informed respectively.

(xxvii) China – WAPI standard requirements

226. The representative of the United States raised concerns about China's requirement that mobile handsets enabled with WiFi be dual enabled with the WAPI wireless standard. He explained that in 2009, China's Ministry of Industry and Information Technology, MIIT, had established a process for approving handheld wireless devices, such as cell phones and smart phones, that were internet-enabled. In bilateral discussions, MIIT had indicated to US Government officials that it would only approve devices that used the relevant international WiFi standard developed by IEEE if the devices were also enabled to use the WAPI standard. He pointed out that there was still no written or published measure providing for this requirement and that China had not notified this requirement to the WTO. Furthermore, the United States was unaware of any other government that had mandated the use of a particular commercial security standard. Since the measure had not been published, there was no written explanation on the basis and technical aspects of the measure, and thus no opportunity for stakeholders to comment. Additionally, it was the US view that the WAPI standard did not appear to have been developed in an open, transparent, consensus-based process. Therefore, the United States asked for an explanation from China about why it did not mandate this particular measure through a written and published regulation in an area as broad as type approval and network access for mobile devices in the world's leading mobile handset market. Finally, he stated that the United States would also appreciate if China could provide a technical explanation for why the relevant international WiFi standard, which was in widespread use in the global marketplace, was ineffective or inappropriate to achieve China's objectives.

227. The representative of China explained that Chinese operators hoped that WLAN-networks and relevant equipment would support both the WAPI and WiFi standards in order to ensure the safe operation of network and businesses and to provide users with safer and more reliable wireless broadband communication services. In this respect, MIIT had launched a pilot programme of network access for WAPI and WiFi dual mode mobile phones and enterprises were free to apply for participation in this programme. He further explained that dual mode mobile phones equipped with both WAPI and WiFi standards aimed at mitigating security problems of WLAN networks in order to decrease users' concerns about the leak of personal information or commercial secrets. In the 9 months since implementation the programme, nearly 100 types of mobile phones had passed the tests of the programme, which was proof that the dual mode programme was not restrictive to trade.

228. In response, the representative of the United States voiced his opinion that the fact that there had been many requests for approval did not mean that the measure was not trade-restrictive. The *requirement* to enable phones with WAPI in order to sell WiFi enabled phones in China was perhaps the reason for the high number of applications.

(xxviii) United States – Chemical Facility Anti-Terrorist Regulation

229. The representative of Chile raised concerns about a US regulation published on 20 November 2007 by the Department of Homeland Security, known as the "Chemical Facility Anti-Terrorist Regulation or Standard". The regulation applied a procedure to establish the location of products which were on sale that may present potential safety risks as they could be used for terrorist attacks. He gave details that the list of substances to which this requirement would be applied included potassium nitrate and sodium nitrate under Appendix A of the regulation, which meant that any person or enterprise in possession of certain volumes of those chemicals on their premises was required to inform the Department of Homeland Security, which would then decide on the application of security measures to that installation. He pointed out that Chile was the principal world producer of

potassium nitrate and sodium nitrate and that significant volumes were exported to the US market. He informed the Committee that these products were used as fertilizers on a large scale, as well as in industrial manufacturing and for the generation of solar energy. Moreover, especially in the US market it could be used in organic agriculture.

230. Chile was of the view that the appendix of the regulation would affect the competitiveness of those products vis-à-vis other fertilizers on sale in the US market, since the costs of these products would increase, thus favoring other nitrate family products with indistinguishable properties, such as calcium nitrate and magnesium nitrate – despite there being no difference in risk. Moreover, there would be a less rigorous monitoring of other chemicals which in fact did pose a risk in terms of potential terrorist activities in the United States, such as ammonium nitrate, nitric acid, and others. He emphasized that Chilean potassium nitrates and sodium nitrates were not explosive products and could not be detonated either on their own nor when mixed with a fuel product. He stated Chile's belief that the likelihood of those nitrates being used by terrorists in criminal activities was very low – nevertheless they featured in the regulation, while other products that could be used as explosives or weapons of mass destruction were exempted. He noted that the requirements for the substitution of products would affect the entire supply chain, which would also affect the retail market. This was because the product would be less attractive to the final consumer, availability of the product would be reduced and this in turn would mean that substitute products would tend to be favoured by consumers. He further noted that the majority of Chilean nitrates would have to be notified to the Department as "high risk" products, and that producers would be subject to security vulnerability assessments by the Department of Homeland Security. In the first step of this assessment, expert surveys would be required by the Department, which would mean that the clients of Chilean businesses would need to invest money in order to comply with these standards if they wished to continue to use Chilean nitrate. He voiced Chile's belief that the most reasonable decision for the affected clients would be to replace Chilean products with other, non-regulated products. He informed the Committee that Chile had been raising its concerns to the US Government since 2007 and that it had submitted a technical background document justifying the exclusion of sodium and potassium nitrates from the Appendix of the US regulation.

