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Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 5-6 NOVEMBER 2009

Chairperson: Mr. Ami Levin (Israel)

Note by the Secretariat[1]

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

I. ADOPTION OF THE AGENDA

1. The Committee adopted the agenda contained in WTO/AIR/3457.

II. IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

A. STATEMENTS FROM MEMBERS UNDER ARTICLE 15.2

2. The Chairman recalled that the latest list of statements submitted under Article 15.2 of the TBT Agreement was contained in G/TBT/GEN/1/Rev.8, issued on 2 March 2009. Since the previous meeting of the Committee, Colombia and Egypt had submitted revisions to their statement under Article 15.2 (G/TBT/2/Add.18/Rev.3 and G/TBT/2/Add.34/Rev.1 respectively). 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.

3. The Committee took note of the information provided.

B. SPECIFIC TRADE CONCERNS

1. New Concerns

(i) Saudi Arabia, Bahrain and Kuwait – Halal Food Requirements (G/TBT/N/KWT/20; G/TBT/N/BHR/131; G/TBT/N/SAU/69)

4. The representative of Australia raised concerns about certain proposed requirements for accreditation of Halal food certification bodies, notified by Kuwait, Bahrain and Saudi Arabia. While Australia appreciated the commitment by countries of the Gulf Cooperation Council (GCC) to adopt standards of the Gulf Standard Organization (GSO), GCC members were encouraged to nominate one Member acting as a single TBT notification authority on behalf of the GSO or the GCC Secretariat. This could simplify the process of delivering notifications and responding to comments provided by other WTO Members. With regard to the above-mentioned notifications, the representative of Australia informed the Committee that written comments had been sent to the enquiry points of all the Members concerned but no reply had been received to date. She looked forward to a satisfactory response to her delegation's concerns with a view to working cooperatively with GSO countries.

5. The representative of Saudi Arabia said that the comments by Australia would be conveyed to capital for due consideration.

(ii) United States – Ban on Clove Cigarettes (G/TBT/W/323)

6. The representative of Indonesia raised his delegation's concern as outlined in document G/TBT/W/323 with respect to the US "Family Smoking Prevention and Tobacco Control Act", which had entered into force on 22 June 2009. He particularly regretted that the new measure prohibited the production and marketing of cigarettes containing certain additives, including clove, but permitted the production and sale of other flavoured cigarettes, such as cigarettes containing menthol. Indonesia believed that the US measure discriminated against imported clove cigarettes and created an unnecessary barrier to trade under the TBT Agreement. Therefore, the representative of Indonesia urged the United States to revoke the measure.

7. The representative of the United States indicated that the United States was not going to reverse the ban on clove cigarettes given the high priority the Obama Administration placed on protecting the health of Americans, especially youth. US health authorities support a ban on clove

cigarettes to protect the public health. He noted that clove cigarettes were particularly appealing to youth and represented a "starter product" that could lead to the use of regular cigarettes. In particular, he stressed that clove cigarettes made it easier for new smokers to start smoking by masking the harshness of cigarette smoke and, like other banned fruit flavours, could ease the transition to addiction. Evidence also indicated that clove cigarettes could pose a range of additional health risks over conventional cigarettes. With regard to the allegation of discrimination, the US representative noted that substantial differences related to consumption, use patterns, and epidemiology existed between clove and menthol cigarettes, which made the two situations not comparable. He noted that the US Food and Drug Administration (FDA) had established a Scientific Advisory Committee that would support additional studies of menthol cigarettes before deciding an appropriate public health action. His delegation was open to further discussing the issue with Indonesia, so that Indonesian regulators could better understand the scientific basis for the US action.

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

8. The representative of Argentina raised a concern regarding Canada's legislation "Cracking Down on Tobacco Marketing Aimed at Youth Act", which had entered into force on 8 October 2009. He stressed that his delegation supported Canada's objective to prohibit the production and marketing of tobacco products which could attract youth. However, he emphasized that this measure was more trade-restrictive than necessary to achieve Canada's legitimate objective. The representative of Argentina noted that the measure prohibited the use of various additives in certain tobacco products, including cigarettes, cigarillos and blunt wraps. In this regard, he stressed that cigarettes made of several types of tobacco, such as blended cigarettes, contained several additives prohibited by the Canadian regulation. These additives, however, were not used to give a characterizing flavour to the product, rather they were used as an essential component to mitigate the strong flavour of Burley tobacco. A prohibition of these additives could therefore represent a *de facto* prohibition of blended cigarettes. The representative of Argentina further noted that a ban on the production and sale of products with a certain flavour would represent a less trade-restrictive mean to achieve Canada's objective, and thus be in line with Article 2.2 of the TBT Agreement. He also said that Canada based its legislation on the ingredients contained in a product without considering the effects of such ingredients on the final product, contrary to the obligations under Article 2.8 of the TBT Agreement. The Argentinean delegate noted that Canada had not notified the measure to the WTO. In this regard, he informed the Committee that prior to the adoption of the measure, the Argentinean Federation of Tobacco Producers and the Government of the Province of Salta had sent written comments to the Canadian Ambassador in Buenos Aires expressing their concern. However, these comments had not been taken into account. Finally, Canada was invited to amend this measure according to its obligations under the TBT Agreement.

9. The representative of Mexico supported the comments made by Argentina with regard to the Canadian legislation and regretted that Canada had neither notified the measure to the WTO nor taken into account other Members' views. In this regard, Mexico expressed a systemic concern regarding legislative branches in a number of countries, including Canada, not seeming to see themselves bound by the transparency obligations of the TBT Agreement.

10. The representative of Switzerland shared the concerns expressed by previous speakers. While Switzerland supported the objective of protecting human health, concerns remained that the legislation had not been notified to the WTO.

11. The representative of Colombia echoed the concerns expressed by Argentina, Mexico and Switzerland regarding the new Canadian legislation on tobacco. She believed that the legislation was not 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". While the legislation had the *de facto* effect of banning blended tobacco, there was no scientific evidence

proving that blended cigarettes were more attractive to youth than traditional cigarettes, which represented ninety-eight per cent of the Canadian tobacco market. Therefore, Colombia invited Canada to consider less trade-restrictive alternatives to achieve its objective and ensure that its measure was consistent with the obligations under the TBT Agreement. The delegation of Colombia further emphasized that, absent such changes, exports of tobacco products to Canada would be seriously disrupted and the development of expansion plans for the growing of Burley tobacco would be negatively affected.

12. The representative of the European Communities[2] joined other delegations in expressing concern regarding Canada's measure on tobacco. In particular, the EC representative reiterated the importance of Members fully complying with their transparency obligations under the TBT Agreement, in particular those related to the notification of technical regulations and conformity assessment procedures. She also noted that this issue had been raised in an EC submission to the Fifth Triennial Review of the Operation and Implementation of the TBT Agreement.[3] The EC representative regretted that the Canadian measure had not been notified to the WTO and recalled that, according to Article 2.9 of the TBT Agreement, Members needed to ensure that draft legislation that could have a significant impact on trade be notified to the TBT Committee at an early appropriate stage when comments could still be taken into account. Therefore, the European Communities urged Canada to postpone the implementation of the legislation and notify the Committee at an early stage any measure which laid out its implementing provisions.

13. The representative of Turkey echoed concerns expressed by others. He emphasized the importance of tobacco exports for the Turkish economy and noted that the measure was currently under consideration by Turkish authorities. Comments on the legislation would be provided in due time.

14. The representative of the United States strongly supported Canada's objective of deterring youth from tobacco use. However, he asked the Canadian delegation to provide further information on the approach taken and on any measures necessary to implement the new regulation. Could Canada confirm when Sections 4 and 5 of the Tobacco Act would enter into force? Could Canada confirm that its Government had the authority to amend the schedule of additives regulated? Was the Government of Canada considering any amendments to the schedule of additives? Could Canada provide further information on the criteria used to develop the list of prohibited additives? Finally, could Canada explain what specific efforts had been made to identify the relationship in general between prohibited additives and products marketed to or that are innately attractive to youth? The United States looked forward to receiving Canada’s responses and improving the US understanding of the measure and its relationship to the TBT Agreement.

15. The representative of the Former Yugoslav Republic of Macedonia (FYROM) supported the comments made by previous delegations with regard to the Canadian legislation and highlighted the importance of the tobacco sector for his delegation's economy. While the Former Yugoslav Republic of Macedonia supported the objective of protecting human health, concerns remained that the regulation could constitute an unnecessary barrier to trade.

16. The representative of Canada explained that the "Cracking Down on Tobacco Marketing Aimed at Youth Act" was designed to address public health concerns by reducing the incentives for

[2] On 1 December 2009, the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community (done at Lisbon, 13 December 2007) entered into force. On 29 November 2009, the WTO received a Verbal Note (WT/L/779) from the Council of the European Union and the Commission of the European Communities stating that, by virtue of the Treaty of Lisbon, as of 1 December 2009, the European Union replaces and succeeds the European Community.

[3] G/TBT/W/309.

young people to smoke. She clarified that the new legislation prohibited, *inter alia*, the use of various flavours and other additives in certain tobacco products, including cigarettes, cigarillos and blunt wraps sold in Canada. She stressed that the legislation did not ban any type of tobacco or tobacco product. In this regard, it was Canada's understanding that since non-blended Burley cigarettes were currently sold on the Canadian market it was not correct to state that the ban on additives constituted an implicit ban on Burley tobacco. The Canadian delegate assured delegations that Canada's trade obligations had been taken into account in drafting the legislation and that Canada was committed to respecting its international trade obligations while meeting its legitimate public policy objectives.

17. With respect to the allegation on the lack of scientific evidence, Canada believed that the dangers of tobacco use were well documented in scientific and public health literature; indeed there was sound scientific evidence to demonstrate that certain additives, including flavours, increased the attractiveness of tobacco product. In this regard, the Canadian representative explained that some documents produced by the tobacco industries and subsequently made public by courts through litigation, had shown that the use of the additives banned by Canada made tobacco products more appealing to youth. She further noted that several other countries had introduced legislation that aimed at protecting youth from tobacco marketing. However, while the approach of such countries was only limited to banning specific flavours, the approach of the Canadian Government targeted a broader range of additives that were used to make cigarettes and other products more appealing to youth and novice smokers. In particular, the Canadian legislation introduced a list of prohibited additives that included additives with flavouring properties but also other additives such as sweeteners, vitamins, minerals and colouring agents. It was Canada's view that this legislation provided for more precision and certainty and that there was sound scientific evidence for prohibiting the use of such additives.

18. With regard to more systemic concerns about the non-notification of mandatory measures, the Canadian representative said that comments would be conveyed to capital for due consideration. She also reassured Members that any implementing measure of the tobacco legislation would be notified to the WTO at an early stage.

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

19. The representative of the European Communities expressed concerns about measures relating to the import of organic products in Chinese Taipei, notified in G/TBT/N/TPKM/65 and 69. She informed the Committee that comments on this measure had been sent to Chinese Taipei in February, May and October 2009. While the European Communities welcomed the clarifications received, important concerns remained. The EC representative particularly regretted that, despite the information provided by her delegation, the measures at issue were applied by Chinese Taipei differently between the twelve newer and fifteen older EC member States. She stressed that this distinction was unjustified and discriminatory. The EC representative recalled that the same organic legislation was uniformly applied across all the EC member States and that this legislation had been recognized by the Chinese Taipei authorities to be equivalent to that applied in Chinese Taipei. She noted that organic production, labelling and control was regulated at the European Communities level and was implemented identically throughout all EC member States. Furthermore, in the case of recently acceded EC member States, the organic legislation was implemented without any transition period from the date of their accession to the European Communities. The European Communities believed that sufficient information had been provided to Chinese Taipei authorities to carry out an equivalence assessment between the respective legislations on organic products. Chinese Taipei was therefore invited to extend its approval procedure to the twelve new EC Member States without further delay.

20. The representative of Switzerland noted her delegation's concern with Chinese Taipei's legislation on organic products. She stressed that the administrative procedures established for

achieving equivalence status for plant organic products were burdensome and non-transparent, could cause heavy delays, block merchandise and provoke financial losses for exporters concerned. Switzerland therefore invited Chinese Taipei to assure prompt and pragmatic administrative procedures for the remaining steps to be undertaken to achieve equivalence status for animal organic products.

21. The representative of Chinese Taipei explained that its review of organic equivalency covered not only regulations and technical specifications concerning organic agricultural products and processed products adopted in foreign countries, but also the development of the organic agriculture sector, as well as the implementation and enforcement of organic management systems. She stressed that Chinese Taipei had recognized the EC regulations and technical specifications concerning organic agricultural products and processed products as being equivalent. However, concerns remained about the lack of information with regard to the development of the organic agriculture sector and with regard to the effective implementation of the EC organic management system in the twelve newer EC member States. The recognition of equivalence for the twelve newer EC member States was still pending until such information was provided. In this regard, the representative of Chinese Taipei invited these Members of the WTO to provide further information about: (i) the organization structure, workforce and division of labour of the competent authority, and evidence of implementation of the relevant EC regulations; (ii) the ratio of agricultural area certified as organic to the total agricultural area of the country, and the total numbers of certified organic farms, processing operators and main product items; (iii) the results of tests or inspections of organic products performed by certification bodies including the number of cases, the compliance rates, and the disposition of non-compliant products for the last three years; (iv) the substantive content of plans for monitoring of organic products by the competent authority and reports of the last three years, including the number of cases, the compliance rates and the disposition of non-compliant products.

22. Finally, the representative of Chinese Taipei informed the Committee that a meeting between Chinese Taipei's Council of Agriculture and the European Economic and Trade Office had been held on 29 October 2009. She noted that the European Economic and Trade Office had agreed to provide the required information as soon as possible for Chinese Taipei's review. Chinese Taipei looked forward to working constructively with the European Communities until the concerns were fully resolved.

(v) Canada – Milk Class 4m

23. The representative of New Zealand raised concerns regarding a current proposal before the Canadian Milk Supply Management Committee to make available domestic milk proteins for cheese-processing at reduced prices compared to imported milk proteins under milk class 4m. New Zealand was concerned that such a proposal could create a two-tier pricing system for milk proteins in cheese manufacture, with domestic prices undercutting imports, currently priced in more expensive milk classes 3(a) and 3(b). The representative from New Zealand stressed the fact that it had been difficult to obtain further details on the proposal and hence to determine the exact nature of the programme, including any implications under the TBT Agreement. New Zealand was therefore also considering raising this issue at the next WTO Agriculture Committee Meeting. New Zealand requested Canada to provide specific details of the proposal.

24. The representative of the European Communities echoed the concerns and remarks made by New Zealand and noted that the proposed measures were currently under consideration and that further information in this regard would be useful.

25. The representative of Australia shared the concerns raised by New Zealand and echoed by the European Communities. Australia would welcome more specific details from Canada on the proposal

and in particular clarification by Canada whether the dual pricing system was consistent with Article 2.1 of the TBT Agreement.

26. The representative of Canada took note of the comments made by New Zealand, the European Communities and Australia. She informed the concerned delegations that there was no specific proposal on the table at the moment, but only related discussions taking place. Furthermore, she noted that Canada failed to see the relevance of the WTO TBT Agreement in connection to the concerns raised.

(vi) Canada – Ontario Ice Cream Subsidy

27. The representative of New Zealand expressed concerns about the Canadian dairy industry's ice-cream subsidy programme, and the extent to which it might be an 'import replacement' programme supported by the Canadian Government. She explained that it had been difficult to obtain details on the programme and thus to determine the exact nature of the programme, including any TBT implications. She announced that New Zealand was considering raising this issue at the next WTO Agriculture Committee Meeting. New Zealand requested Canada to provide the TBT Committee with specific details on the programme including on the role of the relevant federal agency, the Canadian Dairy Commission, in facilitating the programme.

28. The representative of the European Communities supported the comments made by New Zealand and announced that the EC delegation was studying this measure in order to determine whether it contained any elements related to the WTO TBT Agreement. She also requested Canada to provide further information on the programme.

29. The representative of Canada took note of the concerns expressed by New Zealand and the European Communities regarding this initiative. She explained that Canada failed to see the relevance to the WTO TBT Agreement, because the initiative was neither a Government of Canada nor a Canadian Dairy Commission program. She explained that the Canadian Dairy Commission merely calculated the pooling returns on behalf of producers, but that producers decided for themselves the manner in which they disposed of their revenues.

(vii) Israel – Regulation 31/08, the "Regulation for Labeling of Imported and Locally Produced Automotive Products – Name of Manufacturer and Country of Origin Requirements"

30. The representative of the United States expressed serious concerns regarding Israel's country of origin labelling requirement for automotive products under Regulation 31-08. The US representative explained that the United States did not object to Israel's requirement that automotive products be labelled with the country of origin, a requirement that had existed for some time. However, under this new regulation, US automotive products would be treated differently than Israeli products and products of other trading partners by requiring the label to include, in addition to the country of origin, the US state and possibly the city of manufacture. These requirements had generated significant concern among US auto parts manufacturers. He recalled that Israel had not provided a plausible justification for the difference in such treatment and that the US was also unable to find such justification. Furthermore, he noted that the United States had procedural concerns, as Israel had not notified this regulation to the WTO for comment which hampered the efforts of other members to provide meaningful comment on the measure. Given that the regulation appeared to treat US automotive products differently to those from other countries and raised procedural concerns, the US representative requested that Israel's Ministry of Transportation repeal the additional marking requirements for US products

31. The representative of Israel announced that after a bilateral meeting between the United States and Israel the matter had already been brought to the attention of the Ministry of Transportation, the

government body currently analyzing the issue. He recalled that when implementing Regulation 31-08 the relevant authorities applied a liberal approach requiring in many cases only to mention simply the country of origin of the goods. Regarding the specific US trade concern, the representative of Israel said that the issue was being discussed by the relevant Israeli authorities and that his delegation would soon be in the position to inform the United States of the decision adopted.

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

32. The representative of the United States raised a concern regarding Halal certification in Indonesia. He began by noting that the United States respected Indonesia's right to regulate trade in Halal products. However, Indonesia's regulations should be developed in a manner that is transparent and does not disrupt trade. In the US view, the development of Indonesia's Halal certification system was not transparent and, as a result, many traders and certifiers had been caught by surprise. Some, including poultry traders that have provided Halal products to Indonesia's market for many years, had found themselves shut out of the Indonesian market. He further noted that the rules which accredit Halal certifiers were unclear and would act to restrict or eliminate exports of certain foods to Indonesia. As a first step in addressing the current situation, the US representative urged Indonesia to allow previously recognized Halal certifiers to continue to certify Halal products while Indonesia addressed the concerns of trading partners in revising the measures. The US representative also stressed the importance of continuing to accept and review applications from certifiers that had not yet been approved.

33. Regarding the final certifiers list released on 22 October 2009, it was noted that the previous list of Halal certifiers had apparently been cancelled on 1 October 2009, but the Government of Indonesia had not posted the new certifiers list on the MUI website until 22 October. This delay affectively had eliminated imports of legitimate Halal goods for three weeks. In addition, the process to apply for and gain MUI approval had not been set out in the 9 March decree and had not been publicly announced. As a result, many certifiers did not know that they were required to reapply and were not aware of the current rules for Halal accreditation. The US representative asked Indonesia to explain the criteria used to recognise Halal certifiers and whether Indonesia would make these criteria available and allow stakeholders to provide comments. The new list of Halal certifiers also did not include any certifiers for poultry or lamb; until 1 October 2009 there had been eight US poultry certifiers accredited by MUI and now these certifiers were apparently no longer recognised by Indonesia. Could Indonesia explain why it no longer recognized these certifiers? This omission of any poultry certifiers from the recognized list functioned to block US exports of poultry to Indonesia. Moreover, an attachment to the certifiers list indicated that the certifiers set out therein could only certify raw materials. This suggested that these certifiers could not certify the Halal finished or retail level goods, including processed foods. The representative of the United States therefore asked for clarification from Indonesia whether this was indeed the case and if so, to explain the rationale and explain how finished or retail level goods could be certified Halal if not by the bodies contained in the list. Was there a separate list of certifiers for finished or retail level goods and, if so, could Indonesia publish the list?

34. The US representative noted that his delegation had not received an official response to a letter from USTR, dated 28 September 2009, which had addressed many of the above-mentioned issues, and asked Indonesia when a response could be expected. He also noted that the US was unclear on the scope of the regime in Indonesia, whether certification was voluntary or mandatory and, if mandatory, what products were covered. The representative of the United States noted that Indonesia and the United States share the common goal of ensuring that foods labelled "Halal" meet Indonesia's requirements; however, the United States believed that Indonesia's objective could be accomplished without disrupting trade. He stressed that this would require additional transparency by the Government of Indonesia. Suppliers and certifiers needed to be made aware of when there would be new requirements; they also needed to be able to review and comment on such requirements in

draft form and have their comments taken into account by the relevant authorities; and they had to be provided with a reasonable time period to comply with new requirements. The US representative claimed that his government continued to seek bilateral discussions on this issue with Indonesia in the near term and requested that experts meet to discuss the technical details of the Indonesian Halal regime to help ensure that legitimate trade in Halal products was not further disrupted, for the benefit of Indonesian consumers, as well as traders, suppliers, and certifiers.

35. The representative of Indonesia informed the TBT Committee that their delegation had taken note of the concern and that they would work with relevant government institutions to take the necessary actions to resolve the matter.

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

36. The representative of the United States raised a concern regarding Indonesia's new requirement for producers of food, food supplements, drugs and cosmetics to obtain distribution licenses from the National Agency of Drug and Food Control under a measure that was announced on 31 August 2009. The United States respected the right of Indonesia to regulate Halal in the Indonesian market. However, this could be done in a way that did not disrupt trade. As in the case of the 9 March decree with respect to Halal certification, Indonesia had not provided any notice of the 31 August decree which had come into effect on the date it was published. The US representative said that the new requirements were unclear in several respects and could restrict exports of certain foods and food supplements, drugs, such as gelatine capsules, vaccines, and cough syrups, and cosmetics products. The US representative stressed the importance of Indonesia suspending implementation of the 31 August decree while taking comments into account in revising the measure. He also noted that his country had many questions on how the licensing process worked, as the requirements for obtaining a distribution license were vague and unclear.

37. Regarding specific provisions in the decree, the representative of the United States raised the following questions: how was an emergency determined for purposes of the decree, since a license would only be granted for pharmaceutical products in the event of an emergency; who made this determination; and what were the specific criteria used in this process. The US representative explained that because little clarifying information had been included in the decree, the measure could disrupt trade in critical medicines, such as vaccines. He also noted that vaccines that were developed to address a pandemic could contain porcine and thus could be banned in Indonesia under this decree. Moreover, because swine sourced, swine derived, and swine containing products in the food and beverage sector were also subject to similar emergency provisions, failure to clarify how these provisions operated could block exports of certain foods and beverages to Indonesia as well.

