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Chairperson: Mr. Ami Levin (Israel)

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

I. ADOPTION OF THE AGENDA

1. The Committee adopted the agenda contained in WTO/AIR/3373.

II. ELECTION OF CHAIRPERSON

2. Pursuant to Article 13.1 of the TBT Agreement, the Committee elected Mr. Ami Levin (Israel) as the Chairperson of the TBT Committee

III. IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

A. STATEMENTS FROM MEMBERS UNDER ARTICLE 15.2

3. The Chairman recalled that the latest list of statements submitted under Article 15.2 of the TBT Agreement was contained in G/TBT/GEN/1/Rev.8, issued on 2 March 2009. Since the previous meeting of the Committee, Ecuador had submitted its statement under Article 15.2 (G/TBT/2/Add.101). In total, since 1995, 118 Members had submitted at least one Statement on implementation under Article 15.2. Additionally, the latest list of enquiry point contacts was contained in document G/TBT/ENQ/35/Rev.2, issued on 13 May 2009.

4. The Committee took note of the information provided.

B. SPECIFIC TRADE CONCERNS

1. New Concerns

(i) European Communities – Tariff Rate Quota on Meat and Meat Products

5. The representative of Australia raised a concern regarding an agreement signed between the EC and US delegations on 13 May 2009 related to a dispute on Measures concerning Meat and meat Products.² This agreement provided that a tariff rate quota would be opened by the European Communities for beef products produced without growth-promoting hormones. In particular, the quota requirements set out specific product characteristics, including dietary requirements and evaluation criteria, which mandated a government-approved evaluation method and government-appointed evaluators. It was Australia's understanding that these requirements could have a significant effect on trade and appeared to be trade restrictive.

6. The Australian representative noted that discussions with the European Communities had taken place and suggested that bilateral talks to resolve the issue should continue. However, her delegation encouraged the European Communities to clarify what the exact requirements and conditions of the tariff rate quota were, and how these had been developed. The EC delegation was also invited to clarify whether the product characteristics or the other quota conditions related to, or were intended to, address health and safety concerns. Moreover, Australia asked for further information on the objective and rationale for including the evaluation criteria mandating a government-approved evaluation method and government-appointed evaluators. The EC delegation was finally encouraged to explain how this tariff rate quota would be implemented in a manner consistent with Article 2.1 of the TBT Agreement.

7. The representative of Uruguay echoed the concerns expressed by Australia. His delegation requested further clarification on the requirements and implementation of the tariff rate quota, and on its conformity with Articles 2.1 and 2.2 of the TBT Agreement.

² Dispute No. DS26.

8. The representative of Paraguay supported the comments of previous delegations and asked for further information on the implementation of the tariff rate quota and on its conformity with Article 2.1 of the TBT Agreement. In particular, the EC delegation was encouraged to clarify the requirements contained in Article 6 of the EC-US agreement, which seemed to constitute an unnecessary barrier to trade within the meaning of Article 2.2 of the TBT Agreement.

9. The representative of Argentina joined the concerns already expressed by other Members.

10. The representative of the European Communities explained that the product definition of a tariff rate quota did not fall within the scope of the TBT Agreement. However, she informed the concerned delegations that the product definition of this tariff rate quota had not yet been finalized by the European Commission. Her delegation assured Members that the proposed measure would be implemented in conformity with Articles 1 and 13 of the GATT Agreement.

(ii) *Korea – Labelling Standards for Food (G/TBT/N/KOR/192)*

11. The representative of China raised concerns regarding Korea's proposed revision of labelling standards for food. Written comments had been sent to Korea in February 2009 and his delegation looked forward to receiving a reply. While China appreciated Korea's efforts to protect consumers and improve public health, concerns remained on the proposed revision of the Korean standards. In particular, China was concerned about requirements related to the compulsory labelling of nutritional ingredients of food products and referred to the relevant Codex standard in this regard (Codex 146/1985). The Chinese delegate stressed that the proposed revision of the Korean measure would increase manufacturing costs that were not necessary to pursue a legitimate objective. Therefore, in order to avoid unnecessary barriers to trade and to fulfil the obligations under Articles 2.4 and 2.2 of the TBT Agreement, China invited Korea to use the relevant international standard as a basis for its measure.

12. The representative of the European Communities joined the comments expressed by China regarding the revision of the Korean labelling standards for foods, which required mandatory labelling for foodstuffs. In particular, she was concerned that all the goods for which the brand owner and the producer were different companies from different countries, i.e. the so-called Original Equipment Manufacturer (OEM) products, would have to be labelled as "OEM products". It was her delegation's view that this requirement was unnecessary, overly restrictive and burdensome. The EC representative also noted that increasingly burdensome and constantly changing labelling requirements for foodstuffs had been introduced by Korea. It was stressed that at least six different agencies regulated labelling obligations for foodstuffs. For example, imported alcoholic products were required to include at least eighteen pieces of information on the label, some of which were only required for imported products. In the EC's view, this contributed to confusion and lack of predictability for economic operators, who would have to repeatedly change labels in order to comply with Korean requirements.

13. The representative of Korea explained that the measure had been adopted for protecting consumers from being misled and confused. He noted that the measure had been notified on 24 October 2008 and had entered into force on 4 June 2009. He also stressed that the OEM labelling requirement applied only to imported products that were manufactured abroad but were labelled with the trademark of the Korean outsourcing company. This requirement did not apply to products labelled with the trademark of the foreign manufacturer or products of foreign and multinational companies. With regard to the other specific concerns, the representative of Korea assured the Committee that they would be conveyed to the competent authorities for due consideration.

(iii) *United States – Test Procedures for Fluorescent Lamp Ballasts in stand-by mode (G/TBT/N/USA/452)*

14. The representative of China raised a concern regarding the US test procedures for fluorescent lamp ballasts in stand-by mode. While the Chinese delegation appreciated the US efforts to improve energy efficiency, it was stressed that, although written comments had been sent to the United States on 9 April 2009, no reply had been received. Since there was no relevant international standard on the energy consumption of fluorescent lamp ballasts in stand-by mode, the United States was requested to provide scientific data on which this requirement was based. Furthermore, the Chinese representative referred to Article 3 of part 430 subpart b) Appendix Q of the US regulation, which contained a test method for power line camera control signal. He pointed out that EMC had not been taken into account and this could result in divergences of test results for different laboratories. The US delegation was therefore requested to review the test methods and avoid unnecessary barriers to trade. Finally, the United States was encouraged to provide the test data and share relevant experiences on this matter with other WTO Members.

15. The representative of the United States noted that the proposed regulation had been notified to the WTO on 30 January 2009 and that the comment period had expired on 6 April 2009. He reassured Members that the Department of Energy would review the comments and suggestions submitted by China and other interested parties, and would take them into account when finalizing the regulation.

(iv) *European Communities – Decision on Restrictions of the Marketing and Use of Organostannic Compounds (G/TBT/N/EEC/244 and Add.1)*

16. The representative of Japan thanked the EC delegation for its reply to the comments made in March 2009 about the draft decision regarding restrictions of the marketing and use of organostannic compounds. However, concerns remained that this measure would constitute an unnecessary barrier to trade. In particular, the Japanese delegation believed that the ban of Dibutyltin compounds in all articles and mixtures and Dioctyltin compounds in specific products was not adequately based on scientific grounds.

17. The representative of the European Communities recalled that the draft decision regarding restrictions of the marketing and use of organostannic compounds was notified to the WTO in January 2009 and adopted on 28 May 2009. She explained that the decision was based on a risk assessment which had been peer-reviewed by the European Commission's Independent Scientific Committee on Health and Environmental Risks. The risk assessment set out how organostannic compounds used in articles contributed to the exposure in humans using these articles. It also identified the different risk levels of different organostannic compounds and the different exposure scenarios. Based on this risk assessment, Dibutyltin compounds would be prohibited in all articles and mixtures as of 1 January 2012, except in certain articles and mixtures for which no suitable alternatives would be available until 2012. For these articles and substances a transition period was foreseen until 1 January 2015.

18. The EC representative confirmed that the use of Dioctyltin compounds would also be prohibited as of 1 January 2012. However, these compounds would only be prohibited for certain specific consumer articles, which had been found to contribute most to exposure in humans using them. The reason behind a different treatment of these substances was that certain Dibutyltin compounds had been classified as toxic for reproduction (Category 2), which was not the case of Dioctyltin compounds. Exposure to Dibutyltin compounds had to be reduced as far as possible and preferably eliminated. Therefore, the different treatment was based on scientific grounds and on the impact assessment that identified the best measures to reduce risks to human health, also considering

their effectiveness, practicality and socio-economic impacts. Japan was invited to provide solid and concrete scientific arguments and discuss them bilaterally with the EC delegation.

(v) *European Communities – Biocide Dimethylfumarate (G/TBT/N/EEC/258 and Add.1)*

19. The representative of Japan drew the attention of the Committee to the EC measure requiring EC member States to ensure that products containing biocide Dimethylfumarate (DMF) were not placed or made available on the market. He was concerned that this measure would have a significant impact on international trade. In addition, since Japan had observed a differential enforcement of this decision across the EC member States, the European Communities was requested to ensure a uniform application of its measure across all member States.

20. The representative of the European Communities explained that the decision to ban products containing DMS from the EC market as of 1 May 2009 was notified under the urgency procedure established in Article 2.10 of the TBT Agreement on 23 March 2009 (G/TBT/N/EEC/258). She stressed that hundreds of consumers had suffered from serious dermatitis when using upholstered furniture and footwear containing DMF. Therefore, it was necessary to act quickly to avoid further cases of serious consumer health effects. The EC delegate emphasized that these risks could not be immediately addressed under REACH, but a permanent measure would be established under REACH in the coming years. In response to the Japanese allegations, she clarified that DMF had never been authorized in the European Communities and therefore products containing this biocide should have not been placed on the EC market. She also added that her delegation had no indications that products imported from Japan contained DMF and therefore no impact on trade was expected. On the uniform implementation of this decision across EC member States, the European Communities representative explained that the provision was simple and clear: the maximum concentration limit of DMF allowed in consumer products was 0.1 mg per kilo.

(vi) *Korea – Conformity Assessment Procedures for Lithium-Ion Batteries (G/TBT/N/KOR/193)*

21. The representative of Japan raised a concern with regard to Korea's conformity assessment procedure for lithium-ion batteries, notified on 31 October 2008 under G/TBT/N/KOR/193. Considering that Korea had designated only few testing laboratories for conformity assessment procedures so far, the Japanese delegation believed that this measure could create unnecessary barriers to trade. Japan requested Korea to authorize foreign laboratories to perform the requested conformity assessment procedures.

22. The representative of the European Communities joined the statement made by Japan and raised some other specific concerns. Did the six month grace period only apply to the stock of batteries already on the market or also on new imports? Also, could Korea clarify the conditions under which foreign test results would be accepted?

23. The representative of Korea explained that the regulation on lithium-ion batteries had been introduced due to increasing public concerns about the safety of mobile devices using these batteries. Considering the current global economic crisis, however, Korea had decided to provide a six month grace period for the implementation of the labelling requirements. On the test reports obtained by foreign laboratories, the representative of Korea pointed out that the Korean Agency for Technology and Standards would accept test reports from laboratories that were accredited by a body which was part of the MRA with ILAC. Finally, the Korean delegate said that the questions on the exact scope of the six month grace period and on the conditions for laboratory designation would be conveyed to the relevant authorities for due consideration.

(vii) *Brazil – Health Products (G/TBT/N/BRA/328)*

24. The representative of the European Communities raised concerns about a Brazilian regulation concerning Good Manufacturing Practice (GMP) certificates for the registration of certain health products, which had been notified to the WTO on 18 May 2009. The EC representative regretted that this regulation had been published as an adopted text in the Brazilian Official Journal only four days after the date of notification to the WTO. She believed that Brazil had thereby failed to comply with Article 2.9.2 of the TBT Agreement. This was particularly troubling because some key issues of the Brazilian regulation required further important clarification. For example, the regulation did not indicate the competent authorities responsible for issuing the GMP certificate. In this regard, it was the EC delegation's understating that the objective of the measure was to reinforce the existing audit requirements by requiring submission of a GMP certificate at the time of application or re-registration of all, domestic and foreign, class III and class IV devices. The EC representative further inquired whether Brazil would continue to accept ISO 13485 certification as evidence of compliance with these requirements and if this would not be the case, Brazil was invited to give the reasons for such a refusal. Finally, she asked Brazil to clarify whether a GMP certificate would also be needed for low risk products that were currently excluded from registration.

25. The representative of the United States had serious concerns with Brazil's new inspection requirement for certain medical devices. In particular, the United States was concerned that the *Agência Nacional de Vigilância Sanitária* (ANVISA) could lack sufficient resources to inspect all Brazilian and foreign facilities subject to the new requirements by the deadline of 22 May 2010. As a result, a serious disruption in the trade in medical devices was to be expected. Brazil was therefore invited to clarify whether ANVISA planned to conduct all the inspections by May 2010 or would extend the deadline. The US representative further stressed that failure to clarify these issues would lead to serious trade disruptions, and would jeopardize the adequate supply of essential medical devices to the Brazilian market.

26. The United States was also concerned about the procedural history of this measure. While the US delegation was grateful that Brazil eventually notified the measure to the WTO, the adoption of the measure only four days after its notification denied foreign stakeholders a meaningful opportunity to comment. In this regard, US industry had submitted some suggestions that would ensure that trade in medical devices not to be disrupted in the event that ANVISA would be unable to complete all the inspections by the deadline. Brazil was requested to take those comments into account when implementing the new inspection requirement. In addition, the representative of the United States noted that, up until now, Brazil had been accepting inspection and quality system certification by US Food and Drug Administration (FDA) as a basis for allowing imports of US medical devices without requiring ANVISA inspections. ANVISA had not identified any specific problems with this system in terms of safety and effectiveness. Therefore, it was the US delegation's opinion that allowing imports of US medical devices to continue pending inspections did not compromise safety or efficacy concerns. Finally, the representative of the United States noted that his delegation continued to monitor the situation closely and looked forward to further discussion with Brazil on this issue.

27. The representative of Mexico shared the concerns expressed by previous speakers. In particular, he regretted that Brazil did not appear to have fulfilled the obligations under Article 2.9 of the TBT Agreement. Moreover, the Mexican representative sought clarification on the issue of inspections and on whether Brazil would continue to accept ISO certification as evidence of compliance with the new requirements.

28. The representative of Switzerland shared the concerns expressed by other WTO Members and looked forward to a written reply to her delegation's comments. It was Switzerland's understanding that, so far, ANVISA had required suppliers of imported medical devices to be certified in conformance with international recognized quality standards such as ISO 13485, and that quality

inspection carried out by conformity assessment bodies under this standard had been accepted. The representative of Switzerland noted that this reliance on internationally recognized quality inspections represented the same approach followed by the Swiss government, and asked Brazil to identify the part of its new regulation which deviated from relevant international standards. She also asked Brazil to explain why such deviation had been considered necessary. With regard to the deadline for inspections by ANVISA, the Swiss delegate emphasized that there were many plants worldwide producing medical devices to be imported in Brazil. Therefore, her delegation sought confirmation that registrations and re-registrations of medical devices for suppliers certified in conformance with international standards would still be possible if inspections by ANVISA would not take place within the deadline due to time constraints. Otherwise, the new regulation would create an unnecessary barrier to trade thus violating the less trade restrictive principle contained in Article 2.2 of the TBT Agreement.

29. The representative of Singapore echoed the comments made by the European Communities, the United States and Mexico about the Brazil's new inspection requirement for certain medical devices. In this regard, she urged Brazil to provide a sixty-day period for comments on the regulation, as recommended by the TBT Committee. Furthermore, her delegation invited Brazil to clarify whether ANVISA inspections could be completed by the deadline and whether there were plans to extend the deadline if inspections could not be completed.

30. The representative of Brazil pointed out that the adoption of Resolution 25 had been preceded by one month of public consultation during which interested parties had had the possibility to comment on the draft text of the regulation. However, since Brazil's Federal Prosecutors had determined that ANVISA should treat equally national and foreign suppliers, it was impossible to further delay the adoption of the measure. In fact, before the adoption of Resolution 25, only national producers were required to present a GMP certificate. The Brazilian representative stressed that this situation illustrated how difficult it could be to comply with more stringent notification obligations, as it had been demanded by some delegations during the preparation of the Fifth Triennial Review.

31. Furthermore, the representative of Brazil drew the attention of the Committee on the simplification of registration procedures related to health products, which had been reoriented to focus essentially on risk. He explained that Resolution 25 was aimed at implementing provisions contained in the Brazilian Federal Law 6360 (1976) regulated by Decree 3961 (2001), which established that the register of products subject to the Brazilian Health Surveillance required the presentation of a GMP certificate. He further clarified that Brazilian health products were categorized in four risk-levels. Categories I and II were classified as low risk levels, while Categories III and IV were high risk. In this regard, the Brazilian representative noted that health products under low risk categories were now exempted from registration obligations. No certification was required for these products, which had simply to be notified through an electronic form on the ANVISA webpage. The Brazilian delegate stressed that these new provisions were laid down in Resolution 24, which had been published jointly with Resolution 25, and significantly simplified a wide range of procedures.

32. Brazil confirmed that Resolution 25 would enter into force within one year, and reassured WTO Members that ANVISA had the operational capacity to certify all companies that required to be certified. The Brazilian delegate also noted that the majority of health product companies that supplied the Brazilian market had already requested certification. ANVISA had increased the number of inspectors responsible for issuing GMP certificates and was fully prepared to meet demand. Moreover, it was emphasized that Resolution 25 was not a new subject for health product companies. Since 2001, Brazilian legislation established that a GMP certificate had to be presented to register health products, but such determination was not being fully implemented. Finally, the representative of Brazil reaffirmed his delegation's position that Resolution 25 was not discriminatory and was intended to achieve the legitimate objective of protecting human health. His delegation was open to further discuss the issue bilaterally with interested delegations.

(viii) *Canada – Labelling for Food Allergens (G/TBT/N/CAN/248 and Add.1)*

33. The representative of the European Communities raised a concern regarding Canada's proposed regulations on Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites, notified to the WTO in G/TBT/N/CAN/248. She stressed that her delegation supported Canada's objective to improve consumer information. However, the European Communities believed that this measure would constitute an unnecessary burden for European foods producers wishing to export to Canada. The EC representative pointed out that the Canadian proposal required a mandatory declaration of food allergens on the label of all pre-packaged products, either in the list of ingredients, or in an allergy and intolerance declaration. However, unlike legislation currently in force in the European Communities and in other major trading partners of Canada, the draft regulation did not foresee any exception from this declaration requirement, for example in cases where the name under which the foodstuff was sold clearly referred to the possible allergen ingredient itself. Moreover, in the case of sulphites, Canada required a mandatory format of the labelling consisting of the statement "Allergy and Intolerance Information: contains ...", which did not appear to be in line with internationally-accepted practices and would impose significant labelling costs on economic operators, as they would have to specifically adapt their labels to the Canadian market only. This was particularly concerning for alcoholic drinks producers. The European Communities therefore asked Canada to review its requirements and to accept the EC label as sufficient for placing products on the Canadian market.

34. The representative of Canada explained that the proposed allergen labelling regulations would enable allergic and celiac consumers to identify the source of allergens and gluten in a systematic fashion, using simple and plain language wording in English and French, with the aim of mitigating health risks associated with the unintentional consumption of allergenic ingredients. She noted that this objective had to be achieved without prejudging the level of popular knowledge on the sourcing and manufacturing of foods, or the level of literacy and education of consumers. For instance, any food deriving from milk ingredients like cream, butter, cheese and yogurt, would have to indicate their source, that is milk. This would be the case of any other food allergens, gluten sources or sulphites.

35. The Canadian delegation understood that EC regulations provided an exemption from requirements to label food allergens if the name under which the foodstuff was sold clearly referred to the ingredient concerned. However, there was no consideration being given to including a similar exemption in the Canadian regulations. In Canada's view, it was better to make certain that the specific name of the food allergen appeared on the label of the food, either in the ingredient list or in a contained statement. This approach would ensure the consumers had the information they needed to make an informed decision on whether to eat a product or not. With respect to the specific issue of sulphites, Canada was considering the EC comments and would continue to consider them when finalizing the regulations.

(ix) *China – Green Dam Youth Escort internet filtering software*

36. The representative of the European Communities drew the Committee's attention on Circular 2009/226, issued by the Chinese Ministry of Industry and Information Technology (MIIT) on 22 May 2009. The EC representative explained that, according to this measure, all computers sold in China, whether imported or domestically manufactured, would need to be equipped with the so-called Green Dam Youth Escort internet filtering software as of 1 July 2009. He noted that the Green Dam software would be either preinstalled in the computers or provided on a DVD included in the package. Computer manufacturers would also need to report to the Software Service Department of MIIT on the monthly sales volume of computers equipped with this software.

37. The European Communities fully acknowledged the legitimate objective of protecting children from exposure to pornographic internet content. However, the EC delegation was seriously concerned by the absolute lack of transparency in the procedural history of the above-mentioned measure. In this regard, the EC delegate remarked that the regulatory process had been characterized by opacity and no notice had been issued about the intention to introduce this mandatory requirement, as provided in Article 2.9.1 of the TBT Agreement. The measure had not been notified, thus violating Article 2.9.2 of the TBT Agreement. Moreover, the European Communities was concerned that the extremely short implementation period did not fulfil the obligations established by Article 2.12 of the TBT Agreement. For the above-mentioned reasons, China was strongly urged to suspend the entry into force of the measure and to notify the draft to the WTO, in order to allow Members to better understand the proposed measure and react accordingly. In addition, the representative of the European Communities noted that it was not the first time that measures issued by MIIT were adopted without prior consultation with foreign stakeholders and without having adequately discussed implementation issues. Therefore, the European Communities urged Chinese authorities to reconsider the adequacy of the regulatory process in this field and to take appropriate measures to ensure full compliance with the obligations arising from the TBT Agreement.

38. The EC delegate further noted that, based on a preliminary analysis of the requirement and the software, technical concerns had been raised by EC industry particularly in respect of system reliability and performance. For example, would this software be compatible with all operating systems? How would this software interplay with the manufacturers original software and other hardware components? Concerns had been raised about networking systems security and integrity. Since the software foresaw regular on-line updates, the computers would become more vulnerable to hacking and other forms of malicious attack. Specific concerns had also been expressed with regard to product liability in case the software would cause the computers to crash. For example, who would be responsible for the damage suffered by the computer user? In conclusion, it was the EC delegation's hope that a debate could be engaged on less trade restrictive measures available to achieve the legitimate objective pursued by the Chinese authorities.

39. The representative of the United States noted his delegation's concern with Circular 2009/226, which mandated the installation of the Green Dam internet filtering software or the inclusion of a disk with respect to all personal computers sold in China. While the United States respected the Chinese concerns about the ability of minors to access illicit or inappropriate internet content, the above-mentioned measure appeared to be an overly draconian measure in the area of internet filtering software, with little evidence that the stated objectives would be effectively achieved. The US delegate said that numerous questions about the software had been raised by worldwide media, Chinese citizens and global technology companies. These questions included issues related to technical problems with the software, whether the Green Dam software would filter illicit content or religious and political content, the security weaknesses in the software that could enable hackers to exploit personal computers, and allegations that the software infringed on the intellectual property of a California-based software company.

40. The representative of the United States stressed that the scope of this requirement was dramatic. In this regard, it was the US delegation's opinion that no other country in the world had or would mandate the installation of a largely unknown and untested piece of software on all personal computers with less than six weeks notice. It was recalled that the TBT notification obligations were intended to help facilitate the development of technical regulations in an open and transparent manner. Indeed, worldwide concern on this issue was in no small part provoked by the lack of transparency in the procedural development of the Green Dam software. Therefore, the US representative requested China to revoke the measure; he looked forward to solving this serious trade concern before the Strategic Economic Dialogue meeting in July 2009. He said that the US government and global industry would welcome the opportunity to engage with China in a meaningful dialogue on the topic of internet parental controls where the two countries shared many fundamental goals.

41. The representative of Japan expressed concerns about Circular 2009/226, which had not been notified and was still substantially unclear. Japan asked China to clarify: when and how this requirement had been notified to all computer manufacturers operating in China; who would bear the costs of the software and, who would take responsibility if software errors occurred. Finally, Japan invited China to provide further clarifications on the measure and ensure a longer implementation period.

42. The representative of China thanked the delegations which made comments and clarified that the so-called Green Dam youth escort was an internet filter software with the only function of preventing harmful information such as pornographic content. The software did not revise any internet content and was fully under the control of the users. The Chinese representative noted that the use of technical means and tools to prevent harmful information was a common international practice. He explained that the Chinese government purchased the software in form of government procurement and confirmed that the software could be freely downloaded from internet or preinstalled on computers, in order to avoid extra costs. The Chinese delegate also informed Members of the Committee that, in order to ensure adequate time for manufacturers to make production plans, pre-install and test the software, MIIT had held a meeting with main manufacturers in March 2009 and related concerns had been fully discussed. He also stated that an understanding had been reached in that meeting and that consensus had emerged with regard to the timeline and method to pre-install the software. Comments and questions would be conveyed to capital for due consideration.

(x) *Tunisia – Labelling and Presentation of Pre-packaged Food (G/TBT/N/TUN/20)*

43. The representative of the European Communities raised concerns regarding Tunisia's proposed measure on labelling and presentation of pre-packaged food, notified to the WTO in G/TBT/N/TUN/20. She informed the Committee that comments on this measure had been sent to Tunisia on 16 October 2008 and that her delegation had not yet received any reply. Concerns were raised on several issues. With regard to the labelling of the "Best Before" date, the Tunisian proposal foresaw that products having surpassed half of their validity period would not be allowed into Tunisia. In this regard, the Tunisian authorities were invited to indicate the reasons that justified the introduction of such a measure, which appeared to be both arbitrary and discriminatory. Additionally, it was noted that, according to Article 4 of the draft proposal, alcoholic drinks labels would have to contain the mandatory statement "Products containing alcohol". The European Communities noted that such a statement was not required either in the EC or in other major markets, and appeared redundant in light of the fact that alcoholic products were already labelled with their alcoholic content in percentage of volume. Furthermore, Article 5 of the draft proposal introduced a prohibition to use adhesive stickers in order to convey the information requested by Tunisian authorities on the label. The EC delegation invited Tunisia to clarify why it was considered necessary to introduce such a prohibition, given that adhesive stickers would represent a less burdensome, but equally effective, means to achieve the objective of consumer information than permanent labels. Finally, Tunisia was requested to take these concerns into account and provide a written reply to them.

(xi) *Argentina – Testing Requirements for Imported Toys (G/TBT/N/ARG/51, Adds. 1-4 and Suppl.1)*

44. The representative of the United States expressed concerns about Argentina's testing and certification requirements for phthalates contained in Resolution 583/2008, notified under G/TBT/N/ARG/51. He stressed that the United States strongly supported the objective of protecting children from exposure to potentially hazardous substances in toys and children's articles, but the testing and certification requirements of the above-mentioned measure appeared to apply only to imported products. US industry was also concerned about the need to perform the required testing *in* Argentina. In this regard, it was the US delegation's understanding that imported toys and children's articles needed to be accompanied by a certificate demonstrating compliance with certain

requirements, and that such certificate had to be issued by an official Argentine government laboratory of the National Institute for Industrial Technology (INTI). The US representative regretted that certificates from other laboratories, including accredited laboratories in the country of production, would not be accepted. Considering that INTI sometimes took 130 days to acknowledge and process a certification request, US companies were raising complaints that the new requirements would result in delays and trade disruption after their entry into force on 15 August 2009. Therefore, the United States invited Argentina to consider less trade-restrictive alternatives and ensure that its measure did not afford less favourable treatment to imported products. In particular, Argentina was encouraged to recognize test results from ILAC accredited laboratories as equivalent to those issued by INTI. The US representative noted his understanding that Argentina could be considering the possibility of allowing other laboratories to conduct the testing, and requested that Argentina provide an update on that issue. Finally, the US representative noted that Argentina and US toy regulators had had a constructive meeting in May 2009 and reiterated his delegation's desire to share information and work together with toy regulators in Argentina and other countries to enhance the safety of children's products.

45. The representative of China shared the concerns raised by the United States. In particular, it was his delegation's view that the Argentine regulation accorded discriminatory treatment to imported toys, thus violating the obligations established by Article 5.1 of the TBT Agreement. China invited Argentina to give further clarifications on this measure and amend it according to the obligations under the TBT Agreement.

46. The representative of the European Communities agreed with the concerns expressed by previous delegations and noted that the new testing requirements would cause further delays to the already extremely long procedure associated with Argentina's non-automatic import licence and general policy for toys. He explained that these requirements made it impossible for importers to access the Argentine market at the beginning of the season for which the toys were designed. Argentina was therefore encouraged to clarify whether an amendment of the new requirements was being considered, in order to make the system more reasonable and less trade restrictive.

47. The representative of Argentina drew to the Committee's attention the fact that his delegation had held bilateral consultations with the United States on this issue, during which the majority of the concerns expressed had been addressed. He explained that Resolution 583/2008 would modify the scope of previous regulations, extending provisions to all games and children's articles for phthalates DEHP DBP and BBP and for children's articles and toys that could be put into children's mouth for the phthalates DIMP DIDP and DNOP. The ban established in this and previous regulations covered without distinction the manufacture, import, export and sale of the products in question. However, since the ban was based on the volume percentage of phthalates DIMP DIDP and DNOP, it was essential to verify the percentage through testing. He further explained that the responsibility of the testing had been assigned to the Centre for Research and Technological Development for the Plastics Industry, which reported to INTI with respect to all products sold on the domestic market or exported. In this regard, the Argentinean delegate stressed that the testing requirements were mandatory for products both imported and of domestic origin.