231. The representative of Chile further noted that his country's industry, as well as representatives from other countries, had requested a meeting with the Department of Homeland Security to consider the scientific data which backed up their argument. A meeting had been held in November 2009, supported by the USTR, where a formal request to modify the appendix had been submitted. The representative of Chile stressed that Chile considered the discriminatory treatment of products that carry the same risk as running counter to the provisions of Article 2.2 of the TBT Agreement and that the regulation thus created an unnecessary obstacle to the trade of potassium and sodium nitrates, while products that were equally or even more dangerous, were not being covered, which would favour other fertilizers coming for instance from the EU and Norway. He stated that Chile agreed with the national security objectives of the United States, yet at the same time would request a fair and equal treatment to all products available on the market. He re-emphasized that the fertilizers he was referring too were directly competitive products and that the United States had not notified their regulation at the necessary time to the WTO, which was a failure to comply with Article 2.9 of the TBT Agreement. He concluded by stating that as of yet, Chile was waiting for a formal document by the Department of Homeland Security concerning the outcome of the November 2009 meeting.

232. The representative of the United States confirmed that Chile and the United States had discussed the issue bilaterally. He informed the Committee that in the US Department of Homeland Security's final rule-making, it had been determined, based on available evidence, that sodium and potassium nitrates were to be considered explosive precursors and that facilities possessing specified quantities of those chemicals needed to submit certain information, known as "top screens", so that the Department could make preliminary determinations as to which facilities were high risk and would be subject to regulation under the Chemical Facility Anti-Terrorism Standards. He emphasized

that the Department only regulated high risk chemical facilities, not the chemicals themselves, and that the regulation imposed no restrictions on the buying, selling, use or importation of chemicals listed in Appendix A of the regulation. He further noted that Chile had not explained how the measure would fit within the definition of a technical regulation for purposes of the TBT Agreement.

233. The representative of the United States said that, based on its review of the available information at the time of finalization, the Department of Homeland Security had not listed calcium ammonium nitrate in Appendix A. He noted that Chile's industry disagreed with that decision, yet he stated that US regulators had taken into account the available evidence on record, including evidence put forward by the Chilean industry during the notice and comment period. He said that the United States was not aware that Appendix A had created a competitive disadvantage for producers of potassium and sodium nitrates in comparison to producers of calcium ammonium nitrates and that the industry had not reported to the Department any disruptions in the agricultural supply chain, or problems with completing the top screen or related procedures under the regulation. Likewise, Chile had not identified to USTR any actual trade impact on its producers. Moreover, he said that the Department had only considered scientific and technical factors in identifying substances that could potentially pose a significant risk to human health or life, and that the countries where each substance was or potentially could be produced was not one of these factors. He concluded by informing that the Department of Homeland Security was planning to review Appendix A, but had not yet set a timetable for this review.

(xxix) European Union – Toys (G/TBT/N/EEC/184 and Add.1)

234. The representative of China raised concerns regarding the inclusion of chemical requirements in the new EU Toy Safety Directive (TSD), since these would significantly increase the costs for Chinese toy makers. He explained that while China understood the EU objective of enhancing the safety of toys, the relevant international standard, the ISO 8124-3 for the safety of toys, would set requirements on only eight metal elements. Thus, in order to be in conformity with the TBT Agreement principle of using international standards so as to avoid unnecessary barriers to international trade, and taking into account the special development, financial and trade needs of WTO developing country Members in the preparation and application of technical regulations, standards and conformity assessment procedures, he asked that the European Union postpone the implementation of its new directive, that it would make toxic and clinical tests, modify the limits on harmless or low-toxic elements such as copper, zinc, aluminium, boron, cobalt, manganese, nickel, tin and strontium, and grant a larger number of exemptions according to the principle put forward in the COM (2008) 9 (Article 3.4) revision of the directive so that the directive would not lead to the increase of any toy makers' burden and costs.

235. The representative of the European Union informed the Committee that the new TSD had been adopted in June 2009 and that it aimed at enhancing the safety of toys, thus replacing and modernizing the 20-year old current TSD. He explained that the revision had a three-fold objective. First, it provided for enhanced safety requirements to cope with recently identified hazards. Second, it strengthened manufacturers' and importers' responsibility for the marketing of toys. And third, it reinforced market surveillance obligations of member States, in particular with regard to controls at the EU external border. He noted that EU member States were expected to adopt and publish relevant implementing provisions by 20 January 2011, and apply them from 20 July 2011, with a longer transitional period foreseen for the application of chemical requirements, namely until 20 July 2013. He said that based on a mandate issued by the European Commission in July 2009, the existing European harmonized technical standards on toy safety were being reviewed with a view to adapting them to the requirements of the new directive; the relevant technical work was under way and was expected to be accomplished in time for revised standards to be made available before the new directive became applicable. Comprehensive guidance documents aimed at facilitating the practical application of the new directive were being finalized and would be made available in the near future

on the European Commission's website. A full translation in Chinese of the new directive was already available, and all important guidance documents would continue to be translated into Chinese, made available on the internet as well as communicated directly to AQSIQ for wider dissemination among interested stakeholders in China.