38. According to the United States, the application of the current labelling requirements suggested the use of a label for products that were manufactured using swine content. The representative noted that this did not appear to be workable since there appeared to be no test for detecting such materials in drugs. Additionally, the decree indicated that the use of traditional drug products, cosmetics and food supplements was, in general, not an emergency and therefore it appeared that products sourced from, containing, or derived from certain animal substances would presumptively not be given a distribution license. However, the rule indicated that the use of such products could be an emergency in some instances, but there was no elaboration on what types of cases would constitute such an emergency. Finally, the representative of the United States claimed that his government continued to seek bilateral discussions on this issue with Indonesia in the near term and requested that the relevant experts meet to discuss the technical details of the Indonesian licensing regime to help ensure that legitimate trade in food, food supplements, cosmetics, and drugs to Indonesia would not be further disrupted. The United States also noted that it would be providing a list of technical questions to Indonesia following the meeting.

39. The representative from the European Communities said that her delegation was also looking into the same issue as it had been approached by industry. The representative expressed regret that the legislation had not been notified under the TBT Agreement before it had been adopted. She also asked Indonesia to clarify: what would be the emergency situations in which drugs containing certain substances would be awarded a distribution license; what would an evaluation of their safety, use and quality entail, who would perform the evaluation and what would be an envisaged time frame. The representative of the European Communities also asked Indonesia to notify the measure to the TBT Committee in order to allow interested Members to provide comments and to take these comments into consideration. Pending such notification the European Communities urged Indonesian authorities to suspend the application of the measures and to actively engage in a dialogue with foreign operators to ensure that the measure at issue was not more trade restrictive than necessary to achieve its objectives.

40. The representative of Indonesia noted that concerns expressed by the United States and the European Communities relating to the distribution license requirements of certain drug products, cosmetics, food supplements and food and said that she would discuss the measure with relevant agencies in capital and submit responses as soon as possible.

(x) United States – Country of Origin Labeling for Dairy

41. The representative of Mexico noted that on 14 October 2009, Senator Al Franken had presented an initiative entitled Dairy COOL, S. 1783 before the US Senate which was intended to amend the Agricultural Marketing Act of 1946. It was stated that the objective of the initiative was to broaden the coverage of country of origin labelling requirements in order to include dairy products. The Mexican representative explained that the Senate bill established that retailers inform consumers about the country of origin of each of the ingredients as well as where the product was processed. In the case of dairy products produced exclusively in the United States, the requirement to inform about the country of origin of the dairy product could be done indicating the region, the state or the locality where it was produced and as such, it was not necessary to specify the United States as the country of origin.

42. With respect to the initiative, the representative of Mexico explained that the coverage of products was rather widespread and included, for example, fluid liquid milk, cheese, including cottage cheese and sour cream, ice cream, butter and within quotes "any other product". He highlighted that there was no exhaustive list of these "any other products", nor was there a clear specification of the coverage of the concept dairy. If approved, the representative from Mexico stated that in terms of milk, cream, cheese, powdered milk, fats and dairy content in chocolate, USD119.8 million in exports from Mexico to the United States could be affected. Moreover, Mexican exporters would have to know the origin of each input used in these products and state this on the labels and furthermore, keep registers of all movements in this area. He stressed that this would be very burdensome for exporters. Regarding US producers using Mexican dairy inputs, Mexican exporters would have to inform the US customers of the status of each one of the products they were going to sell.

43. In addition, US producers that used both imported and domestic inputs would have to have a register of the movements of inventory. This would mean a disadvantage for imported products as compared to nationally produced products. The representative of Mexico stated that although this measure was still just an initiative, he noted the importance of such cases in the context of the US obligations under the TBT Agreement. He asked the United States to keep Members informed about the progress of the legislation; notify it at the appropriate stage thereby allowing the opportunity for comments; assess the risks for which this measure was being implemented; and explain the legitimate objective that was presumably being sought. Lastly, regarding the draft law in its current form, he noted that his country thought it was inconsistent with the corresponding Codex standard and

contained elements which made it inconsistent with obligations under, *inter alia*, GATT 1994 and the TBT Agreement.

44. The representative of the United States noted that this was a new issue that had not been previously raised. He stated that given Mexico's interest, his delegation would monitor the progress of this bill and would be available to discuss this bilaterally after his delegation had reviewed the issue in capital.

2. Previously raised concerns

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

45. The representative of Cuba reiterated his delegation's concerns with REACH. While Cuba recognized the importance of protecting human health and the environment, concerns remained about the complexity of the REACH regulation, its trade-restrictiveness and the overall difficulties faced by developing countries and least developed countries in its implementation. Therefore, he asked the European Communities to provide technical assistance and to take into account the difficulties faced by developing countries in a time of financial crisis.

46. The representative of Canada supported the objectives of protecting health and the environment, but reiterated her delegation's concern about REACH. In the interest of time, Canada limited its oral intervention to expressing concern about the treatment of natural vegetable oils sourced from genetically modified soybeans, canola and corn under REACH. In this regard, the representative of Canada noted that Article 9, Annex V of the REACH regulation provided for an exemption from the obligation to register under REACH. This exemption extended to fats, vegetable oils, vegetable waxes, animal fats, animal oils, animal waxes, fatty acids from C6 to C24 and their potassium, sodium, calcium and magnesium salts, glycerol obtained from natural sources. However, it was Canada's understanding that during recent CARACAL meetings some EC member States had questioned whether vegetable oils sourced from genetically modified soybeans, canola and corn should continue to benefit from this exemption. The Canadian delegate stressed that industry had estimated that a change in this situation would result in a need for three thousand additional registrations and would cost approximately EUR 35 million. Most importantly, since none of these products were currently pre-registered or registered, trade in oils sourced from genetically modified (GM) plants would effectively be halted.

47. The representative of Canada noted that genetically modified organisms (GMO) derived substances were regulated by specific EU legislation. This legislation required pre-market safety assessment of such products before they entered the marketplace for food and feed use. It was Canada's understanding that the safety assessment was a comparison between the GM product and its conventional counterpart, as recommended by the Codex Alimentarius "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology" (CACIGL 44-2003). Canada stressed that it would have been disproportionate to re-evaluate and alter the treatment of these substances under REACH. The European Communities was therefore requested to provide an update on the status of the treatment of oils sourced from GM plants under REACH, and to confirm that it would give serious consideration to the views expressed by industry and trading partners.

48. The representative of Canada then referred to a Room Document providing a summary of its outstanding concerns, many of which had previously been raised. With respect to the issue of the Only Representative (OR), Canada remained concerned that REACH could have a disproportionate impact on Small and Medium-sized Enterprises (SMEs), and that the OR requirement was biased against non-EU based companies because of the extra costs it entailed. In this regard, Canada

believed that a company wishing to comply with REACH had to either hire an OR, open an office in the European Communties, attempt to navigate the complexity of REACH on its own, or choose to abandon the EC market. In Canada's view, there was no option that would not require Canadian companies to incur extra costs. In addition, the representative of Canada expressed concerns about the protection of confidential business information that non-EC firms were expected to provide to their OR. She further noted that the Canadian industry had sought clarification on several issues. What would happen if a company wished to set up a distributor in a different EC member State than where their OR was located? Would that company have to involve the OR in this new relationship? What would happen if a company wished to end the relationship with its distributor in the European Communities? Would it need to transfer its registration? What would the cost be? Was the OR's permission needed in case the distributor was not the same as the OR?

49. With regard to the subject of test methods, the representative of Canada noted that the European Communities would adopt the OECD test standards. In this regard, she requested that the European Communities give the timeline for adoption of the test methods and clarify what the practical consequences would be. It was also noted that the European Communities had declared that the OECD test standards would be used except in exceptional circumstances. Canada requested that the European Communities clarify what these exceptional circumstances could be and whether they would be published.

50. On the subject of data submitted by industry, Canada believed that industry would be required to generate a large amount of scientific data to demonstrate the safety of their products. What transparency, oversight and peer review measures would be put in place to ensure data submitted was considered?

51. With regard to the Substance Information Exchange Forum (SIEF), the representative of Canada noted that Canadian companies needed to provide data to ORs which, in turn, could be required to report this data to the SIEF. Since only EC-based companies were able to join the SIEF, this could cause an unfair, potentially prejudicial one-way flow of information that could disadvantage Canadian companies. Canada requested the EC delegation to clarify how it considered the relationship between mandatory SIEFs, voluntary, pre-existing industry consortia and how the two could fit into the REACH framework. Furthermore, the European Communities was asked to provide details on the cost and data sharing rules applicable to SIEF and how these rules could apply to Only Representatives.

52. With respect to the issue of authorization and restriction, it was Canada's understanding that internal procedures were being developed to operationalize the authorization and restriction provisions of REACH. Canada asked the European Communities to clarify whether the timelines for future submissions of Annex XV dossiers by EC members States or the European Chemical Agency (ECHA) had been determined. Canada also noted that work packages of substances had been 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 clarification. 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? Was it possible to obtain information on the content of these work packages? For example, were there any nickel-containing substances in these packages?

53. With respect to the treatment of nanomaterials under REACH, it was Canada's understanding that the Directorate General for Health and Consumer Affairs (DG SANCO) had held consultations on this issue in September 2009. The representative of Canada noted that, on 13 October 2009, the European Communities had announced its intention to review a number of policies and regulations covering health and environmental safety issues related to nanomaterials over the course of the next two years. The European Communities was invited to clarify whether trading partners were allowed

to participate in the consultation and regulatory process related to nanomaterials. In Canada's view, it would be helpful for both the Canadian industry and regulators to have regular consultations about risk assessment and management approaches, in order to encourage cooperation to maximize effectiveness of environmental and human health protection measures and minimize potential trade issues.

54. The Canadian representative urged the EC delegation to clarify the relationship between REACH and the directive concerning Restrictions on Hazardous Substances in electrical and electronic equipment (RoHS) and to explain 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.

55. The representative of Argentina reiterated his delegation's concern with regard to REACH. The complexity and lack of transparency of REACH showed that this regulation constituted an unnecessary barrier to trade. In general terms, while Argentina recognized the importance of protecting human health and the environment, the complexity and costs related to REACH were excessive and constituted a serious impediment to the continued presence of Argentinean companies in the European market. These difficulties were particularly serious for SMEs, which did not have the expertise to understand and meet the regulation's requirements. The representative of Argentina also said that the guidance documents on REACH were extensive, complex and were continuously being amended. Serious concerns remained on several issues.

56. With regard to 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, which stated: "the substance is intended to be released under normal or reasonably foreseeable conditions of use". The European Communities was also invited to provide further clarification on the operation of the Substance Information Exchange Forum (SIEF). Furthermore, the Argentinean delegate recalled that many companies pre-registered substances without knowing whether they actually needed to be registered. He stressed that almost three million pre-registrations had been submitted to date. It was Argentina's understanding that this large number was not a symptom of the effectiveness of the system, but rather proof of the confusion generated by REACH. Furthermore, the representative of Argentina noted that the burdensome and disproportionate costs associated with REACH had severe consequences on SMEs of developing countries and constituted a serious impediment to their continued presence in the EC market. Finally, the representative of Argentina invited the European Communities to provide qualified technical assistance to the private sector directly involved in the implementation of REACH. Argentina believed that this type of assistance would be more effective, prompt and precise compared to assistance provided on-line. It was also emphasized that Article 77 of the REACH regulation recognized the need to organize technical assistance activities and capacity building in developing countries. The European Communities were therefore urged to provide appropriate technical assistance and consider more flexible deadlines for developing countries.

57. The representative of Japan continued to have concerns about REACH. In particular, he informed the Committee that inspections for importers' status of pre-registration in the context of ensuring compliance with REACH had been carried out in the United Kingdom, Poland and some other EC member States. Japan was concerned that each EC member State had used different procedures for the confirmation of pre-registration, including requirements to present pre-registration numbers or submit documents to certify that the relevant pre-registration had been completed. This situation caused uncertainty and confusion among Japanese exporters. It was Japan's understanding that lack of the provisions of the REACH regulation requiring importers to present relevant information on pre-registration had caused the situation. In this regard, Japan requested the European Communities to standardize the procedures for confirmation of pre-registration among EC member States and to clarify the relevant information required for inspection.

58. The representative of the United States shared the EC interest in protecting human health and the environment. However, the United States continued to have trade-related concerns about REACH and its implementation. The US representative also noted that concerns were continuously raised by industry. Many of these had been already discussed by the United States and other Members and could be found in the minutes of previous TBT Committee meetings. The representative of the United States reiterated concerns about the different interpretation of REACH provisions across the EC member States. He recalled that six EC member States had expressed disagreement over the 0.1 per cent threshold for the notification and communication obligations with respect to substances on the candidate list. In this regard, the United States welcomed the release of the most recent draft guidance document from the European Chemical Agency (ECHA), which was consistent with the legal position of the European Commission. However, it was the US understanding that, before being submitted to the ECHA Committee's Enforcement Forum and to competent authorities for endorsement, the guidance document had to undergo a limited consultative process in November. Could the European Communities confirm the US understanding of this process and clarify whether comments on the draft guidance would be sought by ECHA?

59. The US delegation also reiterated concerns regarding participation in the Substance Information Exchange Fora. Several US companies had indicated that SIEFs were not functioning effectively and that frequently no company wanted to serve as the lead registrant. US industry had also indicated that many SIEFs were non-functional and would not finish their work in time to meet the November 2010 deadline for registration. Concerns also remained regarding the obligation for foreign companies, unlike their European competitors, to delegate their participation in the SIEFs to their Only Representatives (ORs). The US delegation asked the European Communities to clarify what actions were being taken to address these issues. Furthermore, US suppliers had noted that they were unable to change ORs due to technical problems with the ECHA website. The US delegation sought confirmation that ECHA was working on a solution to fix these technical problems and that, in the meantime, an interim solution was in place.

60. With regard to the enforcement of REACH, it was the US understanding that the European Commission had sent formal letters to initiate infringement proceedings to EC member States who had not notified their enforcement measures by the 1 December 2008 deadline. The US delegation asked the European Communities to provide an update on the status of this process. Finally, concerns remained about the impact of REACH on animal testing. The United States noted that ECHA had recently issued a press release on avoiding duplicative testing on animals and sought further clarification on this.

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

62. The representative of Saudi Arabia reiterated his delegation's concern with regard to REACH and noted its potential to disrupt trade in chemicals. He was particularly concerned about the following issues: the complexity of the REACH regulation; the different implementation of REACH provisions across the European Communities; the lack of clarity with respect to the penalties for non-compliance to REACH; the protection of confidential business information; the ambiguity on registration requirements for monomers and polymers; the burdensome costs and overly restrictive procedures associated with REACH. In concluding, the Saudi Arabia representative urged the European Communities to take into consideration the concerns which had been expressed by WTO Members, and to ensure that REACH was fully consistent with their obligations under the TBT Agreement.

63. The representative of Australia reiterated her delegation's concern about REACH and noted its potential to disrupt and impede global trade in chemicals. While Australia recognized the importance of ensuring a high standard of protection for human health and the environment, the

uncertainty about the process and implementing rules of REACH remained a concern. As a member of the Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue, Australia shared the concerns raised by the APEC Chemical Dialogue in its letter sent to ECHA on 18 September 2009. Australia was particularly concerned about the impact of REACH on small and medium-sized enterprises and the lack of assistance to non-EU enterprises in the implementation of REACH. Concerns also remained about the custom clearance procedures and the penalties for non-compliance with REACH. The representative of Australia further noted that industry was concerned that intellectual property rights could be infringed and confidential formulae be disclosed if enterprises were to comply with REACH registration requirements. She also echoed the concerns expressed by Canada with regard to the treatment of natural vegetable oils sourced from genetically modified soybeans, canola and corn under REACH. Finally, the European Communities was urged to take into consideration the concerns expressed by Members about REACH.

64. The representative of Chile thanked the European Communities for the responses to the comments previously made on REACH. However, concerns remained about several issues. In particular, he stressed that the REACH regulation remained complex, extensive and confusing, especially for small and medium-sized enterprises (SMEs). He also recalled that part of the regulation was ambiguous and that some issues of very high concern for Members had not been clarified by the European Communities. Furthermore, the representative of Chile highlighted the difficulties and the costs imposed by the registration procedure, especially for SMEs of developing countries. In this regard, he requested the European Communities to provide clarification on the exact costs involved in the registration of substances. Concerns remained also about the lack of technical assistance provided to Members in the implementation of REACH. For example, because companies often were unsure whether or not to pre-register a substance, they often pre-registered many more substances than necessary – this entailed burdensome costs for data generation.

65. Concerns also remained on the lack of clarity on penalties for non-compliance with REACH. The representative of Chile recalled that the responsibility for the formulation of penalties under REACH fell under the competences of each EC member State, but only Spain, Sweden, Germany and the United Kingdom provided information about this. The European Communities was therefore urged to take these concerns into account and clarify what the penalties for non-compliance with REACH were. Finally, the representative of Chile reiterated concerns about the protection of confidential business information in the pre-registration process. In this regard, his delegation had been informed that the strictly confidential information of a Chilean copper exporter had been disclosed to all participants of the relevant Substance Information Exchange Forum. It was further noted that this information could be freely obtained by all participants of the above-mentioned SIEF. The representative of Chile stressed that this system enabled competitors to access sensitive information.

66. The representative of China shared the comments raised by previous speakers about REACH. China was particularly concerned about the slow progress of the Substance Information Exchange Forum and its consequent impact on trade in chemicals. China noted that the Substance Information Exchange Forums were of critical importance for industries to communicate and collect data for the registration process. SIEFs were also fundamental for industry of developing countries and particularly SMEs to formulate joint registration submissions and share the costs of registration, thereby reducing registration fees. In this regard, the representative of China stressed that difficulties in the implementation of SIEFs could result in registration delays and create unnecessary restrictions to trade. The European Communities was therefore urged to take these concerns into account and promote the operation of SIEFs.

67. The representative of Colombia echoed the comments made by previous speakers and reiterated her delegation's concern about the REACH regulation. In particular, she expressed concern about the impact of REACH on SMEs.

68. 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 previously provided answers recorded in the minutes.

69. On the current state of play of the procedure concerning substances subject to authorization, the EC representative informed the Committee that fifteen new Substances of Very High Concern (SVHCs) had been identified by ECHA to be included in the candidate list according to the procedure established by Article 59 of the REACH regulation. Therefore, the current candidate list contained the fifteen substances previously identified and fifteen other new substances were proposed to be included. The EC delegate stressed that stakeholder consultations had been carried out in September and October 2009 and that comments received during this consultation would be taken into account.

70. The European Communities also recalled that an important deadline for the implementation of REACH was on 30 November 2009. First, this was the deadline for downstream users of chemical substances to inform their suppliers of the use they made of a substance. In other words, downstream users who wanted their supplier to consider the use of a substance in relation to its registration had to inform their supplier about the use they made of such substance. If a substance needed to be registered before 1 December 2010, the deadline for the user communication was 30 November 2009. Second, this was also the deadline for late pre-registration of certain chemical substances. In this regard, the EC representative referred to Article 28.6 of the REACH regulation, which outlined the conditions for late pre-registration. Further information about these deadlines could be found in the press releases recently published on the ECHA website.[4]

71. On the Substances Information Exchange Forum, the EC delegation stressed that ECHA continued to effectively assist SIEFs and lead registrants. It was also recalled that ECHA had recently organized several events on this issue. In this regard, the Committee's attention was drawn to a lead registrant workshop held in September 2009 and to on-going web conferences for lead registrants. The EC delegate also noted that an exchange platform where lead registrants could discuss SIEF-related issues was available on the ECHA website. She stressed that since the start of ECHA's awareness campaign the number of lead registrants had steadily increased. On the issue raised by Chile about the protection of confidential information in SIEFs, the EC representative noted that a press release had been published by ECHA on 30 July 2009 and urged Members that encountered similar problems to inform the EC delegation. The European Communities stressed that the protection of confidential information was a key concern during the legislative process leading to the adoption of the REACH regulation and that there was neither an obligation to provide SIEFs with confidential business information on substances, such as their specific use, volume, suppliers, formulas, markets strategies. Furthermore, the EC representative noted that opt-out possibilities for joint submission were possible according to Article 11 of the REACH regulation. Guidance documents on data sharing had been made available on the ECHA website.

72. On the issue of uniform implementation of REACH across the European Communities, the EC representative reminded Members that enforcement laid with the EC member States. She informed Members that, in order to coordinate and harmonize the enforcement of the REACH regulation, a Forum for Exchange of Information on Enforcement had been established by ECHA. In this regard, she announced that the issue of REACH enforcement would be discussed during the Third Stakeholders Day to be held on 7 December 2009. Concerned Members were invited to participate in this event, which would also be web streamed and afterwards available on the ECHA website. Regarding the concerns on the disclosure of the pre-registration number of chemical substances, the EC representative recalled that they had been taken into account and were still being examined.

[4] http://echa.europa.eu/

73. On the issue of penalties for non-compliance to REACH, the representative of the European Communities stressed that clarification had already been provided at previous meetings of the TBT Committee. In this regard, she emphasized that the monitoring of the European Commission had been effective and that only two EC member States had not yet adopted the relevant sanctions.

74. On the treatment of natural vegetable oils sourced from genetically modified plants, the EC representative confirmed that the issue was still under discussion and reassured Members that the European Communities was aware of the urgency of this matter.

75. On the issue of monomers in polymers, the representative of the European Communities informed Member of the Committee that the judgement of the European Court of Justice had been issued on 7 July 2009.[5] She noted that the European Court of Justice had confirmed that Article 6.3 of the REACH regulation on the registration of reactive monomers and polymers was valid. In particular, the judgement confirmed that this provision legitimately pursued the objective of human health and environment protection. Moreover, the registration obligation enabled better knowledge of polymers and addressed certain health and environment risks such as monomer residues.

76. With regard to the comments made by Argentina and the United States on the content of Article 7.1 (b) of the REACH regulation, the EC representative invited concerned Members to refer to the available guidance documents. With regard to the questions made on animal testing under REACH, she referred to the two press releases recently released by ECHA. With regard to the comments made by the United States on technical problems encountered on the ECHA website, the EC representative explained that the issue was under consideration. She further clarified that the Only Representative change was one of the functionalities that would be made available in the legal entity change module that was currently being implemented and was planned to be released with REACH-IT in 2010. Finally, regarding the requests for technical assistance, the EC representative recalled that WTO Members having specific needs for technical assistance programmes should direct their requests to the respective delegations of the European Communities in their country. She invited Members who considered that appropriate assistance had not been provided to clarify whether specific requests had not been adequately followed up.

