
Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 1-2 July 2008

Chairperson: Ms Xueyan GUO (China)

Note by the Secretariat¹

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

I. ADOPTION OF THE AGENDA

1. The Committee adopted the agenda contained in WTO/AIR/3204.

II. ELECTION OF CHAIRPERSON

2. Pursuant to Article 13.1 of the TBT Agreement, the Committee elected Ms Xueyan GUO (China) as the Chairperson of the TBT Committee.

III. IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

A. STATEMENTS FROM MEMBERS UNDER ARTICLE 15.2

3. The Chairperson recalled that the latest list of statements submitted under Article 15.2 of the TBT Agreement was contained in document G/TBT/GEN/1/Rev.7, issued on 7 March 2008. Since 1995, a total of 117 Members had submitted at least one statement on implementation under Article 15.2. Since the last meeting, held in March 2008, Albania and Ukraine had submitted their Statements under Article 15.2 (G/TBT/2/Add.99 and G/TBT/2/Add.100, respectively), and Ghana (G/TBT/2/Add.76/Rev.1), Indonesia (G/TBT/2/Add.3/Rev.2) and Paraguay (G/TBT/2/Add.91/Rev.1) had submitted revisions to their Statements. It was also noted that the latest list of Enquiry Point contacts is contained in document G/TBT/ENQ/33.²

4. The Committee took note of the information provided.

B. SPECIFIC TRADE CONCERNS

5. The Secretariat introduced a draft document (JOB(08)/53) containing an overview of specific trade concerns raised in the TBT Committee to date (since 1995).

6. The Chairperson encouraged delegations, when raising a new specific trade concern at the TBT Committee, to inform the Chairperson through the Secretariat, as well as the Member concerned, in advance of the meeting.

7. The representatives of Canada and Chinese Taipei stressed the importance of Members' being informed prior to the Committee meeting about specific trade concerns to be raised. It was proposed that the Committee follow the example of the SPS Committee by setting a deadline for Members to communicate to the Secretariat their intention to raise specific trade concerns at the meeting in order to give sufficient time for the preparation of responses.

1. New Concerns

(i) *Brazil – Regulation on Identification and Quality Standards of Ethyl Alcohol and other Spirits (G/TBT/N/BRA/276, Suppl.1)*

8. The representative of Mexico raised concerns about a draft regulation on identification and quality standards for alcoholic beverages, notified by Brazil on 7 May 2008 (G/TBT/N/BRA/276), which set out, among other things, the specifications for identity and quality of different alcoholic drinks. Although the reference to tequila was of particular concern to his delegation, the regulation of other alcohols such as rum and gin was also a matter of concern.

² Regularly updated information on Members' enquiry points is also available on the following TBT webpage: http://www.wto.org/english/tratop_e/tbt_e/tbt_enquiry_points_e.htm

9. The representative of Mexico drew the Committee's attention to the fact that tequila had been an appellation of origin recognized by the Mexican government since 1974, and had been registered within the trademark office of the World Intellectual Property Organisation (WIPO) in 1977. He recalled that appellations of origin indicate the geographical nature of the country or the region used to designate a product from a certain place whose characteristics are essentially related to the environment, and in particular to natural and human factors. In this regard, the tequila originated from a Mexican region called "Tequila", where a number of natural factors combined and created a unique area which provided the product with its exclusive characteristics. Also, the antique tradition of tequila production, which had been transmitted through many generations, created human factors which permitted tequila to be recognized as a high quality product on international markets.

10. The representative of Mexico also informed the Committee that a complex regulation on the manufacturing of tequila had been in force since 2005 (006-SCFI 2006). In particular, to guarantee the authenticity of tequila, the Mexican government had implemented a protection system which included: (i) an identification of the geographical zone used for the production of tequila's raw material; (ii) specific technical regulations; (iii) a regulatory body which controlled compliance with technical requirements; (iv) export controls; and (v) inspection procedures. The Mexican technical regulation also set out other requirements for specific categories of tequila, including: controls on the manufacturing process, water quality, physical and chemical analysis, labelling and bottling requirements.

11. The Mexican representative emphasized that tequila was a product internationally recognized as originating from Mexico and needed therefore to be produced in compliance with Mexican legislation. It was the view of his delegation that Brazil set a definition of tequila and referred to requirements that were incompatible with those set by Mexican legislation, and there was no scientific justification. The Brazilian draft regulation was therefore incompatible with several provisions of the TBT Agreement, the GATT 1994 and the TRIPS Agreement. In particular, the draft regulation contained requirements that were inferior to those allowed for in Mexico with regard to methanol, aldehyde, lead, copper, and others which limited the percentage of alcohol per volume. It was pointed out that such measures would limit the types of tequila that could be commercialized in Brazil, and would favour the marketing of lower quality products.

12. It was Mexico's understanding that the legitimate objective identified by Brazil with regard to the draft regulation was: the protection of consumers from misleading or deceptive practices. However, the representative of Mexico believed that the draft regulation would not fulfil such legitimate objectives, but would rather constitute an unnecessary barrier to trade. He therefore asked Brazil to clarify the legitimate objectives of the draft regulation in accordance with Article 2.2 of the TBT Agreement and stated that Mexico would present its written comments to Brazil in order to further discuss the issue.

13. The representative of the European Communities shared the concerns expressed by Mexico. She stressed that the proposed draft regulation would have a serious impact on European exports of spirits to Brazil. First, the draft standard defined the category of spirit drinks in terms of chemical components by means of analytical parameters; however, the European Communities - along with other countries - defined categories of distilled spirits in terms of raw materials and production processes. The divergence in standards could constitute an unnecessary obstacle to trade. Second, the alcohol content requirements established in the proposed Brazilian regulation did not conform to the international standards for most spirit categories; therefore, the European Communities urged Brazil to retain minimum strength requirements only and align these with internationally accepted values. Finally, the draft regulations restricted the use of certain flavourings in spirit drinks exported to Brazil, thereby causing negative impacts on European exports to Brazil. In concluding, the European Commission invited the Brazilian authorities to take into account both its oral and written comments.

14. The representative of Brazil recalled that the regulation at issue was still a draft currently under public consultation. He confirmed that Mexico had additional time to submit its comments, and recalled that any comments would be taken into account before the adoption of the regulation. However, Brazil stressed that the draft regulation on identification and quality standards for alcoholic beverages was intended to create identity and quality requirements for spirits, and had no relation with intellectual property issues.

(ii) Germany – Changes in the Prohibition of Chemicals Ordinance

15. The representative of Israel drew the Committee's attention to the changes that Germany intended to apply to its Prohibition of Chemicals Ordinance. He expressed concerns about the fact that, following the proposed changes, some chemicals that were widely used as fertilizers would be listed as propellants for explosives. It was noted that the proposed regulation would require registration and training from the importers of the listed "explosive substances". His delegation was particularly concerned about two substances incorporated in the new list which were mainly produced in Israel: sodium nitrate and potassium nitrate. The representative of Israel pointed out that calcium nitrate, a substance with similar chemical properties, was not listed as an "explosive substance". Israel believed that the inclusion of sodium and potassium nitrate in the list was an unnecessary obstacle to trade and that the measure could create competitive distortions for Israeli products.

16. The representative of Chile shared the concerns expressed by Israel.

17. The representative of the European Communities explained that the draft neither provided for a prohibition of substances nor did it lay down a technical regulation as defined in the Annex 1 of the TBT Agreement; it only provided for certain selling arrangements such as the obligation for buyers to identify themselves. This was why the draft had not been notified under the TBT Agreement. However, the European Communities took note of the comments provided and expressed willingness to discuss this issue bilaterally.

(iii) Colombia – Regulation on Wine labelling

18. The representative of Chile expressed concern about a new standard on the labelling of liquors and wines which had entered into force in Colombia, as contained in the Decree 22/70 of 23 June 2008. His delegation was particularly concerned about the fact that there had neither been consultation prior to the publication of the decree nor a notification to the WTO. The nature of the measure was also unclear. He asked the delegation of Colombia to provide additional information on the nature and objective of the measure and recalled that the obligation contained in the TBT Agreement with respect to providing a reasonable time for comments had not been met.

19. The representative of Colombia took note of the concerns raised, and asked Chile to also send their comments to the Enquiry Point in Colombia.

(iv) Indonesia – Zinc Coated Steel Sheet (G/TBT/N/IDN/17)

20. The representative of Korea raised concerns about the draft Decree of the Ministry of Industry regarding a Mandatory Indonesian Standard (SNI 07-2053-2006) for Zinc coated steel sheet, which had been notified on 1 October 2007 by the Indonesian Government. The Enquiry Point of Korea had submitted questions to Indonesia on 20 June 2008 and an answer was expected. In particular, he pointed out that that intermediate goods which were used in car manufacturing and consumer electronic goods were not directly related to consumer protection. Therefore, they needed to be excluded from a list of necessary accreditation goods in order not to give rise to any unnecessary trade restrictions. He stressed that similar measures should be notified promptly to the TBT Committee in the future.

21. The representative of Indonesia informed the Committee that a reply was being prepared which would be sent shortly to the Enquiry Point of Korea.

(v) *Indonesia – Requirements for Rubber Hoses for LPG Gas Stoves (G/TBT/N/IDN/19)*

22. The representative of the European Communities raised an issue with regard to a Ministerial Decree affecting rubber hoses, notified on 5 February 2008 (G/TBT/N/IDN/19). In particular, her delegation was concerned about the provision which stated that the colour of rubber hoses had to be in orange. It was noted that orange was not the colour generally used for gas stoves; the colours used in common practice were blue or white and these were not imposed by any rule or standard. The European Communities believed that the colour requirement did not fulfil a legitimate objective and thereby created an unnecessary obstacle to trade contrary to Article 2.2 of the TBT Agreement.

23. The representative of the European Communities noted that written comments had been provided, including with respect to certain drafting incoherencies in the notification. Her delegation requested Indonesia to take into account the comments and to clarify whether the Ministerial Decree had already been adopted.

24. The representative of Indonesia took note of the comments and informed the Committee that some amendments were still being made; Members would be informed about progress as soon as possible.

(vi) *Brazil – Wines (G/TBT/N/BRA/238)*

25. The representative of the European Communities raised concerns about a measure on wine, notified by Brazil on 26 March 2007 (G/TBT/N/BRA/238), which imposed, among other things, an increase in the number of parameters that had to be evaluated and on certificates that were requested. At the time of notification the European Communities had submitted written comments, which had only been partially clarified by Brazil. In particular, the European Communities invited Brazil to indicate the reasons for departing from the levels and parameters established at the international level, and to explain the legitimate objective pursued by the measure. Finally, the European Communities invited Brazil to give further information on the public consultation launched on 2 June 2008 on import requirements for wines, and to clarify whether the parameters which had to be evaluated would be reviewed as a result of this consultation.

26. The representative of Brazil took note of the comments made.

(vii) *China – Energy Efficiency and Energy Efficiency Grades for Copy Machines (G/TBT/N/CHN/331, Rev.1 and Suppl.1)*

27. The representative of Japan appreciated the Chinese delegation's reply to comments on the Act affecting copy machines, notified on 19 February 2008 (G/TBT/N/CHN/331/Rev.1). Nevertheless, Japan raised further concerns on two specific points. First, there were no mandatory requirements of this kind at the international level; the measure at issue could, therefore, constitute an unnecessary obstacle to trade. Second, it was all but impossible to measure energy efficiency accurately, and also very difficult to decide whether copy machines were copy or printer based. In this respect, Japan invited China to clarify the scope of the measure.

28. The representative of China took note of the comments made.

(viii) *Korea – Country of Origin Labelling Requirements for Certain Imported Fruit*

29. The representative of the United States appreciated Korea's willingness to continue a dialogue with respect to US concerns regarding Korea's country of origin labelling requirements for certain imported fruits. It was his delegation's understanding that the Korean Customs Service required the labelling of country of origin on the actual product for seven types of imported fruit for bulk sale, namely: sweet pumpkin, bananas, oranges, pineapple, melons, watermelons and durians. Meanwhile, the rules for the like domestic products, which were governed solely by National Agricultural Products Quality Management Service (NAQS) requirements, appeared to be much less stringent. In fact, country of origin labelling did not need to be on each individual piece of fruit, but could rather be on the container surface. The United States noted that the Korean government had begun to modify its labelling requirements for fruits and vegetables; it was its expectation that Korea would take steps to ensure that it treated imported and domestic fruits and vegetables equally.

30. The representative of Mexico echoed the concerns expressed by the United States.

31. The representative of Korea noted that his delegation had had a bilateral meeting with the United States and expected the issue to be concluded soon.

2. Previously raised concerns

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

32. The representative of Argentina reiterated his delegation's concerns with respect to REACH and drew Members' attention to two documents submitted in this regard (G/TBT/W/286 and G/TBT/W/289). The EC regime in the area of chemicals continued to present serious difficulties for Argentina as it distorted conditions of competition in trade in prepared chemical substances. He drew the Committee's attention to the limited capacity of the European Communities and the European Chemical Agency (ECHA) to provide adequate technical assistance to users. In addition, the complexity of REACH, coupled with the lack of appropriate technical assistance, was contributing to increased confusion and concerns among companies that were trying to comply with REACH; Small and Medium sized Enterprises (SMEs) were especially affected.

33. The representative of Argentina recalled that, on 21 April 2008, Argentina had sent, through the focal point of the TBT WTO Committee, two questionnaires with specific questions relating to REACH. Also, the Argentinean petrochemical industry had sent the EC Helpdesk six basic questions and still not received a reply other than a reference to a website which contained information on REACH. This was not satisfactory. Moreover, there were questions about the legal liability of the information provided on these websites. This situation was aggravated by the entry into force of the period of pre-registration. Although Argentina had received some replies to questions on 27 June 2008, these had yet to be analyzed. In sum, the REACH regulation was complex, it lacked transparency and technical assistance was both insufficient and lacking in legal validity. This resulted in confusion and concern amongst enterprises that were trying to comply.

34. The representative of Chinese Taipei associated himself with Argentina's comments and encouraged the European Communities to take into account the impact of REACH on Small and Medium sized Enterprises (SMEs), to publish all the technical guidelines for REACH and inform trading partners about their availability.