236. The representative of the European Union emphasized that his delegation was committed to keeping an open channel of communication with the Chinese authorities, AQSIQ, its local inspection and quarantine (CIQ) offices, and the China Toy Association, regarding the implementation of the new TSD. There was a good bilateral dialogue on toy safety with AQSIQ and the European Union was convinced that this was one of the best working groups in the framework of their regulatory dialogue. In June 2009, a workshop had been organized by the European Commission for the benefit of AQSIQ and CIQ officials in Beijing on the new TSD. Moreover, further awareness-raising activities about the new toy safety requirements in the European Union, which would mainly target the economic operators in mainland China, were foreseen for the second half of 2010 or early 2011. These activities would provide practical training to Chinese toy manufacturers in the most important toy manufacturing clusters in China, as well as extensive information and practical guidance on how to comply with the new requirements, for the benefit of any interested manufacturer, trader, and any other economic operator.

237. With respect to the safety assessment that manufacturers were required to carry out on their toys before placing them on the market, the representative of the European Union explained that it consisted of an analysis of the chemical, physical, mechanical, electrical, flammability and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to them. In this framework, manufacturers performed an assessment of the likelihood of the presence of prohibited or restricted substances in a toy; the scope of testing was based on this assessment. Thus, testing obligations would only apply to those potentially harmful substances that could be expected to appear in the toy in question. For instance, if the outcome of the assessment was that there was no risk for prohibited fragrances, manufacturers would not need to test for fragrances. If there were no electrical hazards, no test in this area would be required. Yet it was the responsibility of the manufacturer to assess whether there was a risk for exposure or not. He informed the Committee that a detailed guidance on the drafting of safety assessments was being prepared which would be made available soon.

238. Regarding compatibility with international standards, and that the new TSD would allegedly introduce chemical requirements beyond those laid down in the relevant ISO standard, the representative of the European Union emphasized that his authorities aimed at a high level of safety, and had decided to set out those chemical requirements based on the best scientific evidence available. He was of the view that the directive built upon rather than deviated from what already existed in the ISO standard in order to provide a high level of safety for EU consumers.

C. EXCHANGE OF EXPERIENCES

1. Good Regulatory Practice

(i) Fifth Triennial Review follow-up: National processes and procedures

239. The Chairman drew the Committee's attention to the relevant recommendation from the Committee's Fifth Triennial Review contained in paragraph 11 of G/TBT/26.

240. While the representative of the European Union stressed the need for time to take stock of and digest the recommendations from the Fifth Triennial Review, he offered some preliminary comments. He suggested that an efficient way to give effect to the recommendations in 11(a) and (b) which referred to the compilation of guidelines and an illustrative list of mechanisms, might be to explore

whether there was an interest in setting up an informal group with those Members which wished to take a more active stake in this exercise: the group could elaborate draft documents that could then be shared with the Committee as a whole for further discussion.

241. The representative of the United States stressed the need for Members, under paragraph 11(a) with regard to the compilation of guidelines, to share experiences with respect to GRP as well as to make the Committee aware of relevant work that had been done in other organizations on GRP. While not ruling out the proposed small group, it was necessary to consider the existing body of work as a first step.

242. The representative of Pakistan stressed the importance of guidance from the Committee on GRP; he agreed with the need to share experiences – and that it should also include those of observer organizations.

243. The representative of the European Union agreed with the importance of inviting interested Members as well as relevant observer organizations to submit papers about their work on GRP. For instance, the Committee could envisage setting up an initial time period during which papers would be submitted followed by a smaller group of interested Members analyzing this body of knowledge. It was important not to prejudge the outcome of this work – perhaps the Committee could agree on certain basic elements of good regulatory practice, and, later, on a recommendation or even a decision by the TBT Committee.

244. The representative of China noted that while GRP was important, there were several other topics to be implemented within the next three years; the number of meetings was limited – and resource limitations also needed to be considered. Whether work was conducted in small or larger groups (the mechanism was not so important) the Committee did need input: it was important that Members submitted papers. The Committee could begin by taking stock of what was on the table, including guidelines available in other fora. It could be useful for the Committee to hold topic-specific informal meetings on the margin of a formal meeting.

245. The representative of Egypt agreed with the need to examine the recommendations closely so as to identify ways in which the Committee could move forward – and he agreed with the views expressed by China: a useful first step would be to hold informal meeting. It was important to ensure that developing countries participated actively in this process, regardless of whether it was informal or small group meetings.

246. The representative of the Rwanda suggested that the Secretariat could look into some of the issues being discussed and provide background to the Committee.

247. The Secretariat noted with respect to paragraph 11(a) in particular – that this was essentially about compiling a list of guidelines; the text of the Triennial Review not only mentioned Members' experiences, which could of course only come from Members, but also that derived from existing work of other organizations. Compiling such work could be a starting point, i.e., to take stock of relevant existing information.

248. The Chairman noted that it was important that written contributions were made, the format for the work was less important. He suggested that the incoming Chair consult with interested Members on the most appropriate manner to take forward the Committee's work on GRP. He stressed that input in terms of submissions from Members was essential.

2. Workshop on Regulatory Cooperation between Members

249. The Chairman recalled that the Committee had agreed to hold a workshop on regulatory cooperation between Members (paragraph 16 of G/TBT/26). He noted that provision had been made in the WTO's 2010 Technical Assistance and Training Plan to assist participation of capital based officials from developing country Members.[9] The Chairman suggested that this activity be tentatively scheduled for March 2011. This timing would give delegations sufficient opportunity to prepare and discuss the programme. The Chairman also suggested that the Secretariat, in consultation with Members and the incoming Chairperson, develop a draft outline of the programme.