48. It was further reported that the Health Ministry of Argentina had held consultations with affected parties, in order to fulfil the legitimate objective of protecting public health. In particular, observations and comments expressed by the chambers of commerce, business persons, supermarket chains and importers of the products covered by the regulation had been taken into account. With regard to the issue of possible delays in testing, INTI had reported that an appropriate operating procedure had been set up, aimed at ensuring the delivery of reports sixty days after the opening of the service request. The representative of Argentina further noted that a network of laboratories, which would ensure that testing take place in a timely and appropriate fashion, had been set up. Finally, the Argentinean delegation reassured Members of the Committee that Argentina would continue to

protect human health in a way compatible with the rights of other WTO Members under the multilateral trading system.

(xii) China – WAPI standard requirements

49. The representative of the United States raised a concern regarding the Chinese WAPI standard requirements. The US industry had reported that the Chinese Ministry of Industry and Information Technology (MIIT) was establishing a process for approving handheld wireless devices such as cell phones and smart phones using the globally accepted 802.11 Wi-Fi standard, but only when also equipped with a chip or software that used the WAPI standard. The WAPI standard was a Chinese domestic wireless standard. The US representative noted that China had agreed to suspend its plans to mandate the use of WAPI in computers, routers and other wireless computer networks in April 2004. He sought confirmation from China that MIIT accepted applications for type approval of mobile handsets using the 802.11 Wi-Fi standard for wireless computing and permitted use of Wi-Fi in mobile handsets. China was also invited to clarify whether it would require that the WAPI standard be included as a dual mode function in such handsets. If this was the case, the United States requested the delegation of China to explain why the relevant international standard had been found to be ineffective or inappropriate to fulfil China's objective. Since services and devices based on Wi-Fi alone were widely available and legally sold in China, the Chinese delegation was also requested to indicate the justification and legitimate objective of this requirement, if this was indeed a requirement.

50. The representative of the European Communities supported the comments expressed by the United States and requested further clarification from China. In particular, he asked the Chinese delegation to clarify whether a mandatory type approval process had been introduced enabling the marketing in China of mobile phones with internet connectivity, and whether a condition for such a type approval process was that the mobile handsets be WAPI enabled and therefore compliant with the Chinese national standard on wireless internet connection in local area networks (LAN). If this requirement existed, China was urged to notify the measure under the TBT procedures and to explain why the existing relevant international standard was considered inappropriate or ineffective.

51. The representative of China pointed out that mobile phones were widely used devices and concerns existed about potential risk of personal information security. Since WAPI standards provided a sound solution to the security concerns of consumers, the Chinese Government decided to impose WAPI standards in the type approval process of mobile phones with WLAN function. However, China did not exclude the use of Wi-Fi standards and they could co-exist with WAPI standards in mobile phones. The Chinese representative assured Members that the comments made would be conveyed to capital for due consideration and encouraged those who had expressed concerns to discuss them bilaterally with the Chinese delegation.

52. The representative of the European Communities sought formal confirmation that a mandatory type approval process for mobile phones with internet connectivity in a WLAN environment existed and that these handsets needed to be WAPI enabled. If that was the case, why had this requirement not been notified? The EC delegation believed that this was another example of the opaque regulatory process concerning measures adopted by MIIT and urged China to notify this measure.

53. The representative of China explained that the WAPI standard had been notified under G/TBT/N/CHN/187, 188 and 1189, and discussed many times with concerned WTO Members.

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

54. The representative of the United States drew the attention of the Committee to EC Regulation 765/2008, which would enter into force on 1 January 2010. This regulation established, among other things, requirements for accreditation for conformity assessment bodies and required each EC member State to appoint a single national accreditation body that would operate as a public not-for-profit entity, independently of any other conformity assessment body. The regulation also prohibited competition among Member States' national accreditation bodies. The United States was concerned that the new accreditation framework would undermine the international accreditation system under the ILAC MRA and IAF MLA. Another concern was whether accreditations by non-EC bodies would continue to be accepted in Europe, and whether products certified by conformity assessment bodies accredited by non-EC accreditation bodies would be allowed to be placed on the EC market once the regulation became effective.

55. Given that the US industry and accreditors remained concerned about how the new accreditation system would operate in practice, the European Communities was invited to provide further clarification on the new framework, especially on its implementation. In particular, would the accreditations issued by non-EC accreditation bodies that were also signatories of the ILAC MRA and IAF MLA be accepted in the European Union? Would the European Communities mandate that existing cooperation agreements between accreditation bodies be renegotiated to include MRAs, the terms of which required foreign accreditation bodies to comply with EC accreditation rules? If such accreditation would no longer be accepted, what were the EC reasons for no longer accepting accreditations from ILAC MRA and IAF MLA signatories? What information did the European Communities rely upon to determine that regulations by a government non-profit monopoly provided a higher degree of confidence than accreditations provided by other accreditation bodies, for example ones that were signatories to the ILAC MRA? Why was the European Communities adopting a new accreditation framework rather than relying on the existing international framework for accreditation under the ILAC MRA and IAF MLA?

56. The representative of the European Communities explained that, where EC product legislation required third party conformity assessment, accreditation was the preferred method of determining that the conformity assessment body met the applicable requirements to carry out the specific conformity assessment activities. The new accreditation framework was first and foremost a tool in support of the EC internal regulatory policy to evaluating the technical competence of bodies which had to undertake specific tasks under EC product related legislation. These bodies, which took the name of notified bodies, were designated by EC member States and notified to the European Commission. The new rules would therefore not affect the way accreditation was operated in third countries. He further explained that, under Regulation 765/2008, the new common framework for accreditation would be fully implemented by 1 Jan 2010. Existing safety product specific legislation would be revised in order to make reference to the new accreditation system, with respect to the tools to evaluate the technical competence of conformity assessment bodies.

57. The EC delegate said that the European co-operation for Accreditation (EA) had been recognized as the supporting infrastructure at the EC level to coordinate the implementation of the new accreditation framework. As part of this process, general guidelines for the cooperation between EA, the European Commission, EFTA and the competent national authorities, had been signed on 1 April 2009. The documents were available on the European Commission website.³ In addition, a framework partnership agreement between the European Commission and EA would be concluded to set out the common cooperation objectives and the legal administrative and financial provisions

³ http://ec.europa.eu/index_en.htm

relating to the Community financing that could be granted to EA. This document would also be made public.

58. With regard to the implementation at the national level, all EC member States were in the process of adapting their national accreditation systems to the new requirements, including the setting up of a single national accreditation body. The representative of the European Communities confirmed that the new system required the single national accreditation body to operate on a non-profit basis. Since the accreditation and support of regulatory policy was seen as the authoritative and last level of control of conformity assessment activities, the EC legislator had considered that this activity should be pursued without undue pressures arising from commercial interest and competition concerns. Therefore, it was considered that the non-profit requirement and the existence of a single accreditation body in each EC member State would act to reinforce the authority and the independence of accreditation.

59. With regard to the practical consequences of the activities that foreign testing organizations were able to carry out for the purposes of new legislation, the EC representative reassured WTO Members that the new rules were not intended to affect the way accreditation operated in third countries. He further stressed that there was no intention to apply these rules outside the European Communities. The new EC accreditation framework was addressed to EC member States and did not affect the existing multilateral arrangements under ILAC and IAF.

60. Regarding the way conformity assessment bodies established in third countries could participate in conformity assessment activities, the representative of the European Communities explained that the designated notified bodies could subcontract specific tasks connected with conformity assessment under private contractual agreements. This included the possibility of subcontracting to third country CAB and testing laboratories. Under these arrangements, notified bodies needed to ensure that the subcontractor or subsidiary met the technical competence requirements relating to notified bodies and retained full responsibility for the tasks performed by subcontractors or subsidiaries. Third country CABs and testing laboratories holding accreditation certificates under IAF or ILAC would generally be presumed to fulfil those technical competence requirements, and therefore be able to enter into subcontracting arrangements with the EC notified bodies. In addition, where international private sectoral voluntary arrangements for the recognition of test results supported by ILAC/IAF accreditation were in place, such as the IECEE-CB Scheme on the safety of electrical equipment or the IECEx Scheme on the safety of equipment used in explosive atmospheres, such arrangements were already widely used by EC notified bodies, in relation to both the voluntary and mandatory third party certification, and thus provided potential for trade facilitation.

61. Finally, the EC representative recalled that similar answers to the comments raised by WTO Members on the EC new accreditation framework had been given in the context of the Trade Policy Review of the European Communities, which had been carried out in April 2009. The EC delegation remained available for bilateral discussions and, once the new framework would be in place, would consider making a presentation to the TBT Committee to give a more comprehensive overview of the new system, its internal implications for regulatory policy and the existing international arrangements in this field.

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

62. The representative of the United States raised concerns regarding Korea's Ministerial Enforcement Regulation for Food Industry Promotion Act, notified on 17 February 2009 under G/TBT/KOR/204. He recalled that his delegation had sent written comments to Korea on 16 April 2009. The new measure, which included guidelines, regulations and certification procedures for organic processed foods, had become effective on 28 June 2009 and would enter into force on 1 January 2010. As a consequence of its entry into force, products certified to their national organics

programs, and previously recognized as organic in Korea, would no longer be recognized as such unless Korea provided procedures for equivalence or recognition. However, Korea's enforcement regulations did not contain any procedure for recognizing a foreign government's conformity assessment body to accredit certifiers, nor did they contain procedures for determining equivalence. Korea was therefore encouraged to extend the grace period for foreign products by eighteen months, or until June 2011, in order to provide time for the Korean Ministry for Food, Agriculture, Forestry and Fisheries (MIFAFF) to recognize or accredit foreign organic certification bodies. The US representative suggested that, during this time period, foreign organic products could be temporarily allowed entry in Korea without the use of the MIFAFF seal. He further emphasized that, without such an extension, many exports of organics products to Korea would be seriously disrupted in the near term, and entirely eliminated by the end of 2009. Korean organics producers, who often needed to source foreign organics products as ingredients, would also be negatively impacted.

63. The United States invited Korea to clarify the procedures that foreign organic certifiers needed to follow to be accredited by MIFAFF, and noted its understanding that MIFAFF had yet to accredit any foreign organic certifier. The United States also asked for an update regarding the procedures to request equivalence of organic regulations from MIFAFF and for an estimate on the amount of time required to complete the review. Furthermore, Korea was urged to provide clarification on the testing requirements for organic processed products, and explain whether such testing was mandatory. The representative of the United States noted that the Codex Alimentarius "Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods" were intended as production guidelines for process-based standards certifying the process of organic production, rather than the final product. In this regard, he noted that the costs of mandatory testing, which did not appear to be necessary in light of the Codex standard's emphasis on process, could be sufficiently high to deter both Korean and foreign producers from participating in Korea's growing market for processed organic foods.

64. Finally, the United States encouraged Korea to adopt a tolerance threshold for the unintended presence of biotech for all processed organic products, in order to be consistent with Appendix 3 of Article 9 of the Enforcement Regulation of MIFAFF's Sustainable Agriculture Promotion Act. The US representative recalled that this Act recognized the unintended presence of biotech in organic feed grains fed to animals which would produce organic meat. The US delegation looked forward to continued discussions with Korea on this issue.

65. The representative of Australia was concerned about the proposed changes to the Korean Food Industry Promotion Act. Australia's assessment indicated that it would be difficult, costly and burdensome for Australian organic certifiers to comply with the new requirements. The Australian delegation had sent written comments to Korea on this matter. The representative of Australia supported the United States in seeking a delay for implementation of the new organic regulations until June 2011, in order to ensure minimal trade disruptions. He said that this would provide time for MIFAFF to recognize foreign organic certification bodies and access equivalence and reciprocal submissions.

66. The representative of the European Communities joined the delegations of the United States and Australia in expressing concerns regarding Korea's Ministerial Enforcement Regulation for Food Industry Promotion Act, notified under G/TBT/N/KOR/204. She noted that her delegation had sent written comments to Korea on this measure on 27 April 2009. In particular, the European Communities was concerned that, under the new rules, imported organic processed products would have to meet exactly the same requirements as domestic products, and that the possibility to accept as equivalent the technical regulations applied by other WTO Members was not foreseen. The European Communities was confident that its legal framework for organic products could ensure that products placed on the market were safe for consumers and did not mislead them in any way. Therefore, the EC representative invited Korea to accept that products made in conformity with the EC regulations

on organic products would satisfy the Korean requirements and could automatically be placed on the Korean market. She noted that the European organic regulations already provided for this type of recognition when a scheme of a third country was deemed equivalent.

67. Furthermore, the European Communities believed that some of the requirements imposed on the certification bodies, in particular with regard to inspections, were unnecessarily restrictive and could generate high compliance costs for economic operators. The obligation to have at least three permanent Certification Inspectors as well as the envisaged inspection visits of the Korean Review Team to the certification bodies appeared to be the most problematic requirements. The EC representative also noted that the draft Korean measure referred not only to organic products, but more generally to "fine foods". In this regard, she sought confirmation from Korea that the proposal was limited in scope to organic products only. Finally, Korea was encouraged to clarify to what extent the Codex "Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods" had been taken into account in the drafting of this measure.

68. The representative of Chile shared the concerns expressed by other delegations on the proposed changes to the Korean Food Industry Promotion Act. In particular, she supported the proposal to extend the grace period for foreign products. She encouraged Korea to take into account Chile's comments and looked forward to have a bilateral discussion on this issue.

69. The representative of New Zealand associated his delegation with the detailed comments made by previous speakers. In particular, New Zealand sought an assurance from Korea that the requirement that all raw materials, ingredients and processed organic foods be certified by MIFAFF, would not be more trade restrictive than necessary to meet Korea's stated legitimate objective. Based on the information provided so far on the accreditation of certification bodies, New Zealand was concerned that only two Korean certifiers and no international or foreign bodies had achieved accreditation. In this regard, the representative of New Zealand encouraged MIFAFF to work with international and foreign certification bodies to clarify the requirements for accreditation, and to provide assurances that these requirements would not be prescribed or applied in a way that would discriminate against international and foreign bodies seeking accreditation. He also sought confirmation from Korea that, under the new requirements, it would be feasible to process all the applications for international and domestic organic products awaiting certification before the deadline of January 2010. In the case that this confirmation could not be provided, New Zealand requested a postponement in the implementation of the regulations for a reasonable period, in order to allow applications currently under review to be processed. Finally, since the Korean proposed regulation failed to provide for the recognition of equivalence, New Zealand urged Korea to consider equivalence agreements with the International Organic Accreditation Service and foreign governments.

70. The representative of Canada associated her delegation with the comments made by previous speakers and urged Korea to consider a postponement of the entry into force of this measure.

71. The representative of Korea confirmed that the proposed processed organic food certification programme was based on the Food Industry Promotion Act and had entered into force on 26 June 2008. He explained that the programme was aimed at improving the quality of organic processed food, encouraging its production, and protecting the consumers. He also confirmed that, as of 1 January 2010, any product with an organic claim needed to fulfil the requirements set by the processed organic foods certification programme. Until then, labelling for organic food products could be based either on labelling requirements according to the Food Sanitation Act administered by the Korean Food and Drug Administration (FDA), or on organic certification guidelines according to the Food Industry Promotion Act administered by MIFAFF. The Korean representative stressed that the programme was applied both to domestic and imported products, and that imported products had to be accredited by either domestic or foreign certifying agents approved by the Korean government.

He reassured Members that his delegation was open to further discussion with all delegations concerned, and that the comments raised would be forwarded to relevant authorities.

(xv) *China – Antibacterial and Cleaning Function for Household and Similar Electrical Appliances (G/TBT/N/CHN/603-604 and G/TBT/N/CHN/606)*

72. The representative of Korea noted that the technical specifications contained in China's notifications G/TBT/N/CHN/603-604 and G/TBT/N/CHN/606 were GB standards, and while GB standards were usually associated with relevant mandatory certification, a corresponding reference could not be found in the notifications. However, he noted that bilateral consultations had been held with China and many of these issues had been clarified. Korea looked forward to continue cooperation with China on this issue.

73. The representative of China welcomed the dialogue with Korea and looked forward to having further discussion on this issue.

(xvi) *United States – Food and Drugs Cosmetic Act*

74. The representative of Mexico raised concerns regarding the Food Safety Enhancement Act of 2009 which was being discussed by the US Congress. It was Mexico's understanding that this regulation contained several measures intended to improve food safety in the global market. However, on the basis of a preliminary analysis, Mexico believed that these measures would have a knock-on effect on foreign producers by imposing requirements to register and store files and directories. Mexico was also concerned that this measure could cause goods to be held at the border, and could make distinctions between more and less favoured countries with regard to the imposition of importation requirements. Concerns remained also on other specific issues, as for example: the requirements for an annual registration of food processing plants; the adoption of a food safety plan as a prerequisite for operations; the registration of plants classified as high risk, low risk and very low risk; the adoption of a system enabling US authorities to determine the traceability of products; the adoption of import certificates for safety of food products; the adoption of fines exceeding USD 150,000; the country of origin system; the registration of importers; the possibility of inspections on foreign soil. Finally, the Mexican representative noted that Mexico was undertaking an analysis which would assess the impact of this programme and its compliance with the TBT and SPS Agreements. He encouraged the United States to take into account the comments which would be submitted and review the draft regulations in line with its WTO obligations.

75. The representative of the United States noted that bilateral discussions with Mexico had taken place on this issue, and that the majority of concerns raised by Mexico seemed to relate to food safety. Therefore, Mexico was urged to discuss this issue with the SPS team of the US delegation. The US delegation reassured Mexico that the comments made would be analyzed and could be further discussed bilaterally.

(xvii) *EC – Poultry Meat (G/TBT/N/EEC/267)*

76. The representative of Brazil raised a concern regarding proposed amendments in the EC regulation on marketing standards for poultry meat (Proposal for a Council Regulation amending Regulation (EC) No 1234/2007 establishing a common organisation of agricultural markets as regards the marketing standards for poultry meat). While Brazil agreed that marketing standards contributed to improvements in quality and consumer information, his delegation was concerned that those proposed in the EC regulation regarding the processing and marketing of poultry meat could be more trade-restrictive than necessary to fulfil the objectives pursued by the European Communities.

77. The proposed amendment altered the current definition of "fresh poultry meat" and included new definitions such as "fresh poultry meat preparation". As a result, "stiffened poultry meat" and frozen poultry meat used in preparations would no longer be marketed as "fresh". These definitions appeared to be more stringent than the definitions of fresh meat contained in international standards such as the OIE's "Terrestrial Animal Health Code" and as well as those contained in the European Communities' own hygiene regulation. Brazil asked that the European Communities to provide the rationale and scientific basis behind this.

78. The representative of Brazil stressed that buying thawed poultry meat as fresh poultry meat was part of consumer habits and tastes. Therefore, the proposed definitions were not motivated by consumers' expectations. On the contrary they constituted a regulatory intervention that created consumer expectations which might negatively impact future competitive imports. His delegation suggested that by labelling poultry meat and its preparations marketed as fresh with a phrase such as "previously frozen" would allow consumers to understand that the poultry meat characteristics were not modified, to know all the processes it has been submitted to, and to make a better informed choices.

79. As well, the delegation of Brazil also asked for clarification regarding the labelling of poultry meat preparations which could be sold either as "fresh", "frozen" or "quick-frozen" as the proposed amendment laid down definitions only for "poultry meat preparations" and fresh poultry meat preparations". Given the distance between Brazil and the EU market, all poultry meat had to be frozen at temperatures between -2°C and 4°C to cross the ocean and therefore the restriction to marketing thawed poultry meat as fresh poultry meat or using it as a basis for fresh poultry meat preparations would be a de facto discrimination in favour of European producers. It would also mean that thawed poultry meat, which was a like-product compared to poultry meat that had never been frozen, would be banned from the EU marketplace without any scientific or other reasonable justification.

80. The representative of the European Communities said the comments would be analysed and a reply sent.

2. Previously raised concerns

(i) *European Communities – 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 G/TBT/N/EEC/264)*

81. The representative of New Zealand reiterated her delegation's interest in the EC new regime for regulation of its wine market, which affected wine trade with the European Communities. While she appreciated the constructive engagement that had been shown by the European Commission, concerns remained about the proposed regulation. The New Zealand representative further noted that her delegation's assumptions remained that the new EC wine regulation implementing regulations and any transitional arrangements included in these, particularly those related to wine labelling, would result in rules for the wine trade that fully complied with the provisions of the TBT Agreement, as well as other principles and disciplines contained in other relevant WTO Agreements. Consequently, there would be no adverse affect on market access for non-members of the European Communities as a result of the implementation of the regulations. Finally, the representative of New Zealand recalled that her delegation had made a submission to the EC TBT Enquiry Point in November 2008 in respect of the intended third country provisions for the use of Geographical Indications (GIs). She noted that a reply from the Commission had been received and a request for further clarification had been submitted to the EC TBT Enquiry Point on traditional terms, grape variety names, certification requirements, certification systems and closures for sparkling wine.

82. The representative of the United States continued to have serious concerns about EC measures that restricted the ability of non-EC wine to use common or descriptive and commercially valuable terms, on the grounds that those terms were traditional to European wines. This was particularly problematic when some of these terms did not have a common definition across all EC member States and there was no effort to monitor or limit the use of those terms within the European Communities. Concern was also expressed with regard to the negative trade impact resulting from the EC's failure to extend the derogation for the use of such terms on US wines sold in the EC market and the EC's recognition of so-called traditional expressions contained in trademarks. In addition, the US representative recalled that various concerns had been raised at previous TBT Committee meetings and could be found in the minutes prepared by the WTO Secretariat. Detailed written comments had also been sent to the European Communities. In this respect, the EC delegation was encouraged to clarify the current status of the measure and how comments received would be taken into account in the implementation of the regulation. The United States also expressed interest in having an experts meeting to review the comments with the EC delegation.

83. The representative of Australia noted that written comments had been submitted to the European Communities in April 2009 and thanked the EC delegation for bilateral discussions held before the TBT Committee meeting. Her delegation raised concerns with regard to the draft EC regulation laying down certain detailed rules for the implementation of EC regulation No 479/2008, which had been notified to the TBT Committee under G/TBT/N/EEC/264. Australia was concerned that the European Communities appeared to claim exclusive rights to use a number of common grape variety names listed in Part B of Annex XV, on the basis that these names partially contained a Protected Designation of Origin (PDO) or a Protected Geographical Indication (PGI).

84. In particular, Article 62(4) of the draft regulation provided that wine grape varieties and their synonyms listed in Part B of Annex XV that partially contain a PDO or PGI and directly refer to the geographical element of the PDO or PGI in question, may only appear on the label of a product with a PDO or PGI or GI of a third country. For example, the names "cortese", "nebbiolo", "primitivo", "sangiovese" and "vermentino" were listed for exclusive use by Italy. Australia did not consider that a sound basis for this protection existed, as these grape varieties were generic and did not include the geographic component of the name. The Australian representative explained that in the case of "nebbiolo d'Alba", the geographic component was the suffix "d'Alba" and the variety name "nebbiolo" did not contain any designation of origin or GI. In this context, she sought confirmation from the European Communities that Australia would not be prevented from using the generic grape variety names listed in Part B of Annex XV in the presentation and description of wines produced in Australia. She also urged the European Communities to provide a reply to the detailed comments previously submitted by her delegation.

85. The representative of the European Communities explained that the comments had been examined and the Commission services were close to finalizing a response. She noted that new implementing provisions would enter into force on 1 August 2009 and thanked Members for the comments provided, which had been taken into account in the revision of the measure. She further emphasized that various bilateral meetings had taken place before the TBT Committee meeting; these had clarified most of the concerns raised by Members. To clarify the remaining issues, an expert from the DG Agriculture of the European Communities informed the Committee of the modifications introduced after the revision of the draft regulation.

86. On protected designations of origin and geographical indications, a clarification relating to the annual verifications of wines with protected designations of origin or geographical indications had been introduced with the view to limiting the scope of these checks to EC wines only. On traditional terms, clarifications concerning the "applicant" were made, in particular when the applicant was a "representative professional organization". Furthermore, the "generic" character of traditional terms was defined, and the relationships between trademarks and traditional terms were clarified to avoid

any legal gap which could negatively affect holders of trademarks. The scope of protection of traditional terms was also clarified. On labelling and presentation, further clarifications were introduced with regard to some optional particulars such as the indication of the holding on wine labels, or derogations as provided for in Article 59. On "varietal wines", the annual verification foreseen for EC wines did not concern imported wines and the text was therefore modified. Finally, the EC representative clarified that the list of wine grape varieties to be used on wine labels for wines bearing, for instance, third countries' geographical indications, listed in Part B of Annex XV of the draft regulation, could be modified upon a EC member State or third country request. He assured Members that a written reply to their comments would be sent in the coming weeks.

(ii) *European Communities – Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH) (G/TBT/N/EEC/52, Adds 1-5 and Add.3/Rev.1)*

87. The representative of Thailand referred to her delegation's previously expressed position on REACH. While Thailand supported the objectives of the protection of human health and the environment, the complexity of REACH was beyond the capacity of many developing and least developed countries to understand and comply with. Such difficulties were particularly evident for SMEs, which were rapidly being forced to shut down. Concerns were also reiterated with regard to the Only Representative (OR) provision, which created severe and insurmountable difficulties for SMEs.

88. The representative of Canada supported the objectives of protecting human health and the environment but reiterated her delegation's concern about REACH. With respect to the issue of authorization and restriction, Canada asked the European Communities to clarify whether the timelines for future submissions of Annex XV dossiers by EC member States or the European Chemical Agency (ECHA) had been determined, and whether substances of these dossiers could be grouped. It was Canada's understanding that work packages of substances were being developed for the June 2009 REACH meeting of Competent Authorities (CARACAL) and some substances were being considered for authorization. In this regard, the European Communities was invited to provide further clarifications. In particular, would EC member States be expected to choose which dossier to notify to the Registry of Intentions (RoI) as the first step in the authorization process? Were there any nickel-containing substances in these packages? On the relationship between REACH and the Directive concerning Restrictions on Hazardous Substances in electrical and electronic equipment (RoHS), the Canadian representative urged the EC delegation to clarify how the two measures would work together and which one would take precedence in case of conflict. Since industry still faced many problems with the implementation of this regulation, the Canadian delegation hoped that REACH Help Desks would be widely promoted and be responsive to enquiries.

89. The representative of Japan continued to have concerns about REACH. On the Substance Information Exchange Forum (SIEF), he noted that big gaps existed in various aspects, pointing out as an example the one between the current number of formally established SIEFs, which were around 10,000, and the fact that around 55,000 substances were expected to be registered before the deadline on 30 November 2010. The European Communities was therefore urged to take practical measures to promote the creation of SIEFs. Concerns were also expressed with regard to the potential applicants of the SIEF Formation Facilitator (SFF), because only a limited number of consultant companies had chosen to be responsible SFF for many substances and sometimes this seemed to be an obstacle for the potential applicant to be designated as SFF. On the authorization procedure, Japan encouraged the European Communities to specify some decision criteria and give opportunities to stakeholders, including from non-EC companies, to comment on the procedure for inclusion of substances in Annex XIV of the REACH regulation. Finally, the Japanese representative noted that ECHA planned to release the Chemical Safety Assessment (CSA), an IT tool necessary for registration, by the end of 2009. Considering that the deadline for registration of substances was on 30 November 2010 and that

registration through an Only Representative was a lengthy process for non-EC companies, Japan requested the European Communities to speed up the procedure for releasing the CSA tool.

90. The representative of the United States shared the EC concern for protecting human health and the environment. However, the United States continued to consider the breadth, costs, burdens and complexity of the REACH regulation in light of ongoing implementation and remained concerned about its potential to disrupt and distort global trade. The representative of the United States noted that new concerns were continuously raised by industry. In particular, he reiterated his concern with regard to the different interpretation of REACH provisions across the EC member States. The US delegate noted that six EC member States 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 percent threshold applied to the article as produced or imported, six EC 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. Since this disagreement could confuse US industry, the European Communities was invited to clarify whether companies should follow the ECHA guidance or EC member States' interpretations.

91. The delegate of the United States also reiterated his concern regarding the negative impact of REACH on Small and Medium sized Enterprises (SMEs), which had to bear a disproportionate burden of the costs associated with the registration process and participation in SIEFs and pre-SIEFs. In this regard, he stressed that many SMEs were being forced to reformulate their products or stop supplying certain substances and products to the EC market -- not because the substances had been found by ECHA to pose a risk, but rather due to the expenses associated with the registration process. Regarding the issue of cosmetics, the US representative recalled that there was no legal certainty yet and the problem remained unresolved. Further concerns remained with regard to the issue of the Only Representative, including the inability of many importers to secure necessary information for registration and the potential compromise of sensitive commercial information. In addition, the United States was concerned that foreign suppliers had to bear an unnecessary burden for the registration of reacted monomers in polymers. In this regard, the US representative noted that a recent advisory opinion to the European Court of Justice emphasized that this requirement was aimed to protect the competitive position of the EC chemical industry, in line with REACH objective to promote EC industry competitiveness, and not due to any health or safety reason. The European Communities was invited to clarify whether ECHA would provide guidance on what information registrants should provide for reacted monomers in material safety data sheets, given that reacted monomers were inextricably bound to the polymers.

92. The representative of Argentina, speaking on behalf of GRULAC pointed out that the procedure established by REACH contained several inaccuracies and its overall cost remained uncertain. It was GRULAC Members' opinion that the complexity of the REACH regulation, coupled with its lack of transparency and proportionality, constituted a serious concern for industry and an unnecessary barrier to trade. The representative of Argentina stressed that the burdensome costs associated with REACH had severe consequences on exporters of developing countries and constituted a serious impediment to their continued presence in the EC market. Therefore, Argentina requested the European Communities to provide appropriate technical assistance to interested Members and consider more flexible deadlines for developing countries. The EC delegation was also invited to provide further clarification on the issue of penalties for non-compliance to REACH.

93. The representative of Argentina reiterated his delegation's concern with regard to REACH. The complexity and serious transparency problems of REACH showed that this regulation constituted an unnecessary barrier to trade. In general terms, the Argentinean representative stressed that the costs related to REACH were excessive and constituted a serious impediment to the continued presence of Argentinean companies in the European market. This situation was further aggravated by looming implementation deadlines. Serious concerns remained also on specific issues.