35. The representative of Mexico joined other delegations in concerns expressed about REACH. While thanking the European Communities for holding a workshop on REACH on 14 April 2008³, he nevertheless noted that concerns remained. Efforts to provide technical assistance to developing countries needed to continue in order to enable these countries to implement the measures at issue in the best possible way. Similarly, special and differential treatment needed to be provided.

36. The representative of Brazil shared the concerns already expressed by others, stressing the difficulties imposed by the "Only Representative" requirement, especially in the case of SMEs. In particular, the representative of Brazil recalled that Brazilian industry was seriously concerned about the registration requirements for reacted monomers in polymers. He noted that REACH exempted polymers from registration and evaluation, as they were widely believed to cause minimal risk. Nevertheless, REACH required manufacturers or importers of polymers to register reacted monomers used in the production of polymers. It was noted that such a situation could constitute discrimination between EC and non-EC manufacturers, since only the monomers in the polymers created by the EC manufacturers would be registered. Therefore, the representative of Brazil encouraged the European Communities to clarify the rationale for the registration of reacted monomers in polymers and give further information on the status of the related case recently submitted to the European Court of Justice.

37. The representative of Australia joined the concerns expressed by previous speakers, emphasizing the challenges faced by non-EC industries in complying with REACH. While Australia supported the objectives of the protection of human health and the environment, the disproportionate impact of such a policy on SMEs and the fact that the "Only Representative" provision could place higher costs on non-EC producers and manufacturers remained a concern. The representative of Australia welcomed the development of REACH guidance documents by the European Communities, but noted that key issues for non-EC industries were unclear. More in-country or in-region assistance from EC experts was necessary to assist the industry's understanding of pre-registration requirements under REACH.

38. The representative of Japan raised some questions concerning REACH. He sought clarification on whether substance manufacturers who did not directly export to the European Communities but were upstream from other businesses could also appoint and register their substance through the "Only Representative". It was noted that, in light of the limited timeframe for pre-registration requirements, many Japanese firms would not be able to respond appropriately if such an issue remained unclear. The representative of Japan sought confirmation on the future REACH schedule, and in particular on the number of substances included therein and on whether the European Communities would ask for Members' comments before reaching a final decision on the schedule. He also requested the European Communities to base their decisions on approval of substances only upon reasonable scientific evidence. He noted that, according to the "Guidance on requirement for substances in articles" published in May, the concentration threshold of 0.1 per cent referred to the average concentration of the entire article as produced or imported. However, dissenting views of some EC member States created confusion and uncertainty in this respect and needed to be eliminated. The representative of Japan also requested that foreign-based firms in European Communities be treated without discrimination, and that their opinions be respected when participating in "SIEF" (Substance Information Exchange Forum) – although, it was noted, an exchange of information had been already underway.

39. The representative of Thailand referred to her delegation's previously expressed position on REACH. While Thailand supported the objectives of the protection of human health and the environment, the complexity of REACH was beyond the capacity of many developing and least

³ Information about the REACH workshop can be found at:
http://ec.europa.eu/enterprise/reach/events_en.htm#video

developed countries to understand and comply with. Particularly for SMEs, which represented the majority of Thailand's industry.

40. The representative of China shared the concerns expressed by previous speakers. In particular, he stressed the need for technical assistance to assist industries of developing countries in implementing REACH. He encouraged the European Communities to send experts to China to discuss the practical concerns of the industry. While appreciating the efforts made by the European Commission to provide transparency, he nevertheless noted that Chinese industries were particularly concerned about the high fees and charges associated with registration procedures, and urged the European Communities to give further clarification on the fee structure, and to provide special and differential treatment for developing countries. The representative of China also expressed concerns about the current uncertainty of the "Only Representative" requirement. His delegation urged the European Commission to further clarify this mechanism, explaining in particular whether non-EC manufacturers could continue their exportation using the information and data already submitted even once the Only Representative designated would go bankrupt.

41. The representative of Chile shared many of the concerns raised by previous speakers. Having set up a committee meant to deal directly with REACH, Chile remained convinced that the implementation of REACH would be complex. The main concerns of Chile were about the complexity of the registration process and possible differences of interpretation among different EC member States which could arise with respect to the implementation of REACH. The representative of Chile reiterated the need for technical assistance from European experts, so that REACH could be better understood and applied.

42. The representative of the United States noted that his delegation supported the objectives of protecting health and the environment. However, concerns remained that the REACH regulation appeared to be overly broad and to adopt a particularly costly, burdensome, and complex approach that could disrupt and distort global trade. The United States continued to study the regulation and its potential trade impact and was closely monitoring the EC implementation process. The representative of the United States recalled the detailed US intervention on the concerns regarding REACH given at the last Committee meeting and shared many of the concerns that had already been raised by other delegations at current meeting about the Only Representative, the candidate list, the burden on SMEs, and the potential for differential enforcement of REACH across the EC member States.

43. Given the start of the pre-registration timeframe for REACH, the representative of the United States also wished to raise the issue of cosmetics. Cosmetics had not previously been discussed at length in the TBT Committee given that the matter had been the subject of intense discussion in the Transatlantic Economic Council (TEC). It was noted that REACH appeared to grant the preferential status of "phase-in substances" to many "existing substances" used in cosmetics that were manufactured in the European Communities, since those substances were listed in the European Inventory of Existing Chemical Substances (EINECS). By contrast, many existing substances in cosmetics that were manufactured abroad, not listed on EINECS or in the European List of Notified Chemical Substances (ELINCS), the EC chemical substance directory that succeeded the EINECS directory, and imported into the European Communities as part of finished cosmetic products could not qualify for "phase-in substance" status. As a result, many cosmetic ingredients used to manufacture products in the European Communities either would be considered as already registered under REACH, thereby avoiding costly REACH registration fees and procedures, or would be eligible for pre-registration between 1 June 2008 and 1 December 2008. In either case, such substances would be considered "phase-in" substances and benefit from transition periods of 3, 6 or 11 years.

44. The representative of the United States stressed that, by contrast, the same treatment would not apply to many ingredients used in imported cosmetics, as these were not included on either EINECS or ELINCS listings since this was not required under the relevant EC directives. Thus, many

substances in imported cosmetics would be considered "new substances" under REACH, despite the fact that they had legally been on the EC market in finished cosmetics for years. Therefore, if those substances would be imported into the European Communities in finished cosmetics in quantities above one ton annually per manufacturer or importer, non-EC cosmetics producers would have had to register them by 1 June 2008 for them to be considered legally on the EC market, that is, without the benefit of the transitional periods. Additionally, it was noted that non-EC manufacturers, seeking to register many substances that would be considered new substances, would not benefit from the data sharing provisions in Articles 27 and 28 and, in many cases, would be obliged to perform additional or duplicative testing, including potentially animal testing, which would undermine what the US understood to be one of the primary tenets of REACH.

45. The representative of the United States noted that US producers shipped approximately US\$2 billion worth of cosmetics to the EC market each year, and that trade was being disrupted, and urged the European Communities to rectify the situation promptly. It was pointed out that the European Communities had already recognized that REACH could discriminate against foreign cosmetics producers, and had promised to provide legal certainty that non-EC cosmetics producers would be able to pre-register their substances, participate in the SIEFs and continue shipping into the EC market. Despite such assurances, the 1 June 2008 deadline had passed and companies still had not received word from the European Commission, except for an ambiguous press release, which would not provide such certainty. Therefore, the European Commission was encouraged to publish an amendment or corrigendum to REACH or provide a binding legal opinion that the ingredients in imported cosmetics qualify as phase-in substances under REACH.

46. Finally, with respect to the implementation of REACH, the representative of the United States urged the European Communities to take into consideration the concerns which had been expressed by its trading partners and other interested parties, and to ensure a meaningful opportunity to reflect the views of other governments and stakeholders in the process. He stressed that discussions between EC technical experts and their counterparts in the United States and other countries would continue in the TBT Committee process and through bilateral channels.

47. The representative of Korea echoed the concerns already raised by other Members. Several questions remained about the pre-registration process. Therefore, Korea urged the European Commission to publish the technical guidelines for pre-registration and give further clarification on some specific issues which were yet unclear to the Korean industry. For example, it was unclear if non-EC manufacturers could undertake pre-registration by appointing an Only Representative, even in the case they did not export chemicals directly to the European Communities. Moreover, Korea encouraged the European Commission to clarify which actor would have priority if non-EC manufacturers and importers wished to make a pre-registration of the same substance.

48. The representative of Cuba reiterated his delegation's position already expressed at previous meetings, and shared the concerns that had been raised by other delegations, in particular regarding the need to provide special and differential treatment to developing countries and technical assistance from European experts.

49. The representative of Canada noted that his delegation supported the objectives of protecting health and the environment. However, she reiterated the concerns already expressed by other delegations and raised some specific questions concerning REACH. On the subject of fees, Canada noted that SMEs had expressed the concern that discounts on registration fees offered were small. Yet, due to the use of outdated definitions for determining size, medium sized firms would not have benefited from reduced fees because under the fee structure, they would be considered large and not eligible for discounts. Therefore, the representative of Canada asked the European Commission to explain whether the European Communities meant to readjust the thresholds for determining the eligibility of a company to benefit from discounts on registration fees.

50. With respect to the issue of the Only Representative, Canada encouraged the European Communities to clarify who could appoint an Only Representative and whether the European Commission was reviewing the requirements regarding the amount and types of confidential business information which non-EC firms were expected to provide to their Only Representative. In addition, the representative of Canada encouraged the European Communities to update the Committee on EC parliamentary discussions concerning the adoption of the Globally Harmonized System (GHS) Regulation. Similarly, she urged the European Commission to explain which areas of the GHS would be implemented and what the timeline for implementation would be.

51. Finally, Canada invited the European Commission to provide further information on which test methods would be adopted to classify chemicals under REACH. In particular, she asked whether the test methods would be based on OECD standards or on EC acceptance processes, and what the practical consequences of such a choice would be.

52. The representative of South Africa joined the concerns already expressed by previous speakers, particularly on the pre-registration process and on the burden on SMEs. He pointed out that industry in his country found it very difficult to understand what was required under REACH requirements and requested the European Communities to provide more technical assistance.

53. The representative of the European Communities appreciated the comments made on REACH and stressed that they would be transmitted to the competent authorities. She pointed out that the obligation to register under REACH had entered into force on 1 June 2008, therefore industry was still able to send registration dossiers and pre-registrations which allowed companies to benefit from extended registration deadlines. It was recalled that 1 December 2008 was the end of pre-registration deadline. It was also noted that 7360 pre-registrations had been received after two weeks of the entering into force of the registration obligation by the European Chemical Agency and almost 1,500 companies had signed up.

54. With respect to the issue of the Only Representative, the representative of the European Communities drew the Committee's attention to the fact that the guidance documents on registration had been modified. In particular, it had been clarified that in cases where Only Representatives would represent more than one non-EC manufacturer, they must submit a separate registration submission for each of the non-EC manufacturers represented (per substance). Moreover, it was added that a subsequent update would further clarify the issue, explaining the possibility for non-EC manufacturers appointing an Only Representative to cover in the registration submission also those quantities of substances that are sold to downstream users outside the European Communities in order to make a preparation, a polymer, or an article that was later imported in the European Communities. With regard to questions on the possibility of changing the Only Representative, the representative of the European Communities noted that a transfer of the registration would be possible by submitting an update of the earlier dossier. She further clarified that the former Only Representative would have to agree with the change and that it would therefore be advisable that these aspects were covered in the private arrangements between the non-EC manufacturer and the Only Representative. It was recalled that the Guidance documents were all available on the ECHA website⁴ and that the Only Representative system was not an obligation, but a possibility given to non-EC manufacturers.

55. It was also noted that the issue of Small and Medium Enterprises (SMEs) was a key concern during the legislative process of REACH. The representative of the European Communities explained that the registration required less information for lower tonnage ranges and significant reductions for SMEs had been foreseen by the Regulation on Fees. Such advantages would be equally applied to SMEs based both inside and outside the European Communities.

⁴ http://reach.jrc.it/guidance_en.htm

56. On the issue of fees regulation, the representative of the European Communities drew the Committee's attention to the document submitted in this regard on 29 April 2008 (G/TBT/N/EEC/52/Add.5)⁵, which set out the level of fees and charges under REACH. It was recalled that the level of fees and charges had been set taking into account the workload necessary for the processes to be managed by the European Chemical Agency, and that fees and charges applied equally to EC-manufacturers and Only Representatives of non-EC manufacturers. Reductions up to 90 per cent would be applied to SMEs. The representative of the European Communities also noted that Annexes IV and V of REACH, which exempted certain substances or groups of substances from the obligations laid down in the registration, were being reviewed. The amendments would be communicated to the WTO in a draft stage.

57. With regard to the questions on the candidate list, the EC representative clarified that substances of very high concern would be identified and included in the candidate list according to the procedure established in Art. 59 of REACH. It was also stressed that interested third parties could comment the process of identification and listing of substances, as set out in Title VII, Chapter I of REACH.

58. On the issue of cosmetics, the European Communities stressed the importance of facilitating compliance with REACH obligations by all economic operators concerned. In this regards, a press release published by the European Chemical Agency (ECHA) in the beginning of June had invited manufacturers or importers of substances that were lawfully on the EC market before 1 June 2008, but which did not have phase-in status under REACH, to contact ECHA.⁶

59. It was also noted that REACH did not regulate the formation of consortia. However, work developed in a consortium before the constitution of the Substance Information Exchange forum would be part of information that would have to be exchanged within the forum.

60. With respect to the request for clarification on the discussions regarding the adoption of the proposal for a Regulation on the incorporation of the Globally Harmonized System, Members were informed that the Commission had adopted the proposal on 27 June 2007, that the proposal was still being discussed in the European Parliament and the Council, and that the adoption and publication was expected by end of 2008.

61. On the issue of uniform interpretation across the European Communities, the EC representative recalled that the legal instrument adopted for REACH was a regulation, which was directly applicable in all member States and applied uniformly throughout the European Communities. The European Commission was closely monitoring the coherent and uniform application of REACH throughout the EC member States. The dissenting views published on ECHA website were not part of the guidelines, but were for information only. However, it was noted that only the text of REACH was legally binding and only the European Court of Justice would have the competence to provide a definitive interpretation of its provisions.