250. It was so agreed.

3. Conformity Assessment Procedures

(i) The European Union's Common Framework for Accreditation

251. The representative of the European Union introduced the main elements of the European Union's new Common Framework for Accreditation.[10] In her presentation, which is set out in full in document JOB/10/2, she stressed the following points in particular:

(a) Accreditation is a formal system which provides an independent and authoritative attestation of the competence, impartiality and integrity of conformity assessment bodies (CABs) – in other words, a system that formally demonstrates that CABs are technically competent to do their job. The CABs themselves assess conformity of product services or processes, to specify requirements.

(b) The fundamental role of accreditation is to deliver confidence to markets. Both the internal EU market and international markets can only function effectively if all stakeholders (consumer, businesses, industry and regulators) have confidence that the products circulating meet the necessary level of safety. As such, accreditation is an essential component of the quality infrastructure and an effective trade facilitation tool.

(c) Accreditation is the last level of control of the technical competence of CABs and, under the new Common Framework, is defined as the preferred means of demonstrating the competence of CABs in the European Union. A "Notified Body" in the European Union is an organisation that has been designated by a Member State to carry out the conformity assessment procedures required to establish that a product meets the essential requirements (for the protection of health, safety, the environment, etc.) set out in the applicable EU legislation. member States are responsible for the competence of notified bodies and accreditation is a tool that supports the process for the designation of notified bodies.

(d) The new European policy on accreditation is set out in the New Legislative Framework for the marketing of products; this is composed of two legal texts, adopted in 2008 and applicable from 1 January 2010.[11] The new Common Legal Framework is intended to increase transparency in the competence assessment and

[9] WT/COMTD/W/170/Rev.1, p. 53.

[10] Annabel Brewka, Regulatory Policy Unit, European Commission's Directorate General for Enterprise and Industry.

[11] Regulation (EC) 765/2008 - requirements for accreditation and market surveillance relating to the marketing of products and Decision 768/2008/EC - a common framework for the marketing of products.

monitoring of notified bodies and to harmonize conditions for the operation of notified bodies in the European Union. Essentially, there are three important objectives, namely, to (i) create and promote: mutual confidence in the quality of CABs and their certificates; (ii) ensure common and transparent rules for the assessment of the competence and monitoring of CABs; and, (iii) stabilize the European accreditation system.

(e) At the *national* level, there should be one national accreditation body (NAB) per Member State - formally recognised by the Member State and appropriately resourced. Accreditation is a public authority activity to be conducted on a not-for-profit basis and free from any commercial interests. Competition between accreditors at national level, as well as at the European level, should not take place. There are also other requirements, *inter alia*: the European Cooperation for Accreditation (EA) was under Regulation (EC) 765/2008 the official European accreditation infrastructure; all NABs had to be members of EA and submit themselves to peer evaluations managed by EA; and NABs could not be involved in conformity assessment.

(f) At the *European regional* level, cooperation between accreditation bodies takes place within the EA, which was created in 1997 and has origins extending back to the 1970s. Currently, there are 34 full Members of the EA. EA's main mission is essentially to harmonize accreditation practices within the European Union and operate and manage the peer evaluation system.

(g) At the *international* level, cooperation between accreditation bodies takes place within two organizations: the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC). Both entities provide multilateral mutual recognition agreements between member bodies. The EA is a regional body member of ILAC and IAF; in turn, accreditation bodies being signatories to the EA Multilateral Agreement (EA MLA) and which are members of IAF and/or ILAC are automatically accepted into the IAF MLA and ILAC MRA. In 2008, the EA has adopted a resolution deeming the attestations of conformity assessment performed by CABs accredited by third country accreditation bodies which are signatories to the international cooperation agreements, but that do not necessarily meet all the requirements that are set out in the European regulation, equally reliable from a technical point of view.

(h) Accreditation is a tool in support of the European Union's internal regulatory policy. It is not intended to change or undermine the international cooperation agreements between accreditation bodies, and it does not affect or force changes in the accreditation practices in third countries.

252. The representative of Thailand asked for some information about the impartiality of the EA and about the peer evaluation process and auditors.

253. The representative of Israel noted that the new legislation limited the number of accreditation bodies to one per member State – did this not prevent competition?

254. The representative of Korea noted that accreditation was not the only way of recognizing the results of conformity assessment; other means were possible. Considering this, did the European Union intend to recognize, for example, existing mutual recognition arrangements such as the IECEE CB Scheme? The representative of Korea asked for more information about how other countries' accreditation bodies could be recognized in the European Union.

255. The representative of the European Union noted, with respect to peer evaluations, that these were done by a team of EA evaluators composed of experts from national accreditation bodies who were trained at EA level to carry out such evaluations. On competition, she noted that it was correct to state that competition was prevented among accreditation bodies within the European Union, but not outside: European accreditation bodies were free to compete on third markets. The issue was not so much about the recognition of foreign accreditation bodies, but how the EU system was designed. In the view of the representative of the European Union, it was the designation process that was fundamental for the acceptance of conformity assessment results, not how the accreditation *per se* was operated.