94. On the registration of substances in articles, the representative of Argentina requested the European Communities to clarify the content of Article 7.1 (b) of the REACH regulation: "the substance is intended to be released under normal or reasonably foreseeable conditions of use ". The Argentinean representative also noted that both the ECHA and EC authorities had not satisfactorily responded to requests for assistance. Moreover, Argentinean companies complained that the lack of uniformity in the information provided by the Enquiry Points of each EC member State had led to different answers to the same questions. As a result many companies pre-registered substances without knowing whether they needed to be registered. In this context, a massive number of pre-registrations had been submitted by a small number of companies, which showed that the competitiveness of the EC market had been seriously distorted and that REACH gave rise to a situation of monopoly in the EC market.

95. Several concerns remained with respect to the lack of transparency of REACH. In particular, the representative of Argentina reiterated his delegation's request to have a list of companies which had already carried out the pre-registration procedure. Argentina also required the European Communities to clarify whether stakeholders needed to follow up on the news related to the implementation of REACH on the ECHA webpage, or whether the ECHA would directly inform the relevant authorities of the EC member States through regular communications. Further concerns remained with regard to the process of inclusion of substances in the Substances of Very High Concern (SVHCs) list, included in Annex XIV of the REACH regulation (List of Substances Subject to Authorisation). Finally, the European Communities was invited to provide further clarifications on the operation of the Substance Information Exchange Forum (SIEF).

96. The representative of Australia supported the concerns raised by previous speakers and reiterated her delegation's concern 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 into the EC market. The Australian representative also asked for further clarifications on the authorization process for Substances of Very High Concern (SVHCs). She urged the European Commission to take into consideration the concerns expressed by Members about REACH.

97. The representative of Brazil supported GRULAC's statement and noted that his delegation recognized the importance of protecting human health and the environment. However, concerns remained that the REACH regulation was unnecessarily trade-restrictive and could disrupt international trade in chemicals and chemical products. In particular, the Brazilian representative highlighted the difficulties related to the pre-SIEF stage of REACH. The Brazilian chemical industry had indicated that around 15,000 pre-registered substances had not organized their pre-SIEF yet. Brazil was concerned that this delay could prevent the registration of many substances within the deadlines, thus causing an interruption of trade. This situation could be aggravated by the fact that the laboratory tests required by REACH were complex and needed a long time to be concluded. Therefore, the representative of Brazil requested the European Communities to provide clarifications on the outcome of the pre-SIEF stage, and in particular whether it was considered necessary to postpone the original REACH registration deadlines. Finally, the Brazilian representative reiterated his delegation's concern with regard to the high costs and trade-restrictiveness associated with the REACH regulation. He regretted that only OECD test methods were accepted for the registration of chemical products under REACH. In this regard, it was his delegation's view that laboratory tests performed according to ISO standards, including ISO 17025, could provide the equivalent level of assurance for EC authorities and be in accordance with the provisions of the TBT Agreement.

98. The representative of China supported the comments made by previous speakers about REACH. Considering the current global economic crisis, the European Communities was urged to take into consideration the concerns which had been expressed many times by its trading partners.

99. The representative of Chile reiterated her delegation's concerns with regard to REACH. In particular, she recalled that there was still lack of clarity on the penalties for non-compliance with REACH. It was her delegation's view that the responsibility for the formulation of penalties under REACH should not fall under the competences of each EC member States. The European Communities was therefore urged to take these concerns into account, to clarify what the penalties for non-compliance with REACH would be and whether criminal penalties were being developed. Finally, the representative of Chile stressed that no measures had been taken to protect confidential business information that non-EC firms were expected to provide.

100. The representative of Kuwait shared the concerns raised by other WTO Members about the adverse impact that REACH could have on trade in chemical products, including petroleum. He was especially concerned about the lack of transparency and clarity of the REACH regulation.

101. The representative of the European Communities recalled that several concerns about REACH had already been raised and discussed at previous meetings of the TBT Committee. She referred to the previously provided answers recorded in the minutes. On the procedure concerning substances that would be subject to authorisation, the EC representative explained that the Substances of Very High Concern (SVHCs) would be identified and included in Annex XIV of the REACH Regulation (List of Substances Subject to Authorisation) according to the criteria laid down in Article 57 of the REACH Regulation. She emphasized that the procedure for substances subject to authorisation consisted of different stages, was carried according to criteria and rules set out in the REACH Regulation and that the process was transparent and open to consultation with all interested third parties. First, a dossier with the substances which could qualify as SVHCs was prepared by ECHA or by EC member States (so called Annex XV Dossiers). General stakeholder consultations were carried out on these dossiers. Second and following this stakeholder consultation, it was decided whether to include the identified substances in the candidate list according to the procedure established by Article 59 of the REACH regulation. Third, ECHA had to identify priority substances to be included in Annex XIV according to the criteria for prioritisation contained in Article 58 of REACH. Extensive stakeholder consultations were held also in this phase. Third and following these consultations, ECHA had to send its recommendation to the European Commission, which had to take the final decision on the inclusion of a substance in Annex XIV. The decision of the European Commission was taken according to the so-called "Comitology Procedure", which involved both the European Parliament and EC member States. On the same topic, the representative of the European Communities explained that in addition to these different steps of the procedure ECHA published a Registry of Intentions before the creation of a Annex XV dossier in order to add even more transparency and predictability to the all process. This registry showed the intention of a Member State or ECHA to start working on an Annex XV Dossier and was available on the ECHA website.⁴ She also clarified that substances of the Annex XV dossiers could be grouped together and that REACH did not foresee any specific timeline for the submission of these dossiers.

102. With regard to the questions on the current state of play of the procedure, the EC representative recalled that the candidate list contained fifteen substances. She confirmed that on 1 June 2009, after stakeholder consultations, ECHA recommended to the European Commission to prioritize seven substances out of the fifteen to be included in Annex XIV. The prioritization was based on the hazardous properties of these substances, the volume used and the likelihood of exposure to humans or the environment. The European Commission was currently working on the final decision.

103. On the issue of uniform interpretation and implementation across the European Communities, the EC representative recalled that a detailed and comprehensive explanation of the EC system had

⁴ http://echa.europa.eu/chem_data/reg_intentions_en.asp

been provided at the previous meeting of the TBT Committee. She stressed that the system contained sufficient instruments to ensure a uniform application of REACH.

104. On the documentation to be provided to custom authorities of different EC member States, the representative of the European Communities noted that enforcement authorities of EC member States had the right to check if the obligations of REACH were respected. She pointed out that there were different ways to demonstrate that substances had been pre-registered or registered and that in practice no problems had been encountered to date. Once the necessary information had been provided to the enforcement authorities, all products had been released and could be put on the market. Regarding the concerns about the protection of confidential business information, the EC representative confirmed that the enforcement authorities were obliged to keep the information provided confidential. However, the concerns on the disclosure of the registration number of chemical substances had been taken into account and were currently being examined.

105. On the Substances Information Exchange Forum (SIEF), the EC delegation clarified that all substances pre-registered would fall under a relevant SIEF, unless the potential registrant deliberately decided not to register because it stopped manufacturing or importing to the EC market and that there was one SIEF per substance. The European Communities stressed that ECHA had recently launched a campaign intended to raise awareness of the urgent need for action for companies which wanted to meet the 2010 registration deadline. Presentations of a stakeholder event organized in May 2009, where many representatives from third countries were present, and two new web sections on SIEF (called HELP and SIEF) were also available on the ECHA website⁵.

106. On the Chemical Safety Assessment (CSA) and the SIEF Formation Facilitator, the EC delegate stressed that the IT tools were not mandatory and that substantial work could already be carried out without these tools.

107. On the relationship between REACH and the Directive concerning Restrictions on Hazardous Substances in electrical and electronic equipment (RoHS), the EC 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, RoHS called for the application of the REACH methodology and REACH provided that chemical substances already restricted under other EC legislation could not be subject to authorization. On the issue of monomers in polymers, the representative of the European Communities recalled that the case was still pending at the European Court of Justice.⁶ On the specific request to have a list of companies which had already carried out the pre-registration procedure, the EC delegation clarified that this was confidential information and could not be provided.

108. Regarding the requests for technical assistance, the EC representative invited WTO Members having specific needs for technical assistance programmes to direct their requests to the respective delegations of the European Commission in their country. Finally, she informed the Committee that ECHA had recently published two new guidance documents called "Guidance in a nutshell", which were the first documents in a series of planned simplified guidelines providing an overview of the obligations under REACH.⁷

⁵ http://echa.europa.eu/home_en.asp

⁶ Case C-558/07.

⁷ http://guidance.echa.europa.eu/guidance2_en.htm.

- (iii) *European Communities – 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)*

109. The representative of the United States drew the Committee's attention to the European Communities' ongoing review of the Directive concerning Restrictions on Hazardous Substances (RoHS). He emphasized that the United States supported the objectives of protecting human health, safety and the environment. He also noted his delegation's appreciation for the transparency and the broad consultations with stakeholders that characterized the RoHS revision process. However, the United States was still concerned about the magnitude of the costs of compliance, in particular for the disproportionate impact on SMEs. In this regard, the US delegation highlighted the high costs associated with re-design, testing, and qualification of components and products, as well as information technology, human resources, supply chain management and compliance costs.

110. The US representative called on the European Communities to ensure that a transparent process be put in place for the implementation and operation of the proposed RoHS revision. He also stressed that EC regulators should ensure a risk and science-based approach to the RoHS review, including evaluating whether to add additional substances or products to the list, set maximum concentration levels for specific substances, or grant exemptions. It was emphasized that a failure to grant exemptions could lead to certain medical technologies no longer being available to patients in the European Union. In addition, the US representative announced that his delegation submitted comments in writing on the notified proposed revision and urged the European Communities to take these comments into account. He stressed the importance of providing adequate legal certainty to stakeholders regarding how substances would be treated and emphasized that any selection and assessment procedure, under RoHS or REACH, should be science- and risk-based and take into account intended end uses and all available scientific and technical information. Finally, the US delegation sought an update on the current status of the measure, requested the European Communities to provide a timetable on the review of the RoHS Directive, and suggested that an experts meeting be set up to review the US comments.

111. The representative of Canada echoed the US comments on the extension of the scope of RoHS to medical device manufactures and raised some specific concerns. First, Canada requested the European Communities to consider delaying the application of RoHS to all medical devices to 1 January 2014. Second, Canada encouraged the European Communities to consider delaying the applicability of RoHS to *in vitro* diagnostic medical devices until 1 January 2016. Third, the European Communities was encouraged to consider excluding implanting medical devices from the scope of RoHS. The Canadian representative stressed that industry was concerned about the costs associated with RoHS, in particular for SMEs.

112. The representative of Japan recalled that the purpose of the RoHS Directive was "to contribute to the protection of human health and environmentally sound recovery and disposal of waste electrical and electronic equipment". In this context, he requested the European Communities to provide clarification on the intended relationship between the revision of RoHS and REACH, including the procedure for adding new substances to the RoHS Directive and the criteria used for identifying the substances regulated by RoHS. On the review of exemptions, Japan requested the European Communities to provide an adequate transitional period of at least two years when the exemption of substances was terminated. The European Communities was also encouraged to ensure that a transparent process be put in place for the granting and renewing of exemptions, including by ensuring opportunities for comments by all interested stakeholders. On the same topic, the representative of Japan considered that it was neither economically nor technically reasonable to set a maximum period of four years for the exemptions. It was his delegation's view that this timeframe should be set on scientific and technological grounds, also considering the availability of alternative

technology and the economic and social impact on the market. In this regard, Japan requested to change the "exemption expiry period" in a "revision period".

113. Finally, the attention of the Committee was drawn to four substances (HBCDD, DEHP, BBP, and DBP) that had been considered as additional candidate substances of the RoHS Directive revision. In this regard, Japan recalled that at the last TBT Committee meeting the EC delegation recognized that it was not necessary to include the above-mentioned substances in the revision of the Directive. Therefore, the European Communities was urged to formally remove them from Annex III of the draft RoHS Directive.

114. The representative of Jordan shared the concerns expressed by the United States and Japan regarding the revision of RoHS and announced that her delegation had submitted comments in writing on the ban of Deca-BDE. She urged the European Communities to take these comments into account and review the status of Deca-BDE.

115. The representative of China joined the comments made by previous delegations on the revision of RoHS and the ban on the use of Deca-BDE. Written comments had been sent to the European Communities in May 2009 and his delegation looked forward to receiving a reply. China noted that the draft revision of the RoHS Directive expanded its scope and would create unnecessary barriers to trade. In addition, the CE conformity assessment requirement could cause an extension of the production cycle and increase costs. The European Communities was therefore urged to take a reasonable and scientific approach in evaluating whether to add additional substances to the list. The needs of manufacturers, especially in developing countries, to adjust product design and value-chain had to be taken into special account when setting deadlines. Finally, China noted that the definition of a "manufacturer" contained in the draft of the RoHS review and the definition contained in the REACH regulation were different and requested the European Communities to clarify this point.

116. The representative of the European Communities thanked the delegations which submitted comments on the revision of the RoHS Directive. The European Communities was in the process of reviewing them and would reply within the shortest delay. On the issue of medical devices raised by Canada, the EC representative noted that Article 4.4 of the RoHS Directive established that the restrictions should not apply to spare parts for the repair or the reuse of among others, medical devices and monitoring and control instruments as of 1 January 2004 and individual diagnostic medical devices as of January 2016. Implantable medical devices remained excluded from the scope of application of RoHS, subject to a review by 2010. Moreover, exceptions for the use of banned substances in medical devices were proposed in the new Annex 6.

117. On the inclusion of new products under the scope of RoHS, the representative of the European Communities explained that the decision had been based on an in-depth study, which considered various elements such as reliability of substitute materials, characteristics of the equipment and impact on users. This study provided scientific and technical information necessary to propose the inclusion of these product categories in the scope of RoHS. On the declaration form that had been proposed in Annex 7, the EC representative noted that the current RoHS Directive did not provide for declarations of conformity. Therefore, there were no existing declaration formats to rely upon. It was also stressed that the proposed Annex 7 format had been formulated according to the new EU legislative framework on marketing of goods.

118. With regard to the concerns raised on the review of exempted applications, the EC delegate clarified that exemptions were temporary derogations from a ban granted to manufacturers to facilitate the transition to substance-free products in case substitutes were not available. The need for a transition period could be assessed on a case-by-case basis when exemptions were reviewed. The representative of the European Communities also clarified that the four years period could be prolonged if stakeholders could prove that the exemption was still justified.

119. With regard to the four substances Japan had mentioned, the European Communities reiterated that restrictions had not been proposed. While the Annex III substances were those identified as potentially dangerous for the environment, the European Commission considered the data on these substances not sufficient at this stage to justify restrictions. However, these substances would be monitored and their status reviewed when new information would be available.

120. On the definition of a "manufacturer", the EC delegate explained that the definition contained in the draft RoHS Directive was in line with similar definitions of other EC legislation, for example Regulation (EC) No 768/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products.

121. With regard to Deca-BDE, the EC representative referred to the comments made by her delegation at the previous TBT Committee meetings.

(iv) European Communities – Ban on the Use of Nickel-Cadmium in Batteries (G/TBT/N/EEC/98)

122. The representative of Japan raised a concern on the EC Directive on Batteries and sought an update on the current status of the measure. While the Directive would enter into force on 26 September 2009, the methods for measuring the batteries capacity had not been announced yet. The Japanese representative emphasized that EC companies could be able to comply with the Directive, since they were only required to ship the batteries before the deadline. However, in the case of electrical and electronic equipment where batteries were enclosed in the product, or in the case of lead storage batteries embedded in automobiles, a certain amount of time was required to measure the capacities of the individual batteries, to design and manufacture the labels, to transport the products and clear the distributor inventory. In other words, it was impossible for non-EC companies to respect the proposed deadlines. The Japanese delegation stressed that this process was contrary to the obligations arising from Article 2.1 of the TBT Agreement. Therefore, the European Communities was requested to delay by one year the implementation of the Directive.

123. The representative of the European Communities clarified that the European Commission, together with EC member States, was currently in the process of drafting rules for the implementation of capacity labelling requirements for rechargeable batteries, automotive batteries and accumulators in accordance with Article 21.2 of the Directive on Batteries. The purpose of the labelling requirements was to harmonize the labelling requirements within the European Union. With regard to the capacity labelling of non-rechargeable batteries, the EC delegate confirmed that further assessments were needed. The EC delegate noted that, due to their complexity, the new rules would not be adopted before the end of 2009 and stressed that in absence of the implementing rules required by Article 21.2, there was no obligation for the EC member States to impose the capacity labelling obligation on producers. In other words, the producers did not need to indicate the capacity of batteries before the entry into force of the implementing measures. The same requirement applied to EC and non-EC manufacturing companies, without discrimination. Finally, the representative of the European Communities reassured Members that enough time for preparation would be granted to industry and that implementing measures would be notified to the WTO in due time.

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

124. The representative of Japan was concerned about India's mandatory certification for pneumatic tyres. His delegation believed that the regulation caused unfair excessive testing and certification costs as well as time constraints for foreign-based firms. Furthermore, the testing and certification capacity within India was insufficient to meet the needs. Japan therefore requested India to ensure that domestic and foreign based firms could conduct testing and conformity assessment procedures within a reasonable period of time, in order to avoid business disruptions. The Japanese delegate also reiterated that there needed to be a longer implementation period, at least two years, in

order to allow industry to adapt. He recalled that concerns had been expressed at the TBT Committee meeting in March 2009 and that a reply from India to the Japanese comments made had yet to be received. A written reply was also pending for the comments submitted to the Indian Enquiry Point.

125. The representative of the European Communities shared the concerns raised by Japan, in particular with regard to the new Indian proposal for tyres and tubes for automotive vehicles that was notified as an addendum to a previously discussed notification (G/TBT/N/IND/20/Add.1). In this regard, the EC representative stressed her delegation's appreciation for India's notification of the measure and for the exemptions granted for tyres which were originally equipping new vehicles. However, serious concerns remained with regard to the rules on replacement of tyres. First, the EC delegate emphasized that the tyres needed to carry a specific mark of the Bureau of Indian Standards (BIS) and that the "E-mark" providing compliance with UN-ECE regulations was not recognized as equivalent. She also stressed that the labelling obligations would imply changes of thousands of tyre moulds and could stop production lines. In order to avoid unnecessary costs and disruption of trade, India was urged to recognize tyres complying with UN-ECE regulations as equivalent.

126. In addition, it was the EC delegation's understanding that only imported replacement tyres for which no domestic equivalent existed were exempted from the certification and labelling obligations. However, once a certain type of tyres was domestically produced in India, imported tyres would have to comply with the above-mentioned obligations. This provision seemed to have the only objective to support local production and did not appear to be based on a legitimate objective as required by Article 2.2. of the TBT Agreement. With regard to tyres which were not exempted from the certification and labelling requirements, the EC representative asked for further clarifications on whether tyres could be certified in other laboratories than the only accredited laboratory in India and on the functioning of the licence procedure, as the notified draft contained no details in this regard. Were the clarifications given by India at the last TBT Committee meeting also valid for the revised draft? Furthermore, the representative of the European Communities noted that the revised text should come into force 120 days after its publication in the Official Gazette. 120 days appeared to be a period too short since the text provided for fundamental new requirements and relevant implementing guidelines were not known yet. The EC representative noted that her delegation was in the process of finalizing comments that would be sent to India and invited India to take these comments into account and to reply to the requests for clarification.

127. The representative of India said with respect to tyre testing, that India had a well established laboratory for testing of tyres. Test reports from accredited laboratories abroad could also be accepted, provided that they complied with ISO IEC 17025 and were accredited by a body which was a part of the MRAs with ILAC on a reciprocal basis. On the same topic, the Indian delegate explained that the Indian test standards were different from those contained in UN-ECE regulations because of the different conditions of Indian roads and vehicle use. Due to these differences, re-testing and approval was still necessary. With regard to the comments to be provided by the European Communities, the Indian delegation noted that a written reply would be sent in due time.

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

128. The representative of the European Communities reiterated her delegation's concerns related to the Indian order laying down a registration procedure for imported cosmetics products. She appreciated India's explanation concerning the necessity of the measure due to quality and safety concerns provided at the last TBT Committee meeting. However, concerns still remained on the time limits of the registration procedure, the foreseen inspection requirements at the manufacturer's site in Europe, the recognition of testing requirements and the conditions for taking samples. The notified draft seemed unclear and excessive in this respect. The EC representative also stressed that detailed comments had been submitted to India in July 2008, which could be found as usual on the EC's TBT

website.⁸ While India had promised to send additional written information in order to provide further clarification, a reply had not been received. Finally, India was urged to foresee reasonable timeframes for the registration procedure, recognize certificates that prove compliance with ISO 22716 on good manufacturing practice for cosmetics and specify the rules on sampling and testing, which were currently vague.

129. The representative of India explained that the measure did not discriminate against foreign manufacturers and that all comments received in response to the notification were currently being considered. The EC delegation was encouraged to organize a video conference with the Indian Ministry of Health to clarify the remaining technical issues.

(vii) *Israel – Infant Formula*

130. The representative of the United States noted his delegation's continued concerns that Israel had not published a draft regulation on its measures related to infant formula for comments, nor notified it to the WTO. He noted that the detailed comments of the United States could be found in the minutes of previous TBT Committee meetings and sought an update on the current status of the draft regulation. The US representative also noted that the United States had had a fruitful bilateral meeting with the Israeli Ministry of Health. It was his delegation's hope that continued bilateral discussions would help to resolve this issue before the end of 2009.

131. The representative of Israel thanked the US delegation for the comments provided and explained that this highly sensitive issue was currently being addressed bilaterally. The delegation of Israel would update the Committee about the progress.

(viii) *Saudi Arabia – International Conformity Certification Programme (ICCP)*

132. The representative of the United States reiterated his delegation's concern about Saudi Arabia's apparent failure to abide by its accession commitments to publicize in English its Conformity Certificate requirements. He stressed that Saudi Arabia had committed to remove the burdensome requirements of its former International Conformity Certificate Program (ICCP) administered by the Saudi Arabian Standards Organization (SASO), and replace it with a "Conformity Certificate" program to be administered by the Ministry of Commerce and Industry. Saudi Arabia had also committed to provide detailed public guidance on how to comply with the new conformity assessment requirements post-ICCP. These commitments did not appear to have been fulfilled.

133. The representative of the United States stressed that the lack of publicly available information on the requirements had created confusion and had allowed the company previously contracted to provide services for Saudi Arabia's previous certification program to falsely advertise on the internet that its services were a mandatory requirement for access to the Saudi market. Saudi Arabia should take steps to dissolve the "ICCP.com" website. In March 2009, the United States discussed with Saudi Arabia the types of information that should be placed on the Ministry of Commerce website. These included: (i) the current requirements for product testing and certification; (ii) the list of entities that Saudi Arabia believed were qualified to complete testing and certification work for the country; (iii) the criteria that Saudi Arabia was using to recognize approved test laboratories and certification bodies to provide services to the Saudi market; (iv) a formal notification process for accrediting or approving such bodies; (v) clear procedures for approved bodies to follow when issuing conformity certificates or marks to convey that a product complies with the relevant requirements. Publication of this information would provide the necessary clarity that companies needed to trade their goods in the Saudi market. The US delegation noted that a list of specific

⁸ <http://ec.europa.eu/enterprise/tbt/index.cfm?dspLang=en>

questions had been submitted to the Saudi Arabian Ministry of Commerce and a reply was still awaited.

(ix) *European Communities – Fire Performance of Construction Products (G/TBT/N/EEC/92 and Add.1)*

134. The representative of Japan thanked the European Communities for the expert meeting about the EC's decision on Fire Performance of Construction Products organized in December 2008. He also acknowledged receipt of the test data and complementary note which served as the basis for the EC decision. However, concerns remained that the EC decision was not based on sufficient scientific grounds. Japan had sent comments on the test data received and looked forward to receive a reply from the European Communities.

135. The representative of Thailand supported the statement made by Japan.

136. The representative of the European Communities thanked Japan for the fruitful bilateral discussions that had taken place in December 2008. She explained that the Japanese comments were currently being examined and a reply would be provided in due time.

(x) *European Communities – Dangerous Chemical Substances: Draft Commission Directive amending, for the 30th time, Council Directive 67/548/EEC (G/TBT/N/EEC/151 and Add.1-2) and European Communities – Dangerous Chemical Substances; Draft Commission Directive amending, for the 31st time, Council Directive 67/548/EEC (G/TBT/N/EEC/212 and Add.1-3)*

137. The representative of the United States reiterated his delegation's concerns about both the 30th and 31st Adaptation to Technical Progress (ATP) of the EC's classification of borates and certain nickel compounds under the Dangerous Substances Directive (DSD). With regard to borates, he pointed out that the results of the private risk assessment commissioned by the European Communities validated the concerns that the United States and other WTO Members had been raising. The assessment demonstrated that there was no appreciable risk of exposure from using the borate-containing products analyzed (e.g., detergents, glass and fertilizers). This called into question why certain borate-containing products needed to be labelled. The replacement of the Dangerous Substances Directive (DSD) by the Classification, Labelling and Packaging (CLP) Regulation provided the European Commission with a good opportunity to revise its determination and to take into account the results of new studies. He sought confirmation that the European Communities was open to revising its determination based on new available information. While the European Communities had stated that the CLP Regulation contained provisions for transferring determinations from the Dangerous Substances Directive, the differences in the labels, categories and classification methodologies between the CLP Regulation and the DSD required clarification in terms of how substances would now be treated.

138. Specifically, the two systems had different cut-off levels for acute toxicity, different qualitative descriptions and evidentiary standards. Moreover, the product and packaging restrictions under the regulatory regimes were different. For example, the two regulations used different warning and risk phrases and labels (the skull and crossbones label would be replaced by an exploding man), and it was not clear that the classifications under the CLP Regulation would have the same downstream consequences as the classifications under the DSD. US industry had concerns about how shifting the classifications to the CLP Regulation would work in practice, given all these differences.

139. The representative of the United States further stressed that, irrespective of whether Community law provided for the classification shift from the DSD to the CLP Regulation, the first ATP to the CLP Regulation appeared to be a new proposed measure with respect to the TBT Agreement and should therefore be notified. His delegation would continue to monitor the potential

adverse trade impacts of the nickel and borates classifications, and analyze the EC's classification methodology and analyses that had led to these classifications, in the context of REACH and other EC measures.

140. The representative of Japan reiterated concerns about the inappropriate classification of nickel compounds following an inadequate read-across methodology. This would have an impact not only on nickel compound producers, but also on the users. He recalled that the European Communities had announced that the content of the 1st ATP to the CLP Regulation had been transferred from the 30th and 31st ATPs to the Dangerous Substances Directive. However, the 30th and 31st ATPs had resulted from a flawed methodology. He requested that the European Communities discuss the methodology for the classification and base this on science, considering the important consequences that EC decision would have. Also, the European Communities should consult thoroughly with all concerned trade partners and stakeholders both within and outside the Communities.

141. The representative of Canada was disappointed to learn that, despite repeated expressions of concern from Canada and the international nickel industry, the European Communities was proceeding towards the adoption of the 1st Adaptation to Technical Progress (ATP) to the new Classification Labelling and Packaging (CLP) Regulation. Her delegation was also disappointed that the European Communities had yet to notify the CLP's 1st ATP, as required by the TBT Agreement and stressed that notification of proposed measures and the provision of reasonable comment periods was a cornerstone of the Agreement.

142. Moreover, now that the CLP - and not the DSD - was to be amended, trading partners should have the opportunity to analyze and comment on the amendment's trade impacts. Furthermore, Canada noted that, despite the EC's characterization of the nickel classifications as "mere labelling requirements", concerns on their downstream impacts were longstanding and had yet to be allayed. In fact, the classification had already started to have an impact: for example, recently proposed EC legislation could result in a prohibition on the use of nickel substances in children's toys. Additionally, nickel metal producers were being asked to certify that their products did not contain the substances classified as carcinogenic under the ATPs.

143. The representative of Canada further pointed out that, at a recent meeting of the International Agency for Research on Cancer, delegates had suggested that the EC classifications of nickel compounds provided grounds for the classification of nickel metal as a carcinogen. Nickel metal was not covered by any of the ATPs in question. She stressed that, if this proposal proceeded, the odd result could be a European ban on the use of stainless steel. Given their potential to negatively impact nickel producers and exporters, it was essential that any classifications of substances be based on transparent, sound science, regardless of what legislation or regulation they were made under. To this end, Canada sought assurances that the European Communities would give serious consideration to the research data that industry was producing as part of the REACH registration process, as well as other relevant sound scientific information, and that in light of this information the European Communities would review the classifications of nickel in a transparent manner.

144. With respect to how the harmonization of classifications of chemicals could be proposed and updated, the representative of Canada sought confirmation that, once a substance received a harmonized classification, only an EC member State competent authority could submit a proposal for an updated harmonized classification. She noted that, like all countries, Canada shared the EC commitment to the protection of human health and the environment. This commitment, however, did not diminish Canada's concerns regarding the trade impacts the EC's classification of nickel could have, particularly since the potential trade restrictiveness of the measures flowing from these classifications remained to be seen. Canada would therefore continue to closely monitor the EC's regulation and risk management of nickel substances and urged the European Communities to ensure that any measures taken did not create unnecessary obstacles to international trade.

145. The representative of Cuba reiterated that the adoption of the 31st ATP was a matter of concern to Cuba, as well as to many other Members, since it affected nickel, one of Cuba's main export products. As stated previously, Cuba's main concerns were related to the incorrect application on the part of the European Communities of the OECD methodology, referred to as "read-across", which had failed to take into account - with no justification - certain important steps, for example the absence of water solubility data for nickel compounds, this being the main characteristic which the European Communities had used as its basis for the classification. She pointed out that nickel carbonate, nickel sulphite and nickel oxide were not even soluble in water.