62. On the issue of monomers in polymers, the representative of the European Communities recalled that the case was still pending at the European Court of Justice.⁷

63. The representative of the European Communities emphasised that the Commission and ECHA had made considerable efforts to provide guidance and explanatory tools to help industry,

⁵ The text of the fees regulation is also available on the website of ECHA: <http://ec.europa.eu/echa/> and at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:107:0006:0025:EN:PDF>

⁶ The press release can be found under: http://echa.europa.eu/doc/press/PR_08_12_Received_Submissions_Inquiry20080609.pdf

⁷ Case C-558/07.

including from third countries, in complying with REACH. She drew the Committee's attention to the workshop held in Brussels⁸ and to the continuous work of the ECHA and REACH helpdesks.

64. On the missing reply to the queries of Argentina, the EC representative confirmed that the European Communities had received several letters from the Argentinean government on REACH. Those letters had been sent to various departments of the European Commission. Where the letters had not been sent to the departments directly responsible for REACH, it took time to ensure translation, reattribution and coordination of replies to all letters received. However, a comprehensive reply to all outstanding letters had been sent on 27 June 2008.

65. For specific technical assistance to third countries, the EC representative recalled the intervention of the representative of UNIDO at the last TBT Committee. The representative of the European Communities invited Members having specific needs for such technical assistance programs, to direct their requests to the respective delegations of the European Commission in their country.

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

66. The representative of Argentina reiterated his delegation's concerns with respect to the EC regulation on production and labelling of organic products, and drew Members' attention to two documents submitted in this regard (G/TBT/W/284 and G/TBT/W/291). Argentina was concerned with the Regulation 834/07, which had been notified to the TBT Committee in February 2006. In particular, Article 24 of the regulation stated that the label of an organic product should contain an indication of the origin of the raw materials, taking one of the following three forms: (i) "EU Agriculture", when raw materials originated from the European Communities; (ii) "non-EU Agriculture", when raw materials did not originate from the European Communities; and (iii) "EU/non-EU Agriculture", when part of raw materials originated from the European Communities and part from third countries. Moreover, it was also allowed to mention directly the country where the raw materials were obtained.

67. It was highlighted that such a compulsory identification of origin for products processed in the EC territory was not necessary in order to avoid the risk of misleading European consumers on the qualities of an organic product. In fact, to be considered as organic, the quality of raw materials was already guaranteed by the fulfilment of EC requirements. It was stressed that the requirements proposed in the draft EC measure could give consumers false impressions. In addition, the representative of Argentina pointed out that the regulation was neither supported by WTO Agreements nor by Codex standards and could therefore be considered as inconsistent with existing multilateral commitments.

68. The representative of the European Communities noted that Argentina had referred to the provisions of Article 24 of Regulation 834/07 on the labelling of organic products, with the particular concern that the processed products which contained raw materials from non-EU countries would have to carry the label "EU/non-EU Agriculture". Her delegation informed Argentina that the European Commission had adopted a proposal which would postpone the application of Article 24 until 2010 with a view to selecting a new EU organic logo before it became mandatory; therefore, Article 24 would not enter into force in January 2009 as had initially been foreseen.

⁸ Web-stream available at http://ec.europa.eu/enterprise/reach/events_en.htm#video

(iii) *European Communities – Regulation on Certain Wine Sector Products (G/TBT/N/EEC/15, Corr.1-2 and G/TBT/N/EEC/57)*

69. The representative of Argentina reiterated his delegation's concerns with regard to the EC approach to wine labelling, as reflected in Regulation 753/2002 and in the amending Regulation 316/2004. In particular, the representative of Argentina remained concerned that EC standards granted EC member States an exclusive right to use the traditional expression "para el Reino de España".⁹ In fact, it was stressed that there were no legal bases for the protection of such expressions under the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS), as this was not protected as a Geographical Indication (GI) under the Article 22 or the Article 24.6 of that Agreement.

70. The representative of Argentina also recalled that at the EC level there was no common definition of such complimentary labels; rather, they originated from diverging legislations of different EC member States. He noted that, since there was no single definition for those traditional expressions at the EC level, it was impossible for non-EC States to comply with the requirements requested for the certification. In any case, Argentina stressed that the European Communities could not use a unilateral standard to exclude the use of those expressions by third countries. Therefore, Argentina asked the European Communities to amend Regulation 753/2002 and Regulation 316/2004, which, in their view, were inconsistent with the Article 2 of the TBT Agreement and could create unnecessary barriers to trade.

71. The representative of the United States shared Argentina's concerns regarding the European Communities' efforts to restrict severely the ability of non-EC wine producers to use common or descriptive and commercially valuable terms used on wine labels all over the world, on the grounds that those terms would have been traditional to European procedures. Furthermore, it was noted that the European Communities appeared to be trying to claim exclusive rights in such terms, asserting that the use of these terms in connection with wine that – in the view of EC officials – did not follow traditional production methods or met other criteria theoretically associated with such wine would be deceptive or confusing for consumers. However, despite repeated requests from third countries, the European Communities had never presented any evidence of consumer confusion or deception with the current use of such terms by foreign wines on the EC market.

72. It was the United States' understanding that the European Communities wanted exclusive use of the above-mentioned terms by EC producers except under certain limited circumstances where the third country would have regulated the terms to the satisfaction of the European Communities. In this regard, the representative of the United States encouraged the European Commission to consider the concerns expressed by Members with the current regulation when it published implementing regulations on traditional terms later in 2008.

73. The representative of Canada shared the concerns already expressed by the previous speakers.

74. The representative of New Zealand supported the comments made by other delegations and encouraged the European Commission to take into account the concerns expressed by third countries with the existing regulation when developing the detailed rules for implementing the new common market organization for wine. Her delegation looked forward to being consulted in that process.

75. The representative of the European Communities confirmed that a new common market organization for wine had recently been adopted but the implementing rules had not been developed yet; these would be notified to the WTO at an appropriate time. She stressed that the regulation at issue already contained some provisions on labelling and use of geographical indications which would

⁹ In English: "for the Kingdom of Spain".

simplify and clarify those in force. For example, the new labelling provisions, which would be further detailed by the implementing rules, would apply to both categories of wine, with or without a geographical indication (GI) and only introduced significant modifications in respect of GIs. With regard to the point raised by the delegate of Argentina in respect of a consignment which had been detained in customs due to incorrect labeling under the current rules, the representative from the European Communities clarified that the use of certain traditional expressions was protected under EU law in so far as they related to a given language and to a specific category of wine. Third countries could therefore freely use these expressions for all the other remaining wines. It was, however, imperative that a request was made by that third country according to Article 24 of Regulation 753/2002. It was pointed out that, in this vein, South Africa had filed an application and was exporting wines to the European Communities labelled with the Spanish expression "Vino Fino"¹⁰, being a traditional expression which was protected in the European Communities for three types of Spanish wines. Therefore, the EC representative invited Argentina to submit an application according to Article 24 of Regulation 753/2002.

(iv) *European Communities – Dangerous Chemical Substances; Draft Commission Directive amending Council Directive 67/548/EEC (G/TBT/N/EEC/151)*

76. The representative of Colombia expressed his concerns with regard to the 30th Adaptation to Technical Progress (ATP) to the Dangerous Substance Directive 67/548/EEC, and introduced a submission to the TBT Committee (G/TBT/W/288). Colombia did not consider either the responses provided by the European Communities regarding the concerns raised by various delegations at the most recent TBT Committee meetings, or the response provided bilaterally and which concurred with those provided to other interested parties, to have allayed concerns or to have explained satisfactorily the justification and reasons for the classification of a group of nickel carbonates and related substances as dangerous substances.

77. The representative of the Dominican Republic associated his delegation with comments made by Colombia, and in particular reiterated concerns on the proposed re-classification of nickel carbonates and other components of nickel, which her delegation considered to lack sufficient scientific evidence. She also noted that the comments expressed by various delegations at the meetings of the TBT Committee on 20 March 2008 had not been taken into account for the amendment of Directive 67/548/EEC. It was her delegation's view that, having been adopted in these circumstances, the above-mentioned directive did not satisfy the requirements of Article 2.9 of the TBT Agreement.

78. On the other hand, the representative of the Dominican Republic welcomed the provisions of the above-mentioned directive which allowed for reconsidering the classification of nickel if proper justifications were submitted, and encouraged the European Communities to give further information on the application of these provisions. Moreover, she recalled that nickel exports represented, in 2007, more than 50 per cent of the total exports of the Dominican Republic and that the proposed directive would have a negative effect on industry and the economy of the country as a whole. In concluding, she expressed her delegation's concerns with regard to the project of the 31st amendment, which would include the reclassification of 140 additional chemical compounds, and therefore urged the European Communities to notify such amendment to the TBT Committee prior to its final adoption, so that comments from Members could be taken into account and necessary modifications made.

79. The representative of Cuba shared the concerns expressed by previous delegations. Her delegation regretted that the European Communities had adopted the 30th ATP to Directive 67/548/EEC without taking into account either the concerns previously expressed by Members of the

¹⁰ In English: "Fine Wine".

TBT Committee, or the arguments contained into the joint letter sent by a number of Ambassadors to the EC commissioners of trade and environment on 12 March 2008. Furthermore, Cuba also regretted that the provisions on special and differential treatment in the TBT Agreement did not seem to have been taken into consideration, in particular Article 12.3, which provided that Members should take into account the special needs in the area of development, finance and trade of developing countries when preparing technical regulations, so as to ensure they are not creating unnecessary obstacles to exporters.

80. The representative of Cuba recalled that the new classification of nickel carbonates as hazardous substances did not have a scientific basis. She emphasized that the comparison between nickel borates and nickel sulphate seemed to be unfounded, and urged the European Communities to carry out further studies on the matter. It was also stressed that researchers on cancer would not adopt any position on the carcinogenic affects of nickel soluble components until March 2009. Moreover, Cuba noted that the proposed modified 31st ATP to Directive 67/548/EEC should have been notified earlier. She considered that the EC amended Directive was not in line with Article 2 of the TBT Agreement, as it limited trade more than necessary to achieve the pursued objectives.

81. It was also stressed that nickel exports represented an important part of Cuban exports, and that the new classification would have negative impacts both on the nickel industry and industries which used nickel in their production such as the automotive, electronic and aviation industry. In concluding, the representative of Cuba invited the European Communities to revise the new classification for nickel carbonates in light of the comments and concerns expressed, and urged the European Communities to notify the 31st ATP within due time.

82. The representative of Brazil expressed his concerns with regard to the decision of the European Communities to adopt the 30th ATP without taking into account either the request by various Members of the TBT Committee to postpone its adoption until there was scientific evidence on the actual risk posed by nickel compounds, or the study presented by the industry that had brought new elements indicating that the proposed classification for nickel compounds could be based on wrong assumptions. It was pointed out that in this case the European Communities had adopted a disproportionate approach classifying nickel carbonates as a proven human carcinogen although there was no sound scientific evidence supporting this decision.

83. Bearing in mind that Article 2.2 of the TBT Agreement stated that regulations should not be more trade restrictive than necessary to fulfil a legitimate objective, Brazil invited the European Communities to review the classification of nickel carbonates under the 30th ATP, and not to extend the Category 1 classification to nickel compounds under the 31st ATP until the results of the studies conducted by the industry could be analysed.

84. The representative of Canada pointed out that her delegation attached great importance to this issue. Canada was the world's second-largest producer and exporter of nickel and related substances and had a major interest in ensuring that the EC measures did not entail unnecessary barriers to trade. Her delegation regretted that the European Communities had adopted the 30th ATP despite the many concerns raised at the WTO and in other fora by several of the EC's trading partners. Canada was further concerned that the European Communities did not provide any information on the 30th ATP before adoption, despite the information provided by the nickel industry that the EC's proposed classification for nickel carbonates was not based on sound scientific analysis. She was concerned that a dangerous precedent for a large number of assessments to be performed under REACH could be set.

85. Canada noted that industry had begun to submit scientific information, including the report of The Weinberg Group on the issue of "read-across methodology". More scientific information was expected in 2008 and by mid-2009, and such information should have been considered by the

European Communities before adopting the 30th ATP. The representative of Canada welcomed the new recital to the adopted 30th ATP which stated that the classification would be reviewed as soon as new scientific information was available; she sought further clarification on the implementation of this provision. She also encouraged the European Communities to provide precise dates for official publication of the 30th ATP, and if changes were made, to provide copies of the version that would be published. She stressed that Canada was not taking a position on the toxicity or carcinogenicity of particular nickel-based substances; rather, it was the process by which the European Communities had reached its conclusion that was of concern. She expressed her delegation's request that such assessments be scientifically based and conducted in an appropriate manner and urged the European Communities to ensure that any measures taken to protect human and environmental health represented the least trade restrictive options available, in conformity with Article 2.2 of the TBT Agreement.

86. With respect to the notification of the draft 31st ATP, it was Canada's understanding that the European Communities intended to notify the 31st ATP at the same time that it would be circulated to EC member States for consideration. Canada welcomed this decision and encouraged the European Communities to continue to notify all of its new measures in sufficient time to allow comments by Members to be taken into consideration. Moreover, it was her delegation's understanding that the 31st ATP Directive would contain further nickel classification proposals. Therefore, she requested the European Communities to clarify the status of the 31st ATP and explain how the new recital in the 30th ATP would impact the 31st ATP. The representative of Canada also requested that the 31st ATP be withdrawn or at the minimum that its implementation be delayed; that scientific data submitted by industry be analyzed; and, that the delay in adoption allow sufficient time for information submitted by industry to be properly considered.

87. The representative of Australia reiterated her concerns, as expressed in the written response to the European Communities in January 2008 and at the TBT Committees held on 9 November 2007 and 20 March 2008, regarding the EC's reclassification of nickel carbonate under the 30th ATP and with the EC's proposed reclassification of more than 140 other nickel compounds under the draft 31st ATP. She stressed that the EC proposed reclassification of nickel substances under the 30th ATP would have a significant economic and commercial impact on all nickel producing and exporting countries like Australia, including developing countries. It was also pointed out that the potential economic impact was even greater with respect to the draft 31st ATP.