77. The representative of Argentina thanked the European Communities for its response. However, he reiterated his delegations' concern with regard to the content of Article 7.1 (b) of the REACH regulation.

78. The representative of the European Communities stressed that detailed guidance documents on Article 7 of the REACH regulation were available on the ECHA website. However, the European Communities was ready to further discuss the issue with Argentina if specific concerns still remained.

(ii) 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 and Add.1)

79. The representative of New Zealand reiterated concerns raised at the previous TBT Committee meeting in June 2009 regarding the European Communities' new regime for the regulation of its wine market, which in turn affected wine trade to the European Communities. In particular, New Zealand requested clarification following the EC notification of their new labelling regulations. While clarification had been received in a number of areas, some aspects of the regulations still remained unclear, such as the mechanism during the transition period by which third countries could notify the European Commission of their intention to use certain wine grape variety names so that they were not disadvantaged vis-à-vis European Community producers. Other open questions concerned the

[5] Case C-558/07.

traditional terms as well as bottle shapes and closures. She stressed that New Zealand's assumption remained that the new EU wine regulation, implementing regulations and any transitional arrangements included in these regulations - particularly those relating 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. New Zealand therefore expected that there should be no adverse effect on market access for non-members of the EU as a result of the implementation of the regulation.

80. The representative of Argentina reiterated concerns with regards to the intention of a number of EC member States to protect the use of a number of traditional expressions in all languages of the European Communities. Independent of the subsequent amendments and annulments to the regulation 753/02 and 316/04 and independent the provisions of the new regulations, Argentina was still concerned that several restrictions remained on the right to use a number of traditional expressions on the labels of non-Community wines, and therefore maintained its previously raised objections. He recalled that in the TBT Committee meeting of March 2009, the European Communities had explained that the new regulation allowed use of traditional expressions on products from third countries as long as they fulfilled identical or equivalent requirements that were imposed on EC member States. However, in document G/TBT/W/290 in June 2008, Argentina had observed that the European Communities had not yet established a common definition of the additional comments of quality or additional information on quality. Argentina had therefore argued that it had been impossible to request the certification of fulfilment of an unequivocal single community criterion on this matter. Furthermore, Argentina was of the view that the additional information on quality, like other traditional expressions, referred to specific production or quality methods and therefore could not be protected as intellectual property rights under the TRIPS Agreement. He emphasized that Argentina did not see any logical, legal or specific grounds under which the EC could claim exclusive rights over traditional expressions and was not satisfied with the response provided by the European Communities on 9 September 2008.

81. The representative of Argentina recalled that at the July 2008 meeting of the TBT Committee, the European Communities had recognized that they had detained a shipment of wines from Argentina and had invited Argentina to present an application for conformity with Art. 24 of Regulation 753/2202. In response to this invitation and in order to avoid future detention of consignments, the European Communities were requested to register the use of the expressions "vintage" and "special vintage" on labels coming from Argentina. He noted, however, that Argentina considered the restrictions to the use of traditional expressions as not compatible with the TBT Agreement and therefore requested the revision of the regulations in order to bring them into compliance with the TBT Agreement. In addition, he urged the European Communities to provide information on whether other traditional expressions had been the subject of border controls. Furthermore, the delegate requested that the European Communities report back to the TBT Committee on the detentions that had been operated on other wine shipments from other origins since 2008 as a result of the implementation of regulations 753/02, the amendments thereof and the regulations that had subsequently replaced that regulation.

82. The representative of the United States reiterated serious concerns regarding the EC measures at issue. The measure severely restricted the ability of non-EU wine producers to use common or descriptive and commercially valuable terms to describe their products, on the grounds that those terms were traditionally associated with European wines. He explained that this was particularly worrisome when some of these terms did not have a common definition across all EC member States; moreover, the United States was not aware of efforts to monitor or limit the use of those terms within the European Communities. He informed the Committee that the United States remained concerned with respect to negative trade impacts resulting from the termination on 10 March 2009 of the three-year derogation for the use of such terms on the labels of US wines sold in the European

Communities, as well as the EC's recognition of so-called traditional expressions contained in trademarks.

83. The delegate of the United States noted that while draft Regulation EEC/264 had been replaced by an amended regulation, No. 607/2009 of 14 July 2009, the United States continued to have concerns about several issues in Regulation EEC/264 and that bilateral discussions with the European Communities in October 2009 had failed to resolve these concerns. It appeared that the European Communities was still trying to claim exclusive rights to use terms commonly included on the labels of wines in the EC, such as "chateau", "vintage" and "superior", except under certain limited circumstances, in which the exporting country regulated the use of the terms to the satisfaction of the European Communities. He argued that while the European Communities attempted to justify limitations on the use of traditional terms by indicating that consumers could be misled by their use, the fact that these terms had been used without incident on US wines in the EU market for many years suggested that there was no risk of misleading consumers. Adding to US industry concerns was the fact that the European Communities had not indicated how it intended to enforce the limitations with respect to imported wines. For example, would the EC member States take action to block importation of US wines bearing a traditional expression? Furthermore, he noted that the European Court of Justice had expanded the scope of the measures and, contrary to the assurances provided by EC officials, the traditional terms were also protected in languages others than the ones for which protection was identified. In addition to TBT-related aspects of the EC regulation, the delegate of the United States also had concerns about provisions of the new regulation regarding the protection of trademarks and intellectual property, which it had been raising with the EC in other fora.

84. The representative of Mexico announced that his delegation associated itself with the statements made by previous speakers.

85. The representative of the European Communities stated that the new implementing provision on protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products had entered into force on 1 August 2009, including a transitional period for the entry into force for some of the requirements. She recalled that several modifications had been made to the text that had been notified to the TBT Committee to take into account the comments received from different WTO Members and bilateral discussions had also been held to clarify these issues. She also noted that a detailed reply to clarify the outstanding issues had been sent to delegations that had submitted comments in writing..

86. The representative of the European Communities recalled that the new implementing rules allowed the use of traditional terms on third countries' products provided they fulfilled the same or equivalent conditions to those required from EC member States in order to ensure that consumers were not misled. She explained that the competent authorities of member States or third countries or representative professional organizations established in third countries had the possibility to submit to the European Commission an application for the protection of traditional terms. She informed the Committee that the European Commission had already received applications by third countries and was currently examining them. In this respect, the Commission was already in touch with Argentina at a technical level in order to prepare the formal applications and technical discussions were ongoing as well with US industry. Regarding the comment made by Argentina on the enforcement of the regulations, she recalled that the importers had always been informed when a consignment had been detained but this information could not be shared with other countries as it was confidential. Finally, she invited all delegations interested in having their traditional expressions authorized in the European Communities to contact the respective competent authorities of the European Communities.

(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)

87. The representative of the United States drew the Committee's attention to the European Communities' review of the directive concerning Restrictions on Hazardous Substances in electrical and electronic equipment (RoHS). He emphasized that the United States supported the objectives of measures taken to protect human health, safety and the environment, and noted his delegation's appreciation for the improved transparency and the broader consultations with stakeholders that characterized the RoHS revision process. The US representative highlighted the need for continued transparency in the implementation and operation of the proposed RoHS revision, including by continuing to take into account comments from all stakeholders. Furthermore, he stressed the importance of providing adequate legal certainty to stakeholders regarding how substances would be treated. He emphasized that any selection and assessment procedure, under RoHS or REACH, needed to be science-based and take into account intended end uses as well as all available scientific and technical information.

88. It was the US understanding that the EU Council was considering a new proposal to include all electrical and electronic equipment under the scope of RoHS. Since this proposal could have an impact on producers who were not aware that their products could be covered by RoHS, the United States invited the European Communities to provide an update on its status. Would the European Communities solicit comments from interested stakeholders through a new WTO notification? The United States also understood that the EU Council was considering a proposal to modify the criteria for restrictions and exemptions, as well as the link between REACH and RoHS. The United States noted that the above-mentioned proposals had been made after the comment period set out in the WTO notification had expired. In addition, the US representative noted that the Netherlands had recently tabled a non-paper about the interrelationship between RoHS and REACH, and press reports indicated that EC member States were discussing how to avoid overlaps between the two regulations. The United States sought an update on the current status of these issues and asked the European Communities to clarify how the EC would solicit input on them.

89. The representative of the United States recalled that his delegation had submitted detailed comments in writing on the notified proposal and urged the European Communities to take these comments into account. He also asked the EC delegation whether these comments had been shared with the EU Council and the European Parliament. The European Communities was urged to ensure that a transparent and predictable process be put in place for the treatment of exemptions and to consider providing an exemption period for medical devices that would take into account the product development cycle. This would help to ensure long-term investments in new devices and innovations that were critical to hospitals, doctors, and patients in the European Communities. Finally, the US representative reiterated his delegation's interest in setting up a meeting of experts to review the US comments and concerns.

90. The representative of Japan echoed the concern raised by the United States and invited the European Communities to provide an update on the current status of the proposed revision of RoHS.

91. The representative of the European Communities thanked the delegations that had submitted comments on the revision of the RoHS Directive and stressed that written replies had been recently provided. She also recalled that an extensive explanation of the proposed RoHS recast had been provided at the previous meeting of the TBT Committee.[6] On the current state of play of the revision, the EC representative noted that the notified proposal was being discussed by the European Parliament and the Council in the "first reading" of the legislative process. Within this procedure, amendments had been tabled by the Parliament and the Council and were currently under discussion. The EC representative confirmed that proposals had been made to include all electric and electrical

[6] G/TBT/M/48, p. 26.

equipment under the scope of RoHS. She informed the Committee that a public debate on the scope of RoHS had been held on 21 October 2009. During this debate, the European Commission had noted that the issue was still under discussion and that an impact assessment on this proposal was being prepared by Denmark. The EC representative further clarified that the vote on the first reading had been tentatively scheduled for May 2010.

92. With regard to the concerns raised on the validity of exemptions for medical devices, the EC delegate clarified that exemptions were temporary derogations from a ban granted to manufacturers to facilitate the transition to substance-free products in cases where substitutes were not available. The representative of the European Communities noted that the exemption was valid for four years but also clarified that this four year period could be prolonged if stakeholders could prove that the exemption was still justified.

93. With regard to the link between RoHS and REACH, the European Communities clarified that the RoHS directive and the REACH regulation were complementary. While REACH focused on chemical substances, RoHS dealt only with hazardous substances in electrical and electronic equipment. If a substance subject to authorization under REACH was also restricted under RoHS, it would be exempted from REACH obligations. Furthermore, the EC representative stressed that the European Commission was exploring all possible synergies to improve the correlation between the two measures. Finally, she reassured Members that the European Communities would notify to the WTO the text of the proposed measure in case of substantial amendments. Her delegation remained open to further bilateral discussions with interested Members.

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

94. The representative of Japan referred to the above-mentioned TBT notification that stated that the relevant provisions would come into force on completion of 120 days after its publication in the Official Gazette. Japan considered that a period of 120 days was too short and requested India to grant a longer time period to comply with the new requirements. He recalled that Japanese industry had not yet received a reply to their petition submitted to India in April 2009 and urged India to reply to that petition as early as possible. Furthermore, the representative from Japan asked for further clarification by India concerning the corresponding conformity assessment procedure. In particular, referring to the minutes of the previous Committee meeting, he asked about the detailed procedures on how test reports from accredited laboratories abroad could be accepted provided that they complied with ISO[7]/IEC[8] 17025 and were accredited by a body which was a part of the Mutual Recognition Agreements with the International Laboratory Accreditation Cooperation (ILAC) on a reciprocal basis. He also asked about the how India was considering these issues.

95. The representative of the European Communities echoed the concerns expressed by Japan on the Indian proposal for tyres and tubes for automotive vehicles that was notified as an addendum in May 2009. The delegate referred to the concerns expressed by the European Communities at the last TBT Committee meeting as well as its previous requests for certain clarifications. Furthermore, the European Communities had sent written comments to the Indian TBT Enquiry Point on 2 July 2009 without having received a reply. The European Communities therefore requested India to reply to the comments made or to provide answers at the TBT Committee meeting, since the answer provided at the last Committee meeting did not seem to relate to the revised version of the text. Finally, the European Communities requested clarification by India on the timing with regard to the adoption and the entry into force of the notification.

[7] International Organization for Standardization
[8] International Electrotechnical Commisssion

96. The representative of the United States noted that his delegation was also following these issues and continued to seek bilateral discussions with India.

97. The representative of India informed the Committee that India had decided to postpone the implementation of the new regulation; he welcomed further bilateral discussions with concerned delegations.

(v) United States – Country of Origin Labelling (G/TBT/N/USA/25, G/TBT/N/USA/83 and Corr.1, G/TBT/N/USA/281 and Adds.1-4)

98. The representative of Australia expressed concerns with respect to the potential trade restrictive nature of the United States Department of Agriculture's Final Rule on Mandatory Country of Origin Labelling (MCOOL), which had entered into force on 16 March 2009. In particular, Australia was concerned that the administration of MCOOL imposed additional costs on US processors and could create incentives for those processors to favour domestic over imported products. The delegate from Australia informed the Committee that a preliminary trade analysis since MCOOL's implementation indicated that it was having a negative trade impact on Australian beef exports. She therefore requested advice from the United States about what measures it had implemented to assist the US industry transition to the MCOOL in order to ensure there was no adverse trade-restrictive outcome. In general, Australia was supportive of country of origin labelling and believed that it was a legitimate means of providing relevant information to consumers. However, Australia considered that MCOOL could be implemented in a less trade restrictive manner. Australia appreciated the opportunity to discuss these issues bilaterally with the United States and announced that Australia would closely monitor MCOOL's ongoing trade impact on Australian exports. Australia was also aware that both Canada and Mexico had initiated dispute settlement proceedings against the United States over MCOOL.

99. The representative from Mexico noted that the dispute settlement proceedings initiated by Mexico concerned that 1783 decision called the Dairy COOL Act of 2009 and was unrelated to the MCOOL raised by Australia.

100. The representative of the United States recalled that it was common for WTO Members to require that goods be labelled as to their origin. The United States was confident that its measures provided information to consumers in a manner consistent with its WTO commitments. He informed the Committee that Canada and Mexico had requested that a WTO dispute panel be established to examine the matter, and that the panel process was currently underway.

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

101. The representative of Cuba reiterated his delegation's concerns regarding the adoption of the 31st Adaptation to Technical Progress (ATP) to the Dangerous Substance Directive 67/548/EEC (DSD) and its incorporation into the 1st ATP to the regulation on Classification, Labelling and Packaging of substances and mixtures (CLP). As stated previously, Cuba's main concerns were related to the incorrect application of the OECD methodology, referred to as "read-across", which had been used as the basis for reclassifying 117 nickel compounds. It was Cuba's view that this decision was based on questionable scientific and procedural grounds. For example, the representative of Cuba stressed that some of the scientific evidence on which the European Commission had based this decision, such as skin sensitivity to oxide compounds, differed from the evidence used for registration purposes under REACH. The European Communities was therefore urged to apply the read-across methodology in a scientifically sound manner and follow the relevant guidelines established by the OECD.

102. The representative of Cuba drew the attention of the Committee to the timetable established by the European Communities for the adoption of the 31st ATP. He considered that the European Communities did not allow sufficient time for consultations to be held. In particular, he noted that the Technical Progress Committee (TPC) approved the 31st ATP on 19 November 2008, within 24 hours of the end of the notification comment period. His delegation believed that the European Communities did not have time to take into account the comments provided by other WTO Members the day before. Moreover, Cuba was concerned about the absence of a notification and consultation on the 1st ATP to the CLP regulation. In this regard, the Cuban delegate stressed that new criteria for assessment had been included in this regulation, which constituted a new regulatory framework. He also recalled that the 31st ATP had been adopted despite calls from several delegations, including developing country Members, for a postponement of its entry into force.

103. In addition, contrary to previous EC statements to the effect that the 31st ATP only related to labelling and would not result in bans or restrictions on the use of chemical substances in consumer products, the sale to the general public of substances classified as carcinogenic Category 1A and 1B had been prohibited. Cuba also stressed that that new studies on the toxicity of nickel compounds were expected to be published in the coming months by the Nickel Agency and the International Agency for Research on Cancer (IARC), and asked the European Communities to postpone the implementation of the 31st ATPs until such studies were made available. While Cuba recognized the importance of protecting human health and the environment, the EC measure appeared to create an unnecessary obstacle to trade within the meaning of Article 2 of the TBT Agreement, as it restricted trade beyond necessary levels to achieve its legitimate objective. Finally, concerns were reiterated about the negative impact that the 31st ATP would have on the demand for nickel, particularly for developing country Members such as Cuba which were highly dependent on nickel exports.

104. The representative of Canada reiterated her delegation's disappointment that, despite repeated expressions of concern from Canada and the international nickel industry, the European Communities had proceeded towards the adoption of the 1st ATP to the CLP regulation. Furthermore, Canada noted that, despite the EC's characterization of nickel classifications as "mere labelling requirements", concerns on their downstream impact were longstanding and had yet to be allayed. In fact, the reclassification of nickel substances had already started to have an impact: for example, recently amended EC legislation on toys had resulted in a complete ban on nickel substances classified as carcinogenic Category 1 under the 30th and 31st ATPs to the DSD. The Canadian delegate also noted that nickel substances had been added to the so-called "Substitute It Now" (SIN) list drawn up by a coalition of environmental campaign groups, which was aimed at speeding up the implementation of REACH. Additionally, nickel metal producers were currently being asked to certify that their products did not contain the substances classified as carcinogenic under the ATPs.

105. Given the potential of negatively impacting nickel producers and exporters, it was essential that any classification of substances was transparent and based on sound science, regardless of what legislation or regulation they were made under. 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 scientific information, and that in light of this information the European Communities would review the classifications of nickel in a transparent manner. Finally, the representative of Canada noted that, like all Members, 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.

106. The representative of Brazil regretted that the 1st ATP to the CLP regulation had been adopted without taking into account the many concerns raised by WTO Members about the inadequate classification of nickel compounds. In Brazil's view, the European Communities had failed to give satisfactory answers to questions on several aspects of the process, such as: (i) the data on which the classifications was based; (ii) the use of water solubility as the sole criterion for grouping substances; (iii) the trade consequences of the measure. Regarding the latter, Brazil noted that in statements provided at previous meetings of the TBT Committee, the European Communities had assured Members that the new classification of nickel compounds only related to labelling and would not result in bans or restrictions on the use of chemical substances in consumer products. However, the European Communities had recently notified to the TBT Committee a proposed amendment to the REACH regulation (G/TBT/N/EEC/297), which prohibited the sale of a number of newly classified carcinogenic, mutagenic and reprotoxic (CMR) substances, including nickel compounds. Therefore, the European Communities was requested to take into account any new data available on the risks of these substances and to review the 1st ATP with a view to avoiding unnecessary obstacles to trade.

107. The representative of Japan raised concerns about the application by the European Communities of the CLP regulation. He noted that, following the adoption of the CLP regulation, both the classifications based on the Dangerous Substances Directive and the Globally Harmonised System (GHS) were used as transitional measures. He also noted that during this transitional period certain substances were temporarily required to be classified and labelled as "explosive" with the revision of the DSD. Japan stressed that the cost of compliance with this new requirement would create an excessive and unnecessary burden for industries and could disrupt trade in chemical products. The European Communities was therefore requested to ensure that the system did not require handling based on the temporary classification only applicable during the transitional period. In addition, the representative of Japan noted that the CLP regulation required all components in a mixture classified as hazardous substances to be notified when a mixture was imported to an EC member State. However, since mixtures usually contained several different components, Japan was concerned that several notifications had to be submitted for the same mixture. Japan was also concerned that non-EC manufacturers were required to provide importers which notify substances in EC with details on the composition of the imported mixture and consequently disclose confidential business information. For the above-mentioned reasons, the representative of Japan believed that the EC measure substantively discriminated against non-EC producers and urged the European Communities to take these concerns into account when implementing the regulation.

108. The representative of the United States noted that, in light of the most recent risk assessment commissioned by the European Commission, borate usage in the cases examined either did not pose a risk to the general public, or the risk was negligible. He welcomed that, as a result of this study, it had been proposed that the placing on the market and use of borates-containing substances in household cleaners, detergents and certain photographic mixtures should not be restricted. However, the US representative reiterated his delegation's concerns about certain aspects of the 30th and 31st ATPs to the DSD, as well as the subsequent classification of borates and certain nickel compounds under the CLP regulation without further analysis or notification.

109. The representative of the United States noted that in its analysis of certain nickel compounds, the relevant competent authority appeared to skip certain steps when applying the OECD read-across methodology, which raised questions as to whether the European Communities adequately took into account available scientific and technical information and intended end-uses of the relevant nickel compounds. Since nickel compounds were used for many important applications, this issue was of great concern to the nickel plating industry and customers in the automotive and other industrial sectors. The EC recently provided additional information in this regard, which the United States will investigate and will follow up, as appropriate. With regard to borates, the US delegate pointed out that the results of the various risk and impact assessments commissioned by the European Communities validated the concerns that the United States and other WTO Members had been raising

about the impact of the DSD/CLP classification under other EC legislation, if the EC does not examine intended end uses under such legislation. In particular, the borates assessment demonstrated that there was no appreciable risk of exposure from using the borate-containing products analyzed. It was the US understanding that this was the first case where the European Communities had commissioned such a risk and impact assessment and did not automatically ban substances classified as "Category 2" under the Dangerous Substances Directive. In this regard, the European Communities was invited to confirm that it would continue to examine available scientific and technical information and intended end uses of substances classified under the CLP regulation before subjecting them to restrictions under other EC legislation.

110. Furthermore, the United States requested the European Communities to provide clarification regarding the procedures for transferring the borates and nickel classifications from the DSD to the CLP regulation. In particular, the US delegation stressed that industry was concerned that the European Commission automatically transferred classifications under the DSD to the CLP, instead of following the new procedure for harmonized classification and labelling of substances specified under Articles 36 and 37 of the CLP regulation. Could the EC delegation explain why the European Commission used the automatic transfer procedure set out in Article 53 of the CLP regulation rather than the procedures set out in Articles 36 and 37? The United States noted that stakeholders continued to assert that the European Commission erred in its initial evaluation of borates and nickel compounds under both the 30th and 31st ATPs to the DSD by not considering the normal handling and use of these substances, and that this error could have been corrected by using the procedures set out in Articles 36 and 37 of the CLP regulation in the transferring of classifications between the two measures. He also urged the European Communities to clarify the impact of its borates classification on cosmetics since that product was not covered by the EC risk and impact assessments. Could the European Communities clarify whether borates were banned for use in cosmetics or were they still subject to the threshold for boric acid under the Cosmetics Directive? The US delegation would continue to monitor the potential adverse trade impacts of the nickel and borates classifications and the potential methodological issues raised.