146. The representative of Cuba also recalled that the 31st ATP was adopted despite the numerous requests for a delay in implementation expressed by delegations. In addition, several concerns had been raised which, in her delegation's view, had not received a satisfactory response. Moreover, she was concerned about the absence of a notification and consultation on the 1st ATP to the CLP Regulation, which the European Communities claimed would incorporate the 30th and 31st ATPs. She stressed that new criteria for assessment were included in this regulation, which constituted a new regulatory framework. Therefore, this was not an exact transfer of the 30th and 31st ATPs. Cuba was also concerned that the European Communities had failed to supply a satisfactory response to the request for clarification with regard to expert opinions. Concerns remained also about the effect that this measure could have in other Member countries, as well as the possibility of other Members imitating the EC procedures. She recalled that the European Communities had claimed that the 31st ATP would only have a knock-on effect on health and security for facilities situated within the territory of its member States, and that there would be no effect on third countries. However, the costs of transportation of highly hazardous substances would increase by approximately 70 per cent, let alone the cost of operations of insurance handling and storage. Additionally, the damage inflicted on the image and reputation of nickel industry could affect its use in numerous industrial processes and products, for example stainless steel products worldwide.

147. The representative of Cuba stressed that the measure was an unnecessary barrier to trade within the meaning of Article 2 of the TBT Agreement, as it restricted trade beyond necessary levels to protect health, safety and the environment. She called on the European Communities to review the 30th and 31st ATPs of the DSD as well as the draft 1st ATP of the CLP Regulation in light of the comments made by Members, with a view to adopting a more appropriate classification for nickel compounds based on clear scientific evidence. She also invited the European Communities to notify the 1st ATP to the CLP Regulation promptly, as provided for in Article 2.9 of the TBT Agreement at a stage where amendments would still be possible and to provide sufficient time for Members to take comments and discussions into account. Additionally, she reiterated the request to the European Communities to take account of the provisions of Article 12 of the TBT Agreement concerning special and differential treatment, in particular paragraph 3, with a view to ensuring that there was no unnecessary creation of barriers to trade for developing countries.

148. The representative of Australia reiterated her delegation's concerns and disappointment regarding the EC's adoption of the 31st ATP, while the concerns of WTO Members and other stakeholders remained outstanding. In particular, her delegation remained concerned that the EC's decision to reclassify 117 nickel compounds under the 31st ATP was based on questionable scientific and procedural grounds. Regulatory decisions of this nature, with potentially far-reaching commercial implications, needed to be based on sound, defensible and transparent science, which took account of all relevant research as well as meaningful consultations with stakeholders.

149. Concerns were also expressed about the fact that industry had reported that there were moves in the European Communities to further restrict the use of nickel carbonate via REACH processes. Despite assurances by the European Communities that the only impact on industry from the reclassification of nickel would be a requirement to label products differently, there was some evidence of stigmatisation of nickel resulting from the reclassification of various nickel compounds.

For example, the 2008 London Olympic Games Sustainable Sourcing Code listed nickel, in relation to battery applications, as a material to be avoided. Australia recognized the importance of ensuring a high standard of protection for human health and safety and for the environment and supported the development of regulatory strategies to insure such protection. However, Australia noted that, in accordance with Article 2.2 of the TBT Agreement, the EC's regulatory regime for nickel should not create unnecessary obstacles to international trade.

150. The representative of Australia also supported the US call for the 1st ATP to the CLP Regulation to be notified. The CLP was a different instrument from the 30th and 31st ATPs and, as Cuba had also pointed out, would have a greater global effect. As such, it was likely to be viewed differently from the EC's previous regime, which made the necessity for notification ever more relevant.

151. The representative of Indonesia recalled that at the previous meeting of the Committee her delegation had expressed serious concerns about the classification of nickel substances in the 31st ATP. Indonesia's nickel industry had the same concerns as Cuba about the absence of water solubility data for nickel compounds proposed for classification, which was the only classification criteria used by the European Communities. She was also concerned about the lack of consultation with WTO Members on the draft of the 1st ATP to the CLP Regulation, on the ground that consultations had already taken place on the 30th and 31st ATPs. However, new provisions were added in the CLP which made it a different regulatory framework.

152. The representative of Brazil, speaking on behalf of GRULAC, reiterated concerns about the EC's decision to reclassify, as hazardous, nickel substances in the 31st ATP, despite many procedural, substantive and commercial concerns expressed by this group and several other Members at TBT meetings held in November 2008 and March 2009. He recalled that GRULAC's specific commercial concerns shared by the whole group had been expressed, as well as systemic concerns which had not been satisfactorily addressed by the European Communities.

153. It was stressed that the measure would have a significant market impact for those producers and exporters within GRULAC that hosted some of the world biggest nickel reserves, like Brazil, Cuba, Colombia, Dominican Republic and Venezuela and where nickel contributed in some cases to about 50 per cent of total exports of goods. The implementation of the 31st ATP was likely to further aggravate conditions in an industry already severely affected by the world economic crisis and a fall of world nickel prices, and would cause increased production, transport and insurance costs.

154. Furthermore, it was pointed out these new classifications also affected those countries that manufactured goods using nickel compounds, in a broad range of industries and chemical processes, affecting their access not only to the EC market but also to other major markets. GRULAC Members also had a systemic concern regarding the insufficient level of transparency and the lack of scientific rigor displayed by European Communities which could have implications in future similar classification processes. For example, the absence of data for the classification of nickel carbonate, the flawed application of the OECD read-across methodology, the absence of justification for skipping some important read-across steps, the lack of water solubility data for nickel compounds proposed for classification despite it being the only step used by the European Communities and the fact that the European Commission had failed to demonstrate that the classification decisions were based on any data at all.

155. GRULAC members understood that the European Communities intended to reintroduce the 30th and 31st ATP nickel classifications in the 1st ATP to the CLP Regulation, and that this legislative process had already begun. It was also GRULAC's understanding that the European Communities intended to adopt the 1st ATP to the CLP Regulation at the end of June, without notifying the Committee nor providing WTO Members and interested parties an opportunity to comment. This was

regrettable, since GRULAC and other Members had expressed their expectation that, as required by Article 2.9 of the TBT Agreement, the European Communities would notify any such proposal to the WTO at an early stage, and would fully engage with WTO Members to address any concerns.

156. The lack of consultation of WTO Members on the draft 1st ATP to the CLP Regulation on the grounds that consultation had already occurred on 30th and 31st ATPs did not have a sound basis because the CLP was a different regulatory framework. GRULAC Members also believed that the European Commission had not provided satisfactory answers to Members' requests for clarification. Therefore, Members of GRULAC requested the European Communities to make the appropriate arrangements to take into consideration the concerns raised, and to consult WTO Members about the 1st ATP to the CLP Regulation at an early appropriate stage when amendments could still be introduced and allow reasonable time for other Members to make comments in writing, discuss those comments upon request, and take the written comments and the results of the discussions into account. GRULAC Members also looked forward to a satisfactory response to previous requests for clarification regarding the 30th and 31st ATPs.

157. On behalf of his own delegation, the representative of Brazil regretted that the addenda to the notifications of the 30th and 31st ATPs circulated in March 2009⁹ did not seem to imply that the European Communities was willing to take into account the comments and concerns raised by WTO Members on these measures. In Brazil's view, the European Communities had failed to give satisfactory answers to some fundamental questions regarding the proposed classification for nickel compounds, such as: (i) why had the European Communities skipped some steps recommended by OECD guides on read-across methodology when classifying the nickel compounds; (ii) why was water solubility disregarded when classifying nickel carbonates under the 30th ATP, while under the 31st ATP water solubility was the sole criterion for grouping substances; and, (iii) what exactly would be the consequences of nickel compounds being classified as Category 1 for carcinogenicity under the REACH legislation.

158. The representative of Brazil said that his delegation continued to believe that that the 31st ATP was not based on sound science and that it would create unjustifiable and unnecessary obstacles to trade. He recalled that several developing countries had been pointing out the importance of nickel to their exports and the possible impacts of the 31st ATP on their economies. Several developed and developing countries had also argued that the 31st ATP could cause disruptions in the global supply chain of nickel, thus negatively affecting production, job creation and innovation. In a context of global crisis, it was Brazil's recommendation that the European Communities halt the process of classification until there was sufficient data on the actual risks of nickel compounds.

159. The representative of Turkey shared the concerns expressed by other Members about the 30th and 31st ATPs and the about the transposition of the results of these ATPs into the 1st ATP of the Regulation on Classification, Labelling and Packaging of substances and mixtures (CLP). He recalled that at previous meetings, the European Communities had declared that the classification of borates would have no impact for the European market in terms of production and import of substances and preparations containing borates, as long as they complied with the concentration limits set out by the Directive. He sought clarification on the type of restriction that would be applied if concentration limits exceeded those set by the Directive. While the situation for biocidals in cosmetics was clear, clarification was needed on the issue of the borates in products such as detergents, plant protection products, food supplements or medicinal products.

160. The representative of Turkey further noted that the CLP Regulation imposed an obligation to notify classifications to the Classification and Labelling Inventory, which was managed by the European Chemicals Agency (ECHA). This obligation applied to substances subject to registration in

⁹ G/TBT/N/EEC/151/Add.2 and G/TBT/N/EEC/212/Add.3.

accordance with REACH and placed on the market, as well as to substances meeting the criteria of classification as hazardous and placed on the market, regardless of whether they were subject to harmonized classification or not. He wondered how borates and its derivatives would be treated within the system of CLP and REACH without being affected negatively from the classification decision. He sought clarification on the impact on trade of the classification decision and stressed that any measure which created unnecessary obstacles to trade would hardly be TBT consistent.

161. The representative of China shared the concerns expressed by previous speakers and expressed disappointment at the adoption of the 1st ATP of the CLP Regulation. His delegation believed that the classification of more than 100 nickel compounds was not based on sound scientific information since the European Communities had not provided specific data of water solubility for the nickel compounds proposed for classification. The OECD read-across methodology was not applied completely and no justification for skipping some important steps had been provided. Furthermore, the CLP Regulation was a different regulatory framework from the Dangerous Substance Directive. However, the European Communities had not notified the incorporation of 30th and 31st ATP into the CLP. The representative of China noted that previous clarifications and replies from the European Communities did not address Members' concerns and requested the European Communities not to adopt the 1st ATP to the CLP Regulation until Members' concerns were fully addressed.

162. The representative of Mauritius, speaking on behalf of the ACP Group, stressed that the Group awaited a convincing response from the European Communities about the procedural, substantive and commercial questions raised by the Group and other Members at previous meetings regarding the reclassification of nickel substances. He reiterated the concerns expressed. ACP countries were also deeply concerned that the European Communities intended to transpose the 30th and 31st ATP nickel classifications in the 1st ATP to the EC's new Classification, Labelling and Packaging (CLP) Regulation. He noted that this measure was to be adopted soon and had not been notified, despite Members' requests to allow for consultations in accordance with Article 2.9 of the TBT Agreement. He emphasized that the nickel classification directives would have a significant negative economic and commercial impact on all nickel exporting countries. They would hurt those developing countries, including some LDCs, which relied only on a few basic exports for employment and revenue. For example, Botswana, Cuba and the Dominican Republic were Small and Vulnerable Economies (SVEs) which were highly dependent on mineral exports. In 2007, in each of them, nickel contributed to about 50 per cent of total exports of goods. The nickel market was worth about US\$ 4 billion per year for South Africa. Against the background of the worst world economic crisis which was already affecting developing countries, these directives would further aggravate conditions in the nickel industry and by-products industries and result in increased production, transportation and insurance costs as well as a further reduction in nickel demand, world prices and employment in this sector and related ones.

163. It was also stressed that the EC market alone accounted for some 40 per cent of world nickel use. Therefore, the classification of nickel compounds would reduce access to this vital market and to other major ones through domino effects of other standards and classifications. The ACP Group recognized the need for a high standard of protection of human health and the environment which required appropriate regulatory policies. However, the European Communities had yet to prove that nickel reclassifications were based on a sound or transparent scientific method. Indeed, the ACP Group continued to disagree that the EC's "grouping" and "read-across" methodology used in the 31st ATP for nickel compounds were in conformity with the OECD or the US EPA guidance. The European Communities had skipped, without scientific basis, some essential steps set out in the OECD's guidance.

164. Furthermore, the ACP Group believed that the EC's continued reliance on a single data point, water solubility, as the primary basis for categorizing nickel compounds stood to be challenged, since there was no water solubility data for most of the nickel compounds classified. Besides, according to

the OECD and US EPA guidance, the read-across method required reviewing a number of inputs, rather than only one, such as water solubility. In this respect, a read-across method, based solely on water solubility, gave rise to systemic concerns since this could be used as a precedent for taking regulatory decisions on other substances.

165. It was a fact that the nickel classifications involved highly technical and complex scientific issues and had important commercial implications. Yet, the legislative timetable of the 31st ATP had failed to provide sufficient time for meaningful consultations with other WTO Members, as was required by Article 2.9 of the TBT Agreement. It was the ACP Group's expectation that this would not happen with the 1st ATP to the CLP Regulation. It would be not be correct to assume that there was no need for any consultation on the 1st ATP to the CLP on grounds that consultations had already taken place on the 30th and 31st ATPs. The ACP Group considered that the CLP was a different regulatory framework, that new endpoints were added in the CLP and the transposition of the 30th and 31st ATP into the CLP was also a new element. Furthermore, the European Communities had not provided satisfactory answers to previous requests for clarification.

166. The ACP Group requested the European Communities to notify promptly the 1st ATP to the CLP, as required by the TBT Agreement, so as to allow for consultations with Members at an early stage, when amendments were still possible. Such notification needed to allow reasonable time for Members to submit comments and for these comments to be duly considered. Furthermore, given its significant commercial implications, it was essential that any classification of nickel compounds and any other substances produced by many developing countries took into account the special development, financial and trade needs of developing countries, as was required by WTO agreements.

167. The representative of Botswana associated his delegation with the concerns expressed by Mauritius on behalf of the ACP group and also shared the concerns expressed by other Members. He urged the European Communities to notify the 1st ATP to the CLP Regulation in accordance with Article 2.9 of the TBT Agreement.

168. The representative of the European Communities, referring to the comments made by the United States and Turkey on the 30th ATP, recalled that Members had been informed at the previous meeting that a study had been carried out to examine whether it was necessary to impose, under the EC Directive on the marketing and use of dangerous substances, any restriction on the use of borates in consumer products. This study had concluded that measures were not necessary as there were no products in the market which contained borates beyond the limits set in the 30th ATP. Yet, it was subsequently found that a few products did contain a higher concentration of borates, notably detergents and photographic applications. However, a risk assessment had shown that there was no risk of exposure to these products, therefore there would be no need to impose restrictions. Regarding the US comments on the difference in the labelling obligations imposed by the 30th ATP and the results of this study, she clarified that the former was based on the hazard profile of the classified substance or preparation and the latter to the risk derived from exposure to articles which contain these substances or preparations. . She stressed once again that there was no labelling obligation on articles, only on preparations or substances.

169. Regarding the 31st ATP, the representative of the European Communities noted that all the concerns raised were merely reiterations of concerns previously expressed, and to which her delegation had already adequately replied. Regarding the 1st ATP to the CLP Regulation the EC delegation, after careful review, had concluded that it was not a new measure and that therefore there was no obligation to notify it. She explained that the 1st ATP to the CLP Regulation was made to mechanically transpose the harmonised classifications contained in the 30th and 31st ATPs to Annex VI to the CLP Regulation. This transfer was necessary because, upon its entry into force on 20 January 2009, the CLP Regulation had deleted Annex I to the Dangerous Substance Directive which the 30th and 31st ATPs aimed to amend. The 1st ATP of the CLP Regulation converted for the already

classified substances (over 8000) the corresponding classification and labelling to the GHS classification and labelling codes. This correlation table was already included in Annex VII of the CLP regulation and was notified to the TBT Committee. Annex VII to the CLP Regulation contained a correlation table, which provided how the classification and labelling codes of the more than 8000 currently classified substances should be translated under the GHS.

170. On the methodology, the representative of the European Communities referred to the explanations given by her delegation at previous meetings of the Committee and added that at the meeting of the International Agency for Research on Cancer (IARC) held on 24 March 2009, the EC conclusions on the carcinogenicity of nickel substances had been confirmed. No additional scientific evidence had been presented to indicate that the classifications of the substances concerned would be different to those already agreed. She noted that Canada had raised concerns regarding the possible prohibition on the use of nickel substances in toys and clarified that the new legislation on toys, which had been notified to the TBT Committee at the appropriate time, had only reduced the tolerable limit values that could be used. Furthermore, before the 30th and 31st ATP, several nickel compounds and substances were already covered by the classification obligations. These limit values did not apply to toys which due to their accessibility, function, volume or mass clearly excluded any hazard due to sucking, licking, swallowing or prolonged contact with skin. The restrictions did not apply to stainless steel either. Also, she noted that nickel metal and its powder form were already classified as carcinogenic in Category 3 in the 30th and 31st ATPs, and that delegations had the possibility to comment on them at the appropriate time.

171. The EC representative further explained that, regarding the question on the procedure for the update of classified substances, once the substance received a harmonized classification for a specific hazard class (e.g., carcinogenicity) only a member State's competent authority could submit a proposal for an updated harmonized classification for this specific hazard class. Such proposal could be developed by industry, who could then ask a member State to submit the proposal. Regarding comments made by several delegations including Australia and Cuba on the stigmatization that the proposal could create on nickel, she stressed that several nickel compounds, including the most traded nickel compounds in the world, had been classified in the European Communities for several years and that there had not been any negative impact on trade. With respect to comments made by Australia on the restriction on use of nickel in batteries, she noted that several toy manufacturers had started to phase out nickel cadmium batteries due to scares in the toy sector. Finally, she stressed that the European Communities would revise its classification as and when new scientific evidence was provided.

172. The representative of Cuba regretted that there was not a meaningful dialogue on this issue. Her delegation would continue to raise concerns until comments by all Members were taken into account. She stressed that there should be a step between raising concerns in the TBT Committee and bringing them to the attention of the DSB and recalled that Costa Rica had made a proposal in this regard. The Committee needed to consider a mechanism whereby concerns could be resolved without having to repeat the same comments at each meeting.

(xi) *Norway - Proposed regulation concerning specific hazardous substances in consumer products (G/TBT/N/NOR/17)*

173. The representative of Japan reiterated his delegation's concerns regarding Norway's prohibition of 10 hazardous substances in consumer products and sought an update on the status of the measure. Japan stressed that, when introducing a regulation that was not harmonized with existing regulation in other countries, for example the EC RoHS or REACH, from the viewpoint of substances, conditions and threshold, scientific evidence should be provided. This should be taken into account by Norway. It was also necessary to provide enough time to analyze the measure before its enforcement. Japan also requested Norway that *bisphenol A* be exempt from the scope of

the measures because electric and electronic products did not contain it. In case it was included, an announcement of a clear exposure scenario and providing an opportunity for comments was necessary.

174. The representative of Jordan requested an update from Norway on the examination of the remaining ten substances in the regulation, including HCBDD, and on the timeline for the regulation's entry into force.

175. The representative of the United States also sought an update on the state of play of the measure.

176. The representative of Norway pointed out that the proposed regulation had been subject to an extensive hearing process, both at the national and international levels including in the European Economic Area. The regulation had not entered into force on 1 January 2008 as had been originally proposed in the draft and eight substances had been removed from the list. The Norwegian environmental authorities were currently evaluating the proposal and the comments received. Other modifications, such as limit values or further exemptions, were still being considered for the remaining ten substances and there was neither a set schedule to conclude this work, nor for the regulations' entry into force. He would transmit the questions and comments regarding the need for examination of *bisphenol A* and on HCBDD to the competent authorities in capital.

(xii) *China - Compulsory Certification (CCC) System (G/TBT/N/CHN/399 and Suppl.1)*

177. The representative of Japan noted that the CCC system had not been open to foreign-based certification bodies and reiterated his delegation's request to China that foreign certification bodies be appointed under the system without discrimination, as per Article 6.4 of the TBT Agreement and paragraph 195 of the Working Party Report on the Accession of the People's Republic of China.¹⁰

178. He recalled that, at the previous meeting of the Committee, China had stated that if the Government of China and the Government of Japan concluded a Mutual Recognition Agreement (MRA), foreign-based certification bodies could be appointed under the CCC system without discrimination. On the other hand, even if China and Japan concluded an MRA, Japanese certification bodies in China could not make use of the MRA. He sought information on how Japanese certification bodies in China could be appointed under the CCC system without discrimination. Additionally, he sought information about the date of entry into force of the amended regulation.

179. The representative of China noted that Japan had sent comments about the measure and that a detailed reply had been provided. He also highlighted that a dialogue was on-going with China's trading partners, including Japan, and that joint research on conformity assessment procedures had been carried out with the European Communities in order to exchange experiences and to improve the schemes. The objective of the notified regulation was to streamline the compulsory certification of China and to improve the effectiveness of the CCC system, based on the experience gained. Members' questions about the objective, the scope and the substantial changes in the measure had been answered. He pointed out that the draft regulation was still under review and that its final version would be published once the internal approval procedures were concluded.

180. With regard to Japan's questions about the recognition of foreign certification bodies and their test results, he recalled that there were two channels under the current regulation for foreign certification bodies to be able to perform conformity assessment procedure of China. First, China recognized the test results of laboratories under the IECE/CB Scheme and, second, foreign

¹⁰ WT/ACC/CHN/49 and Corr.1.

certification bodies could acquire qualification for the CCC system through inter-government agreements. China was open to discuss mutual recognition and cooperation with foreign counterparts based on the principles laid down in the TBT Agreement with the view to avoiding duplication of certification and minimizing trade barriers.

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

181. The representative of Japan reiterated his delegation's serious concerns with these measures. He pointed out that the Chinese Government had hosted a meeting for foreign stakeholders in which it was explained that China would implement compulsory certification system on certain categories of IT security products. From 1 May 2010 the application of the system would be limited to government procurement, as indicated the public announcement No. 33 of 29 April 2009, which was available on the website of the Certification and Accreditation Administration of the People's Republic of China (CNCA).¹¹ While Japan appreciated that the Chinese Government had been ready to take into account the comments from stakeholders, it believed that, although the scope of the compulsory certification had been reduced, it could still pose an unnecessary obstacle to international trade within the meaning of Article 2.2 of TBT Agreement.

182. The representative of Japan further noted that his delegation remained concerned about IT IP protection, in particular in light of the characteristics of IT security products, which included sensitive technical information. He stressed that for IT security products, there was a voluntary IT security certification scheme that was used internationally and had a mutual recognition framework. He requested China to explain the reason why a mandatory certification scheme was needed instead of the existing voluntary one and, more generally, the rationale behind these regulations. He further asked China to consider a mechanism which not only achieved improvement of IT security, but also ensured IP protection of foreign enterprises.

183. In addition, the representative of Japan stressed that, according to announcement No. 33, compulsory certification for government procurement would be conducted based on the Chinese Domestic Act. However, the Japanese delegation was concerned about the definition of government procurement in this Act. China was therefore requested to clarify the scope of government procurement. It was also pointed out that implementation rules of this regulation had also been published, despite Japan's request to hold adequate consultations with stakeholders before their publication. It was regrettable that the decision of the Chinese Government had not been based on consultations with other countries. China was requested to continue information exchange between governments and industries of interested countries.

184. The representative of the European Communities thanked the CNCA for keeping an open channel of communication with the European Communities and European industry regarding the concerns raised on these measures. His delegation welcomed the joint announcement by CNCA, the Ministry of Finance and AQSIQ¹² of 29 April 2009, further to which the scope of the proposed regulations would be limited to the government procurement area, and the entry in force postponed until 1 May 2010. While this was a positive development, the substantive rules had not been significantly changed. Hence, concerns remained regarding deviations from the existing ISO, IEC information security standards and the international mutual recognition framework based on the so-called Common Criteria (the Common Criteria Recognition Agreement). Concerns also remained about the commercially sensitive information required of applicant companies in the CCC process, such as the disclosure of the source or design codes or other sensitive proprietary information.

¹¹ www.cnca.gov.cn

¹² General Administration of Quality Supervision, Inspection and Quarantine of People's Republic of China. <http://english.aqsiq.gov.cn/>

185. With respect to the revised version of the scheme, the representative of the European Communities sought clarification about the exact scope of the notion of government procurement. He noted that, in Circular 33/2009, reference was made to Article 2 of China's Law on Government Procurement for the precise definition of the bodies covered by the notion of government procurement. It was the EC's understanding that this would concern all bodies receiving direct funding from the central government. Hence, this concept could potentially be interpreted in a broad sense as including entities that did not belong to the government. He therefore requested China to clarify whether the revised scheme would apply to state-owned enterprises and to suppliers of goods and services to governmental bodies. Even on the assumption that the revised scheme would not apply outside governmental bodies, the scope of the revised regulations remained much broader compared to the practice of other economies, where specific information technology product assurance requirements existed only in relation to national security critical infrastructure, i.e. well defined defence and military applications. He requested China to explain why it provided such broad coverage for mandatory certification requirements in this area.

186. In addition, in the European Communities' view, it was important to discuss the relationship between the CNCA's regulations and other aspects of China's information security policy potentially affecting the commercial area. Specifically, the EC delegation believed it was essential to better understand the relationship between the CCC system on one hand and the encryption regulations managed by the Office of State Commercial Cryptography Administration (OSCCA) on the other, including the role of OSCCA in the CCC process. It was also important to understand the relationship between the CCC and the Multilevel Protection Scheme under the purview of the Ministry of Industry and Information Technology and the Ministry of Public Security. This was necessary in order to avoid any overlapping requirements and to ensure coordination between all these different schemes. Now that a decision had been taken to implement mandatory rules in this field following consultations also with other Members, China was invited to communicate the final version of this scheme in the text that it planned to implement as of May 2010 to the TBT Committee for the sake of greater transparency.

187. In concluding, the representative of the European Communities reiterated his delegation's call for a meaningful dialogue, including an exchange of experiences and best practices on the identification and management of the information security risks. There were common challenges in this area and providing global solutions to those challenges was highly preferable than each economy introducing its own unique approach. In this sense, the European Communities regretted that such dialogue could not take place before the revisions to the CNCA's regulations were announced. His delegation would continue to work with the Chinese authorities and hoped that the same level of openness that CNCA had demonstrated would be shared by the other actors in the Chinese regulatory landscape.

188. The representative of the United States noted China's announcement related to the 13 technical regulations on information security that had been notified to the WTO in August 2007. He sought clarification from China on plans to reduce the scope of these measures to products in the government procurement area. Specifically, his delegation would appreciate clarification from China regarding whether the measures applied only to products purchased by state-owned enterprises or also to products purchased by entities such as public schools and hospitals. He also asked for an explanation of the substantive changes in the recently amended implementing regulations and urged China to notify these amended technical regulations to the WTO. This was important given the long-standing concerns that had been raised in the Committee on this issue and the serious questions that remained about the scope of the application of these regulations, that could extend beyond government procurement into the realm of commercial entities. Despite the concerns, the United States noted and appreciated the willingness of officials from CNCA and China's Ministry of Commerce to maintain an open line of communication with government officials and industry groups from the United States and other countries on this important issue.

189. The representative of Korea welcomed the Chinese Government's announcement that it would postpone the implementation of the regulations on information security. His delegation believed that the announcement was the result of the Chinese Government's pro-active position shown to other countries on several occasions, including at TBT Committee meetings. He pointed out that two days after the announcement, the Chinese Government had also announced that the implementation decrees had been revised. His delegation, after analyzing the revised decree, had noticed that the scope of the covered products had been modified for two product categories and all the related products with embedded information security functions would be covered by the new regulations. He sought clarification from China about what exactly would be the products falling within the scope of the measure. He echoed the comments made by the EC delegation regarding government procurement and was not clear whether government procurement would be the only area covered in the implementation of the new regulations.

190. The representative of China recalled that, upon notification of the measures in 2007, several comments had been received from WTO Members. Moreover, bilateral communication with interested trading partners, including the United States, the European Communities and Japan had been maintained. As a result, the Chinese government had decided to postpone the adoption date of the proposed regulations for about two years, to leave sufficient time for further technical communication and discussion and to ensure the regulations were reasonable and in line with international obligations. He further noted that, after soliciting comments from a wide range of stakeholders, China had revised the draft regulation and published a joint announcement of the final regulation on 27 April 2009. CNCA had subsequently held a news release conference for foreign stakeholders to introduce the final regulation, where representatives from the European Communities and Japan had also been invited. He stressed that China had greatly reduced the scope of the original regulation to government procurement. This change was made in light of the comments made by Members, including at Committee meetings. In addition, in order to leave more time for industry to adapt and as requested by Members, a one year transitional period was given. Therefore, the regulation would be implemented on 1 May 2010. Due to the substantial amendment made to this requirement and according to Article 1.4 of the TBT Agreement, China believed that these measures were no longer covered by the TBT Agreement should therefore not be raised in the TBT Committee.

(xiv) Brazil –Toys (G/TBT/N/BRA/259 and 313)

191. The representative of Thailand thanked Brazil for holding a public consultation on its toy import measures in April 2009 in Sao Paulo. She recalled that the "temporary" measure had first been enforced in October 2007, subjecting imported toys to be retested in Brazil, incurring unpredictably long waits and additional costs for imports. In response to comments from WTO Members, Brazil had modified the measure in June 2008 with even more stringent effects. The modified measure included provisions on consideration of foreign test reports, but not on acceptance. It further required that foreign test reports had to be translated into Portuguese. Additionally, all imported toys had to undergo additional tests in Brazil. Only after completion of the repeated testing and certification process, could importers affix the conformity mark on each toy item, one by one.

192. The representative of Thailand further recalled that these concerns had been raised at the public consultation in Sao Paulo. About a month later, Brazil had responded in writing, in Portuguese. According to the translation, Brazil insisted on requiring translation of test report into Portuguese. The official reply mentioned that product sampling for supplement test had to be done after the arrival at the port, but that additional tests were removed from the toy safety certification in light of the comments received. She noted that Brazil had also mentioned a new certification procedure and greater transparency for the revision of its toy safety measure without providing other specific details. While the removal of additional tests from the toy safety certification procedure was a positive development, clarification was still needed about whether or not imports still required sampling. Moreover, it was Thailand's understanding that Brazil would consider a review of the

measure for greater flexibility shortly after the consultation. To date, no update had been received. In concluding, the representative of Thailand requested that: (i) Thailand's concerns be taken into account; (ii) Brazil ensure flexibility for exporters; and (iii) any new burdens to undermine fair trading be avoided. Brazil needed also to ensure that the review bring the measure into conformity with the TBT Agreement.