88. Her delegation regretted that the European Communities had adopted the 30th ATP without taking into account the concerns previously expressed by Members of the TBT Committee. In this context, Australia noted that Article 2.9.4 of the TBT Agreement stated that if a technical regulation could have a significant effect on trade of other Members, the introducing Member should "allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account". It was recalled that Australia had stressed 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 achieve such protection. However, in accordance with Article 2.2 of the TBT Agreement, these regulations should not create unnecessary obstacles to international trade.

89. Concerns remained on the process by which the European Communities had assessed nickel carbonates, and on the lack of verification that nickel carbonates and the reference chemicals were sufficiently comparable to support the conclusions reached. The representative of Australia stressed that her delegation was not taking a position on the toxicity or carcinogenicity of nickel carbonates; rather, it was seeking a sound, defensible and transparent science-based approach. It was also recalled that her delegation did not oppose the use of "read-across methodology" if applied correctly and in a robust and scientifically valid manner. However, Australian authorities had reviewed the scientific literature available on the issue, including EC and OECD documentation, and had concluded that

there was no reliable data on the carcinogenic potential of nickel carbonates, that the use of "read-across methodology" should be based on groupings of substance which were robust and scientifically valid and that solubility in water alone was an insufficient criterion on which to base "read-across methodologies".

90. The representative of Australia remained concerned that the EC approach to the nickel group could create a precedent for the manner in which other groups of chemical substances would be classified in future, including under REACH. In fact, it was her delegation's understanding that Annex VI of the Proposal for a Regulation of the European Parliament and of the Council on Classification, Labelling and Packaging of Substances and Mixtures and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006 (the CLAP Regulation) would include harmonized classifications, including those of the 30th and 31st ATP, and those coming from REACH, via an ATP procedure. This would create a precedent, and her delegation was concerned about the scientific and procedural grounds of this precedent.

91. Australia welcomed that the European Communities added a new recital to the adopted 30th ATP which stated that the classification would be reviewed as soon as new scientific information would be available, and encouraged the European Commission to take into account the additional scientific information from industry which would be ready in 2008 and by mid-2009.

92. In concluding, the representative of Australia sought clarification about EC plans for the adoption of the 30th ATP. She invited the European Communities to clarify when the decision to adopt the 30th ATP would be formally published, and sought assurances that the 31st ATP would be notified under the TBT Agreement prior to its adoption, providing a reasonable period of time in accordance with Article 2.9.4 of the TBT Agreement.

93. The representative of Japan shared the concerns of previous speakers, in particular with regard to the classification of nickel.

94. The representative of China agreed with previous speakers and regretted that the European Communities had not fully addressed the concerns previously expressed by Members on the draft 30th ATP. China asked the European Communities to consider the impact of the classification and the labelling of nickel carbonates and other nickel compounds on downstream industries. It was noted that nickel carbonates and other nickel compounds would be categorized as Substances of Very High Concerns (SVHCs) and be subject to application of authorization and forced substitution under the REACH Regulation. Therefore, the representative of China invited the European Communities to reconsider the classification and labelling of nickel carbonates and other nickel compounds. Finally, he urged the European Communities to comply with the transparency obligations in the TBT Agreement and notify the 31st ATP.

95. The representative of Chile regretted that the European Communities had adopted the 30th ATP without taking into adequate consideration the comments made by his delegation, especially with regard to the non-toxicity of borates. Chile noted that the modifications which were proposed to be introduced in the Directive 67/548/EEC would further complicate the way in which chemical substances were treated within the European Communities. Chile noted that the European Communities added a new recital to the adopted 30th ATP indicating that the classification would be reviewed as soon as new scientific information would be available, and encouraged the European Commission to take into account all the scientific analysis carried out and to engage in a discussion in order to analyze the information provided. Finally, the European Communities was requested to notify any modification made at a later stage so as to provide an adequate period of time for considering comments from Members.

96. The representative of the United States shared many of the systemic concerns raised by previous speakers regarding the European Communities' analysis for classifying nickel carbonates and other nickel compounds under Category 2 of the Dangerous Substances Directive. In particular, the United States would have the same concerns with regard to those classifications if the European Communities based its analysis solely on hazard, not taking into account intended end uses of nickel-containing products. The US representative also associated himself with the concerns set out in past US statements and communications with respect to a related EC classification: the classification of borates under Category 2 of the Dangerous Substances Directive. In particular, he noted that the European Communities did not appear to have taken into account the normal handling and use of borates-containing products, when proposing its classification of borates, and that the European Communities acknowledged that its classification was entirely hazard-based and did not factor in the actual risks of exposure from intended end uses. The representative of the United States reiterated his delegation's concerns regarding the skull-and-crossbones labelling requirements for certain borates-containing products and the "knock-on" effects under other EC legislation, including a ban on the use of borates in cosmetics, restrictions under the Marketing and Use Directive, and potential placement on the REACH authorization candidate list, of a Category 2 classification and the potential adverse impacts that this could have on the sale and trade of borates and borate-containing products. He noted that the EC approach to classification under the Dangerous Substances Directive was of great concern to the United States, both in the case of borates and systemically. Therefore, he regretted that the European Communities had finalized the 30th ATP and, as a result, classified borates as a Category 2 substance.

97. Additionally, the United States representative noted that the final classification determination contained language indicating that the European Commission would take into account any new studies on borates that could become available, with the possibility of re-evaluating its determination based on any such information in two years' time, and that the European Commission would conduct risk assessments before subjecting borates-containing products to restrictions under the Marketing and Use Directive. He noted that the United States would examine the determination when it was published. However, it was his delegation's view that a solution could be found that protected the health and safety of consumers while avoiding unnecessary restrictions on the sale and use of borates.

98. The representative of South Africa echoed the concerns already expressed on the adoption of the 30th ATP. In particular, his delegation was concerned about the re-classification of nickel carbonates: the evidence on carcinogenicity of nickel carbonates was not scientifically based. Therefore, he requested the European Communities to adopt a transparent science-based approach in the next 31st ATP.

99. The representative of Turkey joined the concerns expressed by other Members on the proposed classification of borates and nickel carbonates under the Directive 67/548/EEC. As a leading producer and exporter of borates, Turkey recalled that, in addition to raising concerns in the last two TBT Committee meetings, his delegation had engaged in a bilateral dialogue with the European Communities and was among the Members that had submitted additional comments on the EC notification at issue. In this regard, the Turkish representative thanked the European Communities for the replies received on 30 June 2008, but stressed that the responses received did not fully satisfy the concerns expressed. In fact, he regretted that the European Communities had adopted the 30th ATP without taking into adequate consideration the comments made by his delegation with regard to the classification of borates.

100. In particular, Turkey believed that the classification had many procedural and scientific shortcomings and was not based on a legitimate objective, thus creating an unnecessary obstacle to trade. The inclusion of a preamble indicating the possibility of re-evaluating the classification of borates in the light of new scientific information was not considered to address the scientific shortcomings of the adopted classification. In this regard, the European Communities was

encouraged to clarify the matter and explain how and when it would reconsider its classification decision. Additionally, the European Communities had also been invited again to take part in a joint epidemiology study which would be conducted in Turkey's borate mines and manufacturing sites. The representative of Turkey invited the European Commission to review its decision and comply with its obligations under the TBT Agreement.

101. The representative of the Russian Federation (as an observer) shared the concerns of previous delegations with regard to the nickel classification and stressed that her delegation attached great importance to this matter. The Russian Federation was one of the main producers of nickel and related substances and had a major interest in ensuring that the EC measure did not entail unnecessary barriers to trade. She therefore regretted that the European Communities had adopted the 30th ATP. Attention was also drawn to the European Communities improper implementation of the "read-across methodology" prescribed by the OECD Guidelines. The proposed classification would have negative downstream consequences under the Globally Harmonized System (GHS) and REACH legislation.

102. The representative of the European Communities confirmed that the new Dangerous Substance Directive 67/548/EEC had been adopted by the Commission on 9 June 2008. The Directive would be published in the European Communities Official Journal and transposed by the EC member States before June 2009; a copy of the adopted text would be sent to the TBT Enquiry Point to the WTO.

103. The European Communities informed the Members that the new recital contained in the Directive 67/548/EEC read as follows: "The classification and labelling of the substances listed in this Directive should be reviewed if new scientific knowledge becomes available. In this respect, considering recent preliminary, partial and not peer-reviewed information submitted by industry, special attention should be paid to further results of epidemiological studies on the borates concerned by this Directive including the ongoing study conducted in China and the outcome of the International Agency for Research on Cancer's discussion of the classification of Nickel substances or any new relevant scientific findings or interpretations given to the data used to establish the current proposals for the Nickel compounds concerned by this Directive".

104. The representative of the European Communities confirmed that, following the TBT Committee held on 20 March 2008, industry had submitted to the European Commission several new scientific studies, which had been examined with urgency by the Commission services and by the scientific experts from EC member States. Indeed, the experts recognised unanimously that these studies were either incomplete or inconclusive; therefore, they did not indicate that the proposed EC classification for those substances was inappropriate, nor did they signify a need to re-examine the classification that had been proposed.

105. The EC representative drew the Committee's attention to the fact that sufficient time had already been dedicated at the last TBT Committee meeting to discuss the questions brought by several delegations, in particular with respect to the hazard approach, the "read-across methodology" and the end uses, and referred Members to the detailed responses provided by the European Communities in the Minutes of the Committee meetings or in the written replies submitted to several Members. She also recalled the objective and extent of the EC proposal: the substances covered by this proposal (over 800) would need to bear, as of 1 June 2009, a label which aimed at informing those who handled these substances, that they should be handled with care. It was her delegation's understanding that this was the least trade-restrictive measure available to convey such information to the people in contact with those substances, therefore in line with Article 2.2 of the TBT Agreement. The EC representative recalled that the label would provide information on the hazardous properties of the preparations, but this classification would not ban or restrict the use of these substances on consumer end-products. As indicated at the previous TBT Committee meeting, a risk assessment would need to be carried out before imposing any type of marketing restrictions, or setting maximum exposure levels

or bans. Interested stakeholders and third countries would be able to participate in this process and measures would be notified to the WTO at a draft stage.

106. With regard to the requests of postponing the implementation of the 30th ATP, the EC representative noted that the Dangerous Substance Directive 67/548/EEC required the European Commission to take measures to harmonise the classification of Carcinogens, Mutagens or substances toxic to Reproduction (CMR) "as quickly as possible", also recalling that its adoption had already been postponed for a year. Furthermore, she pointed out that many of the arguments stressed by the industry were based on speculations, in particular with regard to how these substances would be treated under REACH. She stressed that there was no direct link between the classification of a substance and the authorization process under REACH, and also noted that the candidate list of substances classified as of high concern and the list of substances which would be classified in the 31st ATP had not even been drafted. In concluding, the European Commission informed the Committee that the draft 31st ATP would be notified to the WTO at the time that it was submitted to the EC member States, and confirmed its willingness to discuss any issues related to the implementation of the proposal.

(v) *United States – Chemical Facility Anti-Terrorist Regulation*

107. The representative of Israel reiterated his concerns with respect to the list of "chemicals of interest" (Appendix A), published by the US Department of Homeland Security (DHS) in the 20 November 2007 Federal Register, that were subject to the interim final DHS regulation on security of high-risk chemical facilities, published in the 9 April 2007 Federal Register.

108. In particular, his delegation was concerned that the DHS list of "chemicals of interest" included potassium nitrate and sodium nitrate, but did not include calcium nitrate. Israel believed that the inclusion of potassium and sodium nitrate in the list resulted in an unnecessary obstacle to trade and that the measure could affect Israel's exports to the US market. Available scientific information indicated that all three products were similar and had similar properties, and that they did not pose a security threat. Therefore, they needed to be treated equally and not included in the DHS list. His delegation was ready to consult with the United States on the matter, preferably at an expert level, with the view of finding an agreed solution.

109. The representative of Chile shared the concerns expressed by Israel. Concerns had been expressed about the exclusion from the regulation of nitrates such as alkaline nitrates, calcium nitrates or magnesium nitrates, which had the same chemical properties and competed with those products that had been included in the list of "chemicals of interest" (Appendix A). It was stressed that other chemicals which had been excluded from the regulation, such as nitrates with ammonium, were elements of interest that could be used by terrorists. The representative of Chile noted that comments had been submitted to the United States and that a response was awaited.

110. The representative of the United States recalled that, as Israel and Chile had indicated, both sodium nitrate and potassium nitrate were included in Appendix A of this regulation, which contained the list of "chemicals of interest" covered by the measure at issue. Through a process of scientific risk assessment, as well as consultation with security authorities in other countries and public notice and comment, DHS had determined that the Chemical Facility Anti-Terrorist Regulation (CFATS) would apply to a specific set of substances, including certain nitrates determined to possess the requisite precursor explosive properties

111. It was highlighted that CFATS required handlers – for example distributors – of the chemicals contained in Appendix A to submit screening information to DHS. The screening information would be submitted in the form of a document called a "top-screen", which handlers could submit through an

on-line procedure. DHS had already received completed "top screens" from nearly all of the covered handlers of the nitrates subject to CFATS.

112. The representative of the United States noted that Israel and Chile had conveyed concerns that the application of CFATS to nitrates would be burdensome and could encourage farmers to use other fertilizers. However, his delegation believed that the available evidence did not support these views. DHS had estimated that the average time to complete the online "top-screen" information was 27 minutes, and none of the major industry associations in the United States had reported that their members were encountering any problems with completing the top screen. In addition, in January 2008 DHS had announced an open-ended exemption for farmers and other agricultural users from the screening requirement contained in this measure. Moreover, the online "top-screen" was merely a questionnaire; only those facilities that DHS would subsequently determine as high risk would be subject to regulation.

113. The representative of the United States noted that bilateral discussions had been held with Chile on its concerns, including with DHS, and stressed that his delegation would continue to facilitate information exchange with trading partners, in order to enable their exporters to understand and comply with this new requirement. He noted that DHS was also planning to be in contact with exporters who may wish to serve on an industry advisory panel to provide advice to DHS as it implements CFATS.

