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Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 20 March 2008

Chairperson: Mr. R.S. SIDHU (India)

Note by the Secretariat[1]

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

I. ADOPTION OF THE AGENDA

1. The Committee adopted the agenda contained in WTO/AIR/3154.

II. IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

A. STATEMENTS FROM MEMBERS UNDER ARTICLE 15.2

2. The Chairman noted that the latest list of statements made 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 115 Members had submitted at least one such statement. Since the last meeting, held in November 2007, Mongolia and Switzerland had issued revisions of their original statements (G/TBT/2/Add.44/Rev.1 and G/TBT/2/Add.7/Rev.1, respectively), and Israel and Colombia had submitted supplements to their original statements (G/TBT/2/Add.72/Suppl.1 and G/TBT/2/Add.18/Rev.2/Suppl.1). It was also noted that the latest list of Enquiry Point contacts was contained in document G/TBT/ENQ/32 and Corr.1[2].

3. The Committee took note of the information provided.

B. SPECIFIC TRADE CONCERNS

1. New Concerns

(i) Brazil – Toys (G/TBT/N/BRA/259)

4. The representative of Malaysia raised an issue with respect to a Ministerial Act affecting toys, notified in October 2007 under Article 5.7.1 of the TBT Agreement as a matter of urgent protection of human health. The measure had entered into force in August 2007 and no opportunity had been provided for WTO Members to make comments. His delegation acknowledged Brazil's right to enforce a technical regulation for the purpose of ensuring safety of toys in its market. However, Malaysian manufacturers exporting toys to Brazil were encountering difficulties due to the new requirements for mandatory sampling and testing of samples for all toys in selected laboratories situated in Brazil, and also due to the non-recognition of test reports from any other laboratory, even if accredited. Additionally, the option of pre-market approval as an alternative which was available to Brazilian manufacturers was not available to Malaysian manufacturers.

5. The representative of Malaysia noted that bilateral discussions had been taking place on the issue, and Brazil's willingness to engage in a dialogue was appreciated. However, his delegation was of the view that the regulation was not consistent with the TBT Agreement and invited Brazil to bring it into line with obligations under the WTO.

6. The representative of Thailand echoed the concerns raised. Her delegation understood Brazil's reason of consumer protection, and had no objection to the required toxicology test for toys. However, her delegation considered that Brazil's requirement that imported toys should be tested under System 7 only constituted an unequal treatment, since local products had the option of either System 5 or 7. The measure was considered discriminatory in nature.

7. The representative of Thailand requested that Brazil accept test reports of laboratories accredited under international umbrellas such as ILAC-IAF. She stressed that Brazil should have

[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

confidence in the international standards that had been developed with the contribution of many Members, including Brazil. She asked Brazil to give consideration to less trade-restrictive alternatives and stressed that, should Brazil not introduce modifications soon, bilateral discussions should be pursued to settle the problem.

8. The representative of the European Communities sought clarification with respect to the rationale for the separate certification procedures for imported toys as compared to domestically produced toys. The European Commission had been informed by the toy industry of longer delays in the release from customs of imported toys due to the new testing requirements, which had been enforced due to the changes in the relevant procedural law.

9. The representative of Brazil pointed out that the new requirements for the certification of imported toys had the legitimate objective of protecting consumers' health, especially children, for whom those products were destined. The previous requirement for certification had proven to be insufficient to guarantee the safety of imported toys and several cases of accidents related to those toys had been reported in 2007. He explained that the new requirements applied to all imported toys, regardless of their brand or country of origin. Although delays in the testing and certification process had occurred during the initial months of the implementation requirements, the situation had been normalized and the five laboratories that were accredited to issue these certificates were currently working below their full capacity. He noted that bilateral talks had already been held with the three countries that had raised concerns and that his delegation was ready to engage in further discussions.

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

10. The representative of Israel raised 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. His delegation was concerned that the United States had not submitted a notification for these measures, nor for the proposed list of DHS "chemicals of interest" (Appendix A) that was included in the 9 April 2007 Federal Register publication, as required under Articles 2 and 5 of the TBT Agreement.

11. The representative of Israel noted that the DHS list of "chemicals of interest" included potassium nitrate and sodium nitrate, but did not include calcium nitrate. He believed that the inclusion of potassium and sodium nitrate in the list was 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 should be treated equally and not included in the DHS list.

12. It was further stressed that the products above were propellants, not high explosives, that they did not detonate and did not have the effect of a bomb, since they could not destroy or cause significant damage to a building. Additionally, they were not on the Environmental Protection Agency's Risk Management Program (RMP) list, nor included in the Chemical Weapons Convention (CWC) list of chemicals that needed to be controlled, nor in the US Department of Transportation 1.1 explosives list. The representative of Israel stated that his delegation was ready to consult with the US on the matter, preferably at an expert level, with the view of finding an agreed solution.

13. The representative of Chile shared the concerns expressed by Israel. Her delegation appreciated the willingness shown by the United States to discuss the DHS regulation, whose aim was to regulate the security of chemical facilities that were considered at a high risk of terrorist attacks in the United States. Concerns had been expressed about the inclusion in Appendix A of this measure of fertilizers, potassium nitrate and sodium nitrate, which were products that Chile produced and

exported in high volumes to the US market. She noted that comments had been submitted to the United States and that a response was awaited.

14. It was stressed that the inclusion of sodium and potassium nitrate in the regulation would run counter to the objective declared by the DHS and would be inconsistent with the TBT obligation of avoiding unnecessary obstacles to trade. Other chemicals which could be more dangerous than these nitrates had been excluded from the regulation, or given a less restrictive treatment than that given to potassium and sodium nitrates. The representative of Chile expressed her delegation's hope that the United States would take these arguments into consideration and that the products at issue would be excluded from the regulation.

15. The representative of the United States pointed out that the Chemical Facility Anti-Terrorist Regulation (CFATS) issued by the Department of Homeland Security established risk-based performance requirements to ensure the security of US chemical facilities. 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 this measure. Through a process of scientific and risk assessment, as well as consultation with security authorities in other countries and public notice and comment, DHS had determined that CFATS would apply to a specific set of substances, including certain nitrates determined to possess the requisite precursor explosive properties.

16. It was highlighted that CFTAS 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 "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.

17. The representative of the United States noted that Israel and Chile had conveyed concerns that 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. First, the United States was not alone in regulating these nitrate substances for security purposes: Canada, the United Kingdom and Israel did as well. With regards to burden, DHS had estimated that the average time to complete the online "top-screen" information was 27 minutes. Additionally, DHS had recently announced an open-ended exemption for farmers and other agricultural users from the screening requirement contained in this measure. He noted that bilateral discussions had been held with Chile on their 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.

18. As for the notification, the representative of the United States clarified that the screening procedure was mandated by legislation with implementing regulations to be developed and adopted in an expedited fashion. Even within this tightened timeframe, the DHS had provided notice and an opportunity for interested stakeholders to submit comment through the Federal Register. It was his delegation's understanding that the Chilean fertilizer industry had submitted comments through a fertilizer trade association. Finally, the representative of the United States pointed out that the expedited process mandated by the Congress had appeared to short circuit the US' internal procedures to notify to the WTO, but that a notification would be submitted through the US Enquiry Point.

(iii) Germany – Ban on Seal Products (G/TBT/N/DEU/5)

19. The representative of Canada noted that the German Government had notified the TBT Committee of its proposed regulation prohibiting the importation, processing and placing on the market of seal products. Her delegation did not agree with the indication by Germany that the

legislation on seals responded to two principal concerns: public morality and animal protection. Canada did not believe that this was an issue of public morality. On the second point, her delegation was of the view that the approach outlined by Germany was not justified, given that this was a humane and well-managed hunt of a sustainable natural resource and that the methods used in the seal hunt compared favourably to killing methods used for other wild animals or livestock.

20. The representative of Canada recalled that factual information regarding the management of seal hunt had been provided both to the European Food Safety Authority (EFSA) and to EC member States. While their efforts to ban seal products were perhaps well intentioned, they were both unnecessary and inconsistent with their trade obligations under the WTO Agreements. Her delegation believed that the proposed German ban was, like those in force in Belgium and the Netherlands, inconsistent with Germany's and the European Communities' obligations under WTO Agreements. She urged the European Commission to take effective steps to discourage EC member States from proceeding with bans on seal products.