193. The representative of China shared the concerns expressed by Thailand. In particular, China remained concerned about the discriminatory treatment imposed on imported toys in terms of additional tests and other burdensome conformity assessment procedures. He recalled that, in the public hearing held in April, Brazil had made it clear that additional test requirements on imported toys would be eliminated and that the final test would be available in June. However, no information had been received on the final regulation. He informed the Committee that, in a bilateral meeting, Brazil had confirmed that additional testing requirements would be eliminated. His delegation was also informed that a new draft text would be notified to the WTO and that another public consultation would be held at the end of July, after which a new public hearing would be held in August. The final regulation would then be published within 30 days. He invited Brazil to confirm that this was the case and, if so, he encouraged Brazil to take WTO Member comments' into account and to ensure that the final regulation was fully in line with the TBT Agreement. He further pointed out that the current toy regulation, which had been notified on an emergency basis, had been implemented for almost two years and that Chinese toy exports had been seriously affected.

194. The representative of the European Communities thanked the Brazilian authorities and INMETRO for organizing the public hearing in Sao Paulo and for the transparency with which INMETRO officials had discussed the issue and handled the comments received from his delegation. He invited the Brazilian authorities to confirm that the modifications announced during that meeting would be implemented in the revised version of the Decree. In particular, he pointed out that the modifications concerned the elimination of the requirements for duplicative local testing and the acceptance of testing performed by foreign, ILAC-accredited laboratories. He also sought confirmation that companies holding ISO 9001 (2008 version) certificates would be exempted from the factory audit on their quality assurance system in the context of the so-called System 5 procedure.

195. With regard to the requirement to provide a full official translation into Portuguese of foreign test reports, the representative of the European Communities requested INMETRO to consider in the framework of implementation that a translation requirement should only apply to those parts of the test reports that were necessary to establish the conformity of the product with the applicable Brazilian requirements. Finally, he sought an update on the state of play of the measure.

196. The representative of the United States welcomed the fact that Brazil would no longer impose additional in-country testing requirements on imported toys. He sought an update on the status of the measure and would review the new draft when published. He looked forward to continuing to work with regulators from Brazil and other Members on devising appropriate measures to ensure that children's safety was protected from potentially unsafe toys.

197. The representative of Brazil informed the Committee that the regulation on toys was still under revision. He recalled that, on 14 April 2009, INMETRO had held a public hearing about the draft regulation, which had been attended by representatives from national and foreign producers, as well as government officials from several countries which had had the opportunity to express their views on the draft text directly to INMETRO's regulators. During the public hearing, INMETRO had received significant contributions from interested parties. In view of that, INMETRO was working on a final version of the draft regulation that incorporated some of the comments received. Once concluded, the final version would be submitted to a brief period of public consultation and public hearing and then it would be published as a new regulation. He further informed Members that, in the new draft text, the requirement that complementary tests be made only in Brazil had been removed.

Foreign products would be allowed to be certified under System 5, as long as the tests are performed by laboratories accredited by ILAC. Moreover, INMETRO would require that conformity assessment bodies collected samples in the marketplace for performing toxicological tests, so that controls on the borders could be simplified, whilst enhancing market surveillance and other non-trade restrictive control methods.

198. With respect to the requirement that foreign tests reports be translated to Portuguese, the representative of Brazil pointed out that this could not be removed from the revised text. Brazil's Constitution established that Portuguese was the official language of Brazil: therefore, only documents in Portuguese had official status in Brazil's public administration. He confirmed China's understanding about the timeline for implementation, although slight variations could occur. Finally, he stressed that the process of revision of the Brazilian regulation on toys had been conducted with impartiality and transparency and had been open to all interested parties. The new draft regulation would strike a balance between the need to avoid trade restrictions and the objective of protecting the health of consumers.

(xv) *China – Wines (G/TBT/N/CHN/197)*

199. The representative of the European Communities reiterated her delegation's serious concerns regarding overly strict specifications related to maximum levels of sulphur dioxide in Chinese wines. She recalled that the European Communities had repeatedly raised this issue at TBT Committee meetings, highlighting the concerns of several EU member States, among them Germany, France and Hungary. At the most recent TBT Committee meeting, in March 2009, China had indicated that the process of reviewing this standard had been completed and that the maximum allowed level of sulphur dioxide in wines would be set at 250 milligrams per litre in line with the Chinese food additives standard. The European Communities noted, however, that this fell short of the levels stipulated in international standards such as the Codex, where the levels ranged from 350 milligrams per litre sulphur dioxide content to 400 milligrams per litre, in the case of special white wines. The European Communities urged China to align its specifications to international standards or to provide the TBT Committee with the reasons for which it considered the international standards inappropriate. China was also asked when the revision would be notified to the WTO TBT Committee.

200. The representative of China said that limits for sulphur dioxide in wine had been notified together with a package of standards for wine under TBT notification G/TBT/N/CHN/197. He noted, however, that concerns about these limits were SPS-related. The level of sulphur dioxide in wine had been revised as per notification published by the Ministry of Health on 11 December 2008. According to this notice, the limit had been increased to 250 milligrams per litre which was consistent with the Chinese hygienic standard for food additives. Hence, taking Chinese drinking habits into consideration, and with a view to reducing risks of contaminants caused by food additives, if wine producers would actually increase the limited of sulphur dioxide used in wine, it was possible for them to apply for review of these limits; to date, however, no such applications had been received.

(xvi) *United States - Consumer Product Safety Improvement Act (G/TBT/N/USA/421)*

201. The representative of China reiterated concerns with respect to the US Consumer Products Safety Improvement Act – the CPSIA. It was noted that in previous interventions, China had clearly identified key concerns with regard to transparency, associated conformity assessment procedures and some related technical problems. However, only minor progress had been made. First, the CPSIA fully met the criteria of a technical regulations and needed therefore to be notified to the WTO before adoption so that Members could provide comment. The notification of the subsequent implementing measures could not replace the notification of the Act itself since it already contained technical requirements that had trade effects.

202. Second, with regard to third party laboratories, the United States had made clear that third party laboratories included governmental laboratories. However, the additional requirements for governmental laboratories were too stringent. Based on China's experience, it was difficult for governmental laboratories of other Members, including China, to be assessed and accredited under these requirements. Developing country Members had invested a lot on governmental laboratories as an important part of their conformity assessment infrastructure in ensuring the safety and quality of import and export commodities so as to protect human life and health. These governmental laboratories accredited by ILAC and which used ISO and IEC 17025 as their basis, were fully competent to carry out relevant testing activities and there was no reason to discriminate against them. China therefore urged the United States to provide no less favourable treatment to such laboratories and to initiate the accreditation work of government laboratories expeditiously. An update on this work was requested. China looked forward to written replies to all questions provided to the United States.

203. The representative of the United States noted, with respect to transparency, that at least eight CPSC implementing regulations had been notified to date: he directed China, as well as other interested Members, to the Consumer Product Safety Commission website which had a special section on toy safety that provided key guidance documents on the test procedures, test accreditation, list of accredited laboratories, general counsel advisory opinions and specific guidance for small businesses. The representative of the United States agreed with China that the definition of a technical regulation did not distinguish between laws and regulations. In this connection, the United States asked China to provide information on legislative measures that it had notified to the TBT Committee as the United States was not aware of any such measures. For example, China had not notified the WTO of its draft food safety legislation which contained detailed provisions on ensuring the quality and wholesomeness of foods. Did this mean that China made a distinction between laws and regulations in its notification practice? Was China planning to notify this bill as well as other pieces of legislation that contained technical requirements to the WTO?

204. Regarding China's concerns with respect to laboratory accreditation, the representative of the United States noted that Chinese laboratories were not being singled out in any way. Based on criteria mentioned at the last meeting of the Committee, there were 34 laboratories based in China that had been accepted by the Consumer Product Safety Commission. It was also not accurate to state that the CPSC had not accepted any Chinese Government laboratories. In fact, the CPSC had approved seven Chinese Government joint venture laboratories. Chinese CIQ laboratories had not been accepted because they did not meet the relevant conditions. The United States asked why China continued to raise the issue of laboratory accreditation. The United States had opted for a highly trade facilitative approach in its testing regime for children's articles – one that was based on international standards and acceptance of test results from ILAC accredited labs outside the United States. The United States asked when China would be recognizing test results from ILAC accredited laboratories with respect to the CCC System, as well as SFDA's medical device registration system. China had refused to recognize any United States laboratory that was ILAC accredited under those schemes – its position with respect to CPSIA seemed, therefore, inconsistent.

205. The representative of China wished to offer some clarification. First, with respect to the Chinese notification procedure, the representative of China assured the United States that it fulfilled its notification obligations under the TBT Agreement. For example, it was known to all Members that there was no need to notify standards under the TBT Agreement – nevertheless, China had notified its mandatory national standards to the WTO as technical regulations since these were found to meet the criteria of a technical regulation. The same principles would be followed with respect to laws. For example, the regulation on Import and Export Commodity Inspection enacted by China's State Council, typical Chinese legislation, had been notified to the WTO (G/TBT/N/CHN/182). With respect to the accreditation of US laboratories in China, as had been explained previously in response to Japan's concern on China's CCC System – there were two channels provided for by current laws for

foreign laboratories to be accredited. China remained open to discuss the mutual recognition cooperation with its foreign counterparts based on the principles laid down in the TBT Agreement.

(xvii) *Indonesia - Mandatory Certification for Steel Products (G/TBT/N/IDN/23, Rev.1 and Suppl.1, and G/TBT/N/IDN/24, Rev.1)*

206. The representative of Japan noted that the Government of Indonesia had announced that it would introduce mandatory standards (referred to as the Indonesian National Standards (SNI)) with respect to the above-mentioned measure. At the last TBT Committee meeting, Japan had expressed serious concerns with respect to these measures and requested Indonesia to explain how they were consistent with Article 2.2 of the TBT Agreement. However, Indonesia's response had not been sufficient to resolve the concerns. In Indonesia's notifications of 23 and 24 February 2009, Indonesia had indicated the following objectives: (i) to protect consumers from safety aspects; (ii) to increase the product quality; and (iii) to establish fair trade and competition. Japan asked Indonesia to explain how the second and third objectives were consistent with Article 2.2 of the TBT Agreement in terms of the legitimate objective.

207. The representative of Japan further noted that despite the fact that Article 10 of the Decree of the Minister of Industry on hot rolled steel coils provided that the Director of Industry Development would stipulate technical guidance, Indonesia had implemented the Decree from 6 May without establishing such guidance. Japan was concerned that this delay could harm the transparency and credibility of the measures at issue. In these uncertain circumstances, even if importers tried to go through the procedure for obtaining SNI certification, they would have difficulties in making progress. Therefore, Japan requested Indonesia to enact and release the technical guidance as soon as possible. Moreover, since this was also relevant to the Decree on zinc-aluminium-coated steel plates, which would enter into force on 6 July, Japan asked Indonesia to clarify the schedule for issuing the technical guidance also with respect to these products.

208. It was noted that during the second round of bilateral talks, held on 1 April, Japan had understood that the Ministry of Industry of Indonesia had explained that the scope of these Decrees was steel products for construction use *only* and the scope was not expected to affect steel products for manufacturing use (e.g., automobiles, electronics) in the mandatory certification system. Hence, Japan requested Indonesia to reconsider the scope of the measures and to enforce these measures as flexibly as possible, giving adequate consideration to actual business transactions.

209. The representative of Chinese Taipei echoed the concerns expressed by Japan and noted that formal comments had been submitted on 20 March and 11 May 2009, respectively. However, to date, no response had been received and, in the meantime, the measures continued to create serious trade barriers for industry.

210. The representative of Indonesia noted with respect to the "legitimate objective" that the measure was intended to increase product quality and to establish fair trade competition. The measure had been adopted and notified under emergency circumstances because a lot of steel products on the Indonesian market were of low quality, particularly steel products which were intended for building construction – which was very much related to consumer safety. Therefore, the Government of Indonesia had decided to enforce the two regulations so that only steel products which complied with SMI requirements would be available in the market. By implementing this regulation, product quality as well as competition would be improved; this would enhance consumer protection. The regulation was to be implemented four months after its date of stipulation because it also applied to all hot rolled sheet and coiled steel products which had already been regulated through another regulation (notified in G/TBT/N/IDN/19, Add.1 and Add.2). This regulation was based on the Indonesian Government policy to convert energy consumption from kerosene to LPG.

211. Regarding Japan's question about the exclusion of automobiles and electronics, the Ministry of Industry had stipulated that the new regulation on the mandatory implementation of SMI for hot rolled sheet and coiled steel had excluded hot rolled sheet and coiled steel with particular specifications (with a thickness below 1.8 mm intended for specific technical specifications such as automotive and electronics). The notification for this regulation has been sent to the WTO Secretariat for circulation to the Members (see the Rev.1/Add.1 referred to in title, above).

212. On the concern about product certification, raised by Chinese Taipei, the representative of Indonesia said that this was not a burden for exporters to Indonesia because the product certificate was provided based on a third party certification mechanism. Once the manufacturer obtained a license from the product certification body to use the SMI mark on its product, the license was valid for three years. The Ministry of Industry was currently assessing more certification bodies for approval. On the procedure for applying SMI mark (by the manufacturer), the exporter had to apply for certification to the product certification body. The certification body would then check through data on the management system applied by the manufacturer to ensure product quality and compliance with the SMI. This was done through sampling and testing in laboratories accredited by the National Accreditation Body of Indonesia. It was noted that the testing laboratories could be located outside Indonesia as long as they had been accredited by a respected national accreditation body which had signed an MRA with the National Accreditation Body of Indonesia. The Ministry of Industry had for some time been developing the final draft of the technical guidance for the regulation at issue; once adopted it would be sent to those Member countries that had requested it.

(xviii) European Communities – Seal Products (G/TBT/N/EEC/249 and Add.1)

213. The representative of Canada expressed deep concern about the adoption in the European Parliament on 5 May 2009 of the European Commission's proposed regulation banning trade in seal products, which had not – at the time of the meeting – been notified to the TBT Committee. The stated objective and rationale was "to regulate the internal market and to address EU citizens' concerns on the welfare of seals during commercial hunts". The version adopted by Parliament included a ban on the trade in seal products with some exemptions, but offered no possibility for derogation for products derived from humanely killed seals. Canada was concerned that the European Communities was unilaterally condemning sealing practices without adequate evidence. International standards for animal welfare in sealing had yet to be developed and Canada had repeatedly suggested the need for the development of such standards and would, moreover, welcome the cooperation of the European Community in doing so.

214. The representative of Canada stressed that her country had gone to great length to ensure that the seal hunt was humane, well-regulated and sustainable. As the European Union's own studies had shown, seals could be - and were - killed humanely. There was no justification for a trade ban on seal products. Despite testimony from Inuit communities as to the damaging effects of this proposed measure, the European Communities had not consulted with them to ensure that they were not adversely affected by this regulation. Canada strongly urged the European Communities to reject the trade ban and engage with sealing countries to set international standards for animal welfare in sealing. She stressed that should the EU Council of Ministers adopt the regulation as currently drafted, Canada would take action to defend its WTO rights and interests under the TBT Agreement, and other relevant WTO agreements.

215. The representative of Norway recalled his delegation's previous statement on the relevant EC notification (G/TBT/N/EEC/249). Since the last meeting of the Committee, the European Parliament had adopted a regulation concerning trade in seal products that was different from the draft regulation that the European Commission had submitted to the TBT Committee and which had already been discussed. It was Norway's understanding that the decision by the European Parliament would have to be adopted by the Council of the European Union sometime in the Autumn of 2009, before the final

regulation entered into force. It was also Norway's understanding that the Council of the European Union, based on internal procedures, would adopt the final regulation with identical content (except for possible technical corrections and typographical errors) as the text adopted by the European Parliament. Although the adopted text was different from the text transmitted to WTO Members by the European Commission, Norway's preliminary analysis of the new text confirmed the observations Norway had made previously.

216. Norway had posed a number of questions to the European Commission to gain a better understanding of the rationale and justification for the proposed ban on trade in seal products. These remained relevant and it was not necessary to repeat them – Norway continued to believe that trade restrictions adopted by the European Parliament were inconsistent with the WTO agreements. In particular, the representative of Norway noted that his delegation had repeatedly urged the European Communities to ensure that any regulation adopted include amendments that ensured full consistency with international obligations. The regulation as adopted by the European Parliament fell short in this regard. Norway was thus confronted with a regulation that unjustifiably restricted trade in one of Norway's natural resources, which was harvested in a sustainable and ethical manner. Should there be no changes that addressed Norway's concerns before the final adoption by the Council of the European Union, then Norway would have no option but to seek dispute settlement consultations with the European Communities.

217. The representative of the European Communities informed delegations that the proposal for a Regulation of the European Parliament and of the Council concerning trade in seal products had been amended in the first reading of the EC legislative procedure. This text would be notified to the WTO TBT Committee for information as an addenda to the original notification and the text was expected to be adopted in the Autumn of 2009. The compromise that had been reached between the Parliament, Council and the Commission would allow the marketing of seal products from the hunting practised by the Inuit and other indigenous communities which contributed to their subsistence. It would also allow for the placing on the market of products resulting from hunting for the purpose of controlling seal populations, especially to maintain the balance with available fish stocks. The placing on the market would only be possible under strict conditions which would be specified in implementing rules. The transit of seal products through EC territory would not be affected. Thus, the proposed legislation, as agreed by Parliament and Council, harmonized disparate rules currently in force in some of the EC member States while addressing both the EU citizens' concerns with regard to animal welfare and interests of other groups that could be affected by the new legislation.

218. The representative of the European Communities noted that the Commission had been asked to adopt, in close consultation with the member States and under Parliamentary scrutiny, implementing provisions. During this process, the Commission intended to consult stakeholders and interested WTO Members. It was noted that both the Norwegian and Canadian representatives had indicated that they would defend their rights and interests in the WTO. While the European Communities recognized the rights of both countries under the WTO, the European Communities hoped that the differences would not lead to litigation, in particular given the fact that Canada had not disputed legislation that was maintained in a number of other countries around the world which had a similar effect as the EU measures.

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

219. The representative of Japan welcomed India's decision to postpone implementation of the mandatory certification system by one year as had been stated at the Committee's previous meeting. He recalled that, at that time, Japan had requested India to explain how these measures were consistent with Article 2.2 of the TBT Agreement. It was regrettable that India's response had not been sufficient to dispel Japan's concerns. As far as Japan understood, India had not notified the WTO Secretariat of the said measures, in spite of the fact that more than four months had passed since

postponing the implementation of the measures. Referring to the notification for 2007 (contained in document G/TBT/N/IND/32), India had reported that the main objective of introducing the mandatory certification system was "consumer health and safety." Japan wished to ask how India deemed that there was any possibility that high-value-added Japanese steel products, mainly distributed to manufacturers in India, could threaten the health and/or safety of Indian people.

220. There were also other outstanding problems. For instance, the requirement that foreign companies set up liaison offices in India, and differences in the structure of the certification fee between domestic and foreign companies. With regard to the liaison offices, there were some Japanese steel mills which did not have any branch offices in India. In these cases, Japan was concerned about the consistency of the measure with the Article 2.2 of the TBT Agreement; the establishment of such offices would be a time-consuming and costly process for foreign manufacturers to undertake only so as to obtain mandatory certification of BIS. Although India had already postponed entry into force, Japan requested India to reconsider the necessity of implementing this measure, taking into consideration potential adverse affects on trade. In addition, Japan was of the view that India needed to implement the mandatory certification system in a way that prevented it from being more trade restrictive than necessary, reflecting G20 commitments, as well as giving adequate consideration to actual business transactions.

221. The representatives of Mexico and China supported Japan's position.

222. The representative of India noted that the measure had been postponed by one year and there were no other substantive changes. With respect to the objective of the regulation, it was clearly mentioned in the regulation that the issue was in many cases about: minimizing power loss, structural safety, the safety when steel was being used in high temperatures, including boilers etc. On the issue of the liaison office, the requirement to set up an office in India should not apply if the Bureau of India Standards enters into an MoU with the respective foreign government.

(xx) Thailand – Mandatory Certification for Steel Products

223. The representative of Japan noted that the Thai Industrial Standard Institute (TISI) had announced that it would introduce new criteria for product certification on 26 January 2009. Although the new criteria had subsequently been put into effect, TISI had abruptly abolished the said criteria as of 4 March 2009 and released different criteria, to be put into effect from 1 May 2009. At the last TBT Committee meeting, the delegation of Japan had asked Thailand to explain how the new criteria released on 4 March were consistent with Article 5.1.2 and other relevant provisions of the TBT Agreement, because there was a possibility that the new criteria would create unnecessary obstacles to international trade. Japan had also expressed its serious concern that the new criteria would have a major adverse effect not only on foreign producers' businesses, but also on manufacturers' businesses in Thailand, as well as impacting on the overall industrial competitiveness of Thailand.

224. The representative of Japan noted that the new criteria required importers and foreign producers to: (i) provide a number of documents to certify conformity with the mandatory standard, (ii) allow TISI to conduct sampling tests for every single shipment, and (iii) undergo annual TISI factory and facility inspections. Japan was convinced that these requirements would impose a heavy burden on importers and foreign manufacturers, even though the stated objective of the measures was "consumer protection". For instance, shipment sampling should be carried out in accordance with Article 5.2.6 of the TBT Agreement, which provided that "...the selection of samples are not such as to cause unnecessary inconvenience to applicants or their agents." Furthermore, since this requirement did not match actual business transactions, if it was enforced strictly, there was a possibility that it would cause the cessation of supply of high-grade steel products from Japanese steel mills to the Thai automotive and electronics industries.

225. It was Japan's understanding that detailed guidelines, which were going to be issued in April, had not yet been released. In order to ensure the transparency and credibility of the Thai conformity assessment procedure, and to eliminate uncertain factors for importers and foreign manufacturers to the extent possible, Japan requested Thailand to enact and issue the sectoral guideline promptly. In Japan's view, Thailand needed to acknowledge business realities in order to make the guideline more beneficial. Japan requested Thailand to reconsider the necessity of implementing the new criteria, taking into account any possible adverse impact on their economy and trade. In addition, Japan strongly believe that the new criteria for product certification should not be more strict – or applied more strictly – than necessary.

226. The representative of Thailand noted that TISI's new criteria for certification, which had been effective from 1 May 2009, were in principle the same as the previous criteria. The objective was to ensure quality in line with ISO 9001, as well as ISO/IEC Guides 65 and 67. The difference was that they were now applied strictly to importers as well as to local manufacturers for the purpose of consumer confidence and safety – which was, she noted, a legitimate objective under the TBT Agreement. While early on in the enforcement of the measure some difficulties had arisen, these had mostly related to quality control requirements in relation to ISO 9001. Thailand was of the view that importers already in compliance with the measures would not have any additional burden; in fact, the provision of adequate proof of compliance would facilitate the process for importers to their own benefit. The representative of Thailand reiterated that the criteria were applicable not only to the steel products of Japan but to all products of all origins equally. Transitional issues were worked out gradually and continually with importers. Indeed, if Japan were presently to check with its own importers they would find that the situation had improved. With respect to the strictness of the measure, the representative of Thailand assured Japan that the measure was applied equally to local Thai manufacturers.

(xxi) *Colombia - Quality and identity requirements for distilled spirits (G/TBT/N/COL/121 and Add.1)*

227. The representative of the European Communities referred to the above-mentioned notification on alcoholic beverages. She recalled that her delegation had sent written comments to Colombia on 19 March 2009 and had also raised the issue at the previous TBT Committee meeting. In its comments, the European Communities highlighted various requirements in the Colombian draft measure that could pose significant problems to EC alcoholic drinks exporters – for instance the setting of maximum alcohol content levels, the obligation to translate the brand name into Spanish, or the requirement to have certain warnings on the labels of alcoholic drinks. As a more general remark, the European Communities highlighted serious concerns with regard to the increasingly complex, numerous, and often duplicative requirements that exporters of alcoholic drinks to Colombia faced. In the last eight months alone, Colombia had notified three draft measures on alcoholic drinks to the TBT Committee: G/TBT/N/COL/120, COL/121 and COL/130 (the first of which had since been withdrawn), all containing mandatory and potentially duplicative specifications for the labelling of alcoholic drinks. The European Communities asked Colombia to clarify the relationship between the different notified measures and urged Colombia to provide a written reply to its comments.

228. The representative of the United States noted that his delegation was currently reviewing written responses received and would revert to Colombian officials if there were outstanding concerns.

229. The representative of Colombia noted that the measure at issue was currently being reviewed and revised. Nevertheless, the Colombian government had taken up one part of the measure which had not been subject to objections and had proceeded on an urgent basis to publish this (the Add.1 notification).

(xxii) India – Prevention of Food Adulteration (G/TBT/N/IND/34)

230. The representative of the European Communities once again expressed her delegation's concern with the above-mentioned measure to which comments had been submitted since November 2008; concerns had also been raised at the last TBT Committee meeting. In its comments, the European Communities had highlighted the difficulty to assess the scope of the changes envisaged by India to the Rules on the Prevention of Food Adulteration due to the fact that these had been subjected to several seemingly unrelated revisions. The European Communities requested detailed clarifications on the measure from the Indian authorities, in particular with regard to the requirements on the labelling of alcoholic drinks: for instance, the classification of alcoholic drinks as "non-nutritive products", the obligation to indicate the list of ingredients, and the requirement to include the date of manufacturing and the date of packaging on the label of alcoholic drinks. The European Communities once again urged India to provide an answer to these comments and to make available a consolidated version of the Rules on the Prevention of Food Adulteration, taking into account all revisions to these rules that had recently been notified to both the SPS and TBT Committees. This was all the more urgent in light of the fact that the Revision notified under G/TBT/N/IND/34 had apparently entered into force on 19 May 2009, and the initial 3-month grace period provided for producers to adapt to the new requirements would soon expire.

231. The representative of the United States appreciated India's delay in enforcement of its revised labelling provisions and the response it had provided to the United States on the applicability of certain sections of the requirements to distilled spirits. A few questions and concerns remained, however. The United States was unsure whether India would allow the use of stickers to comply with the labelling requirements. The United States still had concerns as to why India considered that date of production should apply to distilled spirits which had an indefinite shelf-life when, in the US view, lot identification numbers could better provide the identification needed if a product recall was necessary. The United States also had other outstanding concerns on other technical issues which had been discussed bilaterally with India and on which clarification had been requested, possibly through a video conference.

232. The representative of India noted that the original text of the regulation at issue was available from the Ministry of Health of India (contained in GSR66-64, dated 19 September 2008 and a corrigendum issued GSR135, issued on 27 February 2009). India had no formal mechanism for consolidating the various texts and producing a consolidated copy, however, if there were technical issues which were still of concern to United States and the European Communities, these delegations could either request a bilateral in New Delhi, or, alternatively, a video conference. Regarding the issues raised by the United States on stickers and the shelf-life for distilled spirits, these would be passed on to relevant authorities and a reply would be provided as early as possible.

(xxiii) Malaysia - Conformity Assessment Procedures for Steel Products

233. The representative of Japan noted that since the introduction of the measure, imports of 57 steel products had become impossible to clear through Malaysian customs without excessively cumbersome conformity assessment procedures. Consequently, these measures had created a de facto trade obstacle. Moreover, distribution was stagnating and additional fees had become necessary to pay for storage. At the last TBT Committee meeting, Malaysia had explained that the objective of the measures was to ensure the safety of steel products for construction use. Also, Japan had recently learned from the Ministry of International Trade and Industry (MITI) of Malaysia that it planned to expand the scope of the mandatory certification from the current 57 items to all kinds of steel products (627 items) because several accidents had happened with buildings collapsing in Malaysia over a few weeks. Japan was seriously concerned that the measures that the Malaysian government intended to introduce would not be consistent with Article 2.2 of the TBT Agreement which stipulated that

"technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective."

234. In light of the above, the representative of Japan requested Malaysia to prevent any further expansion of the scope of the mandatory certification. If the objective of the measures was to ensure the safety of buildings, Malaysia needed to begin by establishing building standards (building codes). It was inappropriate to introduce mandatory certification for materials (steel products) before establishing building standards. Nevertheless, if Malaysia insisted that the scope of mandatory certification system cover materials (steel products), Japan believed that the scope of the measures had to be limited to steel products for construction use. Furthermore, Japan stressed that all steel products exported from Japan to Malaysia were of high quality and high-value-added, and many of them were not produced by Malaysian steel makers. Japan had never heard of any serious safety-related problems caused by steel products in Malaysia in the past. There was therefore no valid rationale to subject these products to mandatory certification. In addition, Japan recognized that the scope of the measures did include the steel products which were not covered by MS (Malaysian Standards). Therefore, Japan had serious concerns about the effectiveness the measures at issue.

235. The representative of Japan noted that MITI had recently released a "Policy Review for Iron and Steel Industry" and planned to introduce mandatory standards not only for imported long steel products but also for flat steel products on 1 August 2009. In regard to this press release, Japan asked for clarification about the objectives and scope. Although this policy review included some trade liberalization (such as a tariff reduction of steel products from 50 per cent to 25 per cent), Japan was concerned that expanding the scope of the mandatory certification system could lead to more trade-restrictive technical regulations with an adverse effect not only on Japanese steel makers' business, but also on the manufacturers operating in Malaysia. It would also affect the international competitiveness of the Malaysian industry. Based on the above, Japan requested that Malaysia reconsider the introduction of the said measures, including the withdrawal thereof.

236. The representative of Malaysia said that the measure would be implemented consistent with Articles 2.2 and 5.1.1 of the TBT Agreement and was intended to protect safety and health as well as to prevent deceptive practices. Malaysia was considering to review the measures and would take appropriate steps to enhance the effectiveness of their implementation.