(vi) *Sweden – Restrictions on the use of Deca-bromo diphenylether (deca-BDE)*
(G/TBT/N/SWE/59)

114. The representative of Israel recalled that her delegation had raised concerns about the above-mentioned measure several times. The Committee's attention was drawn to the fact that the ban on the use of deca-BDE now concerned the whole of the European Communities. She noted that deca-BDE had been exempted from the "Restriction of Hazardous Substances" Directive (RoHS) following a risk assessment which had concluded that it did not represent any significant risk to health or environment. However, on April 2008, the European Court of Justice had ruled that the exemption given for deca-BDE should be annulled by 1 July 2008 on the basis of procedural flaws in the exemption process. As a result, deca-BDE would not be exempted from the ban within the RoHS Directive, and as of 1 July 2008 would be restricted from use in electronic and electrical equipment. Israel considered this restriction an unnecessary obstacle to international trade within the meaning of Article 2.2 of the TBT Agreement. He noted that the RoHS Directive was being reviewed and urged the European Communities to exclude deca-BDE from its scope.

115. The representative of Jordan noted that the EC risk assessment which had been published in the Official Journal of 29 May 2008 concluded that no risk had been identified for the use of deca-BDE. However, the use of deca-BDE was restricted in the European Communities. He stressed that the European Communities should consider adopting a new exemption or removing deca-BDE entirely from the scope of the RoHS Directive. Failure to correct the situation would undermine the credibility and the usefulness of risk assessments taking place, which would in turn undermine the scientific foundations of both RoHS and REACH.

116. The representative of Japan noted that his delegation's understanding was also that deca-BDE would now be reapplied to the RoHS Directive. Since deca-BDE was produced in large amounts outside the European Communities, this had a considerable impact on international trade. He noted that this issue had not yet been notified to the TBT Committee and sought more information from the European Communities.

117. The representative of Chinese Taipei associated himself with the comments made and noted that his delegation's understanding was that the recent assessment by the European Communities on

deca-BDE was not based on scientific evidence, which did not justify the European Communities claim of protection of human health.

118. The representative of the European Communities explained that the Court of Justice had ruled on 1 April 2008 that the decision exempting deca-BDE from the scope of the Directive on the Restriction of the use of Hazardous Substances should be annulled, as the procedure which the European Commission had followed to grant such exception had not been carried out appropriately. Therefore, as of 1 July 2008, the use of deca-BDE would be restricted in electrical and electronic products placed on the EC market. She pointed out that the European Commission was examining possible scenarios of addressing this matter with a view to reducing the impact on exports from third countries and that any measure which the European Commission proposed in this respect would be notified to the TBT Committee, if appropriate.

(vii) Korea – Fish Heads

119. The representative of New Zealand reiterated concerns about restrictions in Korea on edible hake heads processed on New Zealand boats, which received different treatment compared to fish heads caught by Korean boats. She recalled that Korean officials had announced that hake heads were going to be added to the national Food Code and that the matter would become relevant to SPS. A significant amount of information on the safety of these fish heads processed by New Zealand boats had been provided to the Korean Ministry of Fisheries. She pointed out that another delay had occurred and the changes to the Korean Food Code had not been made. She sought the cooperation of Korea to ensure that the required changes to the Food Code were made so that the matter would not have to be raised again.

120. The representative of Korea regretted that the issue had been raised again. He informed the Committee that after the notification of its draft Food Code to the SPS Committee, the Korean Food Sanitation Council had decided to undertake a site inspection before enactment, which was due in May 2008. He pointed out that Korea and New Zealand were discussing a detailed plan of site visits by Korean experts.

(viii) Brazil – Toys (G/TBT/N/BRA/259)

121. The representative of Malaysia recalled concerns about a Brazilian notification on toys which had been raised by his delegation at the previous meeting of the Committee and pointed out that, since then, bilateral discussions had taken place with the Brazilian delegation on the issue and a written communication had been sent to Brazil. However, no response had been received. He reiterated his delegation's request to Brazil that the technical regulation on toys be reviewed. In particular, he requested Brazil to accept the results of conformity assessment procedures of accredited conformity assessment bodies, without requiring the testing of Malaysian products to be conducted in Brazil. Additionally, both systems 7 and 5 certification procedures should be made available to Malaysian exporters.

122. The representative of Thailand recalled that at the previous meeting of the Committee, her delegation had noted that the INMETRO Decree resulted in unequal treatment for imports and was more trade restrictive than necessary. However, her delegation was concerned that no changes had been made to the Brazilian measure, which required imported toys be tested by lots or batches. This meant that the Brazilian regulation accorded less favourable treatment to imports in breach of Article 5.1.1 and also created unnecessary obstacles to trade in violation of Article 5.1.2, because it was more strict than necessary to give Brazil adequate confidence that imported toys conformed with its technical regulation on toy safety. There were other WTO-consistent alternative measures available to Brazil, such as testing in the country of export, especially when such testing was conducted by internationally recognized and accredited laboratories. She stressed that her delegation agreed with

the objective to ensure that toys destined for children were safe. Nevertheless, such measures had to be applied in an equal way. She requested that the Brazilian Decree be brought into conformity with the TBT Agreement and that a written reply to comments sent be provided.

123. The representative of the European Communities pointed out that concerns remained about less favourable treatment of imported toys compared to domestically produced toys. It was his delegation's view that the so called "system 5" procedure, which was available only to domestically produced toys, was less burdensome than the so called "system 7" procedure which was available to imported toys. The European Communities appreciated Brazil's willingness to enter into bilateral discussions but urged Brazil to consider measures which would restore a level playing field between imported and domestically produced toys. He stressed that initial feedback provided by European Industry on the initial period of application of the new measures pointed to increasing delays for the release of imported toys into circulation in Brazil and to much higher costs compared to the previous regime. In addition, there were concerns about the abilities of the few test laboratories that had been agreed by INMETRO to perform the test required by the system 7 procedure.

124. The representative of the European Communities further highlighted that summer and autumn were crucial periods for shipment of toys in view of the Christmas sales and that the difficulties that had been reported in the initial period of application of the measures were likely to be exacerbated in the coming months. He invited Brazil to consider measures that would allow equal treatment of imported and domestically produced toys and to allow the recognition of results of tests carried out in the country of origin of the toys.

125. The representative of China pointed out that the Chinese industry had reported that, further to the introduction of the new testing process, an average of 70 days delay had been experienced. This created a significant burden for China's exports of toy products. He requested that Brazil ensure toy safety in a non-discriminatory and less trade restrictive manner and that the measures be brought into conformity with WTO obligations.

126. The representative of Brazil pointed out that the new conformity assessment procedures had been adopted under urgent circumstances and with the legitimate objective of protecting the health of consumers. The previous conformity assessment system had proved to be inefficient and several cases of non-conformity, recalls and accidents had been reported in 2007. He noted that these urgent measures were not permanent, and that the adoption of a new and definite system of conformity assessment procedures for toys was under consideration by the competent authorities in Brazil.

(ix) Germany – Ban on Seal Products (G/TBT/N/DEU/5 and Add.1)

127. The representative of Norway reiterated concerns about the banning, by several EC member States, of imports of seal products, the most recent of which had been notified by Germany. Her delegation believed that the ban on seal products was not an animal welfare issue, it was not a conservation issue and it was not a management issue. Rather, it was a public opinion issue, which was considered unsubstantiated and unjustified. She stressed that ban on imports of seals in EC member States set a dangerous precedent for trade in animal products that were harvested in a sustainable and humane manner. It was her delegation's expectation that the European Commission would notify any draft future regulations concerning trade in seal products to the TBT Committee within the time limits of the TBT Agreement. Norway continued to reserve its right to take any appropriate action necessary to defend its interests under the TBT Agreement and other relevant WTO agreements.

128. The representative of Canada reiterated that her delegation shared Norway's concerns on the ban of seal products by several EC member States. Her delegation also believed that this was neither an animal welfare nor a public morality issue, but an issue of public opinion.

129. The representative of the European Communities pointed out that, as noted in the previous meeting of the Committee, the draft proposal had been notified to the European Commission under internal procedures and was currently being examined by the Commission services.

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

130. The representative of the European Communities recalled the concerns expressed by her delegation on the Indian measure and thanked India for having notified the Order in April 2008. However, her delegation regretted that the Order had only been notified once it had already been adopted. She stressed that according to Articles 2.9.2 and 5.6.2 of the TBT Agreement, notifications had to take place at an early appropriate stage, when amendments could still be introduced and comments taken into account.

131. The representative of the European Communities pointed out that written comments would be sent to India shortly and that concerns remained about the burdensome requirements imposed on imported cosmetics. The Order laid down a registration system for imported cosmetics which discriminated against imported products, introduced long delays before the products could be placed on the market, and required the disclosure of confidential business information. At the same time, it was difficult to see how this system would increase product safety, or would help curtail counterfeiting and parallel trade as intended. The European Communities was of the opinion that the Order was in many respects vague and did not set clear rules for the registration procedure. Therefore, the measure was considered as more trade restrictive than necessary and thus not in line with Article 2.2 and 5.1.2 of the TBT Agreement. India was invited to continue the bilateral talks already initiated on this issue and to bring the measure into conformity with the TBT Agreement.

132. The representative of the United States reiterated his delegation's concerns regarding India's "Drugs and Cosmetics (Amendment) Bill, 2007," which India had belatedly notified to the WTO in final form after the last Committee meeting. His delegation continued to seek a better understanding of the objective and rationale of the new requirements, on whether the measure applied to all cosmetics entering the Indian market, not just imports, and specifically on how the registration requirements were expected to increase product safety for consumers. He noted that US industry's concerns had also been conveyed to the Indian authorities, in particular the perception that the measure would be overly burdensome, and could result in costly delays to market for its products.

133. The representative of the United States looked forward to a continued dialogue with Indian authorities on this issue, on the basis of the US comments that had been submitted in early June and urged India not to require compliance with the requirements until industry concerns, particularly on the applicability of the registration requirements to all cosmetics, were addressed.

134. The representative of India noted that constructive bilateral meetings had been taking place on this issue with the European Communities and the United States. Some queries asked by the United States had been answered and new questions had also been raised; these would be transmitted to capital. The forthcoming written comments from the European Communities would also be transmitted to experts in capital, and a duly examined. He stressed that comments would be taken into account before enforcing the measure.

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

135. The representative of the United States reiterated his delegation's concerns related to China's above-mentioned measure notified to the TBT Committee in August 2007. These regulations would mandate a government certification and testing scheme for information security for 13 categories of information technology products. He noted that, for the vast majority of IT products, other countries did not require government testing and certification for information security; this was only the case

for a small subset used by governments for national security purposes. His delegation's general concern was that China's regulations appeared to go substantially beyond global norms by mandating testing and certification of information security for commercial products. He sought clarification from China regarding its rationale, and the technical information it considered, in seeking to extend certification and testing requirements to information security for IT products used commercially in these 13 categories.

136. In addition, many key aspects of the proposed technical regulations had yet to be explained and the scope of products covered remained unclear. It was pointed out that the testing procedures that suppliers would need to utilize to demonstrate conformity with the regulations had not been provided. Moreover, provisions to ensure that intellectual property and other business proprietary information were protected by governmental authorities had not been promulgated. In this regard, transparency in the development of such requirements would be of paramount importance. The representative of the United States urged China to conduct a transparent process that allowed meaningful opportunity for comment and inquiries by all interested stakeholders. He further recalled that his delegation had engaged Chinese authorities bilaterally, suggesting that China delay finalizing the technical regulations to allow time to discuss these technical issues in a constructive manner. China's willingness to engage in these discussions was appreciated. However, it was his delegation's understanding that CNCA had indicated to industry that the technical regulations would soon be finalized and become mandatory for all covered products as of 1 May 2009.

137. The representative of the United States noted that, in addition to the overall concern regarding the need for these regulations, it was difficult to see how they could be implemented on such a tight timeframe, given the critical details that had yet to be specified. If China continued to pursue these regulations, their finalization needed to be delayed so as to enable parties to continue working constructively together to address the concerns that had been raised in a manner consistent with international practice in this area.

138. The representative of Japan noted that in January 2008, IT security products had been added to the category of CCC system, which would come into effect in May 2009. Japan was concerned about the management of intellectual property. He also requested that China allow foreign certification bodies based in China or overseas to be appointed, in accordance with Article 6.2 of the TBT Agreement and paragraph 195 of the Report of the Working Party on the Accession of China.

139. The representative of the European Communities supported the statements made by the United States and Japan and highlighted a few issues of concern. First, he requested China to clarify the rationale for the proposed measures and their implications. If the legitimate objective being pursued was that of national security, the European Communities found difficult to understand why it also applied to products intended for commercial and consumer use. Moreover, his delegation was concerned about the expansion of the Chinese compulsory certification system (CCC) - considered a burdensome and expensive conformity assessment procedure - to new product categories. It was also not clear how the existing international standards (ISO/IEC 15408:2005), which set out the common criteria for information technology security evaluation, had been taken into account in the preparation of the proposed measures.

140. With regard to the practical implementation of the proposed measures, the representative of the European Communities joined the comments made by previous delegations and stressed that the procedures and modalities to have access to the underlying encryption algorithms had not been disclosed. In particular, there were intellectual property rights (IPR) related concerns with regard to the possible need for companies to disclose sensitive commercial information. In concluding, the representative of the European Communities encouraged the Chinese delegation to start discussions both bilaterally and at an expert level with a view to finding an agreed solution, and meanwhile invited China to consider suspending the adoption of the proposed measures.

141. The representative of China noted that the proposed regulations aimed solely at protecting information security, and simplifying the current system. He took note of the comments and stressed that the concerns raised would be discussed with stakeholders.

(xii) Argentina – Measures affecting Market Access for Pharmaceutical Products

142. The representative of Colombia recalled that at the previous meeting of the TBT Committee, his delegation had expressed concerns with regard to the system applied by Argentina for the commercialization of pharmaceuticals (G/TBT/W/280). It was also recalled that some of the measures appeared to be contrary to rights and obligations under the TBT Agreement. He pointed out that no reply had been provided by Argentina on the concerns expressed; therefore, Colombia would consider making a formal complaint under the Dispute Settlement Understanding (DSU).