21. The representative of Norway reiterated her delegation's position with respect to the banning of imports of seal products by several EC member States. She noted that the German notification stated that the importation, processing and placing on the market of seal products for commercial purposes into or within Germany would be prohibited and that the objectives for the ban were claimed to be animal health and welfare and public morals. She stressed that, as in similar cases with notified import bans by Belgium and the Netherlands, her delegation could not see how and to what extent the appropriate assessments regarding available scientific and technical evidence had been made. Norway shared the values and concerns for animal welfare of other European countries. Consequently, regulations concerning sealing had been continuously developed and strengthened over the past 25 years. Sealing was perhaps the most closely monitored industry in Norway; the hunt was conducted in a humane manner.

22. It was stressed that Norway's position had been substantiated by the conclusions of a recent report by the European Food Safety Authority (EFSA) to the European Commission, which had dispelled misconceptions that might have existed concerning the animal welfare dimension of the Norwegian seal hunt. In Norway's view, the ban on seal products was not an animal welfare issue, nor a conservation issue, but a public opinion issue, and this was unsubstantiated and unjustified. The representative of Norway believed that a ban on imports of seals in the EC member States set a dangerous precedent for trade in animal products that were harvested in a sustainable and humane manner. She expressed her delegation's intention to continue to reserve its right to take any appropriate action to defend its interest under the TBT Agreement and other relevant WTO Agreements.

23. The representative of the European Communities noted that the draft act concerning the prohibition of the importation, processing and marketing of products derived from seals notified by Germany aimed at protecting animal life and health, objectives which were set out in Article 2.2 of the TBT Agreement. She invited delegations that had expressed concerns to provide their comments in writing within the deadline set. She informed the Committee that the measure had also been notified to the Commission in accordance with the internal notification procedures and that it was being examined to assess its compatibility with European Community's legislation. Her delegation was available for bilateral discussions.

(iv) European Communities – Lighters (G/TBT/N/EEC/178)

24. The representative of China expressed his delegation's concern with the draft Commission Decision on lighters, on which comments had been sent to the European Communities. In particular, he was of the view that the definitions of child-resistant lighters and child-appealing lighters were ambiguous and conceptually confusing. Consequently, the objective of protecting children's safety

might not be achieved. The draft Decision provided a definition of a "novelty lighter"; however, there were no procedures for determining what these lighters were, and this would increase the uncertainty for manufacturers or distributors and could lead to a waste of resources and to increasing costs.

25. It was also stressed that detailed technical information such as test methods, test parameters and conformity assessment bodies concerning child safety requirements of lighters were not provided in the draft Decision, which could create difficulties in its implementation and unnecessary obstacles to trade.

26. The representative of the European Communities noted that the comments received by China were being examined by the appropriate services in the European Commission and that a response would be provided in due course. She clarified that that the objective of the draft Decision was to establish the conditions for a mandate to be given to CEN, the European Standardization Committee, to revise standard EN 13869 on child safety resistance for lighters. If this mandate was accepted by CEN, it would take approximately two to three years to develop the standard and the definitions and test methods would be further elaborated. Her delegation remained available for additional bilateral discussions with China on the issue.

(v) Canada – Mandatory Container Size

27. The representative of the United States raised an issue concerning mandatory container size restrictions found in Canada's regulations on processed products. It was his delegation's understanding that these restrictions on jar sizes for baby food made it difficult for US baby food producers to export to the Canadian market. He noted that discussions had been taking place with Canadian authorities and looked forward to additional information that Canada had promised to provide after consulting with the Canadian Food Inspection Agency and the Department of Justice, so as to resolve the issue shortly.

28. The representative of Canada confirmed that additional information was forthcoming and that her delegation was ready to discuss the matter further.

(vi) China – General Rules for Restricting Excessive Packaging

29. The representative of the European Communities raised concerns on the above-mentioned measure and noted that comments had been submitted to the Chinese authorities on 27 February 2008. A reply had been received the day before the Committee meeting and still needed to be analyzed in detail. After a first reading, however, the reply did not seem to dissipate the concerns expressed. She stressed that while her delegation fully supported the objective of restricting excessive packaging to protect the environment, there were concerns related to the inter-space ratio through which the Chinese authorities aimed at restricting excessive packaging. In fact, article 5.1 of the notified text laid down that the packaging for certain products could not exceed a certain inter-space and a certain number of layers. It was her delegation's view that this was not an effective and appropriate means of protecting the environment, since the measure only targeted certain product categories and concerned only a small portion of packaging compared to the total volume of packaging in China. On the other hand, the measure had a significant negative impact on the product categories concerned.

30. The representative of the European Communities also noted that the measure singled out certain products which were often premium and luxury products (like alcoholic beverages or cosmetics) and which were often sold in sophisticated or gift-wrapping packaging. Such products were often imported products, and constituted a relatively low share of the market in China. Her delegation considered the measure more trade restrictive than necessary to achieve the legitimate objective pursued and *de facto* discriminatory and therefore contrary to Article 2.1 and 2.2 of the TBT Agreement.

31. Additional concerns were related to article 5.2 of the notified text, which provided that for the same products to which the above-mentioned inter-space ratio applied, the total cost of packaging should not exceed 15 per cent of the commodities' factory selling price. It was stressed that the fact that packaging was costly did not automatically mean that it had the most harmful impact on the environment. China was invited to explain why it considered that there was a direct link between the cost of the packaging and excessive packaging.

32. Furthermore, the representative of the European Communities pointed out that only article 5.1 regarding the inter-space ratio appeared to be mandatory and that the other provisions were recommendatory in nature. She sought clarification as to whether importers were obliged to follow the other requirements or not, for example the provisions on the costs of packaging. If they were not obliged, how would it be ensured in practice that the fulfilment of these requirements would not be requested by the enforcement authorities and therefore be made mandatory in practice? In concluding, the representative of the European Communities invited China to extend the transition period, if the measure was adopted, from 6 months to 18 months. If the transition period of 6 months was to be maintained, existing packaging would need to be destroyed; this would be counterproductive with regard to the pursued objective of the protection of the environment.

33. The representative of China hoped that the reply provided to the comments would address some of the concerns expressed. He pointed out that the restriction on the inter-space for packaging was the most direct and effective measure to restrict extensive packaging. The proposed 55 per cent inter-space ratio was based on comprehensive market surveys, had a sound technical foundation and could meet markets needs. Regarding the relationship between mandatory and voluntary provisions, he stressed that the whole article 5.1 was compulsory, while other provisions were voluntary, and that only article 5.1 applied to the sales packaging. Finally, regarding the period of implementation, he stressed that due consideration would be given to the circulation period of products and that an interval for adaptation between six months and one year would be provided.

(vii) China – Proposed regulations on information security (G/TBT/N/CHN/278-290)

34. The representative of the United States drew the Committee's attention to thirteen proposed regulations on information security, notified by China in August 2007. These measures mandated a government certification and testing scheme for information security for 13 categories of information technology products. After discussing this issue with experts in the US Government and industry, it appeared that these measures went substantially beyond global norms, by mandating testing and certification of information security for commercial products. He sought clarification from China about the objective and rationale in seeking to extend certification and testing requirements to information technology products used commercially, given the far-reaching nature of these proposed regulations.

35. The representative of the United States also noted that new product development and design in the IT industry required a rather lengthy lead time, often several years. Given the extensive array of IT products covered by these regulations, he sought clarification on how implementation would proceed and what types of transition China envisioned. In this respect, he stressed that transparency in the development of implementing regulations for the certification and testing scheme would be of paramount importance and urged China to conduct a process that allowed meaningful opportunity for comment and inquiries by all interested stakeholders. In concluding, the representative of the United States noted that further information detailing his delegation's concerns would be provided to China. It was also his delegation's understanding that the 13 technical regulations would be mandatory for all covered products as of 1 May 2009, but that the date of entry into force had not yet been finalized. China was invited to confirm this understanding.