(xxiv) France – Unique Requirements for Ride-on Lawnmowers

237. The representative of the United States raised serious concerns with respect to the French Ministry of Agriculture's non-transparent "skirt" requirement for ride-on lawnmowers - a measure that was never published in any official law or decree in France. The Ministry of Agriculture requirement for ride-on lawn mowers had already disrupted US lawnmower exports to France. If other EC member States were to adopt this requirement, a significant portion of the approximately USD 800 million in annual US shipments of lawnmowers to Europe could be adversely affected.

238. The representative of the United States stressed that his delegation did not understand the basis for the French Ministry of Agriculture's (MoA) requirement that ride-on lawnmowers be fitted with a "skirt" for bystander protection. Both European and American industry claimed that the MoA had not presented any accident data supporting the need for the requirement, and alleged that the requirement could actually increase the potential for safety problems by increasing the risk of fire caused by accumulating debris in the vehicle. The MoA had not responded to these points. Moreover, it was the US understanding that the skirt requirement represented a unique French requirement that was neither consistent with other EC member States' requirements, nor based on internationally developed ASTM or ISO ride-on lawnmower standards. The United States also noted that, in September 2007, the CEN Technical Committee 144 had voted to reject the French proposal to add the skirt requirement to the existing CEN standard.

239. The United States reiterated its request to DG Enterprise to re-evaluate its initial rejection of the industry petition challenging the MoA requirement's conformity with the Machinery Directive, and urged France to notify the skirt requirement to the WTO and cease enforcement of the requirement until it received and took into account comments from stakeholders and other Members, and provided a reasonable period for industry to adjust to the new requirement, if in fact such a requirement was necessary. In this regard, the representative of the United States asked the European Commission to share any accident data it believed supported the French position – that installation of the lawnmower skirt would increase bystander safety – as well as any analysis undertaken by the MoA on the potential fire hazard that installation of the skirt could create. If this information did not exist or did not support the necessity of the skirt requirement, the United States asked the Commission to recommend that France base its ride-on lawnmower requirements on a relevant international standard and thereby eliminate the skirt requirement.

240. The representative of the European Communities referred to the detailed statement made at the previous Committee meeting where it had been mentioned that this matter was subject to a complaint procedure, since the US industry had filed a complaint with DG Enterprise and Industry. The preliminary findings on this complaint had been communicated to the complainant in March 2009 following which the complainant had challenged some of the findings and submitted additional evidence which was currently under examination by the Commission services. Given the confidentiality of the procedure, the European Commission was not in a position to comment further on the substance of the matter. On the process, the Commission services aimed at finalizing the assessment of the alleged new evidence submitted by the complainant in September 2009, at which time a decision on whether to pursue the procedure and start an infringement proceeding against France, or whether to close the case, would be taken.

241. In respect of the eventual need for a WTO notification, the European Communities was of the view that it was inappropriate to refer to the French measure as introducing a *new* requirement. The requirement to prevent access to moving transmission parts of machinery, both for operators and other exposed persons such as bystanders and children, had been a requirement under the European Machinery Directive for 20 years; therefore, the requirement was not new. The issue, instead, was how the requirement was to be translated into a technical solution capable of achieving the safety objective. The original technical regulation had, in fact, been duly notified to the TBT Committee. But it was not necessary to notify what was, in practice, a market surveillance or enforcement action aiming at ensuring the effective application of an existing requirement.

242. The representative of the United States noted, with respect to the alleged US petition, that it was in fact the *European* industry that had filed the petition challenging this requirement. This showed clearly that both the US and European industry were in agreement that this requirement was problematic. On the notification obligation, while the United States agreed that a prior directive existed, the mandate that emerged from the French Ministry of Agriculture was very specific: not only did there need to be bystander protection but there needed to be a specific piece of equipment attached to all ride-on lawnmowers. The United States did not know when this decision had been taken but had simply faced the fact that lawnmowers had been seized by French customs for not having the said equipment installed. A memo had been issued from the MoA to retailers with instructions not to stock ride-on lawnmowers unless they had this particular piece of equipment installed. This seemed to fit the definition of a technical regulation, i.e., mandating a particular product characteristic. It therefore needed to be notified.

(xxv) *India - Restriction on Chinese toys*

243. The representative of China drew the Committee's attention to his delegation's submission contained in G/TBT/W/304, dated 12 March 2009, which stated China's position with regard to India's restriction on Chinese toys. He recalled that the Indian Ministry of Commerce and Industry, on

23 January 2009, had issued and implemented a regulation imposing a general ban on toys from China for at least six months, without specifying a reason. The Indian Government had not notified it to the WTO. Subsequently, bilateral consultations between China and India had been held several times with a view to resolving China's serious concerns about the regulation. On 2 March, India's Ministry of Commerce and Industry had issued a second Ministerial Notification, No. 91, to replace the first one. However, the discriminative nature of the second measure had remained.

244. The representative of China further pointed out that the Ministerial Notification No. 91 required Chinese toys to conform to the related standards and conformity assessment procedures, while toys manufactured in India and originating from other Members were not subject to the same requirements. Toys produced in India and in other countries, regardless of their conformance to the applicable standards, were not covered by the regulation. China's view was that the regulation No. 91 accorded unfavourable treatment to Chinese toys and was inconsistent with India's obligations of national treatment and MFN under GATT 1994 and the TBT Agreement, in particular Article 2.1 and 5.1. Also, lack of transparency in the second regulation remained.

245. At the last TBT meeting, China had raised serious concerns about India's ban and discriminatory measures on almost all Chinese toys and had asked India to immediately withdraw the WTO-inconsistent measures. At that meeting, India had recognized that the second ministerial notification did not address China's concerns and had hoped to find a solution through bilateral channels. At a bilateral meeting, India had provided China with a revised regulation, Ministerial Notification 113, which had been issued and implemented on 16 June 2009. Again, the third regulation had not been notified and neither comment nor transitional period was provided. After a preliminary reading, China had found that the only substantive change made was substituting "Import of toys from China" with "Import of toys". The new regulation required that imported toys should comply with certain standards, such as ASTM F963, ISO 8124 (Parts I-III), ISO 9873(Parts I-IV) or EN 71, and be accompanied by a certificate of conformance from the manufacturer that the representative sample of the toys being imported had been tested by an independent laboratory which was accredited under ILAC.

246. The representative of China requested India to clarify the following points: (i) Were toys manufactured domestically in India required to meet the requirement of the standards and conformity assessment procedure prescribed in the new regulation? (ii) If so, which standard should Indian toys conform to? He also sought further information about related laws or regulations, due to the fact that the requirement of compliance of Indian toys with the four above mentioned standards was not provided in the new regulation. If Indian toys were not required to conform with the standards and conformity assessment procedures, concerns would again arise about the inconsistency of the measure with the WTO national treatment obligation.

247. It was also noted that the technical specifications of the four standards might differ from each other. Were imported toys required to comply with all four standards? If so, how could compliance of imported toys with all these four different standards, given that they had different technical specifications and might conflict with each other, be ensured? Were imported toys subject to multiple testing? India was asked to indicate whether it could accept the Chinese standard for toys as equivalent, since it was based on the relevant ISO standard.

248. The representative of India pointed out that a bilateral meeting had been held with China, where concerns raised had been discussed. China's concern regarding the MFN implication of the standard had already been addressed and the measure now applied equally to all countries. The Indian toy industry, which was the major competitor of Chinese imported products, was already complying with these standards. His delegation recognized that there were some problems regarding small, unorganized players in the Indian market and this issue was under examination with a view to ensuring that these also complied with the standards and related conformity assessment procedures.

With respect to the comment period, the representative of India pointed out that the measure was based on international standard, therefore no comment period had to be provided. Finally, the representative of India pointed out that Chinese authorities could discuss the matter related to equivalence with Indian authorities.

(xxvi) Chile - Cosmetics (G/TBT/N/CHL/81 and Add.1)

249. The European Communities reiterated its concerns with regard to the above-mentioned measure and referred to its statement at the last meeting of the Committee. It was the EC's understanding that comments were still under review by Chile. Her delegation expected to receive a written reply from Chile shortly and requested that Chile did not proceed with the adoption in the meantime.

250. The representative of Chile stressed that although several comments had been received, the Ministry of Health had had to deal with a number of other urgent matters that had arisen which were of national priority and public health. Therefore, the process of replying to the comments received had been delayed. She stressed that, in Chile, all comments received had to be replied to in writing; moreover, the reply would state whether the comments had been taken into account or not, and if not the reasons why.

(xxvii) Colombia - Draft Decree establishing provisions to promote the use of biofuels (G/TBT/N/COL/96, Adds 1-3)

251. The representative of the European Communities reverted to above-mentioned Decree that provided that all gasoline-engine motor vehicles needed to be flexible-fuel vehicles in the future. Even though it had taken note of the explanations provided by Colombia at the previous meeting, the European Communities had not yet received an explanation why Colombia considered it necessary to address this aim by laying down mandatory technical requirements while there were a number of voluntary measures available for promoting biofuels, which could be more effective with regard to environmental protection. Indeed environmental protection would benefit more from the development of a number of different and new technologies contributing to fuel efficiency, rather than from the use of a single, compulsory fuel standard that could have the long-term effect of stifling innovation. The technical requirement at issue would not only have a negative impact on the imports of many car models currently sold in Colombia, it would also prevent the placing on the Colombian market of new cars which were more fuel efficient. In addition, the requirements would not only prevent the placing on the Colombian market of cars running only on petrol, but also of those which ran on petrol in combination with other alternative fuels, other than the E85 bio-ethanol.

252. Moreover, the representative of the European Communities noted that the timing was a serious concern, since the lead-time to bring new car models to the market was substantial. The periods allowed by the Decree would entail serious consequences because even where manufacturers show a continued interest in the Colombian market, they would not be able to adapt their vehicles in order to provide Colombian consumers with a varied range of products. It was the European Communities' understanding that Colombia had adopted the text and published it on 31 March 2009. She expressed disappointed that Colombia had adopted the text shortly after the last TBT Committee at which time Colombia had encouraged the European Communities to send written comments and promised that those comments would be studied and discussed. Colombia was requested to provide a reply to the written comments.

253. The representative of Mexico associated his delegation with the concerns expressed by the European Communities.

254. The representative of Colombia noted that the draft Decree applied to both national and foreign vehicles. She noted that evaluations made were based on existing technology and there were scientific studies that showed that bio diesel was a viable fuel and less polluting than traditional gasoline, particularly in a country like Colombia where requirements on vehicles were different because of environmental conditions. Colombia remained open to bilateral discussions with both the European Communities and Mexico.

(xxviii) European Communities - Green Paper on Agricultural Product Quality Policy

255. The representative of Mexico referred to the concerns his delegation had expressed on this issue at the last meeting of the Committee. Written comments had been sent to the European Communities and at the last meeting of the Committee and, in this regard, the European Communities had said that the Green Paper and the comments regarding the second quarter of 2008 would be published in a report in May 2009 dealing with their agricultural product quality policy. Mexico asked about notifications and about any particular measure that was envisaged for adoption; he asked for a continued dialogue on the topic.

256. The representative of the United States noted that some of the potential approaches outlined in the Green Paper and the subsequent communication could be implemented in ways that might create trade concerns for US agriculture and food processing entities. His delegation was reviewing the issue closely. He hoped that the European Communities would allow ample time for stakeholder review and consideration of comments on any resulting guidelines or regulations due to the potential serious trade impact.

257. The representative of the European Communities noted that the above-mentioned communication on food quality had been adopted in May 2009. It set out policy orientations but did not contain any legislative proposals. It was drafted in light of comments from stakeholders and third countries to the Green Paper on agriculture product quality; the process had been open for public consultation and received many contributions, including from those countries that were expressing concern at the current meeting. Future analysis would consider: the possible simplification of marketing standards to rely more on voluntary measures, like those developed by UNECE or Codex; the possibility of examining the need for mandatory "place of farming labelling"; in the area of geographical indications there were suggestions to clarify and simplify the legislation and procedures; and there was the possibility of replacing the scheme of traditional specialities which was nevertheless not used by third countries. There were also policy orientations on private certification schemes which had experienced an important increase in number over recent years.

258. She noted that it was in the European Communities' interest to ensure that operators developing these schemes reduce the burden on farmers, especially duplicative audits, and ensured that consumers were not being misled. The European Communities proposed, in the Communication, to approach this issue through guidelines as it had been deemed unnecessary to adopt legislation, at least for the time being. Any initiatives would of course be notified to the TBT Committee and period for comments given for comment, but no legislation was envisaged until, at the earliest, in 2010.

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

259. The representative of the European Communities reiterated her delegation's concern about Canada's measure on compositional standards for cheese. She asked that the Canadian delegation confirm that there were no further plans to extend the scope of the measure to cover other dairy products.

260. The representative of New Zealand requested that Canada provide an update on the federal court challenge to these regulations that was currently taking place.

261. The representative of Australia supported the comments made by the European Communities and New Zealand.

262. The representative of Canada assured the European Communities that no regulatory process had been established for compositional standards for other dairy products. Regarding New Zealand's request for an update on the judicial review, she informed the Committee that this had taken place on 31 March and 1 April 2009. The judge had reserved his decision, but as there was no time limit for federal court judges to render their decisions, it was not possible to say when the outcome would become known. The representative confirmed that she would provide an update at the November meeting of the Committee.

(xxx) Argentina – Measures affecting market access for pharmaceutical products

263. The representative of Colombia recalled that this concern had been raised in previous meetings of the Committee. She informed the delegations that despite dialogue between the Argentinean and Colombian authorities, the necessary authorization to allow Colombian companies to export medical products into the Argentinean market had not been given.

264. The representative of Argentina informed the Committee that intensive consultations had taken place between the different federal government agencies, including the National Administration of Drugs, Food and Medical Technology, on how to address this issue. Following these consultations, it was agreed that necessary administrative procedures would be initiated so as to address this concern appropriately.

IV. FIFTH TRIENNIAL REVIEW

265. The Chairperson recalled that the Committee was scheduled to conclude the Fifth Triennial Review of the Operation and Implementation of the TBT Agreement at its meeting on 5-6 November 2009, in line with the mandate in Article 15.4 of the TBT Agreement.

1. Good regulatory practice

266. The representative of Jordan introduced her delegation's proposal on good regulatory practice (G/TBT/W/311, paras. 9-11). She emphasized that in order to ensure that Members develop technical regulations and conformity assessment procedures consistent with their obligations under the TBT Agreement, Jordan proposed that the Committee prepare guidelines for good regulatory practice to address, inter alia, the principles of public consultation, use of tools for regulatory impact assessment, performance based regulations, use of standards in technical regulations. Jordan also proposed that the Secretariat updates a list of relevant mechanisms and methodologies related to good regulatory practice used by other Members of the WTO.

267. The representative of Mexico noted that a significant problem that Members faced in accessing markets for their products was the lack of regular compliance with substantive obligations in the TBT Agreement. Therefore, Mexico proposed that the Committee discuss the development of a guide for good regulatory practice that would enable Members to verify compliance with the obligations provided for in the TBT Agreement before completing the definitive version of a technical regulation. In the view of Mexico, it was necessary that such a guide include recommended procedures to facilitate compliance with the substantive obligations under the Agreement and examples of mechanisms that could be used to comply with these. The guide would have to be applicable to any type of technical regulation.

268. The representative of the United States said that good regulatory practice was key to avoiding unnecessary barriers to trade and strongly supported the Committee's work to promote greater

understanding and implementation of the principles of good regulatory practice as well as the successful implementation of these principles. It was recalled that in 1997 the Committee had agreed that coordination between regulatory authorities, trade officials and national standards bodies was essential to ensure that Members effectively implement the Agreement. The US proposals for the Fifth Triennial review sought to help focus the Committee's attention on exchanges of experiences related to particular aspects of that coordination. It was important to focus on the institutional mechanisms for internal coordination, particularly with respect to opportunity for intervention and consultation. It was the US belief that the discussion of specific trade concerns in the Committee would benefit from a better understanding of how comments can be taken into account by other Members. The US submission (G/TBT/W/315) provided an overview of the institutional mechanisms and processes of the United States and described the US reliance on strong central government management of its regulatory regime, an effective interagency trade policy mechanism and robust public consultation in implementing the TBT Agreement.

269. In addition, the United States supported Jordan's proposal (G/TBT/W/311) to exchange national experiences on good regulatory practice mechanisms and methodologies, and to include good regulatory practice in technical assistance plans. Also, the United States was sympathetic with Jordan and Mexico's goal of having Committee guidelines on good regulatory practice but noted that a considerable body of work on good regulatory practice had been produced by other organizations in the past 20 years, including APEC, OECD and others. These documents and principles had endured the test of time and had been recognized at high level by many Members of the TBT Committee. Thus, the United States was of the view that any effort by the Committee at developing guidance needed to make the most effective use of its own area of expertise and not duplicate work, or contradict established principles. The United States would support, for example, the collection and preparation of existing work on good regulatory practice work with Members indicating which of these had been useful in helping them implement the TBT Agreement as part of the process of exchanging national experiences.

270. The United States further thanked Canada and Mexico for their leadership in developing the joint paper on regulatory cooperation (G/TBT/W/317). The representative of the United States was of the view that this cooperation was an essential element in the trilateral effort to minimize the negative impact on trade in the integrated North American market of unnecessary divergences in technical requirements. The paper demonstrated that the NAFTA Parties had been much progress in that regard, but there were still technical barriers in North America that needed to be addressed. The United States welcomed further exchanges of national and regional experiences on regulatory cooperation in the Committee, including through a workshop on this topic.

271. The representative of Israel supported the proposal submitted by the United States (G/TBT/W/315) and that of Canada, Mexico and the United States (G/TBT/W/317) on the issue of good regulatory practices. Israel was of the view that regulatory cooperation and policy coordination both at the international and domestic levels served to reduce the negative impact that technical regulatory frameworks may have on international trade. He expressed particular support for the workshop proposal to hold a workshop on the topic (G/TBT/W/317, para. 24).

272. The representative of New Zealand joined others in stressing that good regulatory practice was the key to reducing technical barriers to trade. In her delegation's view, the proposal that some form of compilation of good regulatory practice guidelines be put together seemed useful; this was a way of building on what had been said at previous triennial reviews. It was important, however, that existing guidelines be used as a basis for any work in the TBT Committee. On the issue of domestic coordination, New Zealand emphasized the importance of coordination in a federal system where multiple agencies, national and sub-national governments all developed different regulations. The representative of New Zealand referred to her country's experience, which had been presented to the Committee at a previous meeting of the Committee (G/TBT/W/294) – she welcomed further input in

this regard. As others had said, regulatory cooperation was an important part of understanding other Members' regulatory regimes and New Zealand, like others, supported the proposal for a workshop on this subject.

273. The representative of Korea welcomed the proposals on good regulatory practice particularly in the area of regulatory cooperation. By way of example he noted that a lack of proper international standards was evident in the area of energy efficiency in electrical and electronic equipment – which had been a key issue at a joint workshop by IEA, ISO and IEC that had been held in Paris on 15 March 2009.

274. The representative of Australia noted that information sharing between regulatory authorities in Members was helpful; in general, Australia was supportive of the proposals on the table. Like others, Australia was of the view that developing a guide to good regulatory practice was something that should supplement existing efforts, including work in the context of APEC.

275. The representative of Chile joined others in underscoring the importance of good regulatory practice and supported, generally, the proposals on the table. In particular, she noted that guidelines would be very valuable especially for Members that did not necessarily have the appropriate technical infrastructure in place for the implementation of the TBT Agreement. She also referred to work done by other organizations and the need to avoid duplication.

276. The representative of Argentina expressed support for the proposal tabled by Mexico in relation to good regulatory practice (Section IV or G/TBT/W/313).

277. The representative of the European Communities noted that the Committee had accomplished useful work on good regulatory practice in the past; at this point Members agreed, in general, that good regulatory practice was about more effective implementation of the TBT Agreement. Based on what the Committee had done, there was now a need to link guidance to the specific provisions of the TBT Agreement. A sufficient body of information was available for consolidation that could be distilled into basic principles on good regulatory practice that could form part of a Committee guidance document. The European Communities agreed that the Committee would need to draw on work from other institutions although any guidance developed had to be tailored to the specific needs arising from the TBT Agreement: Whatever work the Committee did needed to be linked to compliance with the relevant provisions of the Agreement. On regulatory coordination, the European Communities supported the proposals made and recalled the relevance of proper mechanisms for tracking all measures that should be notified for the fulfilment of the transparency obligations arising from the TBT Agreement. This aspect had been highlighted in the European Communities' submission in transparency. Also on regulatory cooperation, the representative of the European Communities highlighted the importance of deepening the information exchange in this regard. This was also relevant to the discussion on trade facilitation arrangements discussed under conformity assessment. He supported the proposal to focus on good regulatory practice in technical assistance projects – new technical assistance projects already foresaw a component in this area.

278. The representative of Canada supported the proposals regarding the Committee's work on some form of annotated compendium of good regulatory practices based on what Members had worked on and developed.

279. The representative of Pakistan strongly supported the proposals on good regulatory practice and the related area of good regulatory cooperation. She also noted the usefulness for developing countries of conducting workshops held back-to-back with the Committee meetings where several countries shared experiences.

280. The Chairman concluded by noting that during the discussion delegations had echoed the fact that the principles of good regulatory practice remained important for the work of the Committee. These were an effective means of avoiding, to the extent possible, unnecessary barriers to trade. Members had also emphasized the fact that the Committee needed to build on experiences already gained in order to avoid duplication and to take into account the work of other institutions working on similar issues. Many delegations expressed their support for the compilation of guidelines on good regulatory practice in this regard. Members also voiced their overall willingness to continue to share experiences on regulatory cooperation and coordination and in this regard, several delegations voiced their desire to have a workshop on the topic. Moreover, delegations seemed to agree, generally, on the importance of technical assistance in respect to good regulatory practice.

2. Conformity Assessment Procedures

281. The representative of New Zealand referred to her delegation's proposals on the subject of conformity assessment (G/TBT/W/295 and 306). In particular, she emphasized the importance that New Zealand attributed to exchanges of information on different types of trade facilitation arrangements, ranging from regulatory cooperation arrangements, mutual recognition arrangements (MRAs) through to equivalence agreements. In this respect, the New Zealand proposal was broader than just conformity assessment procedures given that mutual recognition agreements were often broader in scope. In New Zealand's view, practical guidance on *when* the use of particular instruments was most appropriate in a *particular situation* would be useful – and the Committee could consider pursuing such work on guidelines, including through the establishment of working groups.

282. The representative of Singapore introduced his delegation's proposal on conformity assessment (G/TBT/W/312). Singapore supported New Zealand's proposal to exchange information on MRAs and regulatory cooperation agreement. In Singapore's view, the pursuit of MRAs was based on industrial interest: they brought benefits in the form of market access certainty and reduced cost for business due to elimination of duplicative testing and certification and hence faster time to market which was crucial due to the shorter lifecycle of consumer products today. MRAs served as a confidence building exercise for the WTO Members and their domestic regulatory agencies. In other words, it had been Singapore's experience that a better understanding of different regulatory regime and a closer regulatory cooperation gained through an MRA had helped promote regulatory convergence and harmonization in ASEAN. The MRA had also provided a useful platform for relevant regulators to come together, also contributing to greater confidence building. Singapore proposed that the Committee draw up a template – or a voluntary guide similar to the Code of Good Practice – that would give the Members a head start in the MRA negotiations and help them address some of the challenges involved.

283. The representative of Singapore also lent his delegation's support to New Zealand's proposal to revisit the TBT Committee's indicative list of different approaches to facilitate acceptance of results of conformity assessment, adopted during the Committee's Second Triennial Review (Annex A of G/TBT/1/Rev.9). He underscored, in this regard, the need to take into account the *quality* of the conformity assessment procedures rather than the *origin* of the product. In other words, the basis to recognize and accept other Members' conformity assessment bodies needed to focus on the competence of the body rather than on the origin of the product. The origin of the product was irrelevant when assessing whether or not a particular product met the requirements set out in a technical regulation.

284. The representative of Mexico supported New Zealand's proposal and the statement made by Singapore as a useful way for the Committee to make headway in the area of conformity assessment. He referred to his delegation's proposal in this regard (G/TBT/W/313) and stressed that TBT Agreement recognizes the possibility there could be various viewpoints on conformity assessment; in fact, Members' regulatory bodies had the possibility of having *various types* of conformity assessment

procedures. New Zealand's proposal was appropriate in this regard because it showed the usefulness of an exchange of information on various forms of cooperation in respect of conformity assessment. Mexico also stressed the importance of technical assistance in the area of conformity assessment: such assistance was fundamental to allowing Members the capacity to select and implement the most appropriate conformity assessment a particular situation. Moreover, Mexico supported the idea that practical guidelines on the way of handling effective and efficient trade facilitation agreements be developed.

285. The representative of India noted that while his delegation also believed that MRAs and equivalence agreements were important tools available to the Members, currently there were only a few MRAs that existed between developed and developing countries. Therefore, India suggested that the Secretariat conduct a factual study of MRAs and equivalence agreements and evaluate their success in terms of enhanced trade flows. Such a study could highlight the features of successful MRAs and equivalence agreement and provide useful lessons for other developing countries to follow. India also proposed that that a Code of Good Practice could be developed for the development of conformity assessment procedures for testing of certification requirements and that applied to non-governmental standardizing bodies. This was important because non-tariff barriers that developing countries often grappled with were in the form of testing and certification requirements. Hence there was a need to frame a comprehensive guide to good practices for the application of non-governmental conformity assessment requirements. The representative of India referred to the guidelines on conformity assessment produced in ISO and IEC as useful background.

286. The representative of Chinese Taipei supported the proposal from Singapore and noted that discussions on the possible elements of MRAs could also lead to more regulatory cooperation.

287. The representative of Pakistan supported the proposals made regarding MRAs and noted that this was one area where better cooperation between developing country Members, as well as between developing and developed country Members, could improve trade flows and would be beneficial. An effort to provide guidelines for developing country Members as a means of improving effectiveness was welcomed by Pakistan.

288. The representative of Indonesia supported the proposals presented by delegations, in particular with respect to the exchange of information on MRAs so as to build a better understanding of the issues that need to be considered. Indonesia also echoed calls for the development of practical guidelines on MRAs and the importance of capacity building in the area of conformity assessment.

289. The representative of the United States expressed support for the recommendations from New Zealand and Singapore to continue to exchange information on MRAs and other arrangements for regulatory cooperation, and to examine how to design trade facilitative arrangements within the context of risk management approaches to yield the needed level of assured compliance. He noted that Singapore had specifically mentioned the ASEAN framework agreement as an example of guidance – or "template" on MRAs – and the United States invited Singapore to further elaborate on its experience on this subject so that the Committee could better understand their recommendation. The representative of the United States was also interested in receiving more information on Singapore's view with respect to the relationship between its proposal to develop voluntary guidelines specifically on MRAs and New Zealand's more general proposal to develop practical guidance on trade facilitating risk management arrangements.

290. In addition, the United States expressed interest in the Mexican recommendation to prepare a guide for quality infrastructure development. However, as this was a highly technical area, the United States was not sure that the Committee had the appropriate depth of experience to produce a definitive guide on this important topic. The United States looked forward to a bilateral discussion on the

subject with Mexico and welcomed more information exchange among Members regarding resources, case studies and practices in this regard.

291. With respect to the recommendations that the Secretariat or the Committee undertake broad studies on the types of issues discussed above, the United States expressed reservations and questioned whether this was the most efficient use of delegates' and the Committee's expertise. In the view of the United States, there was a considerable body of work in other international organizations on many issues related to good practices in conformity assessment. The United States was of the view that the way forward on MRAs proposed by Singapore and New Zealand was useful and did not see the value added of a study by the Secretariat on this topic.

292. The representative of Chile supported New Zealand's proposal with respect to MRAs but underlined the need to better understand the benefits of MRAs, for instance: had they resulted in significant reductions of costs and an increase of trade? Chile also supported the Singapore's proposal.

293. The representative of Australia expressed broad support for New Zealand's and Singapore's contributions. In respect of the development of voluntary guidelines (Singapore's proposal), he asked for more information about the ASEAN experience.

294. The representative of Argentina supported, in particular, the proposal from Mexico with respect to the importance of technical assistance in the area of conformity assessment and the need to develop a guide to facilitate Members' infrastructure (as set out in para. 15 of G/TBT/W/313).

295. The representative of Singapore indicated his delegation's intention to provide more information on the ASEAN MRA.

296. The representative of India clarified, in response to US comments, that, currently very few MRAs and equivalency agreements existed between developed and developing countries; hence the suggestion was that the Secretariat conduct a *factual* study of such MRAs and equivalence agreements to evaluate their success in terms of actual trade flows. Members – not the Secretariat – could then draw useful lessons from this information. If time constraint was an issue for the Secretariat, the data collection work could be outsourced.

297. The representative of the European Communities noted that conformity assessment was at the core of many specific trade concerns raised in the TBT Committee. On a general note, he said that while in much of the discussion emphasis had been put on trade facilitation arrangements and MRAs, and while the European Communities agreed that these were relevant topics worth discussing, he nevertheless wished to stress that the problem needed to be tackled at its roots: the *criteria* to be applied for choosing the most appropriate and least trade restrictive conformity assessment procedures. For instance, many problems could be addressed if conformity assessment procedures were closely linked to, for instance, the level of risk to be managed. Thus, the European Communities suggested that the Committee should also deepen its exchange of experiences on the use of the most appropriate conformity assessment procedures in a given situation. He noted that, in the past, this issue had been discussed in detail with respect to SDoC. There was, however, a full range of intermediate conformity assessment procedures in between the extremes of third party certification and SDoC capable of meeting the requirements and legitimate objectives of Members that could be explored.