256. On the issue of the acceptance of conformity assessment schemes such as the IECEE CB Scheme, it should be noted in the first place that the EU has no mandatory third-party conformity assessment for the safety of electrical equipment. There was therefore no (need for) direct recognition, as such, of the Scheme. Nevertheless, the European CABs were participating actively in these schemes and the European Union was convinced of the potential of the IECEE CB Scheme as a useful tool for the facilitation of acceptance of conformity assessment results worldwide. Furthermore, the Scheme's certificates or, more generally, foreign conformity assessment results could be recognized via bilateral agreements, sub-contracting agreements, for instance – or any type of private arrangement allowed by EU legislation between EU CABs and non-EU CABs. It was important to stress, however, that it was the EU notified bodies that had the ultimate responsibility for the certificate.

257. The representative of Brazil asked the representative of the European Union to clarify in what way the process of designation of notified bodies was a “political process”. Also, what was the difference between the competence of accreditation bodies and “notified bodies” in the member States of the European Union?

258. The representative of Pakistan noted that international bodies such as ILAC and IAF, which were international accreditation forums, developed conformity assessment procedures used by member conformity assessment organizations and which were accepted by businesses worldwide. What was the relationship between these bodies and the EU/EA?

259. The representative of the United States noted, on the issue of competition, that in the European model competition was – as had been stated – not seen as appropriate for accreditation and was necessarily a public function. The United States disagreed with this position, noting that many Members of the WTO had more than one accreditor. In the US view, competition did not cause problems with independence, credibility, and reliability. Given this, what was the technical basis for determining that there was a need to limit competition for accreditation?

260. A second related point was that although the European Union was claiming that competition was not appropriate for accreditation – and requirements were being imposed on European accreditors in Regulation 765 – at the same time, the European Union had said that attestations of conformity assessment results issued by bodies accredited by non-European bodies that were ILAC MRA or IAF MLA signatories were equally reliable as those issued by European bodies that complied with those requirements. This seemed to be a contradiction.

261. The representative of the United States noted that the European Union had made a point earlier that it had no intention of promoting its system of accreditation internationally, or spreading that approach: that it was simply the approach being taken in the European market. Yet a document issued by DG Enterprise from the previous year stated that the EU sought to "promote in its

international relations the European model of accreditation".[12] In fact, there were several instances where it was clear that the European Union was doing just that: spreading its approach to accreditation. Had there been a change in policy?

262. There was a concern, also, that the ILAC system would be undermined by Regulation 765. US industry representatives had also asked the USTR about potential anti-trust implications in the US with respect to the European accreditation approach. Moreover, in the TBT Committee, representatives of the European Union promoted the liberalization of conformity assessment procedures, which would benefit EU exporters in the form of increased market access. However, the EU approach appeared, potentially, to be damaging for the liberalization of conformity assessment procedures internationally, for the discussions in this Committee, and for the ILAC system. The new approach could also be seen as an attempt to create a monopoly for accreditors in the European Union member States.

263. The representative of the European Union noted that conformity assessment bodies were not automatically allowed to carry out the conformity assessment tasks referred to in the applicable EU legislation; they had to be designated by the notifying authority first. The issue of technical competence was separate. A body could be technically competent but still not be authorized to issue conformity assessment attestations – for that it would need to go through the "notification process", which was under the responsibility of the member States authorities. It was also noted that the number of notified bodies was also a matter of resources – the ability of the member States to effectively monitor and to supervise those bodies was a factor that needed to be taken into account. Hence, smaller member States normally notified fewer bodies, larger more. In general, the market itself was a good self-regulator that determined what number of conformity assessment bodies a given country (or sector) could absorb.

264. Regarding the difference between accreditation bodies and the notified bodies, the representative of the European Union said that the accreditation body assessed the competence of conformity assessment bodies, which in turn, once notified by the competent national authorities, became the "notified bodies". In other words, the notified body carried out the conformity assessment procedure under the relevant product legislation and the accreditation body accredited the body in question. Hence, while accreditation bodies did not compete, notified bodies did.

265. It was clear that the choice of no competition for accreditation bodies was a policy decision; there was no scientific evidence or a technical basis for this. It was a political choice because competition was not, in the EU view, compatible with accreditation – the EU believed that, in this way, the role of accreditation bodies as last level of control in the conformity assessment chain would be best fulfilled if accreditation was exercised as a public authority activity.

266. On the issue of promoting the EU system, the EU reiterated that its accreditation framework had no extraterritorial application – however, the EU believed, that its common accreditation framework was a good system, built on solid policy choices, and therefore deserved to be promoted or defended – however, there was a difference between promoting and imposing.