36. The representative of the European Communities pointed out that an assessment of the potential impact of the proposed measures was being carried out. As a general point, his delegation was concerned about the expansion of the Chinese compulsory certification system - which was considered a burdensome conformity assessment procedure - to new product categories. He joined the United States in requesting China to clarify the rationale for the proposed measures and their implications, as well as the practical application. He also sought an update on the proposed implementation schedule.

37. The representative of China noted that the proposed regulations aimed at protecting information security. China had notified them to the WTO and provided 60 days for comments from Members. Comments had been taken into account and written replies provided. He stressed that the concerns raised would be reported to capital.

(viii) China – Wines (G/TBT/N/CHN/197)

38. The representative of the European Communities raised 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 to be unnecessarily restrictive and which was below the levels established at the international level, as well as those accepted by the European Communities. 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 which had been indicated in the notification, thereby eliminating her delegation's concerns. In fact, the proposed levels would have severely restricted exports of sweet wines which, until the date of entry into force of this measure, would have been permitted.

39. However, it was highlighted that recent contacts with industry had shown that the problem still existed and that China applied the strict levels on sulphur dioxide that had been announced in the TBT notification. The European Communities was of the opinion that the levels set were restrictive and should be amended to take into account the tolerance level established at international level. In particular, the International Organization of Vine and Wine (OIV)[3], whose recommendations were internationally recognized, had set a limit of 300mg/l for sweet wines and 400mg/l for special white wines. China was invited to promptly look into this matter and amend the currently applied levels to those accepted by the OIV.

40. The representative of China pointed out that comments by the European Communities had already been taken into account and the measure had been amended accordingly. For example, the volatile acid index had been changed to less than 1.2g/l and the levels of tolerance of methyl alcoholin had been adjusted to less than 400mg/l for red wine and less than 250mg/l for white wine. The total sulphur dioxide index had been deleted from the standard and subject to the Food Hygiene Standard of China. He invited the European Communities to address any additional comments to the TBT Enquiry Point in China.

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

41. The representative of China appreciated the EC's efforts to protect human health and safety, but was concerned that the proposed directive could create unnecessary restrictions to trade in toys. In particular, the measure increased requirements on chemical substances used in toys and imposed burdensome examinations on toys. To fulfil requirements in this proposed directive, toy manufacturers and exporters would have to undergo significant tests, which usually meant high fees. He pointed out that, in the toy industry, scaled manufacturers produced thousands of types of toys

[3] http://www.oiv.org

annually and that these increased requirements on testing and information would significantly increase costs.

42. The representative of China further noted that unsafe toys were caused by inappropriate design. Therefore, he suggested that the directive should attribute relevant responsibility for toy safety to designers. Additional concerns were related to uncertainty which could be caused by different implementation in EC member States, for instance, with respect to market surveillance and to the withdrawal or recall of toys. He expressed his delegation's request that the European Communities guarantee that imported toys would not be discriminated against and treated unfairly.

43. The representative of the European Communities pointed out that the time for comments on the notification of the proposed directive was still open and encouraged China to submit written comments, to which a written reply would be provided.

(x) European Communities – Production and Labelling of Organic Products (G/TBT/N/EEC/101)

44. The representative of Argentina was concerned with the Regulation No. 834/07, on the production and labelling of organic products, which had been notified to the TBT Committee in February 2006.[4] In particular, Article 24 of the regulation, entitled "Compulsory indications" stipulated that there should be an indication of the origin of the raw materials, taking one of the following three forms: (i) "EU Agriculture"; (ii) "non-EU Agriculture"; and (iii) "EU/non-EU Agriculture". His delegation was particularly concerned about the situation arising from the "EU/non-EU Agriculture" labelling option, in view of its consequences in terms of consumers perception.

45. It was noted that, in Argentina, a product was considered as organic if it followed certain manufacturing processes, irrespective of where it was produced. The origin of a product did not have an impact on its organic nature and the essential item of information was whether or not the product was organic in accordance with internationally recognized certification systems. It was stressed that the requirements in the EC measure could lead to consumers having false impressions.

46. The representative of Argentina pointed out that the "EU/non-EU Agriculture" label was not supported by WTO Agreements nor by Codex standards. In fact, the Codex standard on the "Production, Processing, Labelling and Marketing of Organically Produced Foods" (in particular Section 3) did not specify any obligation to list the origin of ingredients on product labels. He further stressed that Article 24 and preambular paragraphs 24 and 27 of the regulation were not consistent with the provisions of the TBT Agreement pertaining to necessity and proportionality (Article 2.2), use of international standards (Article 2.4), and special and differential treatment (Article 12) and that the mandatory indication of origin would constitute an unnecessary barrier to trade.

47. It was stressed that the regulation would set an inappropriate precedent by applying requirements additional to international standards. Furthermore, the mandatory indication of origin was not related to the actual characteristics of the food, could lead to deceptive practices, and did not take into account the rights of producers and exporters of raw materials already certified as being organic under the European Union regulation.

48. The representative of Ecuador shared the concerns expressed.

49. The representative of the European Communities noted that there had been discussions with Argentina in the past on this issue and took note of the comments made. Her delegation looked forward to a continued dialogue on the matter.

[4] The full statement detailing Argentina's concerns is contained in document G/TBT/W/284.

(xi) South Africa – Labelling and Advertising of Foodstuffs (G/TBT/N/ZAF/66)

50. The representative of the United States pointed out that his delegation was seeking greater clarity with respect to the proposed above-mentioned measure. Specifically, the regulation created a list of "non-essential" foods which were foods that could not be enriched with vitamins or minerals and on which no claims could be made. He wondered what the rationale or the criteria used by South Africa in developing this list had been and how US comments had been taken into account. His delegation would welcome discussions with South Africa to better understand the regulation.

51. The representative of South Africa took note of the comments made, which would be reported to the Department of Health in South Africa and a written response would be provided.

(xii) Japan - Labelling Guidelines on Wagyu beef

52. The representative of the United States raised an issue with respect to the labelling guidelines on *Wagyu* beef, which were the result of a study panel on meat labelling requested by Japan's Ministry of Agriculture, Forestry and Fisheries (MAFF). Although his delegation had provided comments on the guidelines when they were initially released in January 2007, and asked additional questions in the context of Japan's Trade Policy Review, uncertainties remained about the purpose and status of the guidelines. He stressed that the guidelines could have a significant impact on trade, as they required cattle bearing the *Wagyu* label to be born and raised in Japan even though characteristics of the term *Wagyu*, such as its quality and flavour, were based on genetics and animal husbandry practices and not on where the animal was born or raised.

53. It was the United States' understanding that the guidelines were voluntary and that only members of the Meat Fair Trade Council were subject to them. However, uncertainties remained about the relationship between the Meat Fair Trade Council and either the Japan Free Trade Council (JFTC), or the MAFF. Japan was invited to explain the role of MAFF and the JFTC in the adoption and enforcement of the guidelines. Additional clarification was also sought on the membership of the Meat Fair Trade Council and on whether its members were involved in the distribution and sale of both imported and domestic *Wagyu* beef and on how they would label imported *Wagyu* beef under the guidelines. Uncertainties existed also about the objective of these guidelines. The logic of the guidelines could be applied to virtually any agricultural product, for example *Fuji* apples. Japan was invited to explain the impact of the guidelines on US exports of *Wagyu* beef and, potentially, of other agricultural products.

54. The representative of Australia shared the comments made by the United States and recalled that his delegation had also raised this issue in the context of the Trade Policy Review of Japan, and that the replies provided by Japan were considered unsatisfactory.

55. The representative of Japan said he would convey the concerns expressed to the authorities in his capital.

(xiii) Moldova – Draft Law on Alcoholic Beverages

56. The representative of the European Communities raised an issue with respect to the above-mentioned measure, which was set out in a government decision of August 2007, modified in December 2007 and recently adopted by the parliament, but not yet in force. She noted that this law had not been notified to the TBT Committee and Members had not had the opportunity to examine the text and make comments on it. However, information from European industry indicated that there were elements in this law that required a TBT notification. She wondered whether the measure would be notified and pointed out that her delegation considered that, pending the revision of the law by WTO Members, this measure should not enter into force.