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

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

occurred in 2008, which had reduced the total value of Dominican Republic's nickel exports to USD492 million. As a further example, it was pointed out that a nickel company in the Dominican Republic had been obliged to dismiss more than nine hundred workers in November 2008 and was currently out of business.

113. The implementation of the 1st ATP to the CLP regulation was likely to further aggravate conditions in a very economically depressed area of the Dominican Republic, where the population's income relied only on nickel extractions, as well as causing increased production, transport and insurance costs and worsening conditions in a industry already severely affected by the world economic crisis. The European Communities was therefore encouraged to comply with the obligations set by Article 2.9 of the TBT Agreement, and to notify the draft 1st ATP at an early appropriate stage, allowing reasonable time for Members to comment.

114. The representative of China shared the concerns raised by previous speakers and expressed disappointment at the adoption of the 1st ATP of the CLP Regulation. His delegation stressed that the classification of nickel compounds was not based on sound scientific information and reiterated China's concerns about the incorrect use of the read-across methodology by the European Communities and the lack of transparency when transferring the 30th and 31st ATP of the DSD Directive to the CLP Regulation. China also noted that in statements provided at previous meetings of the TBT Committee, the European Communities had assured the Committee that the new classification of nickel compounds only related to labelling and would not result in bans or restrictions on the use of chemical substances in consumer products. However, the European Communities had recently proposed a new toy regulation that restricted the use of a number of nickel substances. Finally, China noted that the European Communities intended to ban the sale of carcinogenic, mutagenic and reprotoxic (CMR) substances Category 1A and 1B, and urged the EC delegation to clarify what the downstream consequences of this new classification would be.

115. The representative of Australia remained concerned that the EC's decision to reclassify nickel compounds under the 31st ATP was based on questionable scientific and procedural grounds and it had been adopted while the concerns of WTO Members remained outstanding. She 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. The representative of Australia also recalled that the Australian assessment authority, the National Industrial Chemical Notification and Assessment Scheme (NICNAS), had reviewed the scientific literature available on the issue in late 2008, including EC and OECD documentation, and had concluded that: (i) there was no reliable data on the carcinogenic potential of nickel carbonates; (ii) the use of read-across methodology should be based on groupings of substances which were robust and scientifically valid; and (iii) solubility in water alone was an insufficient criterion on which to base the read-across methodology.

116. Furthermore, 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 stigmatization of nickel resulting from the reclassification of various nickel compounds. For example, it was Australia's understanding that: (i) the proposed EC Green Public Procurement Criteria would exclude the use of stainless steel containing more that one per cent nickel in air conditioners and heat pumps; (ii) under the revised EU Eco-Label Directive products incorporating alloy steels and stainless steel containing one per cent or more nickel were not eligible for an EU Eco-label; (iii) EC mobile phone producers were looking to suspend the use of nickel in anti-radiation barriers; (iv) the 2012 London Olympic Games Sustainable Sourcing Code listed nickel, in relation to battery applications, as a material to be avoided. Finally, Australia expressed concern about the recent comments by DG Environment, at the October International Nickel Study

Group Meeting, that the prevailing EC view on the reclassified nickel compounds was that nickel compounds should be substituted.

117. The representative of Indonesia joined other delegations in expressing concern about the classification of nickel substances in the 30th and 31st ATP and their incorporation in the 1st ATP to the CLP regulation. Indonesia was particularly concerned about 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 reclassified nickel compounds 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. Concerns remained also on the lack of consultation with WTO Members on the draft 1st ATP to the CLP regulation on the grounds that consultation had already occurred on 30th and 31stATPs. In this regard, the representative of Indonesia stressed that the CLP regulation was a different regulatory framework. The European Communities was invited to revise its regulation to ensure that it would not constitute an unnecessary barrier to trade.

118. The representative of Turkey continued to have serious concerns about the 30th and 31st ATPs and 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). She recalled that at previous meetings of the Committee 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. This statement had also been confirmed on a bilateral basis. The Turkish delegate also noted that on 10 August 2009 the REACH regulation had been amended to reflect the changes made by the 30th and 31st ATPs to the DSD (G/TBT/N/EEC/297). She pointed out that this regulation amended Annex VI of the CLP regulation, which classified the borates as reprotoxic substances and required warning labels containing standard symbols and phrases to be placed on the substances' packaging. However, it was Turkey's understanding that the above-mentioned legislation did not relate only to classification and labelling requirements. In this regard, the delegate of Turkey noted that substances classified as Category 1 or 2 under the DSD, or Category 1A or 1B under the CLP regulation, would be prioritized and be subject to authorization under REACH. With regard to the new requirements notified by the EC (G/TBT/N/EEC/297), it was Turkey's understanding that, despite the fact that borates and derivatives were listed in REACH Annex XVII, in detergents and in photographic applications, there would not be any restrictions as they did not contain borates above concentration limits.

119. In addition, the representative of Turkey noted that the so-called "Substitute It Now" (SIN) list, which had been developed by a non-governmental organization called ChemSec (International Chemical Secretariat) to speed up inclusion of dangerous substances into the SVHC list under REACH, had been updated on 13 October 2009. She stressed that 89 new substances that were classified as carcinogenic, mutagenic or reprotoxic (CMRs) in the CLP Regulation, including boric acid and derivatives, had been added to the SIN List. Although the SIN list had been created by a non-governmental organization and was not legally binding, some companies had begun to integrate it into business decisions concerning purchasing and manufacturing in order to address growing consumer safety demands. Therefore, it was Turkey's view that the classification of borates as toxic to reproduction and their following inclusion to the SIN list would impose a negative effect on borates sale. Finally, the representative of Turkey sought further clarification on the plans of the European Commission, ECHA or EC member States about borates and their classification and invited the European Communities to reconsider its classification decision.

120. The representative of Korea shared the concerns raised by previous speakers and recalled that the ACP group had submitted comments in writing at the March 2009 Committee meeting (G/TBT/W/307). Korea was particularly concerned that the European Communities had not proved

the nickel classification was based on a sound and transparent scientific method. In particular, the European Communities' reliance on water solubility as the initial and primary basis for categorizing nickel compounds was not supported by scientific facts. The Korean industry was also concerned about costs of registration and data production in the implementation of the CLP regulation.

121. The representative of the European Communities noted that several concerns raised, such as read-across methodology and water solubility, were reiterations of concerns previously expressed and to which her delegation had already adequately replied. On the question raised by Japan about the labelling of certain substances with the term "explosive", the EC representative explained that the requirement to classify and label substances in accordance with the CLP regulation would apply from 1 December 2010. With regard to mixtures, the transitional period would extend until 1 June 2015. However, if a supplier voluntarily chose to apply the CLP provisions on classification before the December 2010 deadline, they had to apply the labelling and packaging provisions of the CLP regulation and not those of the DSD regulation. This rationale also applied to the term "explosives": substances have to be classified and labelled until 30 November 2010 as “explosive” in accordance with the DSD. Voluntarily the CLP provisions for explosive substances or mixture could be applied before these dates, but in that case the label had to respect the CLP criteria.

122. On the comments about the notification obligations, the representative of the European Communities explained that Articles 39 and 40 of the CLP regulation required manufacturers and importers to notify substances subject to registration as well as substances meeting the criteria for classification as hazardous, on their own or in mixtures above certain concentration limits. She noted that this requirement already applied in REACH and was transferred to the CLP regulation with effect from January 2009. She further noted that the notification obligation applied when such substances were placed on the EC market. It was recalled that Article 40.1 (2) of the CLP Regulation exempted information from being notified to the classification and labelling inventory if they had already been submitted to the European Chemicals Agency (ECHA) as part of the mandatory registration under REACH. While substances not classified as hazardous were not subject to notification requirements, substances classified as hazardous only had to be notified when present in mixtures above certain concentration limits. However, there was no requirement to notify confidential business information, such as details on the full composition of a mixture or on the precise use of substances. In this regard, the representative of the European Communities informed the Committee that ECHA was currently developing the tools to be used for notifying substances under the CLP regulation. ECHA was particularly interested in developing a notification process that was clear and simple, especially in the cases of groups of manufacturers or importers and in the cases when the substance had already been notified by another user.

123. The European Communities stressed that the classification of a substance or preparation as carcinogenic, mutagenic and reprotoxic (CMR) did not entail an obligation to phase out the use of these substances, but only to provide information on their hazardous properties. She further emphasized that manufacturers self-declared information about the substance on the label and that there was no mandatory certification process which had to be followed before a product entered the EC market.

124. On the restrictions applied under the EC directive on the marketing and use of dangerous substances, the European Communities confirmed that a proposed amendment to the REACH regulation (G/TBT/N/EEC/297) had been recently notified to the TBT Committee. This draft regulation prohibited the sale to the general public – or the use in mixtures above a certain concentration limit - of a number of substances that were classified as carcinogenic, mutagenic and reprotoxic (CMR) under the 30th and 31st ATP to the Dangerous Substance Directive. It was stressed that only a few products which were sold in the EC market contained borates beyond the limits set in the 30th ATP, notably detergents and photographic films. Since a risk assessment carried out by the European Commission had shown that there was no risk of exposure to these products, exemptions to

the restrictions had been granted. On the impact of the borates classification on cosmetics, the EC delegate pointed out that, according to the EC directive 2000/6, the use of borates in cosmetic products had already been restricted to certain concentration limits since February 2000. This decision was based on the opinion provided by the Scientific Committee on Cosmetic Products after a risk assessment had been carried out.

125. With regard to the nickel compounds classified under the EC directive on marketing and use of dangerous substances and covered by the 31st ATP, it was the EC delegation's understanding that currently there were no products on the EC market that contained nickel, as a substance or preparation, beyond the allowed concentration limits. In this regard, the European Communities stressed once again that the above-mentioned classifications and restrictions did not apply to articles, but only to preparations or substances. There was currently no intention to impose any restrictions on articles containing nickel beyond those that already applied in a number of consumer goods, such as batteries or toys. The EC representative also noted that nickel in stainless steel was considered to be safe under the EC directive on toys. She informed the Committee that the comment period on the notified directive on marketing and use of dangerous substances was still open and invited Members who wished to provide comments to do so.

126. With respect to comments made by Cuba on the incorrect classification of nickel substances, the EC representative recalled that nickel metal was classified as carcinogenic Category 3 in the 30th and 31st ATPs, in line with the evaluation carried out by the International Agency for Research on Cancer (IARC). On the request to postpone the implementation of the classification, she recalled that, as indicated in the adopted regulation, new arguments or scientific evidence submitted with regard to this classification would be examined by the European Communities.

127. With respect to comments made by Australia that there was no data on the carcinogenetic potential of nickel, the EC delegate referred to the conclusions of the meeting held by IARC in March 2009, which had endorsed the opinion of the European Commission that nickel was a carcinogen. Regarding comments made by several delegations 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. Regarding comments that certain industries had decided to phase out nickel or look for alternative substances, she said that this decision was not under the responsibility of the European Commission. Finally, with regard to the questions on how the substances classified were inserted in the REACH candidate list and subject to authorization, the EC representative referred to the explanations provided at previous TBT Committee meetings.

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

128. The representative of the European Communities reiterated her delegation's concern regarding the Indian Order requiring a registration procedure for imported cosmetics products. She explained that the European Communities had followed-up on the invitation by India during the last Committee meeting to contact the Ministry of Health directly and that the European Communities had subsequently been informed that a revised version of the legislation would be published in the autumn. The EC delegate therefore asked India to provide an update on the state of play and to inform the TBT Committee whether a revised version would be notified to the WTO.

129. The representative of India noted the concern raised by the EC delegation and assured the representative of the European Communities that information would be provided. Furthermore, she confirmed that no corresponding notification had been made so far.

(viii) Israel – Infant Formula

130. The representative of the United States reiterated concerns that Israel had so far not published a draft infant formula regulation and notified it for comment to the WTO. He recalled that importers needed clarity regarding the Israeli Ministry of Health requirements for infant formula so that trade was not disrupted. He requested that Israel provide an update on the status and timing of the draft regulation as well as on the ongoing domestic litigation regarding the infant formula regulation.

131. The representative of Israel explained that the issue was currently being discussed in Israel. He said that Israel would inform the US representative about any new developments in a timely manner. He also informed the US delegate that a meeting among interested importers, exporters and high-level health authorities in Israel would be held with the view to further discussing the matter and exploring ways to reach a satisfactory solution.

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

132. The representative of New Zealand reiterated her delegation's on-going concern about Canada's compositional cheese standards and the compliance of the latter with the principles of the TBT Agreement. She stated that New Zealand's assessment was that the standards were overly restrictive in nature; both in terms of the thresholds imposed for the use of dairy ingredients as well as with respect to their impact on trade. New Zealand therefore requested Canada to provide the Committee with an update on the recent outcome of the court challenge on these cheese standards. Furthermore, the delegate from New Zealand asked Canada to comment on suggestions that it intended to introduce similar standards for yoghurt. Finally, the representative of New Zealand noted that the cumulative protective measures Canada had imposed on imported dairy products, including compositional standards for cheese, were inconsistent with Canada's G20 commitment not to introduce trade restrictive measures and urged Canada to remove these measures as soon as possible.

133. The representative of Australia shared New Zealand's concerns about the Canadian compositional requirements.

134. The representative of the European Communities joined the other delegations in reiterating her delegation's concerns with respect to Canada's compositional standards for cheese. She also requested Canada to provide an update on the federal court challenge to these regulations and to confirm that these standards would not be extended to other dairy products, such as yoghurt.

135. The representative of Switzerland also expressed her concerns about the same issue.

136. The representative of Canada explained that when these regulations had been developed Canada took into account international standards and other countries' regulations as well as the comments received during the notification period. Canada therefore believed that the standards were in compliance with their WTO obligations. With respect to the judicial review, the Canadian delegate informed the Committee that the hearing of the judicial review had been held on 31 March and 1 April 2009. However, on 7 October 2009, the federal court had dismissed the application for judicial review made by the applicant. She clarified that the Government of Canada had not initiated any regulatory process for establishing compositional standards for other dairy products.

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

137. The representative of Canada welcomed steps taken by Brazil to ensure that the new regulation by ANVISA[9] was understood by its trading partners and their respective manufacturing facilities and that the regulation did not create an unnecessary barrier to trade. Canada had understood that, to date, Brazil had received 89 requests for inspection, and had arranged meetings with the

[9] Agência Nacional da Vigilância Sanitária

majority of these companies. Canada requested Brazil to provide further data with regards to the exact number of certifications that ANVISA anticipated would be necessary.

138. The delegate from Canada asked how the inspection, certification and registration would work. She also asked for clarification on whether companies which were not yet required to apply for certification because their registration had not expired would still be in a position to participate in public bids, or whether these companies would be disqualified from bidding and what their relationship would be with companies that were already certified.

139. Canada expressed concern that ANVISA might not be able to carry out all of the inspections necessary in the timeframe set out. The Canadian delegate therefore proposed that in the event that the required inspections were not carried out, Brazil should commit to granting exemptions to Canadian products already certified to internationally accepted Quality System Requirements (e.g. US Food and Drug Administration or Health Canada) and allow such exemptions to remain in place until Brazil had the capacity to inspect Canadian facilities.

140. The Canadian representative welcomed Brazil's efforts to inform interested governments as well as to the private sector to explain in more detail how to fulfill the requirements of this new regulation. Canada would also be interested in receiving in writing information pertaining to requirement of the inspections, the fees associated with these inspections, how companies applied for these inspections, and whether a company would be required to undergo an inspection each time it applied for the Good Manufacturing Practices (GMP) certificate from ANVISA. The Canadian delegate also asked whether it was possible for a company to extend their GMP certificate by an additional year if the company had already been inspected and had no records of non-compliance registered.

141. Finally, Canada emphasized that these concerns were raised independent of good cooperative activities between Health Canada and ANVISA regarding the regulation of pharmaceuticals and medical devices. In this respect, Canada appreciated the efforts Brazil had made to accommodate the concerns of trading partners.

142. The representative of the European Communities echoed Canada's comments. She was grateful for Brazil's clarification provided at the last Committee meeting. The European Communities understood from Brazil's answer that Brazil would stop accepting the ISO 13485 certification as evidence of compliance with GMP requirements and that Brazil intended to introduce new GMP requirements in this respect. The European Communities noted that these requirements seemed to diverge from the ISO standard 13485 which was the main international standard on quality management systems. Brazil had not given any justification why this standard would be ineffective or inappropriate to be used as a basis for the new requirements. The EC delegate argued that in the absence of such a justification, the new requirements had to be based on the relevant ISO standard as set out in Article 2.4 of the TBT Agreement.

143. With respect to the certification procedure, the representative of the European Communities stressed that note had been taken of Brazil's assurance at the last Committee meeting that ANVISA possessed the operational capacity to certify the companies that requested to be certified. In this context, the EC delegate also thanked Brazil for the important explanations given in a meeting between representatives of different Members and the Brazilian authorities in Brasilia at the end of October and requested confirmation that only those producers whose current certification would expire before the 22 May 2010 would need to have the new certification by this date. She further pointed out that the European Communities would closely observe the certification process, since industry had still expressed concerns that that there was a risk that this process would not be carried out in a timely manner, especially with regard to new products that needed to be certified. Finally, the

representative of the European Communities proposed to discuss with Brazil possible solutions for the recognition of certification carried out by EC notified bodies.

144. The representative of Mexico supported the concerns expressed by Canada and the European Communities. In addition, she requested that Brazil carry out a seminar on the topic for national experts from Mexico.

145. The representative of Switzerland asked to receive a written response to the concerns raised and in particular to those about the transitional period foreseen during which medical devices could still be exported to Brazil. She said that Switzerland remained concerned about the question whether Brazil would continue to recognize quality inspection results based on the internationally recognized quality standard ISO 13485. This reliance on internationally recognized quality inspections would represent the same approach that the Swiss Government currently followed and was also consistent with the approach recommended by the Global Harmonization Task Force. If Brazil no longer accepted ISO 13485 certification as evidence of compliance with the Brazilian requirements, Switzerland urged Brazil to give the reasons for such a refusal.

146. The representative of the United States recalled that at the June meeting of the TBT Committee the United States had outlined its concerns regarding Brazil's inspection requirement for certain medical devices. His delegation noted that productive meetings had occurred between the US Food and Drug Administration (FDA) and Brazil's ANVISA during the medical device information exchange forum in Brasilia in September, and that the two agencies had agreed to further technical talks. The United States welcomed the ANVISA initiative to organize a meeting with local industry representatives and officials from various embassies to discuss industry's concerns and its offer to provide a technical note with replies to the questions raised by industry about the registration and inspection processes.

147. The US delegate emphasized that Brazil had clarified that class 1 and 2 devices would be exempted from the inspection requirement, that the inspections would only apply to the last place of manufacture and not to all the supplier facilities, and that only facilities that manufactured devices subject to re-registration or new registration would need to be inspected by 22 May 2010. The United States also noted that ANVISA had been hiring additional inspectors and apparently had started scheduling inspections as well. These were all very positive developments, and the United States hoped that Brazil could confirm these points in writing. However, the U.S. delegate conveyed serious concerns from US industry about ANVISA's ability and resources to conduct all the inspections by May 2010 as well as for subsequent inspections. The concern was that the implementation of this measure could substantially disrupt trade and jeopardize the adequate supply of essential medical devices to the Brazilian market.

148. The US delegate welcomed ANVISA's efforts to provide a technical note to clarify the application process. At the same time, he urged Brazil to clarify the number of facilities that were coming up for re-registration before the implementation date, and indicated that it would be helpful if ANVISA could share this information. Finally, he stressed the fact that the United States would monitor the situation closely and would work together with Brazil to ensure that trade in safe and effective medical devices was not disrupted.

149. The representative from Brazil offered some additional clarification to the TBT Committee on ANVISA Resolution number 25. He first noted that measures of the same nature were actually adopted by several other countries, and were justifiable as they pursued the legitimate objective of protecting human health. He recalled that the Certificate of GMP for medical devices that would be required from foreign companies exporting to Brazil was already required from domestic Brazilian producers and therefore would not constitute a discrimination against foreign producers. He emphasized that the main objective of the Brazilian authorities was to ensure access to good quality

medical devices for the Brazilian population. Consequently, the Brazilian Government had no intention of implementing Resolution 25 in such a way which would represent a restriction in the flow of medical devices into Brazil.

150. Responding to concerns regarding the capacity of Brazilian authorities to carry out the necessary inspections by May 2010, he underscored that Brazilian authorities were fully prepared to deal with all the necessary inspections. He recalled that inspections were only necessary in order to renew registration or obtain a new registration for exporting medical devices. He further emphasized that inspections were due only in the plant of the final manufacturer of medical devices pertaining to risk categories 3 or 4 that would export the product to Brazil; there was no need for inspections in the plants of suppliers of parts of the devices. Regarding the inspections already required, he informed the Committee that 89 requests had been made, of which 50 were scheduled for 2009, 26 for 2010 and 13 were in the process of scheduling. He further noted that there had, to date, been no difficulties for scheduling the inspections. In addition, the Brazilian delegate recalled that Brazilian authorities had hosted seminars and other bilateral events to help to provide further information on the measure and to help build reciprocal confidence among trading partners. Brazil stood ready to maintain dialogue with all delegations in order to improve the understanding of Resolution 25.

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

151. The representative from Japan recalled that, following the announcement on 29 April 2009 by relevant Chinese authorities to apply the compulsory certification scheme of IT security products only for government procurement, China had expressed its understanding that this issue was no longer subject to the TBT Agreement. However, in Japan's view the scope of government procurement in China was not defined clearly enough and thus the regulation nevertheless needed to be addressed in the TBT Committee.

152. He expressed two major concerns that arose from the scheme. First, Japan asked for more clarity regarding the coverage of the scheme such as areas and the types of products, including the scope of government procurement. In this context he asked for clarification on whether State Owned Enterprises were not subject to this scheme. Second, the representative of Japan expressed concerns that the standards of the current scheme differed from international norms concerning the certification of IT security products. In this context, the representative of Japan supported the request made by the European Communities in the previous TBT Committee meeting to clarify why the Chinese scheme provided a broader coverage for mandatory certification requirements than international practice where specific requirements only existed in relation to national security critical infrastructure.