298. With respect to the proposals on the table, the representative of the European Communities noted that the success of regulatory cooperation arrangements very much depended on the objective being sought and the level of economic development of the partner countries. He was willing, together with other Members, to work towards the establishment of an inventory of existing practices

and develop a document that could perhaps serve to update the existing list of trade facilitation arrangements.¹³

299. With respect Singapore's recommendations on MRAs, and as had been noted before: MRAs that were not based on a prior approximation of legislation and that were between countries that had very different levels of development and different regulatory environments, in practice did not work. In fact, in these cases, the benefits were very small, sometimes not even matching the administrative costs linked to the operation of the MRAs. As Singapore had suggested, MRAs needed to be seen as a potential instrument to foster regulatory harmonization. MRAs based on equivalence or full harmonization and that led to closer economic integration between countries or regions perhaps had some potential and were worth being explored. However, the European Communities cautioned against putting too much emphasis on MRAs as a trade facilitation arrangement; indeed, the fact that few MRAs between developed and developing countries had been concluded was perhaps because the preconditions for success did not exist. What was needed was to look precisely at the preconditions for successful MRAs, this needed to be done before making any study of the economic effects of MRAs.

300. With respect to the proposal from Mexico on technical assistance, the European Communities agreed with the United States: developing a guide in the TBT Committee might be too far reaching and complex a project for the Committee. Perhaps the Committee could focus on the criteria for the choice of the most appropriate conformity assessment procedure, this would work toward the same objective as the Mexican proposal. Moreover, technical assistance in the area of conformity assessment needed to be seen within a wider context of promoting a culture of better regulation, good regulatory practice, simplification of the regulatory environment, and building an infrastructure in the field of conformity assessment so that developing countries could reap the full benefits of international trade.

301. With respect to the Indian proposal to develop guidelines on non-governmental conformity assessment requirements, the European Communities saw this as linked to India's proposal on private standards. This appeared to be about conformity assessment requirements which would be developed in the private sector and would have no link to any governmental measure, to any mandatory conformity assessment requirements. The European Communities questioned whether the TBT Committee was the appropriate forum to examine this issue and whether the measure would be covered by the scope of the TBT Agreement.

302. The European Communities noted that technical assistance in the conformity assessment area needed to also deal with the appropriate enforcement activities or market surveillance activities that should accompany the application of conformity assessment procedures. In other words, building capacity in the area of conformity assessment should not be limited to building laboratory capacity, or capacity in the field of metrology. The enforcement side was essential. Experience had shown that even the most stringent systems of verification needed appropriate market surveillance mechanisms.

303. The representative of Mexico offered a point of clarification. There was a need to consider different types of conformity assessment procedures. For instance, if a system of SDoC was adopted because it was considered the simplest way of assessing conformity of a product with a standard, there could be consequences: sometime other types of conformity assessment procedures were required, such as third party certification – despite encouragements from trading partners to use SDoC in the first place. It was important that countries had an infrastructure that enabled Member countries to monitor or apply any of the systems in a way that was compatible with their obligations.

¹³ Indicative List of Approaches to Facilitate Acceptance of the Results of Conformity Assessment contained in document G/TBT/1/Rev.9, Part I, Section II (pp. 6-7) and Annex B (on pp. 35-36).

304. The representative of the India noted, with respect to the EC point on the scope of the TBT Agreement vis-à-vis private standards, that TBT Agreement stated that Members "shall take such reasonable measures as may be available to them to ensure that local government and non-governmental standardizing bodies within their territories, ... accept and comply with this Code of Good Practice" (Article 4.1 of the TBT Agreement). Also: "Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such standardizing bodies to act in a manner inconsistent with the Code of Good Practice." He also noted that obligations of Members with respect to compliance of standardizing bodies with the provisions of the Code of Good Practice applied irrespective of whether or not a standardizing body had accepted the Code of Good Practice

305. The Chairman concluded by noting that conformity assessment clearly was essential to building confidence between trading partners and facilitating regulatory convergence, and the Committee attached importance to the continued exchange of information in this area. The point was made that it was important to examine not only how to design conformity assessment procedures but also the criteria used in order to decide the most appropriate conformity assessment approach in a given situation in order to facilitate trade and reduce costs, also taking into account previous work that had been done by the Committee. It was also pointed out that technical assistance remained important in respect to building capacity (supply side) for conformity assessment but, again, awareness needed to be raised about the choice of approach. Issues related to enforcement and product reliability were also mentioned as important to consider in the area of technical assistance. Experiences with respect to the use of MRAs were also recalled and, in this regard, the question of their effectiveness was raised, particularly with respect to developed-developing country partnerships.

3. Standards

306. The representative of Japan informed the Committee that it had withdrawn its proposal regarding the global relevance of international standards (JOB(09)/25).

307. The representative of India noted that the multiplicity of standards, guides, recommendations posed a serious barrier to international trade – and one that had a particularly negative impact on developing country exports. To fully understand the impact of this diversity and multiplicity of standards on developing country exports, India proposed that the Secretariat undertake a factual study to ascertain the impact on trade flows of such standards in selected sectors of developing country export interest. The study could estimate the additional cost borne by developing country exporters in complying with these requirements. Members could thereafter consider the findings and develop ways to resolve the problems so identified.

308. With respect to private standards, the delegation of India reiterated its point about Article 4.1 of the TBT Agreement (see paragraph 304, above). It was noted that private sector commercial bodies were bringing in a range of private standards that negatively affected access of developing countries to certain markets in developed countries. There was therefore a need for the TBT Committee to come up with guidelines on what "reasonable measures" as referred to in Article 4.1 of the TBT Agreement meant. These guidelines could address possible ways in which enforcement of Code of Good Practice could be strengthened in respect of private standard setting bodies.

309. The representative of Mexico supported the statement from India. He noted that the SPS Committee had discussed this issue at length and suggested that the TBT Committee, when discussing the matter, enhance its coordination with other Committees in respect of this issue.

310. The representatives of Kenya and Uganda supported the proposal by India noting that private standards had affected their exports. Even though these standards were not developed by central government, they de facto had the effect of a technical barrier to trade. Both Kenya and Uganda therefore supported the call from India for the TBT Committee to intervene.

311. The representative of Egypt supported the points made by India and Mexico and stressed that the TBT Committee needed to give more attention to the subject of private standards given their effects on developing country exports. It would also be important to invite input other international organizations such as the Codex and the ISO; the Codex had apparently produced an informative study on the matter.¹⁴

312. The representative of Cuba supported calls from more discussion of private standards in the TBT Committee – there was indeed a need for more analysis, particularly in the TBT Committee. Coordination was also necessary with the SPS Committee. The representative of Cuba suggested that a first step for the TBT Committee could be to identify the problem, as had been done in the SPS context, and, thereafter the Committee could begin to consider specific suggestions on further action.

313. The representative of Tanzania stressed the problems his country faced in complying with requirements on the international markets that were based on standards. Technical assistance needed to become a priority in this area. Both actual infrastructure (e.g. laboratories) and awareness of the importance of conformity with standards needed to be raised. Without such assistance LDCs in particular would not be able to benefit from the multilateral trading system.

314. The representative of China supported India's proposal and noted that this was an important issue in both the TBT and SPS context.

315. The representative of Pakistan noted that the issue of private standards was very complex; it required an informed debate. A dialogue needed to be initiated and international standard-setting bodies involved, as had been done in the SPS Committee.

316. The representative of Argentina agreed with delegations' views in respect of the importance of discussing private standards and stressed that the consequences of these measures did not just affect developing country Members but also developed countries.

317. The representative of the European Communities referred to his delegation's previous statements in respect of private standards. He noted that his delegation did not challenge the relevance of the concerns raised, rather, the European Communities questioned whether the TBT Committee was the appropriate forum for discussion. In his view, the problem had not been sufficiently defined: the proponents of the discussion on private standards needed to better qualify their concerns and make a clear distinction between standards for the purposes of the TBT Agreement and what they referred to as "private standards". In the view of the European Communities, standards for the purposes of the TBT Agreement were only those standards developed by "recognized bodies" (Annex 1, para 2 of the TBT Agreement). It was likely that most of the "private standards" referred to by delegations were not developed by "recognized bodies" for the purposes of the TBT Agreement. Delegations were also encouraged to consider paragraph 8 of Annex 1 of the TBT Agreement which clearly defined the concept of "non-governmental body". Any measure falling outside the above-mentioned definitions did not fall within the scope of the TBT Agreement. Any eventual discussion on the subject needed to be undertaken without prejudice to the TBT Agreement and the role of the Committee.

318. The representative of the United States made some preliminary remarks on proposals regarding standards. With respect to Mexico's observation that greater understanding of how standards were used and how regulators and market participants determined which standard was most relevant and effective in meeting their objectives, the United States was of the view that this could be

¹⁴ See Codex document: ALINORM 09/32/9D-Part II (The Impacts of Private Food Safety Standards on the Food Chain and on the Public Standards – Setting Process, Paper prepared for FAO/WHO by Spencer Henson and John Humphrey).

useful. He noted that the Standards Workshop held in March 2009¹⁵ had been a good start to the discussion and suggested that more work was needed before any further Committee recommendations would be appropriate. The United States also supported Mexico's recommendation to look at documented successes. Again, Members' presentations at the March Workshop had given a clear picture of the challenges as well as the economic and social benefits of participating in the development and use of international standards; the exchanges had offered important practical information on the relationship between standards and trade.

319. The representative of the United States also took note of India's proposal to require Members to explain deviations from international standards and specifically the provisions of its proposal to exempt developing countries. However, the United States could not understand the manner in which the use of – or deviation from – international standards was necessarily related to risk. International standards were used for many purposes, including with respect to addressing risk. The United States was interested in learning more from India about the elements of India's regulatory framework and decision-making process, including how Indian regulators made a general linkage between risk and international standards. With respect to India's proposal that international organizations should modify international standards that were not globally relevant to become relevant within a fixed period of time, the United States recalled the relevant Committee Decision of 2000¹⁶ which called on international standardizing bodies to put in place procedures to identify and review standards that had become obsolete as well as to put in place procedures to communicate this with the WTO. Perhaps rather than request a fixed period of time, the Committee could request updates from international standardizing bodies on their procedures to review standards and identify ones that may need updating.

320. With respect to private standards, the United States shared some of the concerns raised by the European Communities. It was not clear what the term "private standard" meant and it was not clear that the Committee had done enough work to include it in the Fifth Triennial Review. The United States questioned the need for the Committee to clarify the term: it was not a term used in the Agreement and, in addition, it was not obvious how clarification could benefit Members' implementation of the Agreement. In the view of the United States, standards driven by the private sector ensured market relevant and efficient technical solutions. The Committee had, moreover, been discussing standards developed in private sector bodies for many years, including at the March Workshop.

321. The United States drew the Committee's attention to a new OECD study on the Use of International Standards in Technical Regulation which was, at the time of the meeting, work in progress and expected to become available in October 2009.¹⁷ The representative of the United States noted that the study laid out both the definitional and analytical challenges involved in identifying whether and how international standards were actually being used in regulation in any systemic way. Despite these difficulties however, one of the OECD study's primary findings was that Canada, the European Communities, Japan, Korea, Mexico and the United States had all taken steps to meet their TBT obligations in using relevant international standards as the basis of technical regulations where possible. The United States supported efforts by the TBT Committee to continue its engagement and exchange of experiences between TBT and standards experts, including by inviting Members to share national experiences on public-private collaboration, particularly with respect to case studies on stakeholder outreach and engagement in the development of national technical committees and

¹⁵ A Summary Report of the WTO TBT Workshop on Good Regulatory Practice is contained in document G/TBT/W/287.

¹⁶ Paragraph 4 of the Decision on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the TBT Agreement, contained in document G/TBT/1/Rev.9, Part I, Section III (pp. 10-12) and Annex B (on pp. 37-39).

¹⁷ TAD/TC/WP(2009)12, OECD, 27 May 2009.

technical infrastructure as the examples from the March Workshop from Peru, Kenya, Pakistan and others made clear. These types of efforts could yield important benefits to trade.

322. The representative of India noted, in reference to the US statement, that while the term "private standards" had not been used in the TBT Agreement, standards framed by non-governmental bodies had been used. Regarding the EC point on the definitions contained in the TBT Agreement, the definition of non governmental body was an inclusive definition which also included NGOs that had legal power to enforce technical regulations. He clarified, on a general note, that India's suggestion regarding private standards was for the preparation of a format similar to the one that had been circulated by the SPS Committee aimed at collecting information from Members who were interested in providing the information.¹⁸

323. The representative of Japan noted, in respect of private standards, that his delegation shared the views of the European Communities and the United States: the TBT Committee needed to distinguish between a standard under TBT Agreement and a "private standard".

324. The representative of Egypt noted that the Committee was at an early stage of understanding what the relevance of the TBT Agreement was to the private standards; no actions or decision could be taken in the Committee before an informative discussion had taken. What was needed was an exchange of opinions and ideas, not a legal discussion on definitions and scope. Moreover, the TBT Committee should not fall behind other Committees that were already discussing the issue.

325. The representative of Cuba agreed with India that the definition of a standard in Annex 1 of the TBT Agreement was sufficiently broad to be able to allow for a relevant discussion within the TBT Committee. Because the issue had not been adequately analyzed and time was short Cuba suggested that delegations continue to analyze this topic and that the Members recommend that discussion be perused in the Committee as part of its future work.

326. The Chairman concluded by noting that during the discussion delegations had focused mainly on the issue of private standards – although other proposals on the table also dealt with other aspects of standards. He noted that it was clear from the interventions that there were concerns from a significant number of developing country Members about the negative impacts on market access of private standards. In general, it was possible to say that the TBT Committee's discussion of private standards was at the early stage and several delegations were seeking continued debate and dialogue. Some delegations had also stressed the need for the TBT Committee to consider the work of other committees in this area, particularly the SPS Committee, as well as the work of other organizations. It had also been pointed out that any discussion of private standards needed to take place without prejudging any legal aspects, including the scope of the TBT Agreement.

327. The Chairman also pointed out that, more generally, the importance of technical assistance in the area of standards was stressed: it remained important to build the capacity to participate in the work of international standardization bodies and to reinforce or build capacity to comply and show conformity with such standards. Members also expressed a wish to continue to exchange information about the benefits of the use of international standards and a few studies and work of other organizations had been mentioned.

¹⁸ See G/SPS/W/232 and G/SPS/GEN/932.

4. Transparency

(a) Notifications

(i) *Technical regulations and conformity assessment procedures*

328. The representative of the European Communities introduced his delegation's paper on transparency (G/TBT/W/309). He pointed out that the EC paper reviewed the existing body of recommendations in the field of transparency and that, in his delegation's view, some of these recommendations were not fully applied by Members. The paper also described the EC experience on the adjustments, which had been made in the EC internal practice to comply with those recommendations. In some cases the paper proposed suggestions on how to further enhance the implementation of the transparency provisions contained in the TBT Agreement.

329. With respect to the proposed recommendations on notifications, the representative of the European Communities stressed that there were cases where measures which should have been notified were not notified. This could be due to the lack of internal regulatory coordination mechanisms. In some cases, however, it could also be a deliberate choice of Members not to notify certain measures which were considered as framework legislation requiring further implementing measures. His delegation believed that this deprived Members from the opportunity to address potential concerns at a sufficiently early stage. There could also be cases in which it could be difficult to determine the appropriate timing of notification, in particular when measures were developed by national parliaments where procedures might be more complex, involving in some cases different drafts being simultaneously discussed. His delegation was interested in other Members' views on these issues.

330. The representative of the United States agreed with the European Communities that in some instances technical regulations and conformity assessment procedures were not being notified as required under the TBT Agreement, or, that they were only being notified after they had been adopted and agreed. The implementation of the notification obligation could be improved. However, his delegation disagreed that the Committee should interpret the scope of that obligation. The Committee's efforts would be better focused on ways to improve Members' notification practice, for example by continuing discussions on ways to promote better internal coordination and application of good regulatory practices. In this regard, the United States emphasized the importance of Members having mechanisms in place for effective internal coordination and drew the Committee's attention to the US proposal in this regard (G/TBT/W/315).

- *Submission of notifications (Format and Guidelines)*

331. The representative of Singapore introduced the proposal contained in G/TBT/W/312.¹⁹ She explained that the proposal was about the refinement of the TBT notification format in order to create a tracking mechanism on the use of international standards. Article 2.4 of the TBT Agreement encouraged the use of international standards where technical regulations were necessary. In light of the importance of the relationship between international standards and technical regulations, her delegation believed it would be beneficial to monitor the use of international standards in the elaboration of technical regulations. One suggested refinement was to include an additional section in the existing TBT notification format, describing whether the technical regulation was based on a relevant international standard that existed.

332. The representative of Singapore further noted that in the SPS notification format, Members were required to state if the SPS measure was based on any relevant existing international standards.

¹⁹ See also JOB(09)/16/Rev.2, para.14.

If the SPS measure deviated from international standards, Members were required to set out the reasons for this. She pointed out that the Committee could consider adopting the SPS notification format and include a similar section to the existing TBT notification template. Based on the revised template, the Committee could then consider a monitoring mechanism on the extent to which the new technical regulations notified were based on relevant existing international standards. This could enable Members to see where regulatory convergence was higher and where it was low. It would also help Members understand and possibly mitigate regulatory divergences.

333. The representative of Switzerland welcomed the proposal from Singapore. However, she stressed that pursuant to Article 2.9 of the TBT Agreement, Members were only obliged to notify draft technical regulations when no relevant international standard existed or the technical content of the proposed technical regulation was not accordance with the technical content of relevant international standards. Therefore, statistics on the extent to which notified technical regulations were aligned with international standards would not be very useful. Moreover, in the context of trade policy reviews, Members had to inform the Secretariat to what extent national standards were based on international standards. In her delegation's view, it would be better to extract information on the Member's alignment with international standards from the trade policy review reports.

334. The representative of Israel supported Singapore's proposal. His delegation remained confident about the benefits derived from greater transparency. In this respect, Members should take into consideration and, to the extent possible, harmonize their local regulatory framework to existing international standards so as to minimize a negative effect associated with regulatory divergences.

- *Notifications of Proposed Technical Regulations and Conformity Assessment Procedures of local Governments at the level directly below that of the Central Government*

335. The representative of the European Communities introduced his delegation's proposal on the topic (G/TBT/W/309, para. 10).²⁰ He noted that this issue was about effective regulatory coordination, in particular between the central level and the local level. This was particularly relevant to those Members with a federal or a regional structure which delegated substantial regulatory powers to the local level. Notifications of measures taken at a level below the central government level had increased in recent years, but were still below the actual level of regulatory activity at some federal sub-state levels. His delegation encouraged the Committee to continue to discuss ways to improve the coordination between central and local state level. He invited those Members with experiences on this issue to share these so that other Members could learn from those good practices. He also invited the Secretariat to continue to provide statistical information on this matter.

336. The representative of the United States supported the proposal by the European Communities. He noted that in the United States the notification of sub-federal regulations posed some challenges. Despite this, the United States had been able to increase the number of notifications: for example, over the last two years, about 120 sub-federal measures had been notified. Unfortunately the United States appeared to be the only Member that was doing this consistently. He stressed the importance of other Members putting procedures in place to ensure that this obligation was met.

- *Length of time allowed for comments*

337. The representative of Jordan introduced her delegation's proposal contained in paragraph 4 of G/TBT/W/311.²¹ She recalled the recommendation adopted by the TBT Committee that encouraged all Members to provide more than 60 days for comments. Jordan proposed that a 75-day comment period be provided by all Members, especially since many notified documents were not provided in

²⁰ See also JOB(09)/16/Rev.2, para. 15.

²¹ See also JOB(09)/16/Rev.2, para. 16.

WTO official languages, and some of the comment period was consumed in translating the document. The representative of Jordan also noted that some Members established a specific deadline for a submission of comments on the notification format. However in some cases, administrative procedures could delay the circulation of the notification. Therefore, Jordan proposed that a period of 75 days be provided, starting from the date of circulation of the notification.

338. While the representative of Canada understood the need to translate notified measures and the fact that one could not always rely on immediate circulation of notifications, there were domestic processes which needed to be taken into account and which relied on having a fixed closing date for the comments. It could be difficult for domestic processes to be held up by any administrative problem which could occur with the circulation of the notification. Therefore, Canada was of the view that the practice of calculating the 60 days from the date of notification be continued.

339. The representative of Costa Rica presented his delegation's proposal on the subject, contained in G/TBT/W/319, paras. 8-11. In particular, he stressed that notification procedures should provide an effective opportunity for Members to become acquainted with draft regulations and conformity assessment procedures as early as possible. This would help them react quickly to any new requirements which might affect market access. If notifications were to achieve this objective, the obligation to make notifications at an early stage, and not when the measure was at a late stage of development or were already in force, should be further stressed. Making notifications at an early stage provided interested Members with the opportunity to ensure that their comments were duly taken into account.

340. The representative of Brazil echoed Canada's comments on Jordan's proposal. For example, he explained that in Mercosur Members had the obligation to provide a 60 day comment period for common regulations.

341. The representative of the European Communities fully agreed with the proposal by Costa Rica on the need to notify at a sufficiently early stage and to communicate the final version of the adopted text. Concerning the proposal from Jordan, he stressed that in the EC submission (G/TBT/W/309, para. 24(b)) his delegation had suggested that a period of 90 days should be provided when the notification was not in one of the three WTO official languages. His delegation's preference was to keep this aspect of flexibility in the length of time allowed for comments and believed that 60 days was in principle an adequate period of time when the notified text was available in one of the WTO official languages. A longer period of 75 days in all cases, as suggested by Jordan, could be difficult to comply with due to internal domestic constraints and applicable domestic procedures. On the other hand, his delegation agreed with Jordan that a comment period of 60 to 90 days was better than a specific date indicated on the notification form and that his delegation also saw the advantage of certainty if the period of time for comments would start from the date of circulation of the notification rather than from the date of notification.

342. The representative of Kuwait supported the proposal by Jordan to allow 75 days for comments starting from the date of circulation of the notification.

343. The representative of Japan shared the views expressed by Brazil and Canada and believed that 60 days for comments was an adequate period.

344. The representative of China supported the point that the comment period should be calculated from the date of circulation of the notification. Indeed, China always provided a comment period of 60 days starting from the date of circulation of the notification.

345. The representative of Chile agreed with Jordan's proposal that the comment period should be calculated from the date of circulation of the notification. However, the proposed 75 days for

comments might pose difficulties. For example, in Chile, there was a Decree on Good Regulatory Practice which required institutions dealing with technical regulations or conformity assessment procedures to leave a period of at least 60 days for comments. This could be longer than 60 days, but could not be definitely set to 75. The comment period could be extended when requested. She stressed the importance of Members leaving an appropriate comment period on the notified measures. Indeed, sometimes difficulties arose when Members did not provide any comment period at all.

346. The representative of Argentina also agreed that the comment period should be calculated from the date of circulation of the notification. He supported the comments made by the European Communities on this point.

347. The representative of Egypt supported the proposal to calculate the comment period from the date of circulation of the notification. He also agreed with a proposal by the European Communities to extend to 90 days the comment period when the measure notified was not in one of the WTO official languages.

348. The representative of Cuba supported the proposal from Jordan and agreed that the time for comments should be calculated from the date of circulation of the notification. She also supported the proposal by Costa Rica in this respect. Additionally, she suggested that the Committee should take note of the way Members took into account the comments made on notified measures.

349. The representative of Ecuador supported the proposal from Jordan. In respect of the length of time for comments, his delegation's preference was 90 days.

350. The representative of Mexico stressed that the debate on transparency should focus on how to comply with the existing set of obligations and recommendations. He pointed out that very few Members were complying with the recommended period of 60 days. In some cases, notifications were made and measures entered into force immediately. In other cases, short comment periods of 15-20 days were granted. Therefore, he believed that Members should at least comply with the recommended comment period of 60 days, starting from the date of circulation of the notification. Furthermore, in many cases, comment periods were established by domestic legislation. In the case of Mexico, for example, public consultation began from the moment of the publication of the regulation in the official gazette. If a different length of time for comments from WTO Members was granted, this would have consequences on the time for comments granted domestically.

351. The representative of the United States supported the points made by Mexico.

- *Handling of comments*

352. The representative of the European Communities presented his delegation's proposal on the issue (G/TBT/W/309, para. 24). He stressed that proper handling of comments was key to enabling an effective exchange between Members on notified drafts. Although the provisions of the TBT Agreement did not provide any obligation to respond in writing to comments made, the TBT Committee had recognized that a written response to comments received was the most effective way to enable a real dialogue and effective exchange between the notifying and the respondent party. He pointed out that in some cases Members did not or rarely provided written answers to comments received. This could be due to a lack of operational capacity of the notification and enquiry points. When this was the case, technical assistance projects could be used to build capacity, especially in developing and least developed countries. However, in other cases, it was a deliberate choice of some Members not to provide a written reply before the adoption of the notified text. His delegation believed that such an approach was not fully consistent with the aim of Article 2.9.4 and 5.6.4 of the TBT Agreement. He pointed out that the Committee should reaffirm the importance of the recommendation to provide written replies to comments made. His delegation was also interested in

continuing to explore ways to further improve effective implementation of the provisions of the TBT Agreement on the handling of comments.

353. The representative of Jordan introduced her delegation's proposal on the topic (G/TBT/W/311, para. 2). She pointed out that the Secretariat could provide a platform for notifying authorities to post comments received from other Members and responses. She also recalled that in the Fourth Triennial Review the Secretariat had been invited to prepare a list of national websites based on information provided by Members.²²

354. The representative of Mexico was in favour of the creation of a website where comments sent and replies received could be posted. He stressed the importance of providing written replies to comments.

355. The representative of Argentina supported the proposal made by the European Communities.

356. The representative of the United States pointed out that his delegation had no difficulty in reaffirming previous Committee's recommendations. However, his delegation did not support re-writing or re-casting those recommendations as the EC proposal appeared to do. He emphasized that "encouraging" and "voluntarily" were key elements in the existing Committee's recommendations on this issue and these terms should remain prominent in any new text. More fundamentally, the aim of Article 2.9 of the TBT Agreement was to ensure that Members took comments and the results of discussions into account. He noted that the US recommendation in its submission on Good Regulatory Practice²³ which encouraged Members to share experiences in this regard sought to address this issue from a performance perspective. The EC proposal sought to address the obligation to take the comments into account from a design perspective, using Members' filing of written responses to comments prior to finalizing the measure as a proxy for taking comments into account. He pointed out that this proxy would not necessarily indicate whether the Member took the comments received into account in finalizing the measure, for example if the response was simply dismissive of the concerns raised. His delegation encouraged those Members who chose to provide meaningful written responses to comments prior to finalizing measures to continue to do so, as these responses could contain useful information and noted that the United States included, along with the publication of its final measures, an explanation of how it took into account the comments received, whether oral or written.

357. With respect to the proposal from Mexico and Jordan to create a platform to collect comments, the representative of the United States welcomed these expressions of interest in sharing comments and agreed that greater transparency in the exchange of comments could improve understanding in the Committee, particularly by those delegations that did not actively participate in the discussions on specific trade concerns. However, he recognized that these types of websites took resources to create and maintain and would be interested in the Secretariat's views as to whether there were sufficient and appropriate resources at its disposal for such a task. He also wondered whether there were other options available. For example, the United States maintained a single website for all regulatory activities²⁴ and noted that other Members had similar websites. He further noted the 2006 Committee recommendation to request the Secretariat to prepare a list of these websites and sought an update of that information.²⁵

358. The representative of India supported the proposal by Jordan and Mexico.

²² G/TBT/1/Rev.9, page 19.

²³ G/TBT/W/315.

²⁴ www.regulation.gov

²⁵ Information on websites is contained in document G/TBT/GEN/39, Rev.3.

359. The representative of China supported the proposal that written replies of comments should be provided, in particular to comments made by developing Members. If a reply to comments was not received, Members might lose the chance of follow-up consultations to further express positions and make contributions to the final texts of the notified measure. Also, if no information was provided about the development of the notified text, a Member would not be able to pass on relevant information to domestic industry at an early stage. This could undermine the objectives of the transparency obligations.

360. The representative of Switzerland welcomed the EC proposal to share information on comments received and replies thereto. Her delegation also welcomed the suggestion by Jordan and Mexico that the Secretariat provide a central platform where all comments and written replies could be posted. She also suggested that the Secretariat could monitor the number of comments and replies issued by the Members and could publish statistics in this respect.

361. The representative of Canada pointed out that in some cases not providing written replies to comments was not a matter of principle, but a matter of law. In Canada, any regulation was cabinet confidence until it was published. While Canada tried to reply in writing to all comments received, it was sometimes limited in how much detail could be provided as a result of its domestic laws. However, even if the written replies were not as complete as other Member might like, comments were taken into account. The representative of Canada also pointed out that in her country comments were not published. Therefore, her delegation would not support the proposal by Jordan and Mexico to create a platform where all comments and replies thereto could be published. She also wondered whether the Secretariat would have the resources to carry out this task.

362. The representative of Cuba stated that the various proposals on the handling of comments constituted a good basis for the Committee's work. However, she was concerned about the cost implications of some of the proposals, for example the creation of websites. She also suggested that experiences in other Committee should be considered.

363. The representative of the European Communities pointed out that the purpose of his delegation's proposal to provide written replies to comments was not to force unnecessary changes in the laws of some Members. At the same time, he noted that, especially for developing country Members, follow-up would be difficult without a written reply to their comments,. Developed countries had more resources and other means to pursue a dialogue bilaterally with the Members concerned. A reply pointing out what the state of play of the notified draft was and giving a contact point for further information could at least be one step forward. The fact that no response was provided and feedback was only given together with the adopted text was not, in his delegation's opinion, a satisfactory response to the legitimate request to have a meaningful dialogue with notifying parties. If there were constraints due to internal laws, Members could reconsider whether those constraints, for instance on the confidentiality, were always fully justified, or whether the necessity of fully complying with the transparency obligation in the TBT Agreement would recommend a revisiting of provisions in internal laws.

364. The representative of Canada noted that her delegation could certainly provide a reply acknowledging receipt of comments as well as providing a contact point.

365. The Chairman noted that discussions had taken place regarding the importance of handling of comments. There were existing recommendations of the Committee in this regard that could be reaffirmed. He pointed out that the Committee would continue to discuss ways to improve the handling of comments.