2. Previously raised concerns

(i) European Communities - Dangerous Chemical Substances - Draft Commission Directive amending Council Directive 67/548/EEC (G/TBT/N/EEC/151)

57. The representative of the European Communities noted that, since the previous meeting of the TBT Committee, additional comments to the relevant notification had been received from the delegations of Australia, Brazil, Canada, China, Japan, Turkey and the United States. The European Communities had provided a detailed response to questions raised, which was publicly available on the Commission's TBT website.[5] Bilateral discussions had also been held with many delegations which had expressed an interest in the notified measure. She pointed out that there seemed to be some misunderstanding as to the coverage of the EC's proposed Directive and stressed that only mixtures and preparations would fall within the scope of the proposed classification, meaning that final products did not need to bear a skull and crossbones symbol. 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. As indicated in the written replies to comments, a risk assessment would 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.

58. An expert from the DG Environment of the European Communities pointed out that two main areas needed to be taken into account: the classification of borates and nickel themselves, and the downstream legislative consequences. Starting with the latter, he emphasized that, within the Community legislation, there was no direct automatic link between the classification of a substance and restrictions or bans of that substance. Before that could happen, the European Commission would have to carry out a risk assessment and any proposal should be based on its results. This was, for instance, the procedure followed in the "Cosmetics" Directive. There was already a ban on the use of boric acid in cosmetics in concentrations above a set level, hence the current classification proposal would have no labelling consequences on that substance. He also stressed that there was no direct link between the classification of a substance and the authorization process under REACH. Therefore, there was no automatism and the objective of the proposal was to provide users of the substances or preparation or mixtures containing these substance with sufficient information about their hazardous properties, in order to handle them safely.

59. With respect to the classification itself of **borates,** the representative of the European Communities noted that there were three main areas on which comments had been received: (i) the analysis of data on animals; (ii) the analysis of available data on humans; and (iii) the "normal handling and use" criteria. Regarding the criteria applied to animal data to reach the conclusion that this substance was a reproduction toxigen, he stated that the US Environmental and Protection Agency (EPA) had come to the same conclusion that this substance negatively affected reproduction in rats, mice and dogs. The criteria used to apply this data was also consistent with the adopted criteria for reproductive toxicity under the globally harmonized system.

60. Regarding the way in which data on humans were treated in the classification process, the European Communities' position, in line with the globally harmonized system, was that there needed to be sufficient evidence to deny that data on animals were not relevant to humans, and this had not been proven in the available studies on humans. This was an inherent problem in toxicology itself and the standard and worldwide accepted approach was to use animal models. The representative of the European Communities stressed that the US EPA had come to the same conclusion regarding the available data on humans.

[5] http://ec.europa.eu/enterprise/tbt/

61. On the issue of "normal handling and use" criteria utilized, the representative of the European Communities stressed that the fact that limits had already been set for intake of borates in food or the concentration of this substance in cosmetic products in many countries across the world, showed that a risk was associated with this substance.

62. A number of the considerations utilized for the classification of borates applied to **nickel** as well. The representative of the European Communities stressed that the "grouping" approach utilized had been evaluated and endorsed by experts of OECD countries within the OECD chemicals programme. Furthermore, as the metals industry had stated on several occasions, the grouping approach could be applied with flexibility and not all the steps of the OECD guidance document needed to be fulfilled. On the "normal handling and use" of nickel, the same considerations as for borates applied.

63. The representative of Cuba considered that the new classification of nickel carbonates did not have a scientific basis. He noted that both nickel carbonates and sulphur carbonates were soluble in water, and that the draft Directive classified 150 nickel components as carcinogenic in Category 2, without any scientific evidence. His delegation was concerned that the possible integration of this reclassification into the complex REACH system would have a significant impact on the nickel industry and a serious impact on Cuban nickel exports to the European market. It could also have a negative impact on the use of nickel in stainless steel worldwide.

64. The representative of Cuba stressed that his delegation considered that the EC draft Directive was not in line with Article 2.2 of the TBT Agreement, as it limited trade more than necessary to achieve the pursued objectives of the protection of health and the environment. His delegation invited the European Communities to revise the 30th and 31st ATP draft Directives in light of the comments and concerns expressed, and adopt a more appropriate and scientifically based form of classification for nickel components which did not affect European market access for developing country producers of nickel. Also, he invited the European Communities to take into account the provisions on special and differential treatment in the TBT Agreement, 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 were not creating unnecessary obstacles to exporters.

65. The representative of the Dominican Republic shared the concerns expressed by Cuba on the proposed re-classification of nickel carbonates, which her delegation considered to lack sufficient scientific evidence. She stressed 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. She expressed her delegation's request to the European Communities not to adopt the 30th ATP Directive and to notify the 31st ATP Directive, as well as to take WTO Members' comments into account before the final adoption.

66. The representative of Brazil thanked the European Communities for the recently circulated answers about the proposed classification for nickel carbonates, under the 30th ATP and welcomed the announcement that the 31st ATP would be notified to the TBT Committee before its adoption. However, without prejudging the actual risk posed by the nickel carbonates, his delegation was not convinced that the classification as proven human carcinogens was justifiable with the scientific evidence as presented by the European Communities. He noted that it had been argued that the hazardous properties listed in the 30th ATP had been discussed by OECD experts who came to the same conclusions as the one proposed by the EC. However, he stressed that the OECD study case was a draft initial assessment profile of nickel compound chemicals, which recognised at the outset that there was no data available about nickel carbonates' carcinogenic effect on human health. The main focus of the OECD study was that five substances were candidates for further work, since there were indications of risks to human health. He pointed out that this was not the same conclusion as the

one proposed in the 30th ATP, since the latter dismissed the necessity for further work by skipping testing requirements and jumping to the conclusion that nickel carbonates were proven human carcinogents.

67. The representative of Brazil requested to the European Commission to postpone the adoption of the 30th and 31st ATP until there was reliable scientific information on the actual risk posed by nickel compounds. He also asked why this issue had not been handled in the context of REACH legislation within existing timetables for testing and evaluation. In this regard, industry was conducting a programme to generate relevant data that could contribute to the appropriate science based assessment and classification of nickel compounds. Bearing in mind that TBT Article 2.2 stated that regulations should not be more trade restrictive than necessary to fulfil a legitimate objective, Brazil invited the European Communities to wait until such data became available.

68. 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. She informed the Committee that her delegation, together with eight other countries which accounted for more than 80 per cent of global nickel production, had sent a letter to European Commissioner for the Environment reiterating their concerns.[6] A response had been received from the European Commission which was currently being reviewed. Like others, her delegation's main concerns were related to the fact that the proposed classification for nickel carbonates was not based on sound scientific analysis, and could set an inappropriate precedent.

69. The representative of Canada sought clarification on: the process used for the classification of nickel carbonates and the decision not to request further testing; the role of water solubility in the process of grouping substances; the use of the OECD guidance, particularly the verification steps contained within, in determining the proposed classifications; and the rationale for inclusion of the OECD Draft Initial Assessment Profile (SIDS) in the EC response. She further noted that, in its response, the European Communities had indicated that the 30th and 31st ATPs would be included in Annex VI of a new Regulation (the "CLAP" Regulation - Classification, Labelling and Packaging of substances and mixtures) which sought to bring the EC into alignment with the United Nations Globally Harmonized System. In this regard, she sought clarification on whether classifications in the proposed 30th and 31st ATPs would be included in Annex VI of the CLAP Regulation at the time it entered into force or whether these ATPs would be added in the first ATP to the CLAP Regulation.

70. The representative of Canada appreciated that the European Communities were willing to analyze data submitted by industry. It was her delegation's expectation that no adoption of the 30th ATP would begin until a scientific analysis of such data had been completed. 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. In particular, she stressed that should inappropriate approaches be taken in such situations, they might set a dangerous precedent for the large number of assessments to be performed under REACH. 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.

71. The representative of Canada also sought confirmation that implementation of the 30th ATP would be delayed, that scientific data submitted by industry would be analyzed, and that the delay in adoption would allow sufficient time for information submitted by industry to be properly considered. With respect to the 31st ATP Directive, it was her delegation's understanding that this would contain

[6] A copy of the letter sent was made available as a room document.

further nickel classification proposals. She hoped that sufficient time would be allowed for Members to review and comment on the draft once it was notified.