267. The representative of Canada noted that, in her delegation's understanding, national authorities of EU member States could refuse attestations of conformity issued under accreditation by non European accreditation bodies that did not comply with the new European requirements – even though they were signatories to IAF and ILAC MLA/MRAs. Moreover, this was not because of non-fulfilment of new European requirements as such. What, then, were the precise reasons for the

[12] General Guidelines for the Cooperation between the European co-operation for Accreditation and the European Commission, the European Free Trade Association and the competent national authorities, European Commission, January 2009, pp. 4,7 and 8.

refusal? Also, it appeared that it was necessary to conclude a government-to-government mutual recognition agreement; was this correct? The representative of Canada recalled that the Committee had in previous reviews engaged significantly in conformity assessment work, including with respect to an exchange of information on the merits and difficulties of negotiating and implementing government-to-government mutual recognition agreements. In the Fourth Triennial Review, it had been noted that possible difficulties and problems could relate *inter alia* to:

> "differences in development levels amongst Members; cost; non-transparency; non MFN nature; limited opportunity to enter into negotiations for the conclusion of MRAs; the need to take into account the quality of the conformity assessment procedures rather than the origin of the product; and, efficiency and effectiveness of MRAs to solve problems of multiple testing and conformity assessment procedures".[13]

268. Other factors to be considered for the conclusion of effective MRAs between governments included: sound regulatory infrastructure, sufficient volume of trade in specific sectors between the parties involved to justify the high administrative costs and the generally long-term nature of the negotiations', and intangible economic benefits.[14] Considering all this, had the contents of the impact assessment – which had been mentioned by the representative of the European Union – been shared with Members so that the Committee could better understand how and why the European Union had determined that the use of MRAs was the preferred approach to accepting attestations by non-EU bodies in the area of mandatory conformity assessment?

269. The representative of the European Union noted that there appeared to be a misunderstanding. What had been said was there could be a possibility for non-EU conformity assessment bodies to undertake conformity assessment work which would be directly recognized (or, in other words, be given the same validity as the conformity assessment results of EU notified bodies): this was within the framework of mutual recognition agreements (MRAs). This did *not* mean that the European Union had made a policy choice to promote MRAs; in fact, the European assessment of the operation of the MRAs it had concluded was not particularly positive. The benefits had not been significant for a number of reasons and the European Union fully subscribed to the criteria which had been listed in previous triennial reviews of the TBT Committee on the matter. Nevertheless, from a strictly legal point of view, there were only two options: either recognition through a notified body – designated as such by a Member State – or, in the framework of government-to-government MRAs. With respect to the latter case, this was so because the MRAs were based on trust that the system of the other party, even if it might not operate entirely according to the same principles as those of the European Union, was effectively equivalent and therefore offered a satisfactory level of reliability.

270. On the question regarding impact assessment, the representative of the European Union noted that the impact assessment which had been the basis of the new legislative framework had been published on the EU website – it was a public document.[15] It was nevertheless drafted from an internal market perspective; therefore, it did not tackle the third country aspect – it focused on the options to improve the single market.

271. The representative of the United States noted, with respect to the spreading of the European Union's approach to accreditation, if EU accreditors were not going to be recognizing conformity assessment results issued by bodies outside the European Union even though these would be accredited by ILAC MRA or IAF MLA signatories and were equally reliable, simply because they are not public authorities, or because there was more than one in a particular WTO Member, this would

[13] G/TBT/19, para. 39.
[14] G/TBT/19, para. 40.
[15] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52007SC0173:EN:NOT.

put pressure on non-European accreditation bodies to consolidate in order to have their results recognized in Europe. That was the implication of this policy. And, if these accreditors did not consolidate then conformity assessment bodies based outside the European Union would bypass them and go directly to the European accreditors since that would be the only way they would be able to have their conformity assessment results recognized in the European Union.

272. Clearly, in the US view, there would be an impact on the work of the TBT Committee. The issue of toys illustrated why. There had been several measures discussed in the Committee over the past year with respect to toys, which the European Union and others had joined in to raise concerns when other Members did not accept conformity assessment bodies to do testing outside their countries. In fact, the European Union and other Members had advocated for those countries to accept conformity assessment results issued by bodies that were accredited by ILAC MRA signatories. But if the European Union would not accept those results, even when equally reliable, how could the European Union continue to make this argument in the TBT Committee?

273. The representative of the European Union stressed that its system for accreditation had flexibility built into it for giving recognition to accreditation certificates issued outside the European Union, and also to conformity assessment results of conformity assessment activities carried out outside the European Union. What the EU system did not allow for was an automatic recognition of the validity; but there were, nevertheless, mechanisms to achieve such recognition. For instance, if a foreign conformity assessment body seeking accreditation already held an accreditation certificate from an IAF or ILAC member outside the European Union there was certain scope for recognition and avoid duplicative accreditation assessments. With respect to conformity assessment results, the EU system explicitly allowed and even encouraged EU notified bodies to have bilateral cooperation agreements with non-EU conformity assessment bodies, and subcontract parts of their conformity assessment tasks; what the EU system did not allow was the total transfer of responsibility from a notified body to a non-EU conformity assessment body – this was a matter of public policy that could not be derogated from.

274. The Chairman thanked the European Union for sharing their experience with the Committee and encouraged other Members to also come forward with such substantive contributions or statements regarding their experiences on conformity assessment procedures for the next meeting of the Committee. It was precisely this type of input and discussion that stood for the quality of the work of the Committee. It would also be useful to hear experiences from developing countries with respect of their approaches to conformity assessment, and challenges faced.