- *Follow-up to notifications*

366. The representative of the European Communities introduced his delegation's proposal (G/TBT/W/309, paras 28 and 19), which was in line with the overall goal of achieving the highest degree of transparency throughout the regulatory process, also at the stage *after* the adoption of a measure. First, his delegation recommended that Members should systematically communicate the adopted text, specifying the date of publication and entry into force by means of addenda to the original notification. Second, when an existing technical regulation or conformity assessment procedure was amended this should be notified as a new notification. His delegation believed that it would be clearer if this notification had a different number from the notification of the original measure. Some cases had been found where revisions had been notified as addenda and this was rather confusing as it was not immediately clear whether the notified text was a new notification. However, he noted that other Members found it useful to have a link to the original notification and that they would rather favour the notification by means of an addendum or a revision. He believed that a common understanding on how to go about the notification of amendments to existing text was needed and that it could be helpful to clarify when an addendum, a revision or a new notification should be made. The Committee could agree on some basic principles to be followed in those cases and to recommend a practice to be followed by all Members.

367. The representative of Jordan introduced her delegation's proposal (G/TBT/W/311, para. 6) which suggested that the notification of the availability of the final text be made directly upon the adoption of the technical regulation or conformity assessment procedure, with emphasis on the actual date of entry into force.

368. The representative of Costa Rica pointed out that his delegation's submission (G/TBT/W/319, para. 11) was similar to the EC and Jordian proposals. Costa Rica also considered it important that Members notify the final version of technical regulations and conformity assessment procedures which were adopted thus providing certainty to exporters. The TBT Committee should therefore establish appropriate procedures in this respect.

369. The representative of Israel supported the proposal by the European Communities and stressed that Israel was already in practice complying with its terms. He encouraged Members to provide details and updated information related to the implementation and modification of domestic regulations. Greater transparency and enhanced communication among Members would help prevent negative effects on trade flows.

370. The representative of Argentina stressed that, while the procedure to follow up and monitor by means of addenda had been useful, sometimes substantive modifications to notified texts had remained hidden in the addenda. Therefore, he supported the proposal by the European Communities.

371. The representative of Cuba supported the proposal by the European Communities and Costa Rica. Any planned changes to notified regulations should be notified as soon as possible to allow the possibility to provide comments and to initiate discussions on their content. Appropriate mechanisms for this purpose needed to be developed. She also stressed that the Committee should be more specific about the meaning of "taking comments into account". She noted that often notifications were made and although Members expressed concerns, the regulation was adopted, in many cases without taking into account the concerns expressed. She believed that this was an essential aspect for the smooth operation of the Committee.

372. The representative of Egypt sought some clarification on the EC proposal of notifying the adoption of the final text by means of addenda. He noted that in the notification form Members were required to specify the proposed date of adoption and of entry into force of the notified measures. He was not sure that Members needed to notify again by means of addenda when the measure was

adopted, as this could be burdensome for notification authorities, in particular when no change on the date of adoption had occurred. If the date of adoption of the measure or its content changed, then this should be notified to the WTO.

373. The representative of the European Communities pointed out that it was a rare occurrence that the date of adoption and the date of entry into force as indicated in the original notification was the actual date of adoption and entry into force. His delegation believed that for the sake of transparency, legal certainty and to give adequate information to economic operators it was important that the final adopted text accompanied by the final date of adoption and entry into force be communicated. He agreed that this was an additional burden on the enquiry point, but believed that the advantages of this practice outweighed the costs. He believed that the TBT notification system was the most effective one because it was the only tool that reached WTO Members in real time.

374. The representative of Egypt suggested that the EC proposal could be modified to specify that an addendum to the original notification providing information on the date of adoption and entry into force of the notified measure should be provided in case there was a change in the date of adoption and entry into force as announced in the original notification form.

375. The representative of the European Communities added that often the original notification did not provide a date of adoption or entry into force, because this was known only *after* the notification had been made. He agreed that if dates set out in the notified text was correct, then no new notification needed to take place. However, this would be rare.

376. The Chairman pointed out that the Committee could discuss a harmonized practice on how to notify modifications in the notified texts and the adoption and entry into force of the final text of the notified measures.

(b) Dissemination of Information

(i) *Publication*

377. The representative of Mexico introduced his delegation's proposal that the Committee establish procedures to ensure the fulfilment and implementation of the obligation under Article 2.9.1 of the TBT Agreement (G/TBT/W/313, para. 7). He stressed that his delegation had brought this issue to the attention of the Committee for a long time, since the Third Triennial Review of the TBT Agreement. However, not much progress had been made on the implementation of this provision, which entailed the publication of a notice at an early stage that work was underway on a technical regulation or conformity assessment procedure. There were not many examples of Members following an appropriate practice in this regard. Mexico always notified the national standardization programme which was published at the beginning of the year. In that programme, Mexico included the list of all issues that would be subject to regulation in the forthcoming year as well as those subject to the preparation of voluntary standards. His delegation believed that this was a practice which could be useful for other Members as well. It would provide useful information for all actors involved, enabling them to be prepared when the publication took place or when public consultation occurred. He suggested that the Committee reiterate the importance of Members sharing this kind of experience.

378. The representative of Costa Rica supported the proposal by Mexico.

(ii) *Texts of Notified Technical Regulations and Conformity Assessment Procedures*

379. The representative of the European Communities introduced his delegation's proposal (G/TBT/W/309, paras. 12-13) for the Committee to reiterate its earlier recommendation that Members provide direct access to the text of the notified draft by indicating in the notification form the link to

the webpage where the full text could be found or otherwise provide an electronic version of the text to the WTO Secretariat which would then circulate the link to Members. This practice was already applied by the European Communities and did not pose an additional burden on the TBT enquiry point; it had resulted in a great value added for other Members who had been given access to the full text of EC notified drafts. He encouraged other Members, especially developed Members, to follow this practice consistently.

380. The representative of Argentina supported the proposal by the European Communities and stressed that the proposal also invited Members who did not yet give access to the text of their measure to consider ways of doing so and to provide information as to why they had not been able to do so.

381. The representative of Egypt recalled that the Secretariat had put in place a facility whereby Members could send the text of the measure together with the notification and this text would then be stored on a server and a hyperlink created in the notification form.

382. The representative of China agreed with the proposal of the European Communities. He believed that a hyperlink in the notification form would save considerable time to make comments within limited time period.

383. The Chairman concluded that the Committee was ready to reaffirm its earlier recommendation to indicate a website in the notification form where the draft text could be downloaded from. Members could also consider using the facility provided by the WTO Secretariat – which the Committee had already agreed upon – whereby texts could be sent to the Secretariat in pdf form and a hyperlink in the notification form would be created by the Secretariat.²⁶

(iii) Provision of Translations

384. The representative of the European Communities introduced his delegation's proposals on the provision of translations (G/TBT/W/309, paras. 14-17) and stressed that the proposals were made with the aim of making the comment period as effective as possible, in particular when notified texts were not in one of the WTO official languages and needed therefore to be translated. He recalled that the TBT Committee had recommended that Members who translated these drafts could share these unofficial translations with other Members, either by posting them on their website or providing those translations to the WTO Secretariat for further dissemination. His delegation was of the view that this was a very useful, especially for developing countries which would have faster access to texts in a language which would be understandable for them. He noted that the European Communities was the only Member which was applying this recommendation and wondered why other Members who were also translating measures were not sharing unofficial translations with the WTO. He invited those Members to explain why this recommendation had not been followed and if there was any impediment in their system to share such unofficial translations with other Members.

385. The second part of the EC proposal dealt with the comment period in cases when a notified text was not in one of the WTO official languages. His delegation believed it would be desirable to provide, in such cases, an extended period for comments of 90 days in principle. In these cases it was also of paramount importance that the description of the content of the notified draft be more detailed in order to give a sufficiently comprehensive overview of the content of the notified measure on the basis of which Members could already start undertaking a preliminary analysis pending the availability of a language version in one of the official languages of the WTO.

²⁶ G/TBT/1/Rev.9, page 24.

386. The representative of Jordan introduced her delegation's proposal (G/TBT/W/311, para. 8) which suggested that notifying Members review unofficial translations of their notified measures and publish them as official, and inform the Secretariat of the availability of such official translations.

387. The representative of Mexico also introduced his delegation's submission on the subject (G/TBT/W/313, paras. 11(a) and 11(c)) and stressed that, like the European Communities, his delegation also believed that unofficial translations could considerably improve transparency and allowed for a better understanding of notified documents, in particular for developing countries that did not have the financial and human resources to carry out the translations themselves. Sharing translations was a way of saving resources and promoted the sharing of information between Members. He reiterated the importance that Members, particularly developed country Members shared unofficial translations they had. With respect to the EC proposal of extending the deadline for comments when a text was not in a WTO official language, he believed that emphasis should be placed on the fact that it be for developed countries.

388. The representative of India illustrated his delegation's proposal with respect to the provision of translation (G/TBT/W/314, para. 2). He pointed out that the non-availability of a full text in English and other WTO languages was a major obstacle in the examination of TBT notifications by developing countries and in the provision of effective comments. This in turn affected their ability to export once the measure was adopted. Even if English translations were later made available by Members such as the European Communities, this involved some delays and the effective period for providing comments was reduced in the process. He stressed that the WTO Secretariat, with the help of developed country Members, should work out a formal mechanism to make translations of full text in English and other WTO languages to available Members. Also, to make up for the lost time in translation process, the comment period should be at least 90 days. While his delegation agreed that the description of the content of the notified draft should be comprehensive and give a more detailed overview of the envisaged technical regulation or conformity assessment procedure, the WTO Secretariat needed to work out an appropriate format on the basis of suggestions provided by Members.

389. The representative of Brazil recognized the importance of enhanced transparency but considered that the EC proposal on provision of translations could pose a significant burden on Members, especially developing Members, in particular those that did not have a WTO language as its official language. Developing countries would encounter difficulties finding the resources needed to translate every new regulation since there were other priorities in their regulatory activities. Brazil also believed that the proposed comment period of 90 days for notified regulations that were not in one of the WTO languages would affect several developing countries that already had operational difficulties to provide the current 60 day comment period. Moreover, there would also be legislative difficulties to implement this proposed comment period in countries like Brazil.

390. The representative of the European Communities explained that the goal in promoting the sharing of unofficial translation was to *assist* developing countries, precisely because they had more difficulties in translating documents. The recommendation was mainly addressed to developed country Members so that they shared translated documents. Developing countries were the beneficiaries of this recommendation. On the comment period, he stressed that 60 and 90 days were already in the existing recommendations, so his delegation was just referring to current practice.

391. The representative of Kenya noted that Members who made unofficial translations, like the European Communities, might do so only for texts of interest to them, which might not necessarily apply for developing countries. The issue of full texts that were only made available in languages other than WTO official language had been a problem especially for developing and least developed countries. Therefore her delegation supported the proposal by India that the Secretariat could look into ways of coming up with a centralized formal mechanism to make translations of full text

available in English and other official languages. This would make it possible for Members to evaluate the implication of such regulations on their exports.

392. The representative of Korea agreed that it was important to make translations available to provide more information to WTO members. However, he pointed out that technical regulations were, by their very nature, different documents from ordinary legal texts and that sometimes referred to standards which were very long, and whose content was difficult to translate. Therefore, he expressed reservations about the EC proposals on this issue.

393. The representative of Singapore supported the proposals made by the European Communities, Jordan, Mexico and India. Even if unofficial, the translated text would promote transparency which was the key area of the Committee's work. Not only would this facilitate a more effective comment procedure, it would also help Members to better understand and comply with the technical regulation and to minimize disruption to trade flows.

394. The representative of Argentina believed that the issue of translations was important for developing countries due to the lack of resources to make the necessary translation of notified texts which were in languages other than WTO official languages. He also emphasized that there was no mandatory requirement for developing countries to provide translations in official WTO languages. He noted that often work was carried out to translate notified texts and when the translation was finally received the comment period had already elapsed. He believed there should be some flexibility from Members to extend the comment period to 90 days. He further supported India's proposal for an appropriate format to ensure that the description of the content of the notified draft was comprehensive and provided a more detailed overview of the envisaged technical regulations.

395. The representative of Chile agreed with the proposal by the European Communities to encourage developed country Members to provide unofficial translations. On the proposal of Jordan for the notifying Member to analyze unofficial translations, her delegation believed that this posed an excessive burden on notifying Members.

396. The representative of Colombia expressed support for the proposals by the European Communities.

397. The representative of China supported the EC proposal that Members should be encouraged to share unofficial translations on documents referred to in the notification. He appreciated the work done by the European Communities in this respect. However, with regard to the EC proposal that Members whose notified texts were not in an official WTO language provide a 90-day comment period, his delegation shared the same concerns expressed by Brazil. In addition, it was his delegation's view that Members whose language was not an official WTO language faced even bigger challenge in terms of burden of translation work. Most of these Members were developing country Members, which made this challenge severe. He drew Members' attention to the recommendation adopted by the Committee at the Third Triennial Review (G/TBT/13, para 26) in which the Committee agreed to recognize that, to improve the ability of developing countries Members to comment on notifications, and consistent with the principle of special and differential treatment, developed country Members were encouraged to provide more than a 60 day comment period. His delegation wished to reiterate this recommendation that developed country Members should provide more than 60 days period for developing country Members to have sufficient time to present their comments, while developing country Members and LDCs were encouraged to provide a 60 day comment period.

398. The representative of the United States agreed with the point made by Brazil, Korea and China with respect to translations. His delegation did not support differential obligations and procedures based on the mother tongue of WTO Members. With respect to Jordan's proposal on

translations, it was his delegation's view that unofficial translations should remain unofficial. Official translations were more costly, more time consuming and carried legal liabilities. If all unofficial translations were forced to be official, it was likely that many Members would be unwilling to provide translations, thus reducing the availability of translations rather than improving it.

399. The representative of Mexico emphasized that his delegation supported the proposal to encourage sharing of translations, but did not support that more days should be provided for comments by those countries whose notified measures were not in a WTO official language. He also shared Chile's views with respect to the proposal from Jordan on the revision of unofficial translations.

400. The Chairman noted that from the discussions it was clear the provision of translation was particularly important for Members. He recalled that a mechanism for the notification of the existence of unofficial translations had been put in place in December 2007.²⁷ Since then, 170 supplements to notifications of the existence of unofficial translations had been received and circulated. From the number of proposals on this issue, it was clear that Members continued to be interested in how to improve access to and sharing of translations of notified text. In light of this, the Committee could possibly reaffirm the earlier recommendation for Members to share unofficial translations by posting them on websites or providing such translations to the Secretariat to the established mechanism for further dissemination. The Committee could consider ways to further improve transparency when notified text were not in one of the WTO official languages including, for example, a more detailed description of the measure in the notification. In order to strengthen understanding of the issue the Secretariat could be to provide statistical information on unofficial translations.

(c) Enquiry Points

401. The representative of the European Communities introduced his delegation's proposal (G/TBT/W/309, paras. 7-8). He stressed that a well functioning enquiry point with good operational capacity allowed better compliance with the transparency obligation and more effective participation of Members in the mechanisms that the TBT Agreement provided in relation to the notification of draft texts. He highlighted that the EC submission discussed potential causes for lack of operational capacity in enquiry points and also pointed at technical assistance as one of the means to enhance such capacity in developing countries. He explained that the European Communities had been involved in several such successful projects and also regularly welcomed TBT experts from developing countries on study visits. Sharing experiences on how the EC TBT Enquiry Point had been set up had contributed to creating better operational capacity. It was important to explore how technical assistance could be used in order to overcome difficulties developing countries in particular faced in this area.

402. The representative of Mexico pointed out that in his delegation's submission there was a section on technical assistance (G/TBT/W/311, para. 31), which also related to enquiry points.

403. The representative of Korea sought more information on the type of technical assistance that the European Communities provided to enquiry points and on how to make a request in this respect.

404. The representative of the European Communities explained that EC technical assistance projects were normally four or five years long and, whenever there was a TBT component, building the operational capacity of enquiry points was one of the typical activities that was undertaken in the framework of such projects. Potential beneficiary countries were encouraged to flag their interest in receiving assistance in this area through the EC delegations in these countries.

²⁷ See G/TBT/GEN/66.

5. Technical Assistance

405. The representative of Jordan proposed that the Secretariat circulate the format for the voluntary notification of specific technical assistance needs and responses (developed by the Committee in 2005) at the end of every year (G/TBT/W/311).²⁸ Also, Jordan proposed that the Secretariat provide feedback to countries requesting technical assistance on the status of their request, as well as feed-back to the provider of technical assistance. Finally, Jordan also proposed that the Secretariat include GRP in its technical assistance and training plan in the form of a specialized workshop.

406. The representative of Mexico drew the Committee's attention to the well-known problem of high turn-over among officials dealing with standards and conformity assessment in developing countries. Frequently, in Mexico, officials that had been trained were attracted by the private sector and when they left this resource was lost to the government. To counter this, Mexico was proposing to set up a certified quality assurance system based on international standards. More detail is set out in Mexico's proposal (G/TBT/W/313, paras. 26.34). Such a system would be superior to the traditional technical assistance activities (workshops, seminars, etc.), for instance because it strengthened institutions – a permanent benefit for the government.

407. The representative of Jordan wished to emphasize the need to enhance the capacity of enquiry points. It was noted that a more targeted type of assistance directed at the operation of enquiry points would be beneficial, for instance through targeted e-training courses. The representative of Jordan also brought up the importance of interaction between Members' enquiry points and pointed at mentoring systems as a possible option to be explored. Both these ideas could enhance efficiency of technical assistance in the TBT area.

408. The Chairman concluded by recalling that the Committee's work and decisions in the area of technical assistance were captured on pages 29-33 of document G/TBT/1/Rev.9. He noted that Members had, on a regular basis, exchanged experiences and information on technical assistance in order to enhance the implementation of Article 11 of the TBT Agreement. In fact, technical assistance had been considered an area of priority work for the Committee since its establishment: it figured on the agenda of the Committee on a permanent basis. The Chairman suggested that the Committee could reaffirm the importance and priority attributed to technical assistance and further emphasize the weight of technical assistance in the areas of GRP and transparency in particular. In the area of transparency, one example of targeted technical assistance could be activities aimed at enhancing the operation of enquiry points, for instance through e-training or mentoring mechanisms. The Committee could also stress the importance of supply side capacity building in the area of conformity assessment for the development of appropriate quality infrastructure and efficiency using national and all regional expertise to this effect.

6. Operation of the Committee

(a) Consideration of Specific Trade Concerns (STCs)

409. The representative of Canada introduced her delegation's proposal on specific trade concerns and noted that the version currently being discussed (JOB(09)/50) was the result of a discussion with several delegations.

410. The representative of India supported the Canadian proposal and drew the Committee's attention to some minor suggestions provided in their submission (G/TBT/W/314). In particular, India proposed that developing countries should have 20 days (instead of 10 days) to respond

²⁸ G/TBT/16, dated 8 November 2005.

appropriately to the STCs raised against them and that these (those STCs raised against developing countries) should be communicated to the at least one month in advance.

411. The representative of Costa Rica noted that his delegation attached particular importance to the discussion of STCs and that it was important for the Committee to ensure that discussions were effective. Costa Rica suggested that the Committee should evaluate the effectiveness of these discussions – this could be done through an analysis, including information on concerns that had been dealt with (solved) and those that had not been dealt with (still pending). It would also be important to know the time it had taken to deal with STCs, whether they remained on the agenda of the Committee and which Members had been involved. Much of this information was, in fact, already included in the Secretariat's document G/TBT/GEN/74/-series.

412. The representative of Switzerland expressed appreciation for the Secretariat's more detailed draft annotated agenda containing information about the STCs to be raised. In her delegation's view, the deadlines proposed by Canada were appropriate; it would not be feasible to announce STCs more than 12 days before the meeting. She stressed that it was important that Members maintained the right and opportunity to support other Members raising a STC (even if they had not flagged an intention to raised it themselves).

413. In response to the point made by Switzerland, the representative of Canada clarified that the intention was to ensure that Member countries be made aware in advance that a particular concern would be raised – whether this would be raised by one or more Members was a different matter.

414. The representative of Japan supported Canada's proposal. In his view it would contribute to a more organized and efficient discussion of STCs in the TBT Committee. Japan agreed that ten days was sufficient time to prepare for the responses to STCs raised and set out in the annotated draft agenda.

415. The representative of Argentina supported the proposal made by Canada and agreed with India that a period of 20 days should be given to developing countries. This period of time would be particularly important for developing countries.

416. The representative of Brazil was of the view that Canada's proposal would enhance transparency and predictability in the Committee's procedures while maintaining a degree of flexibility for all Members. Brazil suggested that the provisions contained in item (c) of the proposal (in JOB(09)/50) also be valid for STCs that were included after the deadline had passed.

417. The representative of New Zealand questioned whether the two-day interval between deadline for submission of STCs and circulation of the annotated draft agenda was enough time for the Secretariat. In terms of the timeframes provided, it was New Zealand's understanding that the STCs would already have been raised bilaterally between the Members concerned before the matter had escalated to the TBT Committee. Therefore, the concerns raised would not normally come as a surprise. The timeframes in Canada's proposal were thus adequate. Nevertheless, flexibility was important and this was also recognized in the proposal. In New Zealand's view, there were other practical ways to improve efficiency of TBT Committee meetings (which did not necessarily require a recommendation from the Committee). For instance, Members could associate themselves with previous statements or statements from other Members rather than individually reading out what was already on the record or what had been said by another delegation at the same meeting. Similarly, Members could prepare joint statements where concerns were similar.

418. The representatives of the United States and European Communities supported the proposal from Canada to improve the operation of the Committee and agreed with the time periods in the Canadian proposal. In addition, the representative of the European Communities supported the

above-mentioned points made by New Zealand and suggested that longer, prepared statements could be submitted for the record in writing and only briefly summarized orally.

419. The representatives of China, Hong Kong, China and Mexico expressed general support for Canada's proposal. It was also noted that the Committee was, in fact, already going in this direction as demonstrated by the more detailed annotated draft agenda and the G/TBT/GEN/74 document series prepared by the Secretariat.

420. The Chairman concluded by noting that there appeared to be general agreement on the need to increase the efficiency of the Committee's discussion of STCs and that the Canadian proposal was a good step in that direction as it would enhance both transparency and predictability in the discussion. The Committee would seek to recommend procedures along the lines of the Canadian proposal that would be flexible and give appropriate timeframes. Some Members had also highlighted the need for delegations' to avoid repeating arguments that had been previously made and/or that had been recorded in previous minutes.

(b) Work Programme on Technical Regulations

421. The representative of Korea introduced his delegation's proposal that the Committee establish a work programme to evaluate the trade restrictive and trade distorting effects caused by technical regulations, in accordance with Articles 13.2 and 15.4 of the TBT Agreement (G/TBT/W/316, para. 6).

422. The representative of Mexico noted that his delegation had, during the Trade Policy Review Process, expressed concern about the increase in unnecessary obstacles to trade. However, it was not clear to Mexico whether the WTO Secretariat could undertake the study Korea was suggesting. The Committee could consider consulting with other international organizations and bodies who possibly might have a study on the matter: for instance the World Bank or the OECD. Although this was an important issue to discuss – and the Committee could continue doing so at its regular meetings – it did not necessarily have to be part of the triennial review process.

423. The representative of Israel welcomed the Korean proposal – it was useful to consider and analyze the impact that technical regulations could have on trade by sharing knowledge and expertise among Members.

424. The representative of the United States agreed with the concerns raised by Mexico. While the United States shared Korea's concerns about the need to ensure that technical regulations were not inconsistent with the TBT Agreement, it was important to note that *more* regulation did not necessarily mean *more* unnecessary trade restrictions. In fact, the growing number of notifications and STCs discussed in the Committee could reflect a better implementation of the Agreement itself. The United States emphasized, in particular, the difficulty of estimating the aggregate trade impact of regulatory measures and noted that many of the issues the Committee had discussed under good regulatory practice and regulatory cooperation were, in effect, ways for the Committee to promote practices to reduce unnecessarily restrictive regulatory outcomes.

425. The representative of Korea said that it was, in his delegation's view, time for the WTO Secretariat to take over the responsibility to take stock of the issues raised in the Korean proposal, particularly in light of the worsening economic situation. For instance, a review of research on the topic could be undertaken.

426. The representative of the European Communities echoed the positions of the United States and Mexico: while the points made by Korea were interesting, the complexity of the analysis that Korea proposed to undertake went beyond the scope of the Committee's work and the WTO

Secretariat's resources to undertake. It was also noted that TPRB was already engaged in a relevant exercise that also covered TBT and SPS measures and that it was important to avoid duplication.²⁹

427. The Chairman concluded the discussion of the various proposals on the table by giving delegations the opportunity to provide further comments, in writing, on the proposals discussed at the meeting until Friday, 17 July 2009.³⁰

V. TECHNICAL COOPERATION ACTIVITIES

428. The Chairperson drew the Committee's attention to a document containing the Secretariat's technical assistance activities (G/TBT/GEN/86).

429. The representative of the Republic of Korea drew the Committee's attention to their technical assistance activities undertaken during the first semester of 2009 (G/TBT/W/322).

VI. UPDATING BY OBSERVERS

430. The Representative of ISO shared information on relevant work in ISO. On conformity assessment, he informed the Committee that ISO/IEC international standards were widely used in the market place and provided a common basis for mutual recognition of conformity assessment results. He highlighted the ISO/IEC Guide 68:2002, "Arrangements for the recognition and acceptance of conformity assessment results" which gave guidance on the content of multilateral recognition arrangements and recommended this guide for WTO Members putting in place government-to-government mutual recognition agreements. He emphasized the importance that the ISO Committee on Conformity Assessment (CASCO) placed on market surveillance in the conformity assessment process and the need for guidance in this matter. He said progress was being made in the development of an information document compiling best practices in the field of market surveillance. He informed the Committee of a joint ISO/UNIDO guidance document on conformity assessment entitled "Building trust" which would be published in September 2009 and recommended this manual as a reference tool for those involved in conformity assessment and trade. He also informed the Committee of regional awareness workshops on conformity assessment which had taken place since 2004.

431. With regard to private standards, the representative of ISO expressed appreciation for the suggestions made by some Members that international standardizing bodies such as ISO should be invited to contribute to work that the TBT Committee might undertake on this issue. Should the Committee decide to proceed in this way, ISO would be pleased to be involved.

432. On good regulatory practice, the representative highlighted the publication "Using and referencing ISO and IEC standards for technical regulations" which had been published in September 2007. The first three-day course based on this publication would take place from 30 June – 2 July for ISO members in Central and Eastern Europe and Central Asia. This publication could be downloaded from the ISO and IEC websites.³¹

433. The representative of ISO also brought the Committee's attention to a recent workshop jointly held with the International Energy Agency and the IEC on energy efficiency standards. This workshop brought together 290 experts from the public and private sector. The IEA, ISO and IEC established high-level committees to assess gaps in current energy efficiency standards portfolios.

²⁹ WT/TPR/OV/W/2, dated 15 July 2009.

³⁰ A fax communication to this effect was sent by the Chairman to all Members on 26 June 2009.

³¹ http://www.iso.org/iso/standards_for_technical_regulations.pdf and http://www.iec.ch/news_centre/onlinepubs/about_pubs.htm

Commitments were made to accelerate the rate of standards development in this field. An International Standard on energy management (ISO 50001) was currently being developed and was due to be published in 2010.

434. The representative of the IEC provided the Committee with an update on its activities during the first half of 2009 (G/TBT/GEN/88). Some of the activities highlighted were: the increase in IEC membership and participation in the Affiliate Country programme from 155 to 159 countries; the IEC new technical committee on Ultra High Voltage; implementation of the IEC recommendations on electrical energy efficiency; progress of the "Smart Grid"; and the IEC Affiliate Country Programme in the field of electrical safety. The IEC also developed guidelines encouraging stakeholders in developing countries to use the free IEC standards for national adoption so as to enable IEC Affiliates to take an active part in the preparation of IEC International Standards, as recommended by the TBT Committee. In addition, she informed the Committee about an upcoming workshop for industrializing countries on safe use of electrical energy in mining and in the chemical, oil and gas industries to be held during the IEC General Meeting on 18-22 October in Tel Aviv, Israel.

435. The representative of the ITC updated the Committee on activities in the International Trade Centre (G/TBT/GEN/89). He highlighted the publication of the "World Directory of Information Sources on Standards, Conformity Assessment, Accreditation, Metrology, Technical Regulations, Sanitary and Phytosanitary Measures".³² In addition, he informed the Committee that the ITC would publish the second edition of "Export Quality Management – An Answer Book for Small and Medium-Sized Exporters" in 2010. The representative of the ITC also updated the Committee on TBT related projects in Bangladesh, Benin and Chad.

436. The representative of the UNECE informed the Committee that the 19th session of the Working Party on Regulatory Cooperation and Standardization Policies would take place on 25-27 November 2009. Given the interest expressed by a number of delegations in the use of risk assessment and management methodologies as a part of good regulatory practice, MRAs and conformity assessment, she informed the Committee that a conference on risk assessment and management would take place back to back with the Working Party. This conference would review the following: risk assessment and management methodologies be used as a basis for the choice of technical regulation objectives and in the decision of whether a regulation is at all needed; risk assessment in the choice of conformity assessment options: suppliers' declaration of conformity vs third party assessment; and, mitigating risks on the markets for consumer products: risk assessment options and market surveillance authorities. The representative invited all Members with expertise in these areas to contact the UNECE secretariat should they be willing to contribute to the Conference. A provisional programme would be circulated mid July.

437. Regarding the Working Party, the representative updated the Committee on two initiatives undertaken. The first was on the establishment of practical mechanisms to facilitate trade at a plurilateral level among interested countries in specific industrial sectors. Giving the example of earthmoving machinery, she explained that an adequate assessment of such complex machinery often only existed in the producing companies themselves. A number of countries therefore relied on Suppliers Declaration of Conformity (SDoC) but many others used third party certification. Following the Working Party's initiative, third party certification would take place on the basis of some agreed principles so as to avoid replication of tests and to make best use of expertise. The second initiative concerned the on-going work in the area of market surveillance where there was a first draft of "Common Terminology for Market Surveillance" and a guidance document for authorities.

³² <http://www.intracen.org/eqm>

VII. DATE OF THE NEXT MEETING

438. The next regular meeting of the TBT Committee will take place on 5-6 November 2009.