72. The representative of Australia shared the comments made by previous speakers and appreciated the EC's response to the joint letter sent. However, 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. His delegation did not oppose the use of read-across methodology if applied correctly and in a robust and scientifically valid manner. However, Australian assessment 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 and that solubility in water alone was an insufficient criterion on which to base read-across methodologies.

73. The representative of Australia sought clarification about EC plans for the adoption of the 30th ATP. He also pointed out that, in its reply, the European Communities had stated that any additional scientific information submitted by industry would be analysed by the Commission services, and that if there were merits, the classification of the nickel compounds could be modified. Further scientific work on nickel carbonates had been completed by the nickel industry, which had been provided to the Communities. Therefore, he invited the European Communities to analyse this additional scientific data before taking any further steps in relation to the 30th ATP.

74. The representative of Australia further noted that, in its response, the European Communities had stated that hazard properties of nickel compounds listed in the 30th ATP had been discussed by OECD experts, and that industry had provided additional information which had been taken into account by them. However, his delegation's understanding was that there was no agreement and that the OECD was looking into producing further guidance on how to apply read-across methodology. The European Communities had attached a draft document (Draft SIDS Initial Assessment Profile) to its response which, they indicated, had been discussed by OECD experts. However, this was still a draft document and there appeared to be recommendations for further work. Australia's understanding was that the process was not intended to classify compounds, but rather involved verifying the quality and availability of data on substances. There appeared to be little relevant data in relation to nickel carbonates. Therefore, Australia was interested in receiving further information as to the status of the document and recommendations for further work.

75. The representative of Australia stressed that his delegation 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 the response to Australia, the EC had confirmed that the nickel group did not provide a model to be used "directly" for other groups of chemicals. However, the response also noted 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 his delegation was concerned about the scientific and procedural grounds of this precedent.

76. It was also pointed out that the EC proposed classification of nickel substances would have a significant economic and commercial impact on all nickel producing and exporting countries, including developing countries. Despite the indication by the European Communities that there would not be a direct consequence on other regulations, industry had already provided examples where there would be a direct flow through.

77. The representative of Australia was encouraged by the European Communities indication that the proposal for the 31st ATP Directive would be notified under the TBT Agreement and that a

reasonable time for comments would be provided. He requested the EC to ensure that the process by which its chemicals regulatory regime was developed be transparent, open to all interested parties, including industry, and scientifically defensible. He noted that the European Communities had stated in their response that the draft Directive had been discussed bilaterally with most countries who had submitted comments. However, it had been challenging for Australia to engage with the Commission on this issue, and the industry had reported similar difficulties. He encouraged the European Communities to ensure that bilateral discussions continued with all interested parties, including industry, and that no action to implement the 30th ATP Directive would be taken until unresolved issues remained outstanding.

78. The representative of China agreed with previous speakers and highlighted that the European Communities had not fully addressed the concerns expressed by his delegation on the draft 30th ATP. On the 31st ATP, he invited the European Communities to comply with the transparency obligations in the TBT Agreement and also to base this measure on scientific evidence.

79. The representative of Chile expressed her delegation's concern about the way in which the reclassification of chemicals was being conducted and stressed the need for the methodology used to determine the risks to be applied in a transparent way and on a scientific basis. Her delegation was also concerned that the reclassification process, in particular regarding nickel carbonates, would create uncertainties also in other areas, namely under REACH, and would have an impact on trade in these products. It was her delegation's hope that the reclassification be reconsidered.

80. The representative of South Africa echoed the concerns expressed. In particular, his delegation's concerns were related to the re-classification of nickel carbonates. His delegation's understanding was that the basis for the classification in the 30th ATP was the read-across methodology, which entailed reading across data from one well characterized substance to another substance with little or no data. However, whilst the read-across methodology was approved by the OECD (as per guidelines for its use contained in OECD's 2004 Manual for Investigation of High Production Volume Chemicals), it appeared to South African industry that the EC evaluation process did not comply with these guidelines as the analysis of the properties of the substances compared was not properly conducted. The same methodology would be used for the upcoming 31st ATP, which covered an additional 140 nickel substances.

81. The representative of South Africa further pointed out that it was his delegation's understanding that both the 30th and 31st ATPs could be adopted before June 2008, to coincide with the pre-registration period for REACH. In fact, under REACH, nickel substances had to be registered. As part of this process, industry had to provide data on the chemical composition of these substances following which the EC would examine such data to make a determination on their toxicity. If both ATPs were adopted before the REACH pre-registration period, South African industry would not be able to provide its own data for REACH registration purposes, as the toxicity determination would have been concluded in terms of the read-across methodology applied in the 30th and 31st ATPs. Of particular concern was the fact that the proposed classification-by-derogation in the 30th ATP and flawed subsequent "read across" in the 31st ATP would lead to future erroneous and trade-restrictive measures under REACH. Therefore, he requested the European Communities to defer consideration of both the 30th and 31st ATPs so as to allow stakeholders, including the nickel industry, to contribute to the evaluation process and ensure a sound science-based approach, with a view to ensuring that the aims and objectives of REACH were not compromised.

82. The representative of the United States appreciated the response provided by the European Communities to the comments made. His delegation shared many of the systemic concerns raised by previous speakers regarding the EC analysis for classifying nickel carbonates and other nickel compounds under Category 2 of the Dangerous Substances Directive. With respect to the proposed classification of borates under Category 2, he referred to the concerns set out in his delegation's

previous statements and communications. In particular, the United States 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.

83. Additionally, the representative of the United States reiterated his delegation's concerns regarding the labelling requirements and the "knock-on" effects under other EC legislation, such as REACH, 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 stressed that concerns would continue to be communicated to EC officials at senior levels and sought information on whether the European Communities had considered alternative approaches to provide consumers with information on borates that avoided the potential adverse effects on trade associated with a Category 2 classification.

84. Furthermore, the representative from the United States Environmental Protection Agency (EPA) highlighted that the characterization of the use of the EPA data by the European Communities was not accurate. She was willing to further discuss this issue at a technical level, and expressed her delegation's request to the EC not to finalize its proposed Category 2 classification for borates in the absence of an assessment that took into account intended end-uses and any risk associated with those end-uses. A solution could be found that protected the health and safety of consumers, while avoiding unnecessary restrictions on the sale and use of borates.

85. The representative of Turkey referred to the concerns previously expressed by his delegation on the proposed classification of borates. He recalled that, in addition to raising concerns in the TBT Committee, his delegation had engaged in a bilateral dialogue with the European Communities. The European Communities had also been invited to take part in a joint epidemiology study which would be conducted in Turkey's borate mines and manufacturing sites. Turkey had also submitted additional comments on the EC notification.

86. In particular, Turkey believed that the classification had many procedural and scientific shortcomings and that although the directive referred to risk, the decision had been taken on the basis of hazard. The European Communities seemed to rationalize its decision instead of adopting a constructive approach with a view to eliminating technical barriers to trade. It was Turkey's understanding that the normal handling and use criteria, the relevance of animal data for humans, the route and doses in the administration of substances, the toxic genetic differences between laboratory animals and humans and the relevance of existing epidemiological data had not been applied properly by the EC Technical Committee in reaching the classification decision.

87. Specifically, with respect to the normal handling and use criteria, the representative of Turkey stressed that in order to increase human exposure levels within one level of magnitude of non-desirable effects level for reproductive toxicity found in animals, humans had to ingest deliberately large oral doses of borates, and increase such ingestion over a certain period of time, which constituted a misuse. He remarked that animal studies had been performed by the oral route. However, the route of exposure to borates during "normal handling and use" would be dermal absorbsion and inhalation. In this regard, he stressed that borates were poorly absorbed through the skin and the very high exposure levels so as to produce effects by inhalation would be never met within "normal handling and use".