153. The representative of the European Communities reiterated the concerns expressed by the delegation of Japan with respect to the thirteen proposed implementing rules for compulsory certification of various information technology products. He reminded the Committee of past arguments expressed by the EC delegation regarding inconsistency with international practice and the overly extensive information requirements for applicant companies. He requested further clarification from China as to whether state-owned enterprises would be excluded from the notion of government procurement. Furthermore, the EC delegate asked China to provide additional information on whether foreign companies investing or established in China would be able to apply for the China Compulsory Certificate (CCC). He also asked about the current status of implementation of these rules which were due to enter into force on 1 May 2010.

154. The EC delegate urged China to provide a general update on the revision of the implementing measures that had been notified and on the specific information security mark currently being developed by the China Information Security Certification Centre. He also invited China to notify the final implementing measures under the relevant WTO transparency requirements.

155. The representative of the European Communities thanked the Certification and Accreditation Administration of the People's Republic of China (CNCA) and other Chinese governmental agencies for keeping an open channel of communications with the European Communities and for offering to meet to clarify some questions. However, he had serious concerns that the CCC was part of a more complex regulatory framework in the field of information security which involved rules developed by various ministries and public agencies. The combined effect of all these measures could be one of severely limiting market access opportunities in China for information security products made by non-Chinese companies, i.e. foreign companies or foreign invested companies legally established in China.

156. First, the representative of the European Communities noted that following the administrative measures for the multilevel protection scheme (MLPS) adopted by the Ministry of Public Security on 22 June 2007, all IT systems in China had to be classified into different levels of security on a scale of 1 to 5 according to the importance of the information handled by the system and its perceived value to national security. Systems classified at level 3 or above were considered as critical infrastructure triggering specific obligations on the IT system managers regarding what products, systems, and information security management technologies should be used to handle the information. It was the understanding of the European Communities that critical infrastructure included banks, insurances, transportation, as well as all public utility sectors. In practice, IT systems operated by the government or government-related bodies as well as by state owned enterprises were all considered as critical infrastructure. While many governments had taken similar approaches to classify the level of security needed for sensitive military and government agencies, the European Communities was concerned by the fact that China had extended this regulatory framework to cover all IT systems of non-government state owned enterprises.

157. The European Communities was of the opinion that China's interpretation of the notion of national security under the MLPS appeared to be much wider than that of any other country, and posed a heavy burden on economic operators. The representative of the European Communities considered the consequences of an IT system being classified as critical infrastructure. Managers of any such system would only be allowed to use products meeting the following requirements: (i) intellectual property rights of core information technology and key components had to be Chinese; (ii) the product developers and manufacturers had to be invested or owned by Chinese citizens, legal persons or the state; (iii) products whose core function was encryption had to have been approved by the Office of State Commercial Cryptography Administration (OSCCA) pursuant to the 1999 Regulation of Commercial Encryption Codes; (iv) products within CNCA's product catalogue, when procured by a system operator, had to have corresponding product and system level classification and have been certified by the China Information Security Certification Centre.

158. Second, it was the European Communities' understanding that the 1999 OSCCA Regulation on commercial encryption prescribed that the production, distribution and sale of information technology products whose core function was encryption was reserved for approved Chinese companies. Hence, foreign manufacturers were currently unable to export encryption products to China for commercial purposes under the terms of the regulation. By the same token, foreign owned companies established in China were equally denied access to the OSCCA business licence and the product certification needed to sell commercial encryption products. The EC delegate argued that the effect of these restrictions was that a foreign company or a foreign invested company in China had no legal possibility to place products whose core function was encryption on the Chinese market, irrespective of the end customer.

159. The EC delegate requested China to clarify the rationale for this system which effectively denied market access to foreign products or even products made by foreign invested companies established in China, in areas which were clearly considered as commercial areas according to global practices. The European Communities further urged China to promptly revise the OSCCA

regulations in order to ensure equal market access opportunities between domestic and foreign companies / foreign invested companies in China, based on technical regulations and conformity assessment procedures aligned with international practice.

160. The European Communities invited China to continue having an exchange of experiences on current global practices for trade in information security products.

161. The representative of Korea welcomed China's decision to postpone the implementation of the regulation and to reduce the scope of the original regulation. However, he expressed the concern of many Korean exporters of IT security products on the burden of compulsory certification and the lack of information on this regulation. The Korean delegate asked China to provide more detailed information to all WTO Members regarding the implementation of this regulation.

162. The representative of China recalled that the regulations at issue had been notified to the WTO in 2007. Since then, comments from some Members had been received and regular communication was maintained through bilateral discussions and other activities. Taking into account the requests from Members, the regulation had been revised and adopted in April 2009 postponing the actual implementation of the relevant measures by almost two years. He recalled that China had informed the Committee during the last meeting in June that the final regulation fully incorporated comments made by relevant stakeholders, both domestically and abroad, and had been significantly adjusted in terms of the applicable scope, particularly by limiting the measures to government procurement. The Chinese delegate was therefore of the view that the TBT Committee was no longer the appropriate forum for discussing the regulation. He also clarified that the certification requirements of the new regulation within the scope of government procurement was neither mandatory for commercial sectors nor subject to the CCC scheme as had been argued by the European Communities. With respect to Japan's concerns regarding the scope of government procurement, he suggested discussing the issue in another forum.

(xii) China – Wines (G/TBT/N/CHN/197)

163. The representative of the European Communities reiterated her delegation's serious concerns regarding overly strict Chinese specifications related to maximum levels of sulphur dioxide in wines. She recalled that the European Communities had repeatedly raised this issue at TBT Committee meetings, highlighting the difficulties of several EC member States in accessing the Chinese market. In particular, concern had been expressed about China's lack of consideration of international standards such as the Codex standard on food additives, which set the maximum allowed level of sulphur dioxide in sweet wines at 400 milligrams per litre. The EC representative noted that at the Committee's previous meeting China had indicated that the more restrictive sulphur dioxide limits contained in the Chinese standard on food additives were justified by Chinese consumers' drinking habits, which were different than those of other consumers worldwide. In this regard, the Chinese delegation was invited to provide the scientific data used to justify the assessment that the above-mentioned international standard was not an adequate means for achieving China's objectives. China was also encouraged to confirm that, following an application filed by a Chinese manufacturer, the standard was being reviewed. The EC delegation urged China to review the limits of sulphur dioxide content in wines sold on the Chinese market, in order to align them with existing international standards.

164. The representative of China noted that an explanation had been provided at previous meetings of the TBT Committee. He recalled that the Chinese regulation aimed at reducing risks of contamination caused by food additives; it took the approach of reviewing applications for new additives and increased amounts of additives. He also stressed that other WTO Members, including the European Communities, had in place regulations of food additives based on the same approach. It was the Chinese delegation's view that its regulation was consistent with WTO provisions and the

limit of sulphur dioxide in wine was based on sound scientific evidence, taking Chinese drinking habits into consideration. Furthermore, the representative of China recalled that he had reminded European Communities of the regulation and had invited EC wine producers to make an application to the Chinese Ministry of Health for review. To date, no such applications had been received from EC producers. However, the representative of China confirmed that a Chinese company had recently filed an application to increase the allowed content of sulphur dioxide in wine. This application was currently under public review and the European Communities was encouraged to participate in the comment process. China noted that more information on this process was available on the Chinese Ministry of Health website.[10]

(xiii) Brazil –Toys (G/TBT/N/BRA/259; 313 and 339 and Add.1)

165. The representative of Thailand recalled that Brazil's proposed INMETRO Decree for toy testing and certification had been notified to the TBT Committee in document G/TBT/N/BRA/339 on 24 July 2009. A reply to Thai comments was still pending. It was Thailand's understanding that Brazil had revised its seal affixation requirement, but, unfortunately, not for the better. A new body called "Product Certification Agency" (PCA) had been introduced with new responsibilities for: issuing the compliance identification seal; ensuring that the quantity of seals requested was compatible with the production capacity of the certification holder; and asking INMETRO to grant numbers in sequential order for the seal. Also certified businesses or individuals were required to "keep records and sequential control over the numbering on the seals granted that are used or in stock." This appeared to be complex. Thailand questioned whether the new provisions on seal affixation had anything to do with ensuring toy quality or safety. They appeared to add in procedural complexity, escalating administrative burdens and delaying costs for importers. In Thailand's view, the measure was more strict than necessary to give Brazil adequate confidence that toys conformed with Brazil's technical regulations on toy safety; as such the measure would create an "unnecessary obstacles to international trade" within the meaning of Article 5.1.2 of the TBT Agreement. Moreover, the measure appeared to be inconsistent with Brazil's obligations under Article 5.2.1 of the TBT Agreement to ensure that conformity assessment procedures were undertaken and completed as expeditiously as possible.

166. The representative of Thailand noted that transitional provisions of the proposed decree discriminated against imports because they effectively granted a one-year grace period for domestically manufactured toys, while requiring immediate compliance by importers. This was inconsistent with Brazil's national treatment obligation under Article 5.1.1. In fact, the imposition of the requirement of immediate compliance on imports meant that imported toys had access to the Brazilian market under "less favourable" conditions than domestic toys.

167. The representative of Thailand also noted that Brazil required reports on tests performed abroad to have a "sworn translation into Portuguese (Brazil)." In Thailand's view this would lead to increased delays and costs for imported goods and was more strict than necessary within the meaning of Article 5.1.2. A reasonable alternative would be for INMETRO to accept conformity assessment reports in English, as did many importing countries around the world.

168. Also, in the view of Thailand, the proposed decree appeared to provide excessive penalties for non-compliance. It stated that if the non-compliant product had been evaluated in accordance with System 5 "the licensed business will be suspended for a period of four months from the time of the last removal of the non compliant products". It was not proportionate that one failed product test be the basis for the "licensed business" itself to be suspended. Such a provision was more strict than is necessary within the meaning of Article 5.1.2

[10] http://www.moh.gov.cn/publicfiles//business/htmlfiles/wsb/index.htm.

169. With respect to the WTO notification, it was noted that Brazil had notified the proposed decree under Article 5.7.1 of the TBT Agreement, which allowed for the omission of the steps enumerated in Art. 5.6 "where urgent problems of safety, health, environmental protection or national security arise or threaten to arise for a member ". In such urgent cases, Art. 5.7.1 provided that the Member adopting the measure was required to "notify immediately other Members through the Secretariat of the particular procedure, including the nature of the urgent problems". However, Brazil's notification sought to justify its derogation from the notification requirements in Article 5.6 with a single brief reference in Section 7 of its notification on the "Protection of human health". This fell short of the standards set out in Art. 5.7.1. Thailand strongly urged Brazil to revise the proposed decree so as to bring Brazil's toy testing and certification requirements into conformity with Brazil's obligations under the TBT Agreement.

170. The representative of China echoed the concerns expressed by Thailand and noted that written comments had been sent to Brazil on 7 August 2009 and a formal reply had only been received shortly before the Committee meeting; it was currently being considered. On a preliminary basis, the representative of China said that, in its reply, Brazil had mentioned that some changes had been introduced to the draft regulation taking into account Members' comments, and that the final regulation, adopted on 29 October 2009, would soon be notified to the WTO. While China appreciated the progress made, her delegation still shared some of the concerns expressed by Thailand, especially on the discriminatory treatment against imported toys in terms of the transitional provisions. He invited Brazil to confirm that the "Compliance Identification Seal" could be affixed in exporting countries as indicated in the bilateral talks so as not to be more trade restrictive than necessary.

171. The representative of the European Communities noted that, according to his understanding, the final decree had been issued and published on 29 October 2009 as Ministerial Act (PORTARIA) No. 321. The European Communities had therefore not yet carried out a detailed assessment of the final text. The EC representative asked for confirmation that, pursuant to the final decree: importers would be free to choose between the System 5 and System 7 procedures; that there would be no seal requirements based on sequential numbers; and that there would be more reasonable penalties in case of non-conformity, linking the suspension of the validity of certificate to the period necessary to bring the product into compliance. With respect to the System 5 procedure in particular, the European Communities asked for confirmation that: it would be possible to affix the seal in the country of export; that tests carried out by ILAC-accredited foreign laboratories would be accepted and therefore there would be no requirement for duplicative in-country testing; and that companies holding ISO 9001:2008 certificates would be exempted from the factory audit on their quality assurance system.

172. The European Communities understood that the final version of the decree established a so-called "system certification authority" (the acronym in Portuguese being OCS) which had to be accredited by INMETRO. The European Communities asked for confirmation that INMETRO would accept accreditation certificates of inspection bodies issued by IAF members meaning that foreign inspection bodies would be able to perform the necessary factory audits. In other words, the European Communities was looking for confirmation that foreign inspection bodies would be able to be accredited by INMETRO for the purposes of a quality assurance system and that if they held international accreditation certificates, this would mean that accreditation by INMETRO would be quite smooth. The representative of the European Communities said that if these understandings were confirmed, the amendments to the initial draft INMETRO decree were indeed welcome improvements, which, based on an initial assessment, would appear to effectively address most of the concerns raised by the European toy industry.

173. With respect to the requirement for importers to supply a "sworn translation" into Portuguese of foreign test reports and of any other relevant documents that should be submitted for the purpose of the System 5 procedure, while the representative of the European Communities fully understood the

need to provide the translation, he asked if a local sworn translation was always necessary and noted that, perhaps, considering the context, this might be considered an excessive requirement. The representative of the European Communities encouraged Brazil to consider whether some flexibility could be introduced as to how this translation could be provided. For instance, the European Communities asked whether this translation could be made by a sworn translator in the country of export or whether the Brazilian authorities could allow the importer to provide a self-guaranteed translation, coupled with the possibility of a penalty for non-conformity of the translation with the original documents. The representative of the European Communities finally thanked Brazil for the transparency and regard for trade partners' concerns that had been shown by INMETRO in the revision of the decree.

174. The representative of the United States welcomed the announcement that Brazil would eliminate the requirement that imported toys undergo a second set of testing in Brazil. Furthermore, the United States welcomed Brazil's decision to allow imported toys to be marketed in Brazil based on testing performed by any laboratory that had been accredited by a ILAC MRA signatory, at least in some circumstances; to give foreign producers the option to import under Systems 5 or 7; and to provide a transition period for producers to comply with the new regulation. The United States thanked INMETRO for having incorporated these elements in the final regulation and having, in the US understanding, published it the day before the current TBT Committee meeting. The regulation would be reviewed and the United States would revert to Brazil with any remaining concerns. With respect to cases where INMETRO did the accrediting, the United States welcomed receiving additional information from Brazil to clarify the accreditation criteria and application process for test laboratories. The United States noted that it looked forward to continuing to work together with regulators from Brazil and other countries on devising appropriate measures to ensure that children are protected from potentially unsafe toys.

175. The representative of Brazil stressed that the measures adopted by the Brazilian Government regarding the toy sector had been designed to ensure safety through the enhancement of conformity assessment procedures that were applied to products whether imported or domestically produced. These measures acquired a special importance since the products – toys – where were destined for children. The representative of Brazil informed the Committee that the regulation had been published on 3 November 2009 in the Ministerial Act No. 321, dated 29 October 2009, replacing Ministerial Acts No. 326 and 376 of 2007. Ministerial Act No. 321 had some new dispositions concerning the conformity assessment procedures applicable to toys aiming at the simplification of those procedures without jeopardizing safety. He stressed that it granted equal treatment to both domestic and foreign producers. Ministerial Act No. 321 was drafted taking into account comments made by the public in general and by other Members through public consultations which had be held since November 2008. The Act had been notified the previous day to the WTO. Brazilian authorities were confident that, after almost a year of work on this matter, the conformity assessment procedures laid down in Ministerial Act No. 321 were the most adequate to ensure the safety of children and were in accordance with the Brazilian obligations under the TBT Agreement.

176. In response to specific questions, the representative of Brazil noted that his delegation had recently sent a reply to the Thai focal point on comments received. With respect to the need for sequential numbers in the seals, the Act did not require the presence of this sequential number, and the seals could be affixed to toys in the territory of the exporting Members. Moreover, the exporter could choose between Systems 7 or 5 if it complied with the requirements of those certification systems.

(xiv) United States – Consumer Product Safety Improvement Act (G/TBT/N/USA/421)

177. The representative of China reiterated his delegation's concerns about the US Consumer Product Safety Improvement Act (CPSIA). He recalled that at previous meetings of the TBT Committee, China had expressed serious concerns including with respect to the non-transparency of

the Act and the unnecessarily stringent requirements on lead limits. China's key concern was the different treatment by the US Consumer Products Safety Committee (CPSC) against Chinese governmental laboratories. It was recalled that the United States had stated that China's relevant governmental laboratories were not recognized because they failed to meet the requirements of the CPSIA. The representative of China said that the reason his governmental laboratories failed to meet the criteria, as determined by CPSC, was not because they were not technically competent, but rather because the criteria set for them in the CPSIA were more stringent than those required for third party laboratories. In fact, the non-profit governmental laboratories of China were legally responsible for the testing of export products to ensure their compliance with foreign requirements; they were free of undue influence from commercial interest, and, indeed, were more impartial than third party laboratories. Therefore, China invited the United States to once again consider its concern and apply the same recognition criteria to China's governmental laboratories as those applied to third party laboratories. In addition, China had received several complaints from its industry regarding the approval procedure for "All Terrain Vehicles" by CPSC under its "Safety Action Plan" within the scope of CPSIA. According to these complaints, the approval procedure was extremely time consuming and lacked transparency. China appreciated the US willingness to pass this concern to competent authorities and so as to explore ways of addressing it.

178. The representative of the United States noted that there had been twelve CPSC measures notified to the WTO and that four of those – with the numbers: 484, 486, 489, and 490 – had been made since the last meeting of the TBT Committee. These measures and proposed measures covered all aspects of CPSC implementation of the statute. He directed China and other Members to the CPSC website,[11] which provided key guidance documents on test procedures, test methods, and accreditation, a list of accredited laboratories, general counsel advisory opinions, and specific guidance for small businesses. There was also a section of the website that provided information in Chinese.

179. On the issue of government laboratories, the representative of the United States noted that 47 laboratories based in China had been recognized by CPSC. It was hence not accurate to say that CPSC had not accepted any Chinese Government laboratories; in fact, CPSC had approved nine Chinese Government joint-venture laboratories. China's CIQ laboratories had not been accepted because they did not meet the relevant conditions. The United States remained puzzled that China continued to raise the laboratory accreditation issue in the WTO TBT Committee. The United States had opted for a highly trade facilitative approach in its testing regime for children's articles, one that was based on relevant international standards and acceptance of test results from laboratories – wherever they would be located – and that had been accredited by ILAC MRA signatories. Under this approach, CPSC had already accredited 47 laboratories based in China. In view of the United States, the CPSC's approach was a model for other countries – including China – that required third party testing for certain regulatory schemes. Given US recognition of several laboratories located in China, the United States asked when China itself would be recognizing test results from laboratories in the United States that had been accredited by ILAC MRA signatories, with respect to the CCC system and other Chinese regulatory schemes.

(xv) European Communities – Production and Labelling of Organic Products (G/TBT/N/EEC/101 and Add.1)

180. The representative of Argentina reiterated his country's concerns pertaining to the EC Council Regulation No. 834/2007 regarding the labelling of organic products, notified in document G/TBT/N/EEC/101. Argentina's concern was that Art. 24 (c) of that regulation was inconsistent with the TBT Agreement. He recalled that Art. 24 (c) stipulated that the labelling of an organic product should contain an indication of origin of the raw materials in one of the following three forms: either

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

EU Agriculture, non-EU agriculture or EU/non-EU agriculture when a part of the raw material originated from the European Communities and other parts came from third countries. He noted that this regulation was part of EC legal framework whose purpose was to "guarantee fair competition as well as ensure that consumer confidence in products labelled as organic is justified". He explained that the organic nature of a product was guaranteed by the fulfilment the EC's regulations on organic labelling, which was independent of the origin of the raw materials. He therefore argued that distinguishing between EU and non-EU origin of raw materials had no bearing on the organic nature of the final product and could thus not be justified by the objective of preventing consumers from being misled. In addition, he emphasized that the regulation was neither based on an international standard nor on scientific evidence. Argentina's view was that this regulation created an unnecessary barrier to international trade because origin-based organic labelling distinctions appeared to be unnecessary and without legal justification. Despite the fact that the European Communities had informed the TBT Committee in the July 2008 meeting that Art. 24 of the regulation 834/07 would not come into force until 2010, Argentina considered that this delay was insufficient to provide a substantive solution to its concerns and urged the European Communities to review Art. 24.

181. The representative of the European Communities recalled that Council Regulation (EC) No. 834/2007 on organic farming - in particular as regards labelling rules on origin - had been discussed previously in the TBT Committee, as well as in bilateral meetings with Argentina. She explained that the Commission's views remained that there was no evidence that the new labelling rules would negatively impact sales of products from Argentina, or other origins, on the EU market. She stressed that the application of Art. 24 of this regulation had been postponed until July 2010 as the new EU organic logo was not yet in place. From July 2010, the new logo would be applied to all organic products throughout the European Communities. She stressed that the placement of the EU organic logo was currently voluntary, but would become mandatory as of 1 July 2010 for pre-packaged food originating from EC member States. The EU organic logo would continue to be voluntary for imported products after this date. She noted that the new logo would help reassure European consumers that the products were of genuine organic origin. The European Communities was confident that many Argentine organic products would be able to use this logo and that the labelling requirements on origin would not result in adverse trade effects.

(xvi) European Communities – Seal products

182. The representative of Norway reiterated his delegation's concern about the European Commission's proposed regulation concerning trade in seal products.

183. The representative of Canada informed the Committee that her delegation had requested dispute settlement consultations with the European Communities on this issue.

184. The representative of the European Communities noted that it was not appropriate to further discuss this issue in the TBT Committee given that the matter would be discussed in the context of the Dispute Settlement Understanding. However, the EC delegation remained open to discuss with Norway the regulation and implementing rules that would be adopted.

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

185. The representative of the European Communities reiterated her delegation's concern regarding India's amendment of the Rules on the Prevention of Food Adulteration (G/TBT/N/IND/34) which outlines mandatory labelling guidelines for pre-packaged food. She noted that in November 2008 the European Communities had submitted comments on this measure, had raised the issue at the last two TBT Committee meetings, and had outlined its concerns with India bilaterally on several occasions. However, the European Communities had not received a reply to its written comments, nor to its requests for clarification on the various revisions to these rules, which had been notified by India to

both the TBT and SPS Committees. Furthermore, she noted that various attempts by the EC delegation in New Delhi to set up technical meetings with the Indian authorities to obtain more clarity on the implementation of these measures had so far been unsuccessful. The European Communities urged India to provide an answer to its written comments and to provide information with regard to the current state of play of the application of these measures given that the grace period allowed for economic operators to adjust to the new requirements had expired in June 2009.