4. Transparency

(i) Sixth Special Meeting on Procedures for Information Exchange

275. The Chairman recalled that the Committee would be holding its Sixth Special Meeting on Procedures for Information Exchange on 22 June 2010, back-to-back with its June regular meeting. He said that this meeting would be an opportunity to discuss issues relating to information exchange and to review the functioning of notification procedures, and the operation of enquiry points – as such, it was a technical meeting. He noted that provision had been made in the WTO 2010 Technical Assistance and Training Plan[16] to fund participation of capital-based officials from developing country Members. The Chairman drew the Committee's attention to the draft programme of the Special Meeting, contained in the document set.[17] That programme, proposed that the meeting focus on a discussion of some of the transparency-related recommendations contained in G/TBT/1/Rev.9

[16] WT/COMTD/W/170, p.52.
[17] Sent to all Members by fax on 11 February 2010. A revised version was circulated as JOB/TBT/3.

(Section IV) as well as those made at the Fifth Triennial Review, and that the Committee also consider the issue of transparency in the context of standard setting.

276. The representative of Canada expressed support for the consideration of the transparency-related recommendations contained in Section IV of G/TBT/1/Rev.9 and/or those made at the Fifth Triennial Review (G/TBT/26). With respect to **notification practices**, Canada suggested that this session could explicitly include a discussion of ways in which Members sought to improve coordination between relevant authorities at the central governmental level and the local governmental level directly below the central level (notifications under Articles 3.2 and 7.2), including through dissemination of good practices – as referenced in G/TBT/26 para. 38(a). Canada also noted that, with TBT Information Management System, it could be useful to discuss this facility as a platform for comments.

277. On **enquiry points**, Canada suggested adding an exchange of Members experiences regarding the use of electronic tools to assist the work of enquiry points. On the challenges associated with the establishment an operating enquiry point, Canada was of the view that the Committee needed to focus on ways to advance and overcome the challenges that have already been identified in past meetings and technical assistance sessions; perhaps a developing country could present on how they have overcome such challenges.

278. With regards to the section on the practices of **standardizing bodies**, Canada was not sure that the Special Meeting would be the best forum to discuss the topic. While Canada did not dispute the relevance and interest of the issue – which could probably be the subject of its own workshop – Canada was not convinced that it added value to the meeting in June as this was targeted at those responsible for information exchange, including enquiry point and notification officials: these participants would not, necessarily, be involved in standard-setting.

279. The representative of Pakistan emphasized the importance of considering ways to improve the TBT IMS; in this regard it was important that Members provided up to date information on Enquiry Points so that hyperlinks could be made directly to relevant websites. Pakistan also noted the importance of sharing unofficial translations.

280. The representative of Brazil stressed the importance that his delegation attached to the enhancement of the functioning of enquiry points. Brazil intended to make a presentation about the experience of the Brazilian Enquiry Point in promoting awareness on the TBT Agreement among SMEs.

281. The representative of El Salvador expressed general support for the Chair's draft programme and the suggestions made by other Members.

282. The representative of the European Union welcomed the draft outline provided by the Chair but questioned whether all three areas covered (notification practices, standardizing bodies, and enquiry points) could be covered in one day. She shared in this respect the argument of Canada that the work of the standardizing bodies was not directly linked to the work of Notification and Enquiry Points. With respect to notification practices, she stressed that the programme covered a variety of issues and that it could be helpful to divide this point in different sub-points. It could be useful to focus specifically on notification practices improving transparency and to facilitate the analysis of notifications; this was related to internal coordination as well as to how notifications were made: e.g., how to provide information relevant to previously notified measures (for instance modifications). Another important issue was the handling of comments and following-up on comments received. Thirdly, the Special Meeting could focus on means facilitating commenting on third country notifications, including through the sharing of translations or the use of electronic tools.

283. The Chairman noted all interventions made and said that the Secretariat would circulate a draft programme after the meeting taking these into account. He asked Members, in order to facilitate the work of the Secretariat in preparing this activity, to communicate to the Secretariat any specific proposals for contributions to the Special Meeting by 12 April 2010.

(ii) Fifth Triennial Review follow-up

284. In respect of follow-up to the Fifth Triennial Review, the Chairman noted that the Committee continued to fine-tune its work on transparency based on a wide range of decisions and recommendations taken to improve the implementation of the transparency procedures of the TBT Agreement. In fact, in the Fifth Triennial Review, Members had emphasized the importance of fully implementing the existing body of decisions and recommendations (G/TBT/1/Rev.9, Section IV). He noted that the next meeting of the Committee, discussions in the context of the Special Meeting could help spark decisions for the regular meeting that would follow.

5. Other Matters

(i) Private Standards

285. The representative of El Salvador expressed concern about the proliferation of private standards and the implications this type of standard might have on her country. She noted that because these standards were often more demanding than international standards, this caused problems for small scale enterprises (SMEs) in complying with such international standards. While El Salvador accepted the need to make the necessary effort to guarantee compliance with international standards – a commitment that, in fact, all Members had assumed in the TBT context – it was important that this effort was not undermined. Her delegation was of the view that the advent of private standards as a non-voluntary prerequisite for accessing markets affected the rights of individuals negatively in this regard. For El Salvador this situation directly affected the competitiveness of its exporters. In her view, the time was ripe for Members to discuss this matter through a sharing of experiences – under Article 4 of the TBT Agreement, and in line with the recommendation from the Fifth Triennial Review.