88. On the issue of the relevance of animal data for humans, the representative of Turkey stressed that there were marked toxic genetic differences between live animals and humans. For instance, rats had a raised risk of renal failure since they could not vomit, so high doses could be used in studies. However, humans could not ingest such high amounts of borates and, moreover, boric acid had other toxic effects in humans such as vomiting and diarrhoea in the intake of high doses. He also stressed that existing epidemiological data, including occupational and environmental human exposure studies carried out in Turkey and in the United States had not shown reproductive effects and had

demonstrated that the effect on humans differed from the effects on animals tested. It was further pointed out that, according to the REACH regulation, a substance classified under Category 1 or 2 had to be authorized.

89. With respect to the obligations under the TBT Agreement, the representative of Turkey noted that the available scientific and safety information and intended end-use of borates did not indicate that, should the objective not be fulfilled, it would create a risk. It was his delegation's understanding that the classification decision did not have a legitimate objective and in fact created unnecessary obstacles to trade and violated the TBT Agreement. He invited the European Communities to consider Turkey's and other Members' concerns before taking any further steps in the application of this measure.

90. The representative of Argentina associated his delegation with the comments made by previous speakers, especially with respect to the possible impact on industry and in particular cosmetic industry.

91. The representative of Indonesia echoed the concerns voiced by previous delegations, including those set out in the joint letter sent to the European Communities on 12 March 2008, as explained by Canada.

92. The representative of Japan shared the views of previous speakers, and the delegation of Cuba in particular. He appreciated the decision of the European Communities to notify the 31st ATP.

93. The representative of Colombia associated his delegation with comments made by previous speakers. The reply provided by the European Communities to the comments made was being reviewed and Colombia would revert to the matter in the near future.

94. The representative of Malaysia reiterated the concerns expressed by his delegation in previous meetings. In particular, it was his delegation's view that the EC measure seemed to be based more on the precautionary principle than on sound scientific evidence. While the EC response to the comments made was appreciated, it did not give enough assurance about the potential adverse effects of the measure. Malaysia was of the view that the proposal was more trade-restrictive than necessary and therefore not in line with Article 2.2 of the TBT Agreement. The measure would result in trade restrictions and would, in turn, impair his country's ability to market its products, in particular rubber from wood treated with borates, one of Malaysia's major export items. On behalf of his delegation, he urged the EC to reconsider its classification of borates as Category 2.

95. The representative of Zimbabwe shared the concerns expressed by previous delegations.

96. The representative of Cuba, speaking of behalf of ACP group, noted that the president of the ACP group in Brussels had sent a letter to DG Environment of the European Commission in which it was explained that if the draft 30th and 31st ATPs were applied as proposed, the directives could constitute a threat to exports of nickel-based substances for ACP countries to the European Union. Additionally, if classified as proposed, the use of nickel substances would be restricted under REACH and would therefore constitute a barrier to trade. ACP countries and other developing countries were still trying to understand and implement REACH, which was already causing them difficulties. He stressed that more time was needed to gain a comprehensive understanding of this issue and that the European Communities should refrain from taking any further action.

97. The representative of Chile, referring to the proposed classification of borates, highlighted that the level of exposure in a mine was not representative of "normal handling and use" for products containing borates, and that the studies in mines had not concluded that there were adverse affects from exposure to borates. There were results of tests carried out in China on more than 1000 workers

exposed to borates, where no adverse affects had been noted. She was also concerned with the direct relation between the directive and REACH.

98. The representative of the Philippines shared the views expressed by Canada, Australia, Cuba and others and recommended the European Communities not to take any further step with respect to the 30th ATP.

99. The representative of the European Communities, in reply to some of the questions raised and starting with concerns on borates, noted that his delegation did not agree with the analysis made by Turkey that it was not possible for humans to intake enough quantities of borates for them to have adverse effects. In particular, the evaluation done by the EC scientific committee on cosmetic products concluded that a threshold was needed to limit the amounts of borates in cosmetic products in order to avoid adverse affects on human health. A limit value had to be set for borates in food for the same reason. While he appreciated the work carried out by Turkey on human studies, he stressed that it was a very complex scientific exercise to prove a negative. Factors such as the effects on future generations, for instance effects on children whose parents had been exposed to borates, had to be taken into account and were difficult to assess.

100. Moving on to nickel, the representative of the European Communities stressed that in the Communities, the precautionary principle was invoked as a risk management tool after a risk assessment had been conducted. In the case of the classification and labelling of these substances, the precautionary principle had not been applied, as classification and labelling was a hazard-based approach, where information on risk and use were considered in very specific conditions and circumstances but not within a traditional risk assessment context. Therefore, there was no basis to invoke the precautionary principle. Indeed, the directive stated that the purpose of classification and labelling was a hazard assessment, and that the criteria of "normal handling and use" in the annex needed to be considered in that context.

101. On the connection with REACH, the representative of the European Communities stressed that there was no automatic link between authorization in REACH and the classification of substances. He also emphasized that not all the identified substances under REACH should undergo authorization. Article 58 of REACH clearly stated the circumstances in which a substance was a candidate for authorization.

102. On the 30th ATP and how to treat new data, the representative of the European Communities said that new studies on substances were produced regularly; these were dealt with in the following way: once a threshold of information to move forward was achieved, a decision was made. The decision would then be adjusted in light of subsequent new information or studies which proved that the decision was incorrect. He added that, if new information from industry was forthcoming, this would be examined as a matter of urgency.

103. Regarding the comment on the classification of all nickel compounds as carcinogenic, the representative of the European Communities clarified that the 31st ATP Directive would clearly differentiate between the nickel compounds considered to be carcinogens from those that were not, and that not all nickel compounds needed to be classified. He stressed that it was too difficult to determine whether nickel was a carcinogen in animals. For example, epidemiological studies had shown that nickel ion was carcinogenic in humans. However, nickel ion tests on animals had not shown that this was so clearly the case for animals. Therefore, the likelihood that tests on animals would show the cancerogenity of nickel in humans was small. Testing requirements under REACH were not likely to resolve this issue because they would be much lower than what was necessary to prove or disprove the carcinogenicity of these compounds.

104. On the OECD study, the representative of the European Communities fully concurred with the fact that it was an initial assessment. However, he stressed that the methodology applied by the Communities for grouping these compounds, in particular nickel carbonate, had been reviewed by OECD experts and that there had not been any significant criticism as to the approach applied. The word "draft" meant that it was an initial assessment profile which had not yet been endorsed by the joint meeting of the OECD. He also clarified that the OECD guideline on groupings had not been applied, in particular the last two steps, calling for confirmatory testing, which meant that further animal tests had to be carried out. Instead, when such confirmatory testing was required to confirm that a classification was necessary, the European Communities had chosen the approach of not classifying at all.

105. On cosmetics, the representative of the European Communities stressed that the cosmetic directive on boric acid would have no immediate consequences for para-borates. The process that would be followed was to consult the scientific committee for cosmetic products about the risk posed by the use of these substances and, if a risk was found, what the limit value should be.

106. The representative of Canada sought clarification on the timing of notification of the 31st ATP. Would this be notified to the TBT Committee only after the directive had been approved by EC member States?

107. The representative of Turkey stressed that his country produced around 70 per cent of known borates, and that no adverse effect had been observed in humans. Additionally, setting limit values for borates in food did not mean that the substance was toxic under "normal handling and use".

108. The representative of the European Communities explained that a notification would be made after the inter-service consultation process at the EC level was concluded. He also pointed out that the timing for the 30th and 31st ATP directives would also have an effect on Annex 6 of the Classification, Labelling and Packaging Regulation (CLAP), which was undergoing the co-decision procedure at the EC level. In concluding, he informed the Committee that all the background material and studies on which the Community had based its classification and labelling for all the compounds in the 30th and the 31st ATPs and the minutes of all the deliberations were available on the website of the European Chemicals Bureau.[7]

(ii) European Communities - Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH) (G/TBT/N/EEC/52, Add. 1-4 and Add.3/Rev.1)

109. The representative of Argentina reiterated his delegation's position that REACH could distort global trade in chemicals and chemical products.[8] It was his delegation's understanding that there could be a lack of uniformity in the application of REACH by EC member States, given the different levels of development, structures and different implementation bodies. Of particular concern was the "single representative" clause in the regulation, which could lead to an unequal treatment between EC and non-EC companies.