186. The representative of India indicated that she was not in a position to answer the questions posed by the European Communities but would convey the concern raised back to capital.

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

187. The representative of the European Communities reiterated her delegation's concerns regarding notification G/TBT/N/CHL/81 and Add. 1 from Chile. She noted that the European Communities had recently held fruitful bilateral discussions and hoped that a written reply to comments raised would be sent soon.

188. The representative of Chile noted that lengthy bilateral discussions had been held. She said that an expert from the Ministry of Health had informed her delegation that the amendment process, based on the analysis of the comments received during public hearing, was still underway. Chile's representative noted that her country would make the necessary amendments to the document taking into consideration the comments received, including those from the European Communities. She stated that there was nothing new to report since the last EC-Chile bilateral meeting held on 25 September 2009 and noted that any new developments would be passed onto the European Communities immediately.

(xix) Colombia – Quality and Identity Requirements for Distilled Spirits (G/TBT/N/COL/120 and Add.1, G/TBT/N/COL/121 and Add.1; G/TBT/N/COL/130 and Add.1)

189. The representative of the European Communities noted that her delegation had sent written comments to Colombia regarding notifications G/TBT/N/COL/121 and G/TBT/N/COL/130 on 19 March and 10 September 2009, respectively. She stated that in previous TBT Committee meetings, her delegation had outlined their main concerns regarding the issue of alcoholic beverages, and referred to the minutes of those meetings for a detailed outline of concerns. Therefore, she asked Colombia to provide an update on the review process currently taking place and to clarify the relationship between the two drafts notified. The EC delegation asked Colombia to provide an answer in writing to the EC's comments.

190. The representative of the United States thanked Colombia for its written response to the comments provided and for clarifying and accommodating many of the concerns raised by his delegation. However, after reviewing the response, he noted that the United States remained concerned about several issues regarding Colombia's intentions towards imported distilled spirits. It appeared that Colombia would still impose a number of requirements regarding spirits' alcohol content, flavour additives, ageing, and colourings. The US representative specified that they had highlighted these issues in their comments and in bilateral discussions, and had requested that Colombia explain the basis for its proposals in these areas. Colombia's use of analytical parameters on certain chemical constituents found in specific categories of spirits was an example of a concern that remained. In particular, the United States was concerned that Colombia planned to maintain maximum alcohol content limits for spirits, which would bar some exports of US Bourbon and Tennessee Whiskey to Colombia. He asked whether Colombia could explain the scientific and technical basis for mandating maximum alcohol content limits for distilled spirits. These requirements, if not modified in the final measure, could block certain US exports of gin, rum, whiskey, and vodka to Colombia. The United States representative noted that his country had sent a

letter to Colombia outlining these concerns and he looked forward to further bilateral discussions. He asked whether Colombia could give an update on how it planned to address the issues raised by industry and trading partners in their comments. The US representative urged Colombia to consider further revisions to its proposed requirements in light of the continued concerns that the United States had raised. He invited Colombian regulators and trade officials to participate in a video conference with the US to discuss the matter on a technical level.

191. The representative of Colombia acknowledged that a bilateral meeting had been held a couple of days prior to the TBT Committee meeting. She also noted that Colombia had responded to the 11 March concerns on 28 May 2009. Her delegation did not have any prepared responses to the latest concerns since the contact point had only received the above-mentioned letter on 28 October 2009. It appeared to her that the remaining concerns were issues of clarification rather than concerns about the creation of unnecessary barriers to trade. She recalled that Colombia and the United States were parties to a free trade agreement which had been approved by Colombia and was awaiting ratification by the United States. Therefore, until the treaty came into force, her country would be unable to apply the measures contained in that treaty. The representative accepted the US's proposal to hold a video conference between officials.

192. Regarding the concerns raised by the European Communities, the Colombian delegate noted that in March 2009, the European Communities had sent a number of observations. After having received them, the technical regulation referred to in notification G/TBT/N/COL/120 on labelling of spirits, had been withdrawn by Colombia as an expression of political good will. The specific questions put forth several months ago on the second regulation notified in G/TBT/N/COL/121 had been answered in writing on 30 October 2009. As to the relationship between the two drafts notified, it was noted that G/TBT/N/COL/130 was a more recent measure which contained some emergency regulations which had to be adopted in Colombia because of problems with contraband and adulteration of spirits, which could cause grave health problems and be life threatening. The representative of Colombia said that they had not received any specific questions regarding this document.

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

193. The representative of the European Communities reiterated her delegation's concerns regarding the decree from Colombia that provided that all gasoline engine motor vehicles would have to be equipped with flexifuel engines. During the last TBT Committee, her delegation had extensively explained the concerns on this matter. It was noted that the European Communities had sent detailed written comments on 1 April 2009 and had been informed by the Colombian TBT Enquiry point that it would receive a reply to those comments during the Committee meeting and that a technical committee had also been reviewing the decree. The EC representative asked if Colombia could give a reply to its detailed comments and provide updated information on the possible revision.

194. The representative of Mexico associated her country with the observations made by the European Communities and asked if Colombia could provide an update on the draft decree.

195. Regarding the decree on the use of biofuels in Colombia, the representative of Colombia noted that her country was committed to promoting the biofuels industry. It was noted that during the week prior to the TBT Committee meeting, the Ministry of Mines and Energy, the body responsible for the implementation of this regulation, had informed her delegation that in response to the concerns expressed, they would be reviewing the decree and would respond to the questions put forth by a German automotive corporation and to the concerns submitted by the European Communities.

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

196. The representative of Japan noted that India had postponed the enforcement of the Second Order from 12 February 2009; he asked the representative of India to inform the Committee of future plans in this regard. He explained that there was no use in imposing mandatory certification regulations on intermediate products, such as iron and steel products, in order to ensure human safety and stated that India should reconsider the introduction of the regulation, including its withdrawal. It was noted that at the last meeting, India had explained that the objectives of the regulation were minimizing power loss, structural safety, and safety when steel was being used at high temperatures. However, he noted that the protection of consumer health or safety depended only on final products, and not on intermediate products. This protection could be achieved by safety regulations for the final products as was done in Japan. Japan had achieved protection of consumer safety by implementing many strict regulations on final products, such as the Building Standard Law or the Electrical Appliance and Material Safety Act. He highlighted that the Japanese Government had not implemented mandatory certification regulations on intermediate products, since such certification was of no use. Moreover, the Japanese delegation asked India to take into account the fact that the regulation would create major adverse effects not only on international steel trade, but also on the manufacturers operating in India – in other words, the international competitiveness of its own industry would be affected. The Japanese representative stated that if the regulation were to be enforced beginning next February as stated, it needed to be implemented in a way that was consistent with Article 2.2 of the TBT Agreement, reflecting the spirit of the series of G20 Commitments, while giving adequate consideration to actual business transactions.

197. The representative of India explained that the notification was concerned with power loss, structural safety, and the use of second grade steel in appliances which were causing concern in terms of consumer safety. She noted that many products in India were hand-made and not mechanized and therefore the safety of the user or the consumer was very relevant. Regarding consistency with the TBT Agreement, she noted that this measure was covered under the TBT Agreement through mandatory certification on products for consumer safety.

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

198. The representative of Japan reiterated concerns regarding Thailand's introduction of new criteria for conformity assessment with the Thai Industrial Standard mandatory certification scheme announced by the Thai Industrial Standards Institute. He stated that his delegation was raising this issue again because Japanese manufacturers importing steel from Japan had faced substantial problems in Thailand. He stressed that not only was it not necessary to impose mandatory certification regulations on intermediate products, such as iron and steel products, but, in addition, the regulation was inappropriate to achieve human safety. Japan was confident that protection of consumer health or safety could be achieved by safety regulations that addressed the final products, not intermediate products. Therefore, Japan strongly urged Thailand to make the new regulations consistent with Article 2.2 of the TBT Agreement. Moreover, Japan reminded Thailand that as a G20 member, it should respect the spirit of G20 commitments. In light of these facts, Japan recommended that Thailand reconsider the implementation of the regulation including its postponement or withdrawal.

199. The representative of Chinese Taipei supported the comments made by Japan.

200. The representative of Thailand explained that the new criteria for certification, which had become effective on 1 May 2009, aimed at ensuring product quality through ISO 9001, as well as ISO/IEC Guides 65 and 67. She noted that, compared with past regulations, the new regulations were applied equally strictly to both domestic and imported products. She informed the Committee that difficulties in complying with the new regulations had only been reported during the transition period and had since been resolved. Thailand had not received further complaints on compliance difficulties.

(xxiii) India – Restriction on Chinese toys

201. The representative of China recalled that as of 23 January 2009 the Indian Ministry of Commerce and Industry had issued and implemented two regulations, namely Regulation No. 82 which imposed a general ban on Chinese toys, and Regulation No. 91 which required Chinese toys to comply with certain standards and conformity assessment procedures. Neither of these had specified a legitimate objective, nor had they been notified to the WTO. The representative of China was of the view that these two regulations accorded unfavourable treatment to Chinese toys, in particular with respect to the fundamental WTO principles of national treatment and most favoured nation treatment under GATT 1994 and the TBT Agreement – Article 2.1 and 5.1 in particular. The regulations also lacked transparency. Therefore China had requested India to withdraw the measures immediately.

202. It was recalled that the Chinese position on this issue had been made clear in a submission to the TBT Committee (G/TBT/W/304) and had been discussed, in detail, at the TBT Committee's March 2009 meeting. At that meeting, the representative of India had responded that while he recognized the regulation No. 91, which was a replacement for the regulation No. 82, still was of concern to China, he hoped that an amicable solution would be found through bilateral channels. Thereafter, the Indian Ministry of Industry and Commerce had published and enforced a new regulation, No. 113, on 16 June 2009. This new regulation was to replace the former one (Regulation No. 91) and appeared to be a step in the right direction. However, China found that the discriminative nature – as well as other inconsistencies with WTO TBT Agreement – persisted in the new regulation. China noted that the only essential modification in the new regulation was substituting "import of toys from China" for "import of toys". Moreover, the new regulation required that imported toys needed to comply with four different standards, including standards prescribed in ASTM F963 or standards prescribed in ISO 8124 Parts 1-3, or IS standard 9873 Parts 1-3, or standards prescribed in EN71. Mandatory testing and certification was required but there was no indication whether toys manufactured domestically in India were required to meet these same requirements prescribed in the new regulation.

203. The representative of China noted that at the last TBT Committee meeting, China had raised concerns about the national treatment of the new regulation and asked India to provide relevant documents which laid down the same requirements to domestic toys. India had responded that their toy industry was already complying with these standards but had not provided China with the relevant documents. Therefore, China again requested India to provide written documents so as to ensure accountability and so as to address China's concerns about national treatment. In addition, the representative of China recalled that at the last TBT Committee meeting, India had recognized that there were some problems regarding small and unorganized toy producers on the Indian market. China asked India to clarify if this meant that small and unorganized toy producers in India had been granted a transitional period to comply with relevant requirements? If so, what were the criteria for such "small and unorganized players", and could foreign small toy producers benefit from the same transitional period on a national treatment basis?

204. The representative of China noted that his country was a world leading toy producer; he was confident of China's ability to provide Indian children with good quality and safe toys. However, an analysis of the above-mentioned four standards (those referred to in the new regulation) had found conflicting technical specifications. For example, IS standards and ISO standards had different machinery requirements compared to ASTM and EN 71. Moreover, flammability requirements and requirements on migratory substances differed between ISO standards and ASTM standards. The Chinese industry had complained that the enforcement of different standards created confusion and it was impossible for one toy to meet all of them. Multiple requirements on toys in the Indian regulation also lead to concerns about unnecessary restrictions on trade. Based on the analysis of those technical specifications in the four different standards, China asked that India notify this new regulation to the WTO according to Article 2.9 of the TBT Agreement. He also requested India to accept the Chinese

standard for toys as equivalent considering that Chinese standards were in accordance with the relevant ISO standards. He expressed regret that the issue had been raised repeatedly, both bilaterally and in the TBT Committee and that, nevertheless, severe trade restrictions persisted and were affecting exports of Chinese toys. China therefore requested India to take prompt action so as to bring its measures into consistency with obligations under the WTO TBT Agreement.

205. The representative of India expressed regret that her delegation had not been in a position to respond positively to a request for a bilateral meeting due to other commitments. She noted that India had issued a notification (No. 113 dated 16 June 2009) amending the earlier notification (No. 91) whereby the import of toys had been prohibited up to 23 January 2010. However, the import of toys was permitted if the toys were accompanied with certificates showing conformity to standards prescribed by ASTM F963, or ISO 8125, the Indian standard 9873, or EN 71. She noted that, in effect, the ISO and the Indian standards were identical. The conformity certificate was to come from the manufacturer. She also noted that toy exporters had to have the toys tested by an independent laboratory which had been accredited by ILAC or through an MRA and found to meet the specifications indicated above. The certificate also needed to link the toys in the consignment to the period of manufacture indicated in the conformity certificate. Clearly, considering the above, there was no discrimination against the import of Chinese toys since imports of all types of toys from all countries faced the same requirements. Furthermore, since Indian standards conformed to international standards, there was no need for flexibility vis-à-vis EN and ASTM.

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

206. The representative of the United States reiterated his country's concerns with respect to the French Ministry of Agriculture's (MoA) "skirt" requirement for ride-on lawnmowers, a measure that had neither been published as part of an official law or decree in France nor notified to the WTO. It was noted that the MoA requirement for ride-on lawnmowers had already disrupted US lawnmower exports to France. If other European Community Member States were to adopt this requirement, a significant portion of the approximately USD1 billion in annual US shipments of lawnmowers to Europe could be adversely affected.

207. The United States representative said that his country did not understand the basis for the MoA requirement that ride-on lawnmowers be fitted with a "skirt" for bystander protection. He said that both the European and American industry had claimed that the MoA had not presented any accident data supporting the need for the requirement, and they alleged that the requirement could in fact increase the potential for safety problems by increasing the risk of fire caused by accumulating debris in the vehicle. He stated that the MoA had not meaningfully addressed these points, except to cite general accident data and note that industry had made adjustments to decrease the risk of fire that the skirt installation had created. The representative of the United States noted that the main issue was the lack of a fact-based justification for imposing the requirement. Moreover, 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 used worldwide. The US representative 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.

208. The US delegate expressed disappointment that the European Commission's DG Enterprise had confirmed its initial rejection of the European industry petition challenging the MoA requirement's conformity with the Machinery Directive. He reiterated his country's request that the Commission share any specific accident data supporting the French position that installation of the lawnmower skirt would increase bystander safety since his country was still unaware of any such data. He stressed that this incident had raised serious concerns about the viability of the New Approach. If the Commission allowed certain member States to impose their own technical

requirements whenever they disagreed with the applicable CEN standard or in advance of the CEN standard being finalized, without any obligation to publish or notify such requirements, this threatened the objective of establishing a common European market. It also threatened the ability of suppliers, both European and non-European, to do business in Europe. The representative of the United States asked the European Communities to carefully consider the systemic ramifications of this case.

209. The representative of the European Communities noted that there had been developments concerning the complaint submitted by the European garden machinery federation. At the last TBT Committee meeting, the EC delegation had reported that the complainant had challenged the initial findings of the European Commission services through a written submission. However, the complainant failed to provide evidence that would cause the initial determination to be amended. Therefore, it was noted that the European Commission had decided to close the case in September 2009. The complainant had been informed of the outcome of the procedure in writing. The EC representative recalled that there had been an exchange of letters with the USTR in which all of the points that had been raised at the last TBT Committee and reiterated today had been addressed in detail. In addition it was noted that, on 8 September 2009, a specific meeting had taken place in Brussels with the representative of the US mission to the European Communities to clarify the functioning of the market surveillance system in EC member States and standardization developments in the field of safety of lawn mowers. The EC representative noted that the meeting had been useful and constructive for all parties.

210. Regarding the concerns raised, the EC representative said that he would not repeat all the arguments that had been developed in previous interventions nor would he repeat the full content of the letter that had been addressed to the USTR in July 2009. Regarding accident data, it was noted that both the European Communities and the United States had records of large number of serious and fatal accidents involving powered lawnmowers, which had been stated in the letter to the USTR. According to estimates produced by the European Union Injury Database for Home, Leisure and Sports Accidents, based on reports for the period 2002-2006, there had been approximately 42,000 accidents per year requiring hospital treatment involving powered lawnmowers in the European Communities. The US Consumer Product Safety Commission had reported even higher figures, with about 10 per cent of the reported accidents involving children. However, the accident data did not make it possible to link accidents to particular aspects of the design of the machinery concerned. It was clear that the principle risk associated with ride-on lawn mowers was contact with the blades and loss of stability. However, it could not be argued that measures should not be taken to prevent a given risk only because it was of secondary importance. Furthermore, he noted that the common European and international standard on risk assessment for machinery, IS0 14121 2007 "*Safety of Machinery - Risk Assessment - Part 1:Principles",* clause 42(d), states that while underlining the importance of accident data, the absence of an accident record should not be taken as a presumption of low risk.

211. Regarding the disruption of exports, the European Commission had obtained information which specified that most manufacturers, including US manufacturers, had now developed designs that complied with the protection requirement of the machinery directive. Therefore, the EC representative did not expect this issue to have any other effects on US exports of lawnmowers. He also stressed that a flexible guard or skirt was neither the only, nor indeed the best way of preventing access to moving transmission parts. Based on information gathered from industry, most of the manufacturers of ride-on lawnmowers appeared to have developed design solutions involving integrated guards instead of skirts which did not give rise to any risk of fire.

212. On the issue of the WTO TBT notification, it was noted that there was no French measure introducing a new requirement, rather it was a market surveillance action aimed at assuring the effective application of an existing requirement. In addition, the European harmonized standard for lawnmowers EN 836:1997 was being revised under ISO lead, according to the so-called Vienna Agreement between CEN and ISO. The representative of the European Communities noted that he

was confident that an agreement between the US and the EC participants to this standardization work would be found in order to have a revised standard that clarified the specifications relating to the safeguarding of moving transmission parts in lawnmowers.

213. The representative of the European Communities noted that on the systemic implications for the New Approach, the US arguments were unfounded. The New Approach's more than 20 year history showed that it had greatly facilitated trade among EC member States and with third countries by ensuring a well-functioning internal market based on a common set of requirements. He stated that it was the duty of national authorities to enforce New Approach legislation and that effective mechanisms were in place to ensure uniformity in the implementation and enforcement in the EU Member States. Where the legislation was of a technical nature, the assessment of a product by market surveillance authorities inevitably implied an assessment as to whether the design of the product with regard to its safety components was compatible with the legal requirements. Therefore, the EC delegation disagreed with the idea that each and every one of these market surveillance actions should give rise to a separate WTO notification. In this case, there was no new measure as this was only about the enforcement of existing legal requirements.

214. The representative of the United States replied that the EC's explanation appeared to justify regulation without any evidence at all. With respect to the fact that manufacturers had installed integrated guards in place of the skirts, the US representative made two points: first, he noted that manufacturers had only installed the guards under duress, so that French customs would allow lawnmowers out of the warehouses. Second, if they had not designed such guards, there would have been a risk of fire for which those companies would have been held liable. The European Communities had cited several thousand accidents that had occurred, but the US representative explained that the relevant question was not the number of accidents but how those accidents had occurred and whether installing a skirt could have prevented them.

215. The representative from the European Communities responded that the manufacturer had to ensure that all the relevant risks were eliminated at the design phase and if this was not possible then to reduce them through integrated design measures. He said that this was the principle that was applied in the European Communities and it corresponded to the one embodied in the ISO standard on risk assessment methodology for machinery. He emphasized that the European Communities would be content with a higher safety standard even in the absence of data providing a clear link between a particular risk and injuries occurred.

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

216. The representative of China reiterated concerns about the above-mentioned Argentine measure affecting the import of toys. As had been indicated at the last meeting of the TBT Committee, the Argentine regulation imposed certification requirement only on imported toys. While the delegation of Argentina had explained that the testing and certification requirements would apply equally to imported and domestic toys, there was nothing in the regulation itself that imposed such requirements to domestic toys. China invited the Argentinean delegation to provide specific information in this regard. In addition, although Argentina had made a commitment to limit the time for delivering testing reports to 60 days, the Chinese industry was still suffering from substantial time delays. These delays – and associated expenses – had been exacerbated by requirements for import licenses after certification. In total it took more than 200 days to import products into Argentina, sometimes even more than 300 days which made it impossible to import products for a particular selling season. The representative of China encouraged Argentina to take into account Members' comments and bring its regulation in line with the WTO TBT Agreement.

217. The representative of the United States supported Argentina's objective to protect children from exposure to potentially dangerous substances in toys and other children's articles. Nevertheless, the United States recalled that it had raised this issue at the last meeting of the Committee because the US toy industry was concerned about the need to perform the testing in Argentina, and also with respect to the overall lack of testing capacity in Argentina, which could increase costs and create substantial delays to market, thereby disrupting trade ahead of the critical holiday season. In fact, it was the US understanding that companies exporting toys to Argentina had already experienced delays. One US company had reported that complying with the in-country testing requirement had added more than 90 days to the process of getting its products to market in Argentina.

218. Nevertheless, the representative of the United States noted that it was clear that Argentina had been taking the concerns expressed both in the TBT Committee and bilaterally seriously. Argentina was working on solutions to these issues, including taking steps to identify additional laboratories to handle testing, and, in its recently-notified measure, allowing products to remain on the market if the supplier certified that the toys met Argentine standards and indicated that a request for a test report had been made to INTI prior to 23 September 2009. As a short-term measure to address the current delays while INTI worked to reduce the time frame for certification, the United States suggested that Argentina could consider extending this timeframe because many suppliers were likely unaware of this flexibility since the notification had been published after the 23 September deadline.

219. The representative of the United States asked Argentina to provide an update on its efforts to take the concerns expressed by industry into account. In terms of a permanent solution to the problem of delays, the United States urged Argentina to consider accepting test results conducted by laboratories that had been accredited by an ILAC MRA signatory, including laboratories located in the country of production. The United States offered to facilitate regulator-to-regulator discussions on this matter so that his delegation could share its experiences, having successfully implemented an ILAC-based testing regime for many children's products, including, among other things, chemical content testing. The United States also pointed at opportunities for participation in APEC that could prove valuable for Argentine regulators.