143. The representative of Chile recalled that her delegation had also expressed concerns on this issue in the previous meeting of the TBT Committee. Chile shared the concerns expressed by Colombia and noted that no reply had been received by Argentina.

144. The representative of Paraguay noted that concerns had also been expressed by his delegation in the previous meeting of the TBT Committee, and that no progress had been made.

145. The representative of Argentina recalled that there had already been contacts between the representatives of concerned Members and relevant authorities. In particular, it was noted that Colombian authorities had met with experts from Argentinean competent agencies on 11 April 2008, and as a result of this meeting an agreement on the inspections required by laboratories was reached. With regard to the concerns raised by Chile and Paraguay, although consultations had been conducted on bilateral basis, Argentina remained convinced of the appropriateness of the measure at issue. Finally, Argentina invited concerned delegations to contact the relevant technical authorities for further clarification.

(xiii) Brazil – Registration Requirements for Medical Devices

146. The representative of the European Communities reiterated her delegation's concerns with regard to the Brazilian registration requirements for medical devices introduced by Resolution 185 but not yet notified under the TBT Agreement. The Resolution 185 required the submission of an economic dossier for each version and accessory of every product covered by the resolution. The procedure required the submission of data which was extremely difficult for economic operators to provide, and in part was confidential business information. The regulation was therefore considered burdensome and not practicable.

147. The European Communities appreciated Brazil's confirmation that the *Agência Nacional de Vigilância Sanitária* (ANVISA) sought to ensure transparency in the implementation of the measure, but economic operators were still facing several problems. In particular, it was not clear what would happen if the economic dossier was not submitted. For instance, it was the European Communities' understanding that if the dossier was not submitted within 30 days after notice of approval of product registration, the product would not be able to be sold. Moreover, it was unclear what would happen if a dossier was incomplete, and when or how the submitting company would be informed about the evaluation of the dossier. Finally, the representative of the European Communities stressed that the procedure of the resolution of disputes had to be clear, transparent and predictable. She encouraged the Brazilian authorities to continue their exchange of views with the economic operators, to provide replies to the concerns expressed and to consider further amending the resolution.

148. The representative of the United States appreciated Brazil's efforts to engage in a constructive dialogue on the concerns which had been raised in respect of the Resolution 185, and thanked Brazil

for the detailed replies provided to industry stakeholders on their recommendations to help clarify the information requirements contained in the Resolution. He reiterated his delegation's view that the requirement to submit economic data was not related to the safety or efficacy of medical devices, and was unnecessarily costly and burdensome. Furthermore, industry had indicated that some of the information required was impossible to provide, either because the information did not exist or could only be provided by contacting other companies to obtain it, which raised potential antitrust concerns. It was also noted that such problems had already led ANVISA to deny commercialization for certain products.

149. The representative of the United States noted that ANVISA had been working with interested stakeholders and appeared to be in agreement with the need for greater transparency and specificity with regard to adjustments in the reporting requirements, particularly given the difficulties associated with fulfilling the Resolution's expansive information requirements. However, Brazil still had not taken any official actions to clarify those requirements for importers, and ANVISA seemed to be inviting suppliers to disregard informational requirements contained in the Resolution that suppliers, in their own judgment, might feel were burdensome or impossible to fulfil. However, companies that did so would operate in the Brazilian market under conditions of great legal and economic uncertainty because such flexibility was not set out in the text of the Resolution and, in practice, ANVISA did not let companies know whether they had complied once they had submitted their data. Such uncertainty had the potential to create unnecessary disruptions regarding trade in medical devices, ultimately to the potential detriment of the Brazilian public. Therefore, the United States urged Brazil to continue working with interested stakeholders to clarify the informational requirements of the Resolution and provide legal certainty for the industry on how to comply with them.

150. The representative of Brazil reiterated his delegation's position that Resolution 185 was neither a technical regulation nor a conformity assessment procedure. His delegation believed that in previous meetings Brazil had clarified why Resolution 185 was not covered by TBT provisions and did not need to be notified to the TBT Committee; therefore, those points were not reiterated.

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

151. The representative of Korea took note of the fact that Norway was reviewing the comments concerning the proposed regulation on the Prohibition of certain Hazardous Substances in consumer products (PoHS), which had been made at the last TBT Committee. His delegation looked forward to having updates on this issue. In particular, it was stressed that there were no scientific bases to prohibit *bis(2-ethylhexyl)phthalate* (DEHP).

152. The representative of Israel supported the comments made by Korea, and recalled her delegation's concerns with respect to two chemicals of export interest to his country, namely: *tetrabromobisphenol A* (TBBPA) and *hexabromocyclododecane* (HBCDD).

153. The representative of Jordan noted that the entering into force of the regulation was delayed and invited Norway to take into consideration his delegation's concerns with respect to the two chemical substances of interest to his country, namely: TBBPA and HBCDD.

154. The representative of Japan also expressed concerns about the above-mentioned proposed regulation.

155. The representative of the United States noted his understanding that implementation of the regulation had been delayed because of the many comments Norway had received from Members and that, in light of those comments, Norway had announced that the proposed measure might need to be

revised. The United States requested Norway to provide further information on how it would take into account the comments received in revising the proposed regulation.

156. The representative of Norway confirmed that the above-mentioned regulation had not entered into force on 1 January 2008, as previously announced, and that the comments received were being evaluated by Norwegian environmental authorities. Useful information concerning the application of some of the substances covered by the proposed measure had been received. Moreover, the Norwegian environmental authorities were holding meetings with interested stakeholders. Limit values for the different substances and possible exemptions were being evaluated, with the aim of finalizing a decision in the first part of 2009. Norway would inform Members on the progress of the regulation through regular procedures.

(xv) *Norway – Restrictions on the use of Deca-bromo diphenylether (deca-BDE) (G/TBT/N/NOR/6, Add.1 and Corr.1)*

157. The representative of Jordan requested clarification on the implementation of the Norwegian regulation on Deca-bromo diphenylether (deca-BDE). Although the proposed measure was expected to enter into force on 1 April 2008, many Members believed that the measure did not have sufficient scientific basis.

(xvi) *European Communities – Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) (G/TBT/Notif.00/310, Corr.1)*

158. The representative of the United States drew the Committee's attention to the European Communities' on-going review of the Directive concerning Restrictions of Hazardous Substances (RoHS), and recalled that several discussions had taken place in the Committee during the development and initial implementation of the original directive, including regarding problems related to the lack of clear guidance and transparency. He noted that the results of a recent study by a global association of electronics companies showed that initial compliance cost associated with the original RoHS directive was US\$32 billion. The United States was concerned about the magnitude of the cost of compliance and, in particular, the disproportionate impact on Small and Medium-sized Enterprises (SMEs).

159. The representative of the United States emphasized that EC regulators should ensure a risk and science-based approach to the RoHS review, including evaluating whether to add additional substances to the list, set maximum concentration levels for specific products, or grant exemptions. The European Communities was encouraged to provide clarity in a timely manner on how RoHS and REACH would fit together and to carry out a transparent process, including a notification to the WTO of proposed changes or amendments to RoHS, that allowed a meaningful opportunity for comment by all interested stakeholders. Additionally, the United States requested the European Communities to provide a status report on how the RoHS directive was being enforced and how the European Communities intended to ensure a unified approach to enforcement across the EC Member States. Finally, the European Communities was urged to provide a reasonable period of time for suppliers to implement any changes made to the directive.

160. The representative of the European Communities confirmed that the RoHS directive was being reviewed. One of the main objectives of this review was to clarify and simplify the provisions of the directive, to reduce the administrative burden and to address reported implementation difficulties. In the review, the European Commission would examine the need and possibilities of extending the restrictions to other hazardous substances and the exemptions granted under the RoHS directive. It was noted that many companies and associations from third countries had contributed extensively to the consultation process. The European Communities also informed Members that an

Impact Assessment was underway and was expected to be concluded by the end of July 2008. The Impact Assessment would lead to the preparation of a proposal by the Commission which would be discussed internally, and subsequently notified to the Committee. In concluding, the representative of the European Communities emphasized that coherence with other product-related legislation as well as with REACH would be ensured, wherever appropriate.

(xvii) China – Draft Standards on Lithium Batteries for Mobile Phones

161. The representative of Japan recalled that at the last TBT Committee meeting his delegation had raised concerns with respect to China's draft standards on lithium batteries for mobile phones and sought clarification on the current status of the draft. He raised concerns on two specific points. First, the representative of Japan pointed out that although the standards on batteries should be based only on safety concerns, they included environment and efficiency issues and were also applied to battery chargers. Furthermore, he recalled that standards should be developed in cooperation with interested business sectors and should comply with relevant international standards. Finally, Japan also expressed concerns about intellectual property matters.

162. The representative of the European Communities supported the comments made by Japan, and thanked the Chinese authorities for the clarifications provided bilaterally. The EC representative welcomed the information that the standards would be voluntary in nature, and there was no intention to make them mandatory. China was encouraged to continue developing the standard in an open and transparent manner and to ensure effective participation of all stakeholders concerned in its finalization, as well as in the development of the parallel generic standard on safety of batteries.

163. The representative of China noted that the draft standards on lithium mobile phone batteries were open for comments from all stakeholders and were still under discussion.

(xviii) China – Domestic Gas Cooking Appliances (G/TBT/N/CHN/237)

164. The representative of the European Communities recalled concerns on the proposed national standard on gas cooking appliances. The European Communities regretted that the new standard had been adopted despite the serious concerns expressed by the EC delegation. However, it was noted that bilateral discussions on the issue were still on-going. The European Communities encouraged China to give positive consideration to the EC proposal, to set up an expert group and to suspend the application of the new requirements pending the outcome of the discussions.

165. The representative of China noted that his delegation had already provided replies to the European Communities in the previous TBT Committees; however, China welcomed the EC proposed bilateral meeting between experts. It was also recalled that the standard was based on a particular need of Chinese cuisine.

(xix) India – Pneumatic Tyres and Tubes for Automotive Vehicles (G/TBT/N/IND/11 and 20)

166. The representative of the United States recalled his delegation's concerns with respect to the regulations on tyres and tubes. He continued to seek a greater understanding of the objective and requirements of the Bureau of Indian Standards (BIS) protocol on conformity assessment procedures for tyres and to allay US industry's concerns that imported tyres may be treated less favourably than domestic tyres. Additionally, the United States representative noted that a draft amendment to the Central Motor Vehicles Rules was proposed on 6 May 2008, and stressed that one of its provisions appeared to govern conformity assessment for tyres and seemed to require that tyres met the applicable requirements on 1 May 2008 – five days prior to the publication of the draft amendment. India was encouraged to provide clarification on how the draft amendment was related to the BIS Protocol, whether compliance was required on 1 May 2008 and whether India intended to notify the

draft amendment to the WTO. The representative of the United States looked forward to sharing the outcome of the current discussion with India with interested stakeholders in capital and to a continued dialogue with Indian authorities on this matter. Finally, given India's clarification that compliance with the BIS protocol would be mandatory once implemented, coupled with the new draft amendment to the Central Motor Vehicles Rules, he urged India not to require compliance with the requirements until industry's concerns were addressed.

167. The representative of Japan expressed concerns regarding the proposed classification system for the regulation of tyres. In particular, the Japanese delegation believed that the regulation had excessive participation costs and implementation periods were too short for foreign based firms.

168. The representative of the European Communities shared the same understanding as the United States and Japan with respect to the regulations on tyres and tubes. The European Communities believed this regulation required burdensome requirements for tyre manufacturers without recognizing the equivalence of tyres complying with the UNECE regulation. In fact, it was the EC delegation's view that these trade barriers could be avoided by applying the globally harmonized specification. The representative of the European Communities therefore expressed her delegation's encouragement for India's active participation in the 1998 UNECE Agreement discussions on a global technical regulation for tyres, and invited India to abstain from the adoption of the regulation which ran counter to international harmonization efforts. She also asked India to give an update on the draft order and to explain if tyres complying with the UNECE regulation would be recognized. Finally, India was encouraged to clarify whether the notified draft had already been adopted and, in that case, when it would enter into force.

169. With regard to the concerns raised by the United States, the representative of India noted that his delegation had had a bilateral meeting with the United States, where a number of issues had been clarified. It was recalled that the United States raised concerns about the amendment in the motor vehicle rules and wanted to know whether this was related to the same measure. The Indian delegation confirmed that the question was transmitted to experts in capital and a reply would be assured as soon as possible. With regard to concerns raised by the European Communities, it was recalled that comments would be sent back to capital and responses would be given at the next TBT Committee meeting.

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

170. The representative of the European Communities reiterated concerns about a measure on wine, notified by China on 2 May 2006, which imposed, among other things, a level of sulphur dioxide which her delegation considered was unnecessarily restrictive and which was below the levels established at the international level, as well as those accepted by the European Communities. In fact, the proposed levels had caused problems to sweet wines which, until the date of entry into force of this measure, were permitted. She noted that comments had been submitted and that a reply had been provided by China in which it was clarified that China would not introduce the level of sulphur dioxide which had been indicated in the notification, and that limits set in the Food Hygiene Standard would apply.

171. However, it was highlighted that these limits were even more restrictive than the previous ones, and were not in accordance with the international level. It was the EC delegation's understanding that the Chinese standards were currently being reviewed and that the maximum level of sulphur dioxide would be increased and aligned to those recommended by international organizations, which set a limit of 400mg/l. The European Communities requested a formal confirmation of this information and urged China to promptly look into this matter and amend the currently applied levels to those established by the Organization of Vine and Wine (OIV), as almost no wine could satisfy the low limits set by the Chinese authorities.

172. The representative of China pointed out that comments by the European Communities had been taken into account and a reply had already been provided. It was stressed that this standard was being reviewed and that the relevant international standards would be taken into account. The reviewing process would probably be finalized by the end of 2008, and once finalized it would be notified bilaterally to the European Communities.