110. Additional difficulties were also related to the product registration process in REACH, where industry was responsible for the conformity process of more than 30,000 substances, even when there did not seem to be a risk indication associated with many of them. The only competent body for conformity registration was in the European Communities, which made it more onerous for industries outside the EC. REACH was also very complex and difficult to understand. This was compounded by the delay in technical assistance granted by the Communities to companies outside the EC. As far as amendments to the regulation were concerned, the representative of Argentina expressed his

[7] http://ecb.jrc.it/
[8] A communication from Argentina was subsequently circulated (G/TBT/W/286).

delegation's request that the EC notify all developments to the Committee so that the comments from Members could be taken into account.

111. 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 implementation process. He recalled that at least twenty WTO Members, and a large number of stakeholders, both large and small and from a variety of industry sectors, continued to raise serious questions and concerns regarding REACH and its implementation.

112. In particular, concerns related to the following issues: a continued uncertainty regarding the scope and applicability of the provisions relating to articles; the need for non-EC manufacturers to register reacted monomers in polymers; placing substances on the authorization candidate list when an assessment of risk had not been undertaken, particularly considering the chilling effect that the placement on the list was likely to have; potential preferential treatment for "existing substances" manufactured in the European Communities as compared to existing substances manufactured outside the European Communities - in terms of whether these substances (e.g., cosmetics) qualified as "phase-in substances"; the lack of transparency in the development of the REACH Implementation Projects (RIPs); the potential for differential enforcement of REACH across the EC member States, including the treatment of articles; the protection of business proprietary information required for registration with respect to different entities in the supply chain and in Substance Information Exchange Fora (SIEFs); fees and others costs associated with REACH; the operation of the "only representative" provision; and REACH's potentially disproportionate impact on small and medium size enterprises (SMEs).

113. 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 registered 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.

114. With respect to transparency, the representative of the United States noted that the European Communities had been developing guidance documents, the so-called REACH Implementation Projects (RIPs). Forthcoming documents would address critical issues such as the "only representative" and the authorization candidate list. Industry, especially small and medium size enterprises, was having particular difficulties monitoring these guidance documents, given their volume, complexity, and ambiguity on many issues. The representative of the United States urged the European Communities to provide a meaningful opportunity for governments and stakeholders to comment on each proposed RIP document.

115. On the provisions regarding the "only representative", the representative of the United States pointed out that REACH required each EC manufacturer or importer of a substance, or article containing a substance, to register that substance. This meant that if a non-EC manufacturer relied on multiple EC importers to export its substance or article to the European Union, each importer had to separately register the substance or article, while companies established in the European Union could register substances or articles on their own behalf. To reduce the significant burden this would entail with respect to imported products, companies that were not established in the European Union could appoint an "only representative" to register their substances. However, the representative of the United States highlighted that, according to industry, the benefit of the "only representative" provision was undermined on account of its potential to disrupt global supply chains, especially SMEs within

those supply chains, and to allow for potentially discriminatory treatment between EC and non-EC actors.

116. In particular, one of the primary questions raised by companies was whether the "only representative" appointed by a non-EC manufacturer could register on behalf of all EC importers of the monomer or additive produced by that manufacturer. With only a few months to go before pre-registration began, the answer to this question was unclear in the new RIP 3.1 on registration. While REACH appeared to allow for all non-EC manufacturers, formulators, and article producers to appoint an "only representative" to register the substances they produced (or that were contained in articles), industry in the United States was still unclear as to whether non-EC manufacturers, formulators, or article producers who did not directly export to the European Union would be able to appoint an "only representative". If such limitation existed, companies that did not directly export their substances to the European Union would find themselves in the position of having to disclose business proprietary information to downstream users in their supply chain that could register the substance. Such a limitation could restrict trade because many companies would refuse to disclose such information within their supply chains, which would prevent their products from being sold in the European market.

117. Moreover, the representative of the United States stressed that not allowing substance producers who were not direct exporters to the European Communities to appoint an "only representative" would also be inefficient. A substance producer could sell to several dozen non-EC companies, all of whom ultimately exported to the European Communities. Rather than each of the individual exporters having to appoint an "only representative" to register the substance, it would be more efficient to permit the underlying substance producer to appoint a single "only representative" to handle the registration process for the relevant substances it produced.

118. The European Chemical Agency (ECHA) should provide complete, stand alone guidance on the issue of the "only representative" that was clear, took into account concerns and questions raised by stakeholders, and ensured that the operation of the "only representative" provision did not discriminate between foreign and domestic suppliers or otherwise distort trade. In particular, non-EC substance manufacturers should be allowed to appoint an "only representative" regardless of whether they directly exported their substance to the European Union. This would help ensure that non-EC substance manufacturers were put in a similar position to an EC-substance manufacturer and would allow the non-EC substance producer to know that its information was being reported correctly and to avoid sharing confidential information with downstream users. Providing such guidance would also create a more conducive environment for the development of "only representative" services.

119. On the registration requirements for reacted monomers in polymers, the representative of the United States recalled that REACH exempted polymers from registration and evaluation, as they were generally believed to cause minimal risk. Yet REACH required manufacturers or importers of polymers to register reacted monomers, which were chemically bound within polymers. However monomers, once reacted, no longer existed as individual substances in polymers, thus rendering the possibility of exposure to be minimal. The reacted monomer registration requirement provided an incentive for distributors to switch to EC polymer suppliers, since the monomers in those polymers would already have been registered, thus avoiding the registration requirement. Many non-EC polymer manufacturers would be unwilling to provide the necessary information to importers due to confidentiality concerns, or because it would be too burdensome to obtain this information, or not economically feasible to register their monomers themselves due to the high registration fees.

120. The requirement to register reacted monomers further complicated the operation of the "only representative" mechanism, since it increased the number of substances that needed to be registered and the number of actors involved. The representative of the United States encouraged the European Communities to set out the scientific and technical information it relied upon in determining that

reacted monomers in polymers needed to be registered, particularly in light of its conclusion that polymers themselves did not have to be registered on account of the minimal risks associated with them.

121. With respect to the effect of placing substances on the authorization candidate list, the representative of the United States noted that the European Chemical Agency (ECHA) was expected to issue a candidate list of those substances that would be subject to authorization on account of them potentially being substances of high concern. His delegation remained concerned that this list was hazard-based, where substances would be placed on the candidate list without evidence that the substances posed a risk in particular concentrations or for particular end-uses and channels of exposure, and without information on the risks to consumers of using an alternative substance.

122. Moreover, it was pointed out that the evaluation of all the chemicals on the candidate list could take decades, and that the status of such chemicals would remain uncertain for the foreseeable future. In light of the significant additional reporting requirements associated with using substances subject to authorization and the potential restrictions on their use, many companies believed the candidate list of substances for authorization would be used as a "black list," causing companies to discontinue using substances on the list before the ECHA had evaluated the information necessary to determine whether the substance posed a risk. If purchasers demanded products free of candidate list substances, product suppliers could find themselves obliged to undertake costly reformulations, despite the lack of science justifying such a change. In addition, such a change could result in the use of relatively untested chemicals whose environmental, public health, or consumer safety impacts were unknown and potentially harmful.

123. To reduce a potential "black list" effect in the development of the candidate list and unnecessary substitution of known chemicals for sub-optimal or untested alternatives, the representative of the United States expressed his delegation's request to the EC to provide guidance on the status and purpose of the candidate list prior to and coincident with the publication of the candidate list and candidate substance dossiers. The EC was also requested to proceed with the publication of the candidate list only when such guidance had been notified to the WTO, and that any comments received had been taken into account.

124. The European Communities were also encouraged to make clear that: (i) only substances on the final authorization list would be subject to authorization and related restrictions, (ii) that the ECHA would evaluate use-based risk assessment information to determine which substances would be subject to authorization; (iii) that producers should not use the inclusion of a substance on the candidate list as a reason not to use that substance, or to use a substitute for it; and (iv) that substitution or reformulation could exacerbate negative environmental, health, or safety concerns as the risks associated with substitutes might not be known.

125. The representative of the United States further encouraged the European Communities to explain how stakeholders could provide ECHA and the European Commission with comments on substances nominated for inclusion on the candidate list, and how ECHA and the Commission would take such comments into account. In addition, once a decision had been made to add a substance to the candidate list, a decision support document should be provided at the time that the candidate list was released.