III. FIFTEENTH ANNUAL REVIEW OF:

A. THE IMPLEMENTATION AND OPERATION OF THE TBT AGREEMENT UNDER ARTICLE 15.3

286. The Committee adopted the Fifteenth Annual Review of the Implementation and Operation of the TBT Agreement, as contained in document G/TBT/28.

B. THE CODE OF GOOD PRACTICE

287. The Chairman drew the Committee's attention to two lists prepared by the Secretariat to facilitate consideration of matters relating to the operation of the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 of the TBT Agreement. The first list, contained in document G/TBT/CS/1/Add.14, compiles the standardizing bodies that have accepted the Code in the period under review. It was noted that during the reported period, four standardizing bodies from four Members had accepted the Code of Good Practice.[18] The second list, contained in document G/TBT/CS/2/Rev.16 compiles all the standardizing bodies that have accepted the Code since 1 January 1995. Since 1 January 1995, 162 standardizing bodies from 122 Members have accepted the Code of Good Practice. In addition, the Chairman noted that the ISO/IEC Information

[18] G/TBT/CS/N/175 (Viet Nam), G/TBT/CS/N/177 (FYROM), G/TBT/CS/N/178 (Cyprus) and G/TBT/CS/N/179 (Cameroon).

Centre had prepared the Fifteenth Edition of the WTO TBT Standards Code Directory, which contains information received according to paragraphs C and J of the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 of the Agreement.

288. The Committee took note of these documents.

IV. TECHNICAL COOPERATION ACTIVITIES

289. The representative from Chinese Taipei informed the Committee of a training workshop that was held from 29 September – 12 October 2009 (G/TBT/W/328).

290. The Representative from Codex drew the Committee's attention to the FAO-WHO Trust fund which was established in 2003 to assist the participation of developing and transitional countries in the work of the Codex Alimentarius Commission. Within the framework of this trust fund, a regional workshop on improving participation in Codex would take place in Tunis in May 2010. A comprehensive document containing all FAO-WHO capacity-building activities would be made available at the next meeting of the TBT Committee.

291. The Chairman drew the Committee's attention to a document containing the Secretariat's technical assistance activities (G/TBT/GEN/94).

V. UPDATING BY OBSERVERS

292. The representative of the IEC provided the Committee with an update on its recent activities in developing countries (G/TBT/GEN/98).

293. The Representative of UNECE updated the Committee on recent events. She highlighted the International Conference on Risk Assessment and Management which had been held during the 19th session of the Working Party on Regulatory Cooperation and Standardization Policies. This Conference, attended by over 120 participants, addressed the principal components of risk management: risk identification, risk assessment, determination and implementation of risk management strategies and risk communication. The representative also provided an update on the Working Party's annual session where progress had been made in the areas of regulatory cooperation and market surveillance.

294. The representative of the OECD provided the Committee with an update on its recent events and on-going work related to TBT (G/TBT/GEN/96).

295. The representative of Codex provided the Committee with an update on its recent events and on-going work of relevance to the TBT Committee (G/TBT/GEN/93). She highlighted the recent work of the Committee on Methods of Analysis and Sampling with respect to procedures for conformity assessment and resolution of disputes related to analytical or sampling issues. She also brought the Committee's attention to a joint FAO, UNCTAD and IFOAM project aimed at facilitating market access for developing countries in the area of organic agricultural products.

296. The Representative of ISO drew the Committee's attention to the recent publication "International Standards and 'Private Standards'".[19] He explained that the purpose of the document was to provide some clarity on the issue of private standards, especially in light of the reference to private standards in the TBT Committee's Fifth Triennial Review. It was important, he said, to differentiate the value of international standards that had been developed under a full consensus based procedure, from those that were not. He also updated the Committee on the state-of-play of the ISO

[19] www.iso.org/iso/private_standards.pdf.

Strategy Plan 2011-2015 and noted that at the recent ISO Council meeting, discussions had focused on where international standards could add value from a trade, societal and an environmental perspective and how ISO was looking at sustainability across these three areas. The representative of ISO also highlighted a joint ISO/UNIDO publication "Building Trust" - a toolbox on conformity assessment.[20] With regard to recent workshops, the representative updated the Committee on a workshop held in March by the World Standards Cooperation (ISO, IEC, ITU) on the interoperability associated with automobiles and the automotive sector and in particular the potential use of various green and automotive technologies, such as batteries, in smart grid technologies.

297. The representative of the ITC provided the Committee with an update on its recent events and on-going work related to the TBT Committee (G/TBT/GEN/95).

298. The Chairman noted that the Committee had received an application for observership (also made at the same time to the SPS Committee) from the Southern Africa Development Community (SADC) Secretariat as well as from the International Telecommunications Organization (ITU).

299. The Committee took note of this information.

VI. ELECTION OF CHAIRPERSON

300. Pursuant to Article 13.1 of the TBT Agreement, the Committee elected Mr. Amit YADAV (India) as the Chairperson of the TBT Committee.

VII. DATE OF THE NEXT MEETING

301. The next regular meeting of the TBT Committee will take place on 23-24 June 2010 preceded by the Sixth Meeting on Procedures for Information Exchange which will be held on 22 June 2010.

[20] www.iso.org/iso/conformity_assessment_.html