(xxi) European Communities – Toys (G/TBT/N/EEC/184)

173. The representative of Korea raised concerns about the above-mentioned measure, notified by the European Communities on 27 February 2008. His delegation believed that the measure at issue was more trade restrictive than necessary to fulfil the legitimate objective and, in addition, was discriminatory to non-EC manufacturers because the safety of imported toys was already assured through the process of EN 71 and CE mark. The European Communities was invited to reconsider the measure and to guarantee that imported toys would not be discriminated against and treated unfairly.

174. The representative of China shared the concerns expressed by Korea and noted that his delegation had already sent its comments to the European Communities in April, but no reply had been provided yet. He encouraged the European Communities to provide a reply about this concern as soon as possible.

175. The representative of the European Communities pointed out that a written reply to the comments submitted by various delegations was being finalized and would probably be issued in two or three weeks.

(xxii) Canada – Compositional Requirements for Cheese (G/TBT/N/CAN/203)

176. The representative of the European Communities reiterated concerns about Canada's regulation governing compositional requirements for cheese. Although certain rules had been revised in its final publication, the European Communities remained concerned about the negative impact of the new requirements. The representative of the European Communities emphasized that the new licensing requirements appeared to create unnecessary obstacles to trade and raised WTO incompatibility concerns; they appeared to be discriminatory as they only applied to importers and not to domestic cheese producers. In this context, the beneficiary of the measure seemed to be the Canadian milk industry. Finally, it was the EC delegation's view that, without clear provisions regarding the enforcement of this measure, operators would not be able to invest in the compliance mechanisms. The representative of the European Communities urged Canada to take into account the comments expressed and postpone the entry into force of the new standards.

177. The representative of the United States recalled that the new compositional requirements for cheese could impair access to the Canadian market, and could impose significant costs on US producers and processors, who would need to comply with the related import licensing scheme. He noted that the issue was being reviewed closely and that the measure's impact on US dairy exports would be monitored as well. With respect to implementation, the new requirements would become mandatory at the end of 2008 but Canada had still not set out the details of the licensing scheme. This was a serious concern to industry, in particular given the apparent lack of a testing methodology that producers and processors could use to verify the milk protein content of cheese derived from raw milk as compared to other sources (e.g., milk protein concentrates). Therefore, Canada was urged to set out the licensing system's draft provisions as soon as possible and to notify them to the WTO.

178. The representative of Switzerland shared the concerns expressed. In particular, her delegation was interested in receiving more information from Canada about the new licensing regime.

Switzerland noted that the new compositional requirements for cheese would enter into force in 2008 and urged Canada to provide the requested information as soon as possible.

179. The representative of Canada recalled the comments already made at the previous meeting of the Committee. With respect to the comments about consistency with WTO obligations, she stressed that these new harmonized cheese standards clarified the permitted ingredients for varietal cheeses and would provide consumers with greater product uniformity. All cheeses bearing a particular varietal name would possess similar characteristics, irrespective of where they were purchased or by whom they were manufactured or distributed. This reduced the risk of consumer confusion and prevented the use of deceptive practices. Her delegation did not agree with those Members who asserted that the regulation was unnecessarily trade restrictive and would not be beneficial to Canadian consumers. Many imported cheeses would already be consistent with the regulations and it was expected that the amended regulations would not lead to reductions in the volume of imported cheeses. Canada filled its annual cheese tariff rate quota, and imported specialty cheeses were in high demand among Canadian consumers.

180. With respect to the licensing regime, Canada was still working to implement the new import licensing regime in a way that would minimize the impact on importers and foreign cheese suppliers. More information would be provided to trading partners on the import licensing regime as it was finalized. With respect to discriminatory treatment, the food industry was responsible for having measures in place to verify that all products met the appropriate regulations, and the Canadian Food Inspection Agency (CFIA) would assess compliance. The licensing regime would continue to require the use of an import declaration whereby the importer attests that the product meets all Canadian requirements. The Canadian delegation believed that the import licensing requirements would not be more onerous than the domestic requirements and therefore there would be no discriminatory treatment. Other measures, such as buyer-seller agreements could be used by the importer in order to provide the necessary substantiation to the Canadian food inspection agency. In concluding, the representative of Canada stressed that the framework for verifying compliance was expected to be provided in summer 2008.

(xxiii) Israel – Infant Formula

181. The representative of the United States recalled that his delegation had expressed concerns about the infant formula regime in Israel at the last several meetings of the Committee. His delegation's understanding was that Israel's Ministry of Health was working with stakeholders on a revised infant formula regulation that would set out requirements for the sale of infant formula in Israel, and that the Israeli Knesset intended to fast-track its passage. He sought further information on the status of those efforts and urged Israel to continue working with stakeholders to resolve this issue.

182. The representative of Israel confirmed that internal consultations were on-going between various Israeli authorities, regulators and stakeholders in order to address this issue and find an agreed solution to the concern of the United States. She recalled that in light of grave public health incidents following imports of infant food, the issue was sensitive. Israel remained available for further consultation on this issue with the United States on a bilateral basis.

(xxiv) China – Revision of the list of toxic chemicals severely restricted in the People's Republic of China in the regulation for environmental management on the first import of chemicals and the import and export of toxic chemicals

183. The representative of Japan recalled concerns about China's Registration System for the import and export of toxic chemical. He noted that at the previous meeting of the TBT Committee China had stated that the regulation was being revised, and sought an update on the matter. He further stressed that the regulation could conflict with Article 2.1 of the TBT Agreement, which states that

“products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country”. In fact, the Chinese regulation required exclusively foreign-based firms to pay US\$10,000 to import one item. China was therefore requested to abolish the registration fee of the regulation.

184. The representative of the European Communities joined the representative of Japan in requesting an update on the review of the Chinese toxic chemicals legislation. In particular, China was invited to clarify when these consultations would be finalized and what the possibilities for foreign stakeholders to take part in the process were.

185. The representative of China confirmed that consultations were on-going and comments would be presented to the newly established Ministry of Environmental Protection.

(xxv) Thailand – Labelling Requirement for Snack Foods (G/TBT/N/THA/215 and Add.1)

186. The representative of the United States recalled his delegation’s concerns with respect to Thailand’s labelling system for certain snack foods. Although the United States appreciated Thailand’s efforts on its revisions to the measure and supported Thailand’s goal of promoting a healthier citizenry, industry groups from Thailand, the United States and other trading partners, continued to raise questions as to whether the measure was necessary in light of alternatives. His delegation had taken note of the response provided by the Thai FDA in January 2008 to questions and concerns raised on the revised regulation, which indicated that nutritional labelling should be directed at all food categories and that mandatory labelling requirements for snack foods and other foods "deemed necessary" would eventually be put in place "at appropriate stages". The United States requested Thailand to issue a status report on when it intended to implement such changes and what other food categories were being reviewed for potential labelling requirements.

187. Finally, the representative of the United States drew the Committee's attention to the ongoing work in Codex to review strategies regarding diet and health, in part stemming from concerns with the WHO’s Draft Action Plan for the Implementation of the Global Strategy on Diet, Physical Activity and Health. He encouraged Thailand to participate actively in the Codex work and to consider approaches that could have the benefit of both encouraging better health and facilitating trade. His delegation looked forward to a continued dialogue on this issue with the Thai authorities.

188. The representative of Thailand noted that, as explained by the Thai Food and Drug Administration (FDA), the Ministerial Announcement No. 305 on snack food labelling served as one of many measures aimed at finding a solution to the problem of children’s malnutrition. All sectors involved were in favour of developing supplementary measures, as illustrated by the efforts of the private sector in monitoring the advertisements for food and drinks consumed by children under twelve. However, the Thai FDA had understood the US concerns and was ready to further discuss the issue.

C. EXCHANGE OF EXPERIENCES

1. Good Regulatory Practice

189. The Chairperson recalled the WTO Workshop on Good Regulatory Practice held on 18-19 March 2008¹¹ and drew delegations' attention to the summary report provided by the Secretariat (G/TBT/W/287). She also recalled that at the last meeting the United States had introduced a paper

¹¹ A Summary Report of the event is contained in document G/TBT/W/287. More information, including the programme and presentations made, is also available on the WTO TBT Website at the following address: http://www.wto.org/english/tratop_e/tbt_e/wkshop_march08_e/wkshop_march08_e.htm

on Determining the Need to Regulate (G/TBT/W/285). She noted that the Committee's recommendations to date were mainly recommendations to "exchange experiences"; this was reflected in the latest revision of the Committee's decisions and recommendations in the area of Good Regulatory Practice, contained in Section I of G/TBT/1/Rev.9.

190. The representative of the United States drew the Committee's attention to a joint paper prepared by the US Office of Management and Budget (OMB) and the Secretariat General of the European Commission, issued on May 2008 as part of the transatlantic High Level Regulatory Cooperation Forum. The paper, entitled "Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment", reviewed existing methodology and practices of both sides and suggested possible ways forward on the subject of considering international trade impacts in the regulatory process.

191. The US section of the paper reviewed how the US regulatory framework enabled regulators to take into account the potential international trade and investment impacts of draft regulations during the regulatory process. It explained that US regulatory agencies have both statutory and executive obligations to take international trade impacts into account when developing regulatory proposals. In particular, OMB Circular A-4 provided that, for economically significant rules: "The role of Federal regulators in facilitating US participation in global markets should also be considered. Harmonization of US and international rules may require a strong Federal regulatory role. Concerns that new US rules could act as non-tariff barriers to imported goods should be evaluated carefully". This guidance was in addition to US statutes, in particular the National Technology Transfer and Investment Act, which obliged agencies to use existing private sector standards, including private sector international standards, as the basis for regulations, or to present a justification for not doing so.

192. As a result of this study, the two sides recognized the importance of four key principles in ensuring that the impacts on trade and investment were taken into account in regulatory impact assessments. First, there was a need for timely announcement of planned legislative or regulatory initiatives, and for transparency in the analysis presented by associated impact assessments. In this regard, OMB noted that it intended to ask all US agencies for the fall 2008 Regulatory Agenda to adopt an approach similar to that of the US Department of Transportation, which maintained an online database identifying regulations that could have impacts to trade or be of interest to major trading partners. Second, it was important to ensure that mechanisms such as public consultation and notice existed to give governments, businesses, and citizens the opportunity to voice comments on planned initiatives and to reflect their input in impact assessment and impact analysis reports. Third, the report emphasized the importance of making policy proposals and accompanying impact assessments (including relevant underlying technical analysis and data) public, thereby allowing governments and stakeholders in other countries to respond if they expected international trade and investment issues to be significant. Fourth, it was important to provide guidance to regulators to ensure they have the information they need to evaluate the impact of a regulation on trade and investment. Such information could include an analysis demonstrating the need for any proposed regulation that could impede international trade; an analysis of the degree to which different groups were affected by such a proposal; or a recommendation that existing standards or regulatory approaches, if applicable, should be analyzed as an explicit regulatory alternative.

193. While OMB concluded that US federal agencies were fulfilling their obligations, it agreed with commenters on the need to offer further guidance on how to consider the international trade effects of US regulations. Thus, OMB determined that it would provide further clarification of the current obligations and responsibilities to US regulators, in order to ensure that they continued to take international trade impacts into appropriate consideration in preparing their impact analyses for draft regulations. The representative of the United States encouraged other delegations to share their regulators' experiences with analyzing the international trade and investment impacts of regulations.

He also invited the other delegations to comment on the joint paper or the broader issue of considering international impacts in the regulatory process.

194. The representative of the European Communities thanked the US delegation for introducing the above-mentioned joint paper. He emphasized that, in the light of that paper, the European Communities was considering amending its impact assessment guidelines to take more account of the impact that proposed regulatory policies could have on international trade and investment flows. The European Communities would update the Committee on latest developments regarding the revision of the EC impact assessment guidelines.

195. The representative of Mexico informed Committee Members that his government was preparing a communication to share Mexico's experiences on Good Regulatory Practice. He appreciated document G/TBT/W/285, which had been circulated among a number of Mexican authorities and helped to understand how to guarantee a correct drafting of regulations. In his view, the TBT Committee's work on good regulatory practice had been extensive, thanks to the submission tabled in the Committee and the recently held Workshop. He stressed the need for further progress on specific recommendations, for instance: on regulatory impact assessment, planning of standardization, proportionality and on the determination of the need to regulate. Mexico proposed to prepare a document of voluntary recommendations in order to provide further guidance for Members in implementing the TBT Agreement.

2. Conformity Assessment Procedures

196. The Chairperson recalled that since 1995 the Committee had issued a number of decisions and recommendations; there were set out in Section II of G/TBT/1/Rev.9. In terms of the Committee's work on conformity assessment, there had been extensive sharing of experiences, with a view to furthering the understanding and the implementation of Articles 5-9 of the TBT Agreement. The Chairperson also noted that the Second Triennial Review Report set out an "Indicative List of Approaches to Facilitate the Acceptance of the Results of Conformity Assessment"¹², and that four separate events dedicated to discussions on various aspects of conformity assessment had been held in 1999, 2004, 2005 and 2006. Members were encouraged to come forward with contributions regarding their experiences on conformity assessment procedures.

3. Transparency

197. The Chairperson emphasized the good progress made in the area of transparency, and this was reflected in document in Section IV of G/TBT/1/Rev.9. She recalled the Committee's Fifth Special Meeting on Procedures for Information Exchange and noted that, at the meeting held on 9 November 2007, Members had agreed on two mechanisms: one to facilitate access to notified draft texts and another to facilitate information-sharing by Members on the availability of unofficial translations.¹³

(i) Translations

198. The representative of Kenya drew the Committee's attention to the issue of translation of notifications issued by Members, in particular with regard to the national enquiry points for developing and least developed countries. She requested the Committee to further deliberate on this issue. Kenya invited Members to consider providing translations on request under the special and differential treatment for developing countries.

¹² G/TBT/1/Rev.9, Annex A.

¹³ G/TBT/1/Rev.9, pp. 24-25.

199. The representative of China welcomed the successful outcome of the Committee's Fifth Special Meeting on Procedures for Information Exchange. In this regards, China encouraged Members to attach a copy of the text of the notified measures to the notification forms, and further notify the adopted final text as an Addendum to the original notification. Additionally, China encouraged Members to share the translations of notified texts; this was especially important for developing countries to provide comments timely and effectively.