126. With respect to the burden on SMEs, the representative of the United States stressed that REACH placed a significant communication burden on global supply chains. Faced with the task of obtaining all of the necessary data to comply with REACH, many manufacturers were requesting each of their upstream substance suppliers to provide them with information required to register the manufacturers' products, or the substances they contained. As a result, substance manufacturers were facing enormous data requests, including for business-sensitive information. Many SMEs, who were

engaged in selling their products domestically, did not have the resources or the ability to discern the data necessary to ensure complete and accurate registration under REACH.

127. It was further highlighted that burdens would be especially acute for many small and medium sized enterprises, in both developed and developing countries. Unlike large multinationals, SMEs would be less likely to have a European presence and, therefore, would effectively have little choice but to appoint an "only representative" to register their products. If several manufacturers of the same substance appointed a single "only representative" to register the substance, the tonnage of the substance exported to the European Union by each manufacturer would be aggregated. The aggregate tonnage of a substance registered by a single "only representative" would then be the basis for determining fees and registration requirements. Such aggregation of tonnage could result in higher fees and trigger the requirement to submit a Chemical Safety Report when lower fees or no Chemical Safety Report would otherwise be required. Industry reported that registration and testing fees could easily exceed US $50,000 per substance; if a particular company used 50 substances in its preparations and articles, the cost could be prohibitive.

128. In concluding, the representative of the United States stressed that many SMEs could not afford to re-tool, or set up separate, production lines for substances, preparations, and articles bound for the EC market. In some cases, they might not know where their products would ultimately be shipped. As a result, many companies that did not themselves export to the EC market could find themselves in the situation of having to ensure that their products, or substances in their products, were registered.

129. The representative of Chinese Taipei echoed the concerns raised on REACH. In particular, questions remained on the way REACH was going to be implemented. In areas such as the availability of guidance on pre-registration, registration fees and penalties for non-compliance, access to detailed information was essential. He requested that the European Communities fully take into account the principle of transparency in order to avoid possible technical trade barriers for third countries. Of particular concern was also the confidentiality of registration documents submitted by manufacturers located in third countries. This process had to be carried out by an "only representative" located in the European Communities. Therefore, his delegation was of the opinion that ECHA should provide a list of "only representatives" registered in the European Communities that had received adequate training in confidentiality, and that it should monitor their operations so as to ensure that confidential documents were duly protected during the registration process.

130. The representatives of Australia and Brazil shared many of the concerns raised by previous speakers. Australia in particular was concerned about transparency and the impact of REACH on non-EC producers.

131. The representative of China stressed that REACH was a complex regulation and that industries, especially SMEs, in developing countries like China faced big challenges and many difficulties in complying with it. Chinese industries were particularly concerned about the complex registration procedures and the associated high fees. REACH would also bring about restrictions on trade in downstream industries due to its broad approach. Additionally, enterprises outside the European Communities could not conduct registration, which raised concerns that they would not be treated equally and fairly. His delegation was also concerned about whether EC member States would apply REACH in a uniform and consistent manner. China was also interested in presenting comments on the REACH Implementation Projects (RIPs).

132. The representative of Chile noted that industry in her country was particularly interested in receiving technical assistance from European experts, so that REACH could be better understood and applied, especially in light of the upcoming pre-registration period, starting on 1 June 2008. Concerns remained about the possible differences of interpretation among different EC member States with

respect to the application of REACH on different articles. The practical implementation of REACH would be very complex and difficult to monitor and this would affect fair competition in the European market and generate discrimination.

133. The representative of Cuba shared the concerns expressed by previous delegations, in particular Argentina. His delegation believed that REACH could create difficulties for Cuba and other developing countries' exports to the EC market. He informed the Committee that, as a result of the ILAC Mutual Recognition Arrangement signed by Cuba in 2005, the reliability of results of Cuba's accredited laboratories was recognized. However, in the Cuban accreditation system, there was a limited number of accredited laboratories and only in some specific types of chemicals, physical-chemicals, electrical, radiological and corrosion tests. Time was needed to accredit further laboratories in accordance with the provisions of REACH. On behalf of his delegation he requested that the European Communities postpone the entry into force of REACH, in particular in light of Article 12.3 of the TBT Agreement which provided that all Members needed to take into account the special development and trade needs of developing countries in preparing and applying technical regulations.

134. With respect to the fact that REACH did not recognize the results of national certification bodies and of test laboratories in countries outside the European Communities, the representative of Cuba stressed that Article 6 of the TBT Agreement provided that Members should ensure, to the extent possible, that results of conformity assessment procedures carried out by other Members were accepted. Additionally, various mutual recognition agreements and voluntary arrangements provided that regional accreditation bodies and international accreditation structures should be mutually recognized, and that the results of test laboratories should be also be recognized. His delegation believed that there was no justification for only recognizing the results of test carried out by EC laboratories as provided under REACH.

135. 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 simply beyond the capacity of many developing and least developed countries. SMEs, in particular, would not have the capabilities to understand the complexity of the regulation, or overcome the severe difficulties in complying with it.

136. The representative of Korea appreciated the efforts made by the European Communities to accommodate his delegation's concerns. However, SMEs had difficulties in complying with REACH. More active consultation and information dissemination activities were necessary with stakeholders outside the European Communities, including training programmes.

137. The representative of Japan raised some specific questions concerning REACH. First, he noted that the guidance about the registration for the implementation of REACH (February 2008) stipulated that the "only representative" could represent one or several non-EC manufacturers. As the "only representative" was fulfilling the registration obligations of importers, the tonnage of the substance to be registered was the total of the tonnages of the same substance covered by the contractual agreements between the "only representative" and all non-EC manufacturers represented by him.

138. However, aggregating the volumes imported from different non-EC companies could cause the total tonnage to exceed the thresholds for the requirements under REACH, even if the volume of each single non-EC manufacturer contracted to the "only representative" was below the threshold. EC manufacturers did not face the risk of their tonnage being aggregated with those of other manufactures with the result that the total exceeded a given threshold for REACH requirements. Consequently, Japan was concerned that aggregating the volumes contracted by an "only representative" could pose discriminatory and excessive burdens for non-EC manufacturers.

139. Secondly, the representative of Japan 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". Thirdly, he noted that, according to Article 33 of REACH "Duty to Communicate Information on Substances in Articles", suppliers of articles were to provide consumers with information concerning substances of very high concern on request by the consumer and within 45 days of receipt of the request. However, depending on the article or substance, suppliers could find themselves needing to inquire from other suppliers in the upper supply chain. In that case, it would be impossible to provide the relevant information at such short notice if adequate information was not provided by the upstream suppliers. He sought clarification on the effective burden for the suppliers in this regard which, in his delegation's view, Article 33 of REACH did not sufficiently clarify.

140. Finally, under REACH, an importer of polymers into the European Communities was requested to register the constituent monomers of the polymers from outside the European Communities. In such cases, there could be problems related to possible leakage of data to manufacturing competitors. In contrast, in the European Communities, the monomers were registered directly by the monomer producers and the polymers manufacturers in the European Communities were not requested to register the composite of monomers. Therefore, information on their composition did not have to be shared with competitors. Japan was concerned that this difference in the registration process could lead to a disadvantage for polymer manufacturers outside the European Communities, thereby constituting a barrier to trade. A similar issue existed in the case of preparations and their constituent substances and the representative of Japan expressed his delegation's appreciation for the efforts made by the European Communities to clarify the situation both bilaterally and multilaterally.

141. The representative of South Africa pointed out that industry in his country was of the opinion that REACH was very complex legislation and that it was difficult to interpret what was expected of them. He requested the European Communities to allow more time for industry to become acquainted with the provisions of REACH.

142. The representative of the European Communities pointed out that the obligation to register under REACH would enter into force on 1 June 2008. He informed the Committee that a workshop on REACH would be held in Brussels in April 2008.[9] He noted that many of the concerns raised were related to the "only representative". For example, on the issue of the accumulation of tonnages when one "only representative" represented non-Community manufacturers, he