220. The representative of the European Communities associated his delegation with the concerns expressed by China and the United States, in particular those relevant to long delays. In this regard, the European Communities was concerned about the apparent lack of sufficient testing capacity in Argentina. His delegation suggested that Argentina consider accepting results carried out in foreign ILAC accredited laboratories.

221. The representative of Argentina noted that protecting the health and safety of children was a common concern to all Members: there is indeed a need for a high standard of security. Since the last Committee meeting of the TBT Committee, in June 2009, consultations had continued on a bilateral basis to attend to the concerns of some of the Members who had taken the floor, particularly the United States. The discussion was reflected in the minutes of that meeting and the representative of Argentina did not intend to repeat arguments already made. He drew the Committee's attention to the fact that Argentina had recently submitted a new notification pertaining to this matter (G/TBT/N/ARG/51/Add.5, dated 19 October 2009). This notification provided clarification with regard to the scope of the original resolution as well as instructions for the implementation of that regulation. Furthermore, certain temporary flexibilities were granted – as had been elaborated by the US representative.

222. With respect to the comment from China on the applicability of the measure to toys produced domestically, the representative of Argentina noted that his delegation had clearly said at the last meeting that this resolution applied to both imported as well as domestic products despite the fact that the text of the resolution did not specifically state this. He asked China to provide evidence that this was *not* the case so that Argentina could address the issue. In fact, the Argentine customs authorities

required the relevant requirements to be met both for imports and for exports, and they demanded documentation that attested to compliance with the applicable regime.

223. With regards to the comments pertaining to the recognition of foreign laboratories, the representative of Argentina informed the Committee that the Argentinean accreditation body, the OAA, had signed the mutual recognition agreement treaties in the context of ILAC. Therefore, it recognized certificates issued by laboratories that had been accredited by other bodies that had signed the aforementioned treaty. He underscored, nevertheless, that the report needed to clearly identify the tested articles as well as the methodology that had been used; this methodology had to be equivalent to the methodology used locally. He noted that these conditions, however, had not been met in the few certificates that had been presented by importers to date. In this respect, the following flaws had been observed. First, there was difficulty in determining the traceability between the samples and the identification codes for the tested samples. Second, there had been differences noted in the sampling methodology (it was pointed out that that Argentina like the United States carried out sampling in parts because if one analyzed a mixture of the article with different components made with different materials, there was a chance that an error would occur because of possible dilution and therefore contamination). The third flaw that had been observed was that the samples presented in international laboratories were not always equivalent to those that had been submitted for import.

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

224. The representative of China raised concerns about several implementing measures related to the EC Energy-using Products (EuP) Directive. These implementing measures covered a very wide variety of energy-using products, including electrical and electronic equipment, lamps and household refrigerating appliances. While the representative of China fully supported the objectives of saving energy and natural resources by increasing energy efficiency, he was highly concerned about the potential adverse impact of these measures on international trade. China had sent written comments on all these measures concerned and had also raised concerns at the March 2009 meeting of the TBT Committee. China's concerns were mainly about the non-use of relevant international standards; the stringent nature of the energy efficiency requirements; and the lack of consideration of the needs of developing country Members. For example, in the latest notification relating to household refrigerating appliances (G/TBT/N/EEC/273 and Add.1), the notified measure required that the measured value should not be less than the rated value by more than 10 per cent; however, the tolerance value in the relevant international standard (IEC 62552:2007) was 15 per cent. Although China had still not received a reply from the European Communities to written comments, it was hoped that European Communities would take into account comments made, as well as the special needs and difficulties of developing country Members. The representative of China stressed, in this regard, the relevance of Article 12 of the TBT Agreement and the need for minimizing adverse affects to international trade.

225. The representative of the European Communities pointed out that the TBT Committee had discussed the measures at issue on several occasions. They were based on technical, environmental and economic analyses carried out in full transparency with the participation of stakeholders from around the world. The reports were available on the EC website.[12] With respect to EEC/273, China had indeed sent comments and a detailed reply, in writing, had been provided the day before the current meeting. With regard to the specific question about the IEC standard 62552:2007, it was correct that Annex E of this standard described a two-stage verification procedure: first, the appliance needed to be tested with the measurement of uncertainty of 15 per cent; and, second, three more appliances needed to be tested with the measurement uncertainty of 10 per cent. Under the notified

[12] http://ec.europa.eu/energy/efficiency/ecodesign/forum_en.htm

legislation the first step disappeared so in other words, the measurement uncertainty remained at 10 per cent. It was noted that the 15 per cent value for the measurements on certainty used in the IEC standard (for the testing of the first appliance) had been provided to include production variability. However, the European Communities was of the view that variability was considered as a part of the overall appliance quality and needed therefore be under the manufacturers' responsibility. Therefore, the verification of tolerances for the measurements of energy consumption and freezing capacity had been reduced in the notified legislation to 10 per cent from the beginning in order to leave production variability under the manufacturers' responsibility. A transition period of two years had been given to provide sufficient time for manufacturers to adapt to this reduction of measurement tolerances.

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

226. The representative of Japan noted that despite receiving responses to comments made, his delegation remained concerned that dibutyltin compounds (DBT) had been banned although no difference had been found between DBT and dioctyltin compounds in terms of risk level in the final RPA Report, a socio-economic impact assessment. Furthermore, Japan was concerned that this would result in an obstacle to trade for boards of highly transparent grade, which used dibutyltin as an essential compound in their manufacture. Furthermore, noting the risk assessment on DBT in the RPA Report which recommended the reduction of risk through a method that estimated the aggregated risk of several exposure sources, he emphasized the point that the Report of the Science Committee on Health and Environmental Risks (SCHER) made the statement on this method that it increased uncertainty in the assessment of exposure and need much information for the effective use of this method. Japan was concerned that, despite this note in the Report, the process which had resulted in the different treatment between DBT and DOT was unclear. Moreover, Japan did not consider it appropriate to expand the regulation beyond those exposure sources which had obvious risks. Therefore, the European Communities was requested to show the details of the scientific grounds on which the implementing regulations were based. After reviewing this information, Japan would consider the need to have an expert level bilateral meeting.

227. The representative of the European Communities recalled that she had explained at the last meeting of the TBT Committee the reasons for the different treatment of dibutyltin compounds and dioctyltin compounds. The main reason for the difference was that dibutyltin compounds had been classified as toxic for reproduction which was not the case for dioctyltin compounds. The European Communities would nevertheless revert to Japan on this issue since more concrete, scientific arguments were made by Japan in the meeting; her delegation remained open to a direct exchange between the experts on the matter.

(xxviii) China – Green Dam Youth Escort internet filtering software

228. The representative of Japan continued to be concerned about China's notice mandating the installation of the Green Dam software on all computers sold in China effective 1 July 2009. This measure raised significant questions about security and system reliability because computer makers would have no choice to select filtering software other than Green Dam although China had announced the postponement of the measure in June 2009. The representative of Japan requested China to ensure that the measure would not be more trade restrictive than necessary following exhaustive discussions with affected Members. Japan requested China to leave the choice of filtering software to consumer and computer producers.

229. The representative of China wished to provide some clarifications. It was recalled that access of minors to pornographic content on the internet was a concern common to parents all over the world. In this respect information technology provided an effective and cost efficient way to address the concern. The so-called Green Dam Youth Escort had been purchased by the Chinese Government

in the form of government procurement and aimed to fulfil the legitimate objectives of protecting minors. It had been provided to computer producers and users free of charge and, as a result, there was no additional cost to computer producers. With respect to installation, computer producers could install the software in computer hard-disks or with a CD that accompanied the product. The software installation process could be managed according to business practice. Therefore it was China's view that there would be no significant effect on computer trade of other Members.

230. With regard to the question about the impact of the software on computer security and system reliability, the representative of China said that this concern had been taken into consideration in the software development process; in fact, the security of the Green Dam software had been tested many times by third party testing bodies. With respect to the application of the software, just like other software – such as Windows – this software could be updated on-line or through updated versions on CDs. Hence, concerns about possible impacts on computer security, system reliability and compatibility had been addressed. Moreover, if stakeholders found any other specific technical problems China was ready to take immediate action to examine and address these. Regarding the request to leave the selection of filtering software to consumers and to computer producers, the representative of China noted that since the Green Dam Youth Escort Software was provided free of charge from the government, universal access could be guaranteed. It was China's view that leaving open the choice of selecting software would lead to significant costs to computer producers and users, thereby undermining the achievement of China's legitimate objectives. In addition, this would also significantly affect international trade since it would not be practical for the government to buy all possible software using public money and providing these free of charge.

231. In respect of the IPR issue that had been previously raised, it was noted that the Chinese Government had attached importance to IPR issues from the very beginning. As a buyer the Chinese Government had required the supplier to provide software with IPRs once a contract was negotiated. Additionally, if there was any complaint about an IPR issue it would be addressed adequately through the Chinese domestic legal system. To date no such case had been filed in China.

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

232. The representative of Canada noted that her delegation had a number of outstanding concerns on this measure despite some clarifications provided to its Enquiry Point on 17 April 2009, as well as bilateral meetings held. Most importantly, Canada reiterated its request to Korea to extend its 1 January 2010 implementation date on the proposed regime. If Korea did not extend its implementation date, it appeared that there would be no viable option for Canadian organic producers to have their products accredited under the Korean Organic standard and therefore Canadian organic products would not be able to be exported to Korea. An extension granted for foreign certifiers and companies would allow them time to review the final Korean organic regime and comply with the organic standards. Canada understood that the proposed amendments to the regime had not yet been finalized and that final versions of regulations were not available. The representative of Canada asked Korea to indicate when the final versions of the amended regulations would be available. As per the principle set out in the TBT Agreement, as well as in Codex, she hoped that Korea would use the delay in the implementation date to include provisions in their regime which allowed for equivalency agreements. Canada would welcome the opportunity to work towards developing an equivalency arrangement on organics with Korea.

233. The representative of New Zealand associated herself with the points made by Canada. New Zealand understood that the Republic of Korea's Ministry of Food, Agriculture, Forestry and Fisheries had signalled that it would delay implementation of the new regulations until 1 January 2011. Could this be confirmed? While the representative of New Zealand welcomed this delay, she remained concerned that the new regulation failed to provide for the recognition of equivalence; she urged the Republic of Korea to consider equivalence agreements with the

International Organic Certification Agency (IFOAM) and/or foreign governments before the new regulation took effect.

234. The representative of the European Communities joined other delegations in expressing concerns about the measure at issue. Comments had been sent in April 2009 and a reply had been received from Korea on 20 October 2009. However, the information provided in the reply did not fully address the EC concerns. As had been previously stated, the European Communities was mainly concerned with the fact that the Korean regulation did not foresee accepting legislation of other WTO Members as equivalent. In the view of the European Communities, this practice was not in line with the Codex Alimentarius Guidelines for the production, processing, labelling and marketing for organic foods, which encouraged the principle of equivalence to be applied for imports of organic products. The European Communities was also concerned about the fact that foreign certification bodies that had been accredited in their country of origin needed to be re-accredited in Korea in order to be able to certify organic products for the Korean market. In this respect, the European Communities drew the Committee's attention to the fact that in order to be accredited in the European Communities, these certification bodies had to undergo a strict approval process followed by close supervision by competent authorities in EU member States. In addition, in order to provide ever greater assurance of their testing and certification ability, as of 1 January 2009 all European certification bodies also had to be accredited to the standard EN 45011, equivalent to the ISO 65 Guide.

235. The representative of the European Communities noted that a large number of European operators exporting organic food to Korea were small and medium enterprises (SMEs), which produced relatively small consignments of organic products for export to Korea. The European Communities was concerned that the high administrative burden that these operators would be faced with in order to certify their products in accordance with Korean standards, would lead many of these companies to withdraw from the Korean market. The European Communities therefore urged Korea to outline the reasons for which the Codex Guidelines for organic foods had not been taken into account. The European Communities also invited Korea to consider recognizing the system for organic production applied in the European Communities as equivalent to the Korean system so as to avoid further certification. To this end, the European Communities would be pleased to provide Korea with the necessary information on the European Communities' organic production framework in order to facilitate an equivalence assessment. Finally, in order to avoid possible trade disruptions in light of the imminent entry into force of these requirements, the European Communities asked the Korean authorities to postpone the implementation of the measures at issue – currently foreseen for 1 January 2010 – by at least one year.

236. The representative of Switzerland noted that the new Korean regulation for organic processed foods was scheduled to enter into force on 1 January 2010. As a consequence, products certified to their national organic programmes, and previously recognized as organic in Korea, would no longer be recognized as such unless Korea provided procedures for equivalence or recognition. However, it was Switzerland's understanding that Korea's enforcement regulations did not provide adequate procedures for recognizing a foreign government's conformity assessment system, nor did they appear to contain procedures for determining equivalence. The representative of Switzerland asked to what extent the Codex Principles for Food Import and Export Inspection and Certification had been taken into account in the drafting of this measure. Switzerland was concerned that market disruption and unnecessary costs would result and asked the Korean authorities for clarification, especially concerning import provisions and procedures to be followed. A number of technical questions still needed further clarification. Given the fact that this would take more time and that economic damages needed to be avoided, Switzerland proposed that Korea extend the deadline for implementation from 1 January 2010 to 1 January 2011. This would allow the various parties to consult with the Korean authorities and to clarify the future modalities in trade.

237. The representative of Korea recalled that some of the issues raised had been discussed at the previous meeting of the TBT Committee and further discussions had been held bilaterally in the margins of the current meeting. He confirmed that the programme was aimed at improving the quality of organic processed food, encouraging its production, and protecting consumers. The certification system was basically quite similar to that used in the United States and Japan where the certifiers applied for accreditation at the Ministry of Food, Agriculture, Forestry and Fisheries and be approved as the Certification Authority under the regulation. The representative of Korea also confirmed that the notification of the introduction of this programme to the WTO had been made in February 2009 and the implementation of the programme was scheduled for 1 January 2010. Korea was open to the comments and concerns regarding implementation and was considering to amend requirements regarding the number of the certification inspectors.

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

238. The representative of Brazil noted that his delegation had outstanding concerns about the impact of proposed amendments to EC Regulation 1234/2007. In particular, Brazil was concerned by the fact that the new labelling rules for poultry meat preparations would have a de facto discriminatory effect against non-EU producers of poultry meat. As a direct result of the regulation, only poultry meat produced in the European Communities would be allowed to be used in poultry meat preparations labelled as "fresh poultry meat preparations". Countries like Brazil that had to freeze poultry meat before export to the European Communities, would not be able to supply poultry meat to the EU market for preparations because the regulation did not foresee any labelling for preparations made of frozen poultry meat. In Brazil's view there was no reasonable justification to prevent the use of frozen poultry meat in preparations. The European Communities had suggested that the changes were due to the need to inform consumers; however, in Brazil's view, this did not have to have the effect of cutting off the possibility of using frozen poultry meat in preparations. The legitimate objective of informing consumers about the characteristics of poultry meat preparations could be achieved through other less restrictive approaches. Brazil had suggested that for preparations made of frozen poultry meat a specific label such as "preparation made of previously frozen poultry meat" could be used. This alternative would give consumers a wider range of options without impeding trade. However, the European Communities had disregarded this suggestion. The representative of Brazil urged the European Communities to revise the newly adopted regulation, which Brazil considered could constitute a major obstacle to trade under the TBT Agreement. Brazil would closely monitor the implementation of these new measures as it evaluated what action to take so as to defend its commercial interests.

239. The representative of Australia asked for some assurances that the amendments proposed by the European Communities would not result in unnecessary restrictions on trade. Australia was concerned by the inconsistency between the EC Hygiene Regulation 853 of 2004 on the definition of fresh meat and the new EC marketing standard for fresh poultry meat. She asked the European Communities to explain the basis for deviating from the definition contained in its own hygiene regulation. Australia considered that poultry that had been quick frozen for transport and/or storage and then thawed for retail trade was safe and wholesome. Moreover, Australia drew the Committee's attention to the existence of technology that could fast-freeze fresh product and then deliver a product of highest quality after defrost. Utilizing this technology, product integrity was maintained during the freezing process and could be delivered into the retail store in a controlled manner. The technology ensured that product arrived in the store at a deep chilled temperature, just below 0 degrees centigrade. Organoleptic trials and scientific data had confirmed the integrity of the product during the fast freezing process and had shown them to be of the same quality as fresh product.

240. The representative of Australia was of the understanding that the European Communities was seeking to address consumer preferences. However it was not clear how the new marketing standards would address consumer preferences or, indeed, how it would address consumer concerns.

Clarification was sought in this regard. Australia also sought advice from the European Communities on whether alternatives had been considered, such as those suggested by Brazil. Such alternatives could include the label: "previously frozen or chilled" product rather than implementing what appeared to be a ban on selling thawed product. Such a ban effectively favoured local producers over more distant producers where freezing was the only practical way of getting it to the market.

241. The representative of the European Communities referred to bilateral exchanges that had taken place prior to the Committee meeting and stressed, in particular, the fact that existing rules – which had been in force since 1991 – already prevented defrosted poultry meat from being sold as "fresh". Therefore the proposed new rules were simply an extrapolation of the rules that already applied to poultry meat and were aimed at ensuring that consumers were duly informed about the products they purchased. It could not be disputed that consumers that bought a preparation which was labelled as "fresh" expected it to be indeed fresh and not one which contained defrosted poultry meat. For this reason the proposal put forward by Brazil for using an alternative label stating "previously frozen" had been discarded. Moreover, the current proposal did not ban the sale of frozen poultry meat preparations; it simply restricted the use of defrosted poultry meat in preparations which were sold as "fresh". Frozen poultry meat could still be sold in the European Communities and be labelled as frozen.

242. In addition, the representative of the European Communities noted that after a thorough analysis of the Brazilian comments, it had been concluded that there would be no substantial trade impact since the vast majority of the EU imports from Brazil were either poultry products or preparations, for which the proposal did not introduce any new provisions. The only goods that could be affected by the new requirements were frozen filets that were currently used for preparations sold as fresh – but these represented a very small fraction of Brazil's exports of poultry meat into the European Communities. The EC representative added that the marketing standards, adopted on 19 October 2009 would go into force in May 2010 – this period assured that operators would have sufficient time to adapt to the new rules.

243. With respect to the possible inconsistencies between the definition on the hygiene standards and that of the proposed regulation, the representative of the European Communities noted that the hygiene rules, in general, did not have the same purpose as marketing standards. The purpose of hygiene rules was to ensure that the food which was put on the market did not present any risk to human health. Marketing standards did not deal with sanitary issues but guaranteed a certain level of quality and ensured that the products put on the market corresponded to consumers expectations. From a hygiene perspective, fresh meat was defined in the EU legislation as meat that had not undergone any preserving process other than chilling, freezing or quick freezing, including meat that was vacuum wrapped or wrapped in a controlled atmosphere. The term "fresh", however, was not linked to the term used in the commercialization of the product. In other words, the notion of fresh in the marketing standards was to be considered slightly more restrictive than the notion of fresh in the hygiene legislation but this was not a contradiction. In fact, the fresh poultry definition had been stricter than the hygiene definition since 1991 and no new elements had been introduced in this regard.

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

244. The representative of the United States said that his delegation continued to have serious concerns regarding the new accreditation framework set out in EC Regulation No 765/2008. This regulation, which would become effective on 1 January 2010 and apply to all sectors, would require each EC member State to appoint a single national accreditation body and would prohibit competition among member States' national accreditation bodies. The regulation further specified that national accreditation bodies shall operate as public, not-for-profit entities and independently of any

conformity assessment body. This meant that only a single, government entity in each member State would be permitted to accredit conformity assessment bodies in the European Communities.

245. The United States was particularly concerned about the regulation's impact on the recognition of non-EU accreditation bodies under the ILAC MRA and the IAF MLA, and the acceptance of conformity assessments performed by ILAC MRA and IAF MLA accredited bodies. It was the US understanding that the regulation left it to EC member States to decide whether or not to recognize non-European accreditation bodies; also, member States would have the discretion whether or not to accept conformity assessments issued by ILAC MRA and IAF MLA accredited bodies. The representative of the United States was concerned that without clear guidance from the European Commission, EC member States could refuse to recognize non-European accreditation bodies and conformity assessments issued by non-European testing and certification bodies. This could both undermine the international accreditation system under the ILAC MRA and the IAF MLA and impede US exports to the European Communities.

246. The United States also continued to have a number of questions about how the new EC accreditation framework would operate in practice – there were, in this regard, a number of reports from industry that raised concerns. These included questions regarding: (i) the rationale behind the new system; (ii) how attestations of conformity assessment results issued by bodies that had been accredited by foreign accreditation bodies that were signatories of the ILAC MRA or IAF MLA, but that did not necessarily comply with the new accreditation requirements would be treated in Europe; and (iii) the potential impact of the new system on the international accreditation framework. The United States had submitted these questions to the European Communities with a view to setting up a technical discussion in the near future to discuss these concerns and to learn about more about the EC accreditation framework, including its implementation.

247. The representative of the European Communities reiterated that the new accreditation framework was a tool in support of EC internal regulatory policy; the effects of the new accreditation system needed, in the first place, to be appreciated in relation to the EU internal market and the operation of the regulatory system in those cases where EU legislation required mandatory third party assessment. The representative of the European Communities referred to the comprehensive overview given at the last TBT Committee meeting on the main features of the new accreditation system, both with respect to internal implications and external effects. It was stressed that there was no intention to force changes in accreditation systems or practices in third countries; on the contrary, the intention was to build on the existing international accreditation system rather than undermining it. The European Communities welcomed bilateral technical exchanges on the matter. Nevertheless, because the issue was of potential interest to the Committee as a whole, the European Communities would consider providing more general information about the new EC accreditation framework under the Agenda Item "Exchange of Experiences" at the next meeting of the Committee.

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

248. The Chairman recalled that, in accordance with Paragraph 18 of the Protocol of Accession of the People's Republic of China (WT/L/432), the TBT Committee would undertake an annual review for eight years of the implementation by China of the TBT Agreement.