(ii) *Functioning of enquiry points*

200. The representative of Mexico supported the comments made by China and recalled an issue often raised by the Mexican delegation. He requested clarification on how the contact points of developed countries succeeded in providing individuals and companies with specific information on notifications circulated by the Secretariat of the WTO. Mexico recalled that previous replies focused on how the contact points worked or what IT system they had, but little had been explained as to how they managed to ensure an effective interaction with industry and individuals.

201. The Chairperson recalled that the enquiry points were set up to answer enquiries and provide information. Stakeholders, companies and individuals interested in their foreign trading partners technical regulations standards and conformity assessment procedures had to be encouraged to approach the enquiry points and ask for information.

4. Technical Assistance

202. The Chairperson drew the Committee's attention to work undertaken by Members in the area of technical assistance and the decisions and recommendations taken so far (Section V of G/TBT/1/Rev.9). She reiterated the importance attributed by the Committee to technical assistance. It was noted that an exchange of experiences and identification of good practices in the delivery and receipt of technical assistance, in line with the mandate from the Fourth Triennial Review, could help advance Members' objective of increasing transparency in the need and availability of technical assistance.

203. The representative of the United States recalled that, at the November 2007 Committee meeting, his delegation had enquired if other WTO Members would be interested in examining the work carried out by international standardizing bodies to broaden and deepen developing country participation in standards development activities at the technical level, as well as their efforts to strengthen developing country use of standards in specific sectors, both in the market place and in technical regulations. A paper was subsequently prepared by the US delegation and circulated prior to the March 2008 Committee meeting as JOB(08)/15.

204. The representative of the United States said that his delegation recommended that the Committee examine the role of international standards in economic development. In this regard, the paper proposed to use case studies to examine the ways in which relevant international standards had improved the quality of products, had solved specific regulatory problems or had facilitated trade in new markets. The US representative further stressed that the paper offered a series of questions for Members to consider and discuss. The goal was to draw out possible elements of interest so that a workshop might be organized that could reflect the broad cross-section of interests across WTO Members.

205. It was stressed that at the last Committee meeting the United States had received support from various delegations on this proposal. Discussions had been held with various delegations, standards development organizations and international organizations on what the proposed programme for the workshop should be. The United States proposed several ideas for discussion at a workshop, for example on: (i) broad strategies and concepts; (ii) regional efforts to promote best practices in

multilateral and bilateral assistance on standards; and (iii) sector specific case studies with standards development organizations, regulators, national standards bodies (e.g., oil and gas, renewable energies, building codes and fire protection). The representative of the United States invited Members to provide additional comments or ideas.

206. The representative of Switzerland supported the objective of the proposed workshop. She stressed that international standards played an important role in economic development and were therefore of particular interest. In her delegation's view, the key outcome of the proposed workshop should be constituted by the recommendations and lessons learned with wide acceptance within Members of the Committee. She noted that, besides the decision on how the proposed agenda of the workshop could look like, this exchange of experiences should be coordinated with relevant international organizations, such as World Bank, UNIDO or UNCTAD, which already had experience on the role of international standards in economic development.

207. The representative of Brazil supported the idea of a workshop on the role of international standards in economic development and offered suggestions to be included in the workshop agenda. In particular, "new trends in standardization" could constitute a topic for discussion and include the participation of developing countries in the development of standards in areas such as biofuels, sustainability, nano-technologies and others. It was also suggested that a second topic could deal with the critical issues in standardization and related activities, such as metrology tests or conformity assessment, and could lead to discussions about developing countries needs in terms of infrastructure, highly specialized personnel and technical cooperation. A discussion on the econometric models to assess the impact of international standards on economic development could be another topic to be included in the proposed agenda.

208. The representative of China welcomed the US proposal and recalled that the participation of developing country Members in international standards setting activities should be discussed in the Committee.

209. The representative of the United States noted that his delegation would continue seeking ideas from delegations, international organizations and standards developers in order to further expand the proposal. He hoped that the workshop could be held in 2009.

5. Special and Differential Treatment

210. The Chairperson noted the Committee's work to date on Special and Differential Treatment set out under the relevant recommendations in Section VI of document G/TBT/1/Rev.9. She recalled that the Fourth Triennial Review encouraged Members to inform the Committee about special and differential treatment provided to developing country Members.

IV. TECHNICAL COOPERATION ACTIVITIES

211. The representative of Paraguay stressed that his delegation attached great importance to technical assistance and thanked the European Communities for the assistance provided in a project aimed at strengthening the competitiveness of Paraguay's exports. He noted that this project helped Paraguay to improve the quality system of technical regulations development and notification, and of standards and processes dealing with conformity assessment. The project had also facilitated an increase of sanitary monitoring systems related to plant and animal health. The representative of Paraguay also appreciated the cooperation of the Mexican government, which helped officials from Paraguay in understanding the notification system of the WTO. Finally, he stressed the importance of setting standards in areas such as biofuels which in light of the critical situation of oil represented an interesting emerging market.

212. The representative of UNECE informed the Committee about a recent interagency publication on the topic of Aid for Trade, which contained contributions from UNCTAD, UNDP, UNEP and the five Regional Commissions of the United Nations. The joint project was officially presented in April 2008 at the UNCTAD XII Conference.¹⁴ The UNECE chapter reviewed technical assistance activities related to standards and technical regulations on the basis of the OECD-WTO Trade Capacity Building Database and a number of official documents. It was stressed that a number of shortcomings of ongoing assistance emerged from the research, in particular as regards the insufficient ownership of the projects by national and regional stakeholders. Many of the projects appeared to aim at facilitating the donor's imports from the country that benefited from the technical-assistance project without sufficient tailoring to the needs and priorities of recipients.

213. The Aid for Trade initiative was aimed to bring increased and additional resources in the area of trade-related standards. The objective was to establish countries' priorities in trade-related standardization matters in consultation with relevant stakeholders; mainstreaming compliance with international standards in projects that focused on the development of productive capacities in specific sectors was also a priority. In this regard, the joint paper identified three broad areas of action: (i) reinforcing effective participation in standards setting and the relevant WTO institutions; (ii) increasing compliance with technical regulations; (iii) furthering the use of standards by business. Reinforcing participation by developing countries and transition economies was an essential step also for sustaining active involvement in the ongoing work of the relevant institutions, including the TBT Committee and the regional and international standards development bodies. In devising programmes directed at increasing compliance, the aim was to prevent rather than respond to critical situations. Particular attention was given to involve the business sector, trying to better understand its priorities and needs. Finally, it was stressed that standards were not only a means of securing market access: they had an extra value because they were developed by international experts and embodied the latest technology, also raising output quality and providing firms with know-how which enabled them to lower costs. They also acted as a selection device, assisting those producers who were able to adapt to them.

214. The representative of UNECE emphasized that the real value of Aid for Trade in the area of trade related standards was to empower recipient countries to make an informed choice regarding the instrument that best met their development needs and the priorities of national stakeholders. In this context, the assistance given through "South-South" cooperation projects was of great value and had to be appropriately recognized, including through the development of a repository of best practice that would represent a useful complement to the OECD/WTO database. The UNECE representative also reported on the establishment of the Interagency Cluster on Trade and Productive Capacity, which included UNCTAD, UNIDO, FAO, ITC, UNDP, WTO and all the UN Regional Commissions. The cluster aimed at assisting countries in the preparation of the UN country plans or United Nations Development Assistance Frameworks (UNDAFs) by strengthening cooperation among the UN agencies at the national level, and also aimed at increasing the assistance that the UN gave for trade-related development goals in the area of standards.

215. The Secretariat informed the Committee that a two weeks specialized course on the TBT Agreement would be held on 27 October - 7 November 2008.¹⁵ The aim of the course was to promote greater understanding of the TBT Agreement and to address implementation challenges in a practical manner, through a series of sessions and practical exercises. It was noted that the first week of the course would include general sessions to increase understanding of the TBT Agreement and focused sessions on topics such as transparency, good regulatory practice and conformity assessment. The second week would focus on the operation of the TBT Committee, in particular, participants would be

¹⁴ The publication is available for download from the UNCTAD XII Conference website: <http://www.unctadxii.org>

¹⁵ See document WT/COMTD/W/160, page 54.

invited to attend the TBT Committee Meeting on 5-6 November in order to observe the work of the Committee. The Secretariat noted that the course was organized for 25 participants from developing country Members or Observers. Selected participants would be expected to be familiar with the TBT Agreement and knowledgeable of national issues relating to its implementation.

V. UPDATING BY OBSERVERS

216. The representative of IEC updated the Committee on the relevant activities undertaken by her organization (G/TBT/GEN/72).

217. The representative of OIML updated the Committee on the work of his organization. With regard to mutual acceptance arrangement, it was noted that OIML had three categories of measuring instruments, with twenty countries participating in two of them. Moreover, OIML was developing guides on the application of conformity assessment to legal metrology, as well as a conformity to type system which endeavoured to ensure that the production of measuring instruments matched the type approved. An international system was also being prepared for the control of pre-packaged goods. With regard to accreditation, two guides had been developed jointly with ILAC and IAF: one on the application of ISO/IEC guide 65 for legal metrology and the other one on the application of ISO/IEC 17025. It was recalled that OIML participated in the work undertaken by the Joint Committee for the coordination of technical assistance to Developing Countries in Metrology, Accreditation and Standardization (JCDCMAS). It was noted that the OIML budget would be decided in October 2008 and that the developing countries fee would be a tenth of that which was currently set as a minimum fee for a Member state.

218. The representative of ITC updated the Committee on two TBT related projects currently being implemented in Bangladesh. The first project, named "Bangladesh Quality Support Programme", was funded by the European Commission and consisted of two components implemented both by UNIDO and ITC. The "supporting export diversification" component was implemented by ITC and its main purpose was to enhance the awareness and capacity of the private sector to cope with international quality standards, TBT or SPS requirements. The ITC representative noted that one of the main results envisaged was to enhance ability of the business sector to take advantage of the TBT and SPS Agreements for maintaining and improving market access. In February 2008, a workshop named "The WTO Agreement on TBT: a Business Perspective" was also held in Dhaka. The workshop helped potential trainers and other participants to understand the information on the TBT Agreement covering standards, technical regulations and conformity assessment procedures, and helped to understand how business could take advantage of the TBT Agreement. In November 2008, two other workshops directed towards export-oriented industry would be organized. The representative of ITC noted that an assessment had been made on the current capacity of the organizations in the private sector and TBT Enquiry Points to obtain and disseminate information. Recommendations were also made to enable private sector organizations to work in partnership with the TBT Enquiry Points and enhance their capability to access and disseminate such information. It was stressed that further assistance would be provided to implement these recommendations. In particular, a study tour to TBT National Enquiry Points in the region would be conducted for participants from the TBT National Enquiry Point and private sector bodies in Bangladesh later in 2008.

219. The second project, which was financed by the Government of Italy, was named "Bangladesh Leather Service Centre for Export Development". Its pivotal element was the creation of a "Leather Service Centre" for the Bangladeshi industry, focusing in particular on added-value products such as footwear and leather goods. The object was to provide assistance to the laboratories of the Bangladesh College of Leather Technology used by the "Bangladesh Leather Service Centre", in order to help them to be accredited by the International Laboratory Accreditation Cooperation

(ILAC). The applications for accreditation would have to be submitted by the end of June, with the aim of enabling the laboratories to obtain accreditation before the end of 2008.

220. The representative of ISO updated the Committee on the relevant activities undertaken by his organization, drawing the Members' attention to the ISO 2007 Annual Report and to the special issue of its magazine "ISO Focus" dedicated to conformity assessment.¹⁶ With regard to technical assistance and participation of developing countries in the development and implementation of ISO standards, it was noted that the Committee had been regularly informed of ISO's programmes in this area, and of its collaboration with WTO, other international organizations and development agencies. The representative also recalled that the ISO Action Plan for developing countries currently being deployed covered awareness raising, capacity building, use of IT tools, regional cooperation and participation in ISO's governance and technical work. Finally, ISO welcomed the proposal of organizing a workshop on the role of international standards in economic development and was ready to share its relevant experience with the Committee.

221. The representative of UNECE updated the Committee on the relevant activities undertaken by the UNECE Working Party on Regulatory Cooperation and Standardization Policies. The UNECE representative explained that the Working Party continued to reinforce cooperation among regulatory authorities in a number of areas, including market surveillance and sectoral initiatives aimed at reducing the barriers to trade in products where authorities and business sectors had manifested interest. The next annual session would take place in November 2008 and would include a session on the role of private standards, or company specifications in a complex environment which also included international standards and technical regulations. She welcomed Members' participation in such session. The UNECE representative expressed her organization's willingness to contribute to the proposed workshop on the role of international standards.

222. The Chairperson drew the Committee's attention to a statement submitted by the Codex Alimentarius Commission, contained in document G/TBT/GEN/71.

VI. OTHER BUSINESS

(i) Preparation of the Fifth Triennial Review of the TBT Agreement

223. The Secretariat introduced draft document JOB(08)/52 containing the ninth revision of the compilation of the TBT Committee's Decisions and Recommendations adopted since 1 January 1995. Members were invited to provide comments on this document by 31 July 2008. Thereafter the document would be circulated as G/TBT/1/Rev.9.¹⁷

224. The Chairperson recalled that the Committee would undertake its Fifth Triennial Review of the Operation and Implementation of the TBT Agreement under Article 15.4 at the end of 2009. In order to facilitate the preparation of the Review she intended to provide delegations with an outline of the process ahead of the next meeting. She also stressed that the Review needed to be driven by substantive proposals from Members and delegations were invited to submit such proposals as early as possible. In terms of the substantive input, the Chairperson proposed that when considering the various topics discussed in the context of the Fifth Triennial Review, Members give particular thought to what actions the Committee might take to forward its work. When considering what areas were worth building on, or further refining, the Secretariat's document G/TBT/1/Rev.9 could usefully serve as a reference point in this exercise.

¹⁶ Both documents were made available at the Committee meeting.

¹⁷ G/TBT/1/Rev.9 was circulated on 8 September 2008.

VII. DATE OF NEXT MEETING

225. The next regular meeting of the TBT Committee will take place on 5-6 November 2008.
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