249. The representative of the United States highlighted some issues contained in his delegation's submission (G/TBT/W/324). He welcomed the progress made at the 20th session of the US-China Joint Commission on Commerce and Trade (JCCC) on several issues that had been raised at previous TBT Committee meetings. On information security, he noted that China had confirmed the announcement made on 29 April 2009 by AQSIQ, MOF and CNCA, that the compulsory testing and certification rules for thirteen categories of information security products would apply only to

products procured by agencies of the Chinese Government. He also noted that China had agreed to establish a dialogue on global practices for trade in information security products. According to the United States, substantial progress had also been made in the area of medical devices. In particular, he noted that China had reassured the United States that product recall regulations would not be duplicative or redundant, and the Ministry of Health and the State Food and Drug Administration (SFDA) would be the relevant authorities for medical device recalls. China had also indicated that a prior approval document of a medical device issued by a foreign country would be accepted, regardless of whether the device had been granted a prior approval document by the country of export or the manufacturer's country of legal residence, to satisfy any prior approval registration requirement. The representative of the United States stressed that, without such changes, trade in medical devices would have been seriously disrupted to the detriment of suppliers and traders, as well as Chinese hospitals, doctors and patients. In addition, he said that China and the United States had agreed to strengthen cooperation on standards and conformity assessment procedures, and to formulate a work plan for enhancing transparency and predictability in their respective regulatory systems.

250. Notwithstanding the progress in such areas, concerns remained about a number of issues that had been addressed in previous Transitional Reviews, including: favouritism toward home-grown 3G telecommunications standards; lack of transparency with respect to certain measures; and the failure to recognize the results of conformity assessment procedures conducted by accredited conformity assessment bodies located outside of China.

251. The US representative noted that his delegation had significant concerns about China's use of China-specific standards in the telecommunications area, especially with regard to the Wireless Local Area Network Authentication and Privacy Infrastructure, or WAPI, standard. He explained that China's Ministry of Industry and Information Technology (MIIT) had recently established a process for approving hand-held wireless devices such as cell phones and smart phones that are Internet-enabled. In September 2009, MIIT had indicated to US government officials that devices using WiFi, (ISO/IEC 8802-11), the relevant international standard, would only be approved if also enabled to support the WAPI standard. MIIT officials had indicated that no published or written measure containing this requirement existed, and China had not notified this requirement to the WTO. Could China explain why it required that mobile handsets be WAPI-enabled, especially given that the United States was not aware of any other government that had mandated a particular commercial security standard? Could China further explain why it mandated compliance with a non-consensus based standard that did not appear to have been developed in an open and transparent process, when there was a relevant international standard thatwas in widespread use in the global marketplace? Could China clarify why the WiFi standard was ineffective or inappropriate to achieve China's objectives? Given that services and devices based on WiFi alone were widely available and legally sold in China, what was China's justification for requiring type approval in this sub-sector of the mobile equipment market? And finally he asked what China's justification was for not mandating these particular technical regulations through written and published regulations, in an area as broad as type approval and network access for mobile devices in the world's leading mobile handset market?

252. With respect to conformity assessment procedures, the United States noted that the TBT Committee had developed an *Indicative List of Approaches to Facilitate Acceptance of the Results of Conformity Assessment*,[13] which included several approaches for accepting the results of conformity assessment, including test results performed by laboratories located outside the territory of the importing Member. This list included use of accreditation to qualify conformity assessment bodies. It was also recalled that there was a variety of accreditation approaches, and that one approach successfully employed by several Members consisted of the use of accreditation by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) Members as

[13] G/TBT/1/Rev.9, Annexes to Part 1, Section A.

a basis for accepting test results performed by laboratories outside the territory of the importing Member. Had China considered utilizing this mechanism, or another mechanism such as government designation or recognition of foreign testing laboratories, as a basis for accepting test results performed by laboratories outside its territory, including with respect to the China Compulsory Certification (CCC) Mark and SFDA requirements? In concluding, the US representative noted that a further discussion on China's consideration of alternative approaches for accepting the results of conformity assessment could be helpful, especially in the context of the JCCT outcomes.

253. The representative of Japan referred to his delegation's submission (G/TBT/W/325). He noted that the "Instructions on factory inspections" intended to be referred to when conducting factory inspections had been uploaded on the website of the designated certification body under the China Compulsory Certification (CCC) scheme. In this regard, China was invited to provide clarification on the legal relationship between such instructions and the mandatory requirements under the CCC scheme. Japan's view was that the instructions on factory inspection uploaded on the website of the certification body were for reference purposes only and did not entail any mandatory requirement. Could China confirm this?

254. Japan was also concerned that China had adopted certain national standards that appeared to deviate from the relevant international standards, causing unnecessary confusion among foreign companies. In particular, the Japanese delegation drew the Committee's attention to the voluntary national standard for labeling GB/T 191:2008, in which the calculation method for maximum allowance of piling up of cardboard boxes differed from the relevant international standard. Although GB/T 191:2008 was a voluntary standard, China made a reference to it in its mandatory standard GB 5296.2:2008. Therefore, Japan's view was that GB/T 191:2008 constituted a *de facto* mandatory standard. According to Article 2.5 of the TBT Agreement, Japan requested China to explain the justification for referring to this national standard and the objective sought. China was also encouraged to align this standard with the relevant international standard, according to Article 2.4 of the TBT Agreement. Finally, the representative of Japan noted that concerns remained with regard to the Chinese regulations mandating certification on IT Security Products, and those had been addressed under the Specific Trade Concerns part of the Agenda.

255. The representative of the European Communities highlighted some points in his delegation's submission (G/TBT/W/326), and noted that this document identified areas where progress had been made as well as areas where concerns remained. Nevertheless, he expressed satisfaction with the well functioning regulatory dialogue between China and the European Communities.

256. The European Communities wished first of all to raise some systemic concerns. On good regulatory practice, it welcomed efforts made by China and highlighted the significant increase in the frequency of public calls for comments. The importance of ensuring transparency in the regulatory process both in the development and enforcement of regulations was emphasized. Likewise, the importance of ensuring that all existing requirements which economic operators needed to comply with be made publicly available was stressed. In China this did not appear to be the case in all sectors and significant differences existed for regulations under the responsibility of different Ministries. The European Communities was particularly concerned about existing practices in the ICT area, where various mandatory requirements had been introduced without being notified to the TBT Committee or even without prior internal notice. In particular, the EC representative referred to several concerns previously raised in the Committee, such as the WAPI standard, the green dam internet filter, and the unified charger for mobile phones. China's Ministry of Industry and Information Technology (MIIT) was therefore invited to reconsider its practices in accordance with the transparency provisions under the TBT Agreement. China was also encouraged to systematically use regulatory impact assessment tools, at least in those cases where regulations had a significant impact on international trade. It was the European Communities' view that the introduction of Regulatory Impact Assessments could help to achieve a better balance between the legitimate regulatory objectives pursued and the need to keep

the level of regulation proportionate to the risks being managed. The European Communities was willing to share experience with China on its own Regulatory Impact Assessments and intensify bilateral cooperation in this regard.

257. Second, the EC representative noted his delegation's concern with regard to the level of regulation in China. He noted that the Chinese approach was characterized by a systematic use of mandatory standards combined with third party conformity assessment, without any genuine attempt to modulate the intensity of regulation (including the stringency of the conformity assessment procedures) depending on the type of risk to be managed. This resulted in a cumbersome system especially for Small and Medium-sized Enterprises (SMEs) exporting to China without a direct presence in the country. In this context, he reiterated concern about the Chinese Compulsory Certification (CCC) system, which was detailed in the EC submission and had been previously raised in the Committee. Despite some positive steps, the CCC system remained a major obstacle for foreign companies exporting to China. In particular, China was invited to review the "one size fits all" approach based on comprehensive third-party testing and factory audits, which assigned the same high level of risk to all products within the CCC scope, despite their different health and safety risks levels. It was the EC delegation's view that alternative approaches had to be considered by China, such as Supplier's Declaration of Conformity for low-risk products, for instance low voltage and ICT products. A choice between quality assurance and product verification conformity assessment modules needed to be offered where third-party assessment was required.

258. The European Communities joined the United States and Japan in requesting that China provide wider acceptance of foreign test results and explain what mechanisms were in place or were being considered in order to facilitate the acceptance of foreign test results. In the meantime, the EC representative invited China to give positive consideration to the proposals for short-term simplification of certain aspects of the current CCC system, as outlined in the EC submission G/TBT/W/326 and in the submission made on the occasion of the previous Triennial Review.[14] On the same topic, the European Communities also noted that China maintained an overly detailed regulation in specific sectors, such as the mobile phones area. There was also a tendency to regulate qualitative aspects of products that in most economies were instead left to the market, as for instance in the textile field with regard to colour fasteners.

259. Third, the European Communities raised another systemic concern with regard to the need for better internal regulatory coordination between Chinese Ministries or agencies having regulatory powers. It was the EC delegation's view that competition between Ministries or agencies over regulating the same product arose in a number of cases and resulted in the creation of multiple and partially overlapping requirements. Examples of this situation, such as the information security case and the certification procedures for ICT equipments, had already been raised under the Specific Trade Concerns item of the Agenda. In this regard, China was invited to explain whether it intended to develop more effective internal regulatory coordination mechanisms.

260. Fourth, in the area of standardization, the European Communities welcomed the announcement made by the Standardisation Administration of China (SAC) in January 2009, that foreign-owned companies established in China would be allowed to participate as voting members in technical committees responsible for the promulgation of national standards, pending the approval of the technical committee's Chairman. The European Communities further encouraged China to ensure effective access of foreign-owned companies to domestic standardization work, including with regard to the so-called industry standards. On the same topic, the EC representative also noted that, on several occasions, a number of Chinese standards deviated from international standards without any explanation being given that the relevant international standards were inappropriate or ineffective.

[14] G/TBT/W/300.

Standards on wine and in the ICT field were examples of this situation. China was urged to limit such deviations to justified cases and provide justifications for deviations in all the other cases.

261. Finally, the European Communities reverted to various concerns which had been raised at previous triennial reviews, but that had not been addressed yet. A common feature of these concerns was that problems often arose from a regulatory approach that appeared to depart from international practice. Regarding the ICT field, the EC delegate echoed the concerns expressed by the United States on the proliferation of home-grown 3G telecommunications standards featuring unique Chinese technologies. China was encouraged to continue working with the international standardization community, rather than developing specific national standards. This would benefit all economic operators including China, which could take advantage of the best technology available. In the mobile phone area, concerns also remained about the systematic black listing of certain features of products, which prevented innovative products from being placed on the Chinese market.

262. With regard to the automotive sector, the European Communities encouraged China to join the United Nations 1958 Agreement on Motor Vehicles under the Economic Commission for Europe (UNECE).

263. With regard to active pharmaceutical ingredients, the EC delegation reiterated concerns about the routine multi-sampling and testing practice mandated for each imported batch of active pharmaceutical ingredients (APIs) imported into China. China was encouraged to intensify cooperation on quality assurance and Good Manufacturing Practices which could lead to mutual acceptance of quality certificates. On pharmaceutical products, the European Communities noted that registration periods in China could take three years or even more, due to a number of cumbersome, lengthy and costly requirements relating in particular to clinical trial approvals. China was therefore invited to expedite work towards the simplification of the clinical trial process, and develop practices compatible with those developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

264. Furthermore, the European Communities representative expressed concerns with respect to the lengthy pre-market approval procedures for non-special use imported cosmetics. In particular, he requested China to unify the notification system for imported and domestic non-special use cosmetics. However, the European Communities considered the simplification of procedures to be only a first step towards lifting all ex-ante approvals for imported cosmetics. China was also requested to develop a single hygiene standard for cosmetics that would replace the two standards separately enforced by the Ministry of Health on one hand, and the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) on the other.

265. Regarding medical devices, concerns remained on duplicative mandatory (re-)registration requirements enforced by SFDA and AQSIQ. The EC representative reiterated his delegation's request to China to treat new or fully refurbished medical devices alike, since the existing ban did not appear to be justified on health and safety grounds. China was encouraged to provide an update on the work under way with regard to this issue.

266. On textiles, concerns remained about the deviations from international standards in relation to import checks. China was invited to consider replacing systematic checks by batch with random checks, and to accept importers self-declarations of conformity based on tests carried out by international accredited laboratories. China was also encouraged to simplify the labelling requirements for textiles and footwear products. In this regard, the proposal on textile labelling

submitted in the context of the NAMA NTB negotiations,[15] was seen by the European Communities as an example that could inspire a simplification of the Chinese requirements.

267. In concluding, the EC delegate requested China to provide an update on the state of play of the on-going revision of *Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals*.

268. The representative of China referred to her delegation's submission (G/TBT/W/327) providing information related to Annex 1A of WT/L/432. In respect of the comments on China's implementation of the TBT Agreement's transparency provisions, the representative of China noted that, to date, her delegation had made 695 TBT notifications, providing in each case a sixty day comment period and copies of full texts of notified measures upon request. Moreover, it was normal practice to extended this period upon a Member's request. The Chinese representative said China was an active participant in the Committee's work on transparency and information exchange and would continue this engagement.

269. Regarding information security testing and certification, the representative of China noted that information had already been provided under the Agenda item of Specific Trade Concerns. However, her delegation would nevertheless provide clarification on the existing relationship between information security testing and certification and the encryption codes regulation system. In particular, the Chinese delegate recalled that, among the thirteen products which needed to obtain the information security product certification, six of them contained encryption technology. These six products were therefore required to pass the detection tests for encryption codes, in accordance with China's policy on the regulation of commercial encryption codes. It was further clarified that the State Encryption Administration Authorities (SEAA) were responsible for the testing of encryption codes, while the Certification and Accreditation Administration of the People's Republic of China (CNCA) was responsible for the product certification. The representative of China emphasized that the current regulation on Commercial Encryption Codes had been enacted in 1999 and was functioning. However, to better adapt to the latest development of information technology, China was considering revising this regulation and had started investigation and research. Comments and suggestions by Members were welcomed by China in this regard.

270. In respect of the implementation of the CCC system, the representative of China noted that improvements were continuously being made. In the current revision of the implementation rules of the CCC scheme, China was committed to simplifying the procedure, mitigate the burden of enterprises and further revise the parts and components report procedure and unit division. It was also stressed that interested parties, such as *EuropElectro*, were closely involved in the process of revision. In this regard, China welcomed any suggestions from Members and interested stakeholders and was ready to continue the cooperation with the European Communities.

271. In respect of the comments on China's conformity assessment procedures, it was emphasized that the regulations on Certification and Accreditation and on Management of Compulsory Product Certification clearly indicated how to accredit the certification bodies and laboratories to undertake CCC certification. It was also recalled that the CCC system recognized the CB reports within the scope of the IECEE/CB scheme. The Chinese representative explained that the International Laboratory Accreditation Cooperation (ILAC) was the cooperative organization of the laboratory accreditation agencies, and the ILAC Mutual Recognition Arrangement (MRA) was the key technical base for mutual recognition between China and other countries.

[15] TN/MA/W/93/Rev.1.

272. In respect of the comments raised by Japan on "Instructions on factory inspections", China confirmed that these documents were only intended to facilitate factory inspection operations and did not impose any mandatory requirement.

273. Regarding the relationship between standards GB/T 191-2008 and GB 5296.2 2008, the representative of China explained that according to Article 5.2.5 of GB 5296.2 2008: "the products with special requirements in the process of transportation and storage should be labelled with the graphic signs and according with the provisions of GB/T 191-2008". She noted that, as the only Chinese recommended standard to regulate the graphic signs of package, transportation and storage, GB/T 191-2008 was quoted in GB 5296.2-2008, with the aim of protecting consumers and helping enterprises to harmonize their operations.

274. On the subject of standardization, the Chinese delegate emphasized that all the foreign-funded enterprises legally registered in China could participate in standardization activities, and all foreign-funded enterprises could participate in the revision activities of China's recommended standards as observers. With regard to the questions on national deviations from international standards, the Chinese delegation noted that China's deviations were necessary in light of geographical and technological differences. Regarding the comments on the maximum sulphur dioxide levels in wines, the representative of China noted that information had already been provided under the Agenda item on Specific Trade Concerns.

275. Regarding the concern raised by the European Communities on voluntary standards rendered mandatory through conformity assessment procedures, the Chinese delegate recalled that the recommended standards were voluntary standards but became binding once incorporated into a mandatory act.

276. With regard to the use of the WAPI standard, the representative of China noted that the Chinese operators decided that the WLAN network and relevant equipment would support both WAPI and ISO/IEC 8802-11 standards. This was to ensure the safe operation of network and businesses, and provide the users with safer and more reliable wireless broadband communication services. Mobile phones meeting the requirements and supporting both WAPI and ISO/IEC 8802-11 standards were allowed to enter the WLAN network. In this regard, it was also recalled that MIIT had launched a pilot programme of network access for WAPI and ISO/IEC 8802-11 dual-mode mobile phones. Enterprises were free to apply for participation in this programme. So far, more than thirty types of mobile phones had passed the test. China would continue to improve work related to the management of network access of mobile phone in light of the progress of the pilot programme and market demand. It was China's view that the WAPI standard did not deviate from the ISO/IEC 8802-11 standard, it was rather a supplement that enhanced the latter. It was also recalled that China had submitted the WAPI standard to the International Organization for Standardization (ISO) for recognition as an international standard.

277. Regarding the draft measure on Medical Devices Registration Administration Method, China reassured Members that it would be notified in due time.

278. Regarding the comments raised by Japan on the Chinese measure notified under G/TBT/N/CHN/426, the Chinese representative noted that a sixty day comment period had been provided but comments had not been received from Members. It was stressed that China had fully fulfilled its transparency obligations under the TBT Agreement.

279. Finally, the representative of China drew the Committee's attention to a question from one Member regarding measures "without legitimate objectives". China strongly refuted the premise of this statement and recalled that the measure at issue had been notified to the TBT Committee in 2008 (G/TBT/N/CHN/426), and that no comments had been received even though 60 days had been

provided. The reason for the notification had been because of a deviation from certain international standards and China was, in this regard, in full compliance with its obligations under the TBT Agreement. In addition, it was noted that there was still no definition of an international standard on which Members could agree. Therefore, in reply to other Members' comments, the representative of China doubted that there existed a definition of international practice.

280. The Committee adopted its report of the Eight Annual Transitional Review (G/TBT/27).

IV. TECHNICAL COOPERATION ACTIVITIES

281. The representative from UNECE informed the Committee that a training workshop on the practical application of risk assessment and management tools would be held on 23 November 2009.[16] This workshop was being organized for market surveillance authorities from countries of the Commonwealth of Independent States (CIS) in cooperation with the Interstate Council for Standardization, Metrology and Certification of the Commonwealth of Independent States. The focus would be on how market surveillance authorities can use risk assessment and management tools in cooperation with other stakeholders in order to increase the effectiveness of their operation and in particular to fight the proliferation of dangerous and non-compliant goods on the market in that region.

282. The Chairperson drew the Committee's attention to a document containing the Secretariat's technical assistance activities (G/TBT/GEN/91).

V. UPDATING BY OBSERVERS

283. The representative of the IEC provided the Committee with an update on its recent activities in developing countries (G/TBT/GEN/92).

284. The representative of UNIDO drew the Committee's attention to two recent publications launched with partner agencies. First, he noted that a handbook entitled "Building Trust - The Conformity Assessment Toolbox" covering all aspects of conformity assessment in international trade had been co-published with ISO. This publication could be downloaded from both the ISO and the UNIDO websites free of charge. The representative of the UNIDO also brought the Committee's attention to the next edition of a publication done within the framework of the CEB Inter-Agency Cluster on Trade and Productive Capacity for coordination.[17] This would contain a chapter on compliance, infrastructure and support services provided by the UN system in relation to conformity assessment.

285. The representative of Codex drew the Committee's attention to document G/TBT/GEN/90 containing an update of relevant Codex work. In addition, he informed the Committee on recent discussions that had taken place during the 31st Session of the Commission with respect to private standards. These discussions focussed mainly on what had taken place in the SPS Committee.

286. The representative from UNECE informed the Committee of the upcoming UNECE Working Party on Regulatory Cooperation and Standardization Policies which would take place from 24-26 November 2009. This session would also include a Conference on Risk Assessment and Management (mentioned above). The Working Party would be asked to review and formally approve the work undertaken during 2009. This would include a proposal for common regulatory objectives initiative targeting electrical and mechanical equipment and the recommendation to use the IECx, the international conformity assessment schemes under IEC, as the preferred means of demonstrating

[16] http://www.unece.org/trade/wp6/documents/2009/2009_workshop.htm
[17] http://www.unctad.org/Templates/StartPage.asp?intItemID=4793&lang=1

conformity. The representative also brought the Committee's attention to two important documents on market surveillance that would be discussed. She invited all Members to attend the Working Party.

287. The representative of ISO updated the Committee on the state-of-play of the consultation process for the ISO Strategy Plan 2011-2015. In this regard, a series of workshops for developing countries would take place over the next six months with particular interest in developing countries input into conformity assessment and participation in the international standardization process. He informed the Committee that ISO would soon be publishing the results of a study of the value of standards at a company level and a sector level. The objective of the study was to be able to determine the value of standards and therefore the participation of industry in the standardization process and the benefit to industry of such participation. ISO would also be conducting a joint education seminar with the IEC and the ITU in June 2010 so as to raise awareness amongst academics on the value of standards and the benefits to trade through their involvement in research and their involvement in standardization. With respect to private standards, the representative of ISO emphasized the importance of ensuring a clear understanding of international standards and international standardization under the terms of the TBT Agreement and in accordance with the principles as laid out in the Annex to the TBT Agreement.

VI. FIFTH TRIENNIAL REVIEW

288. The Chairman recalled that the Committee was mandated under Article 15.4 of the TBT Agreement to conduct the Triennial Review *no later than the end of the third year from the date of entry into force of the WTO Agreement and at the end of each three-year period thereafter*. He stressed that the draft Report, available in all three languages in the Room (JOB(09)/97/Rev.3), was the product of intensive and constructive consultations carried out over the last few months. It was also the product of a work process that had been consensual, structured, inclusive and transparent. He thanked Members for their constructive engagement and flexibility shown during the negotiation of the text which had allowed the Committee to reach agreement. Indeed, the report was substantive in nature and showed not only significant progress made by the Committee in the past, but also important work that needed to be embarked on in the future.

289. The Committee adopted its Fifth Triennial Review Report (G/TBT/26).

290. The representatives of Pakistan and El Salvador wished to put on record their appreciation for the Chair's efforts and those of the Secretariat in preparation of the Review, in particular with respect to the transparent and inclusive nature of the consultations which had allowed also small delegations to participate.

291. The representatives of the United States and the European Communities thanked the Chairman for having successfully guided Members through challenging discussions, as well as the Secretariat for the process used and the drafts produced. The report was indeed substantive in nature, including a range of initiatives. The Committee would now need to turn its attention to addressing these in an efficient and effective manner

VII. DATE OF THE NEXT MEETING

292. The next regular meeting of the TBT Committee will take place on 24-25 March 2010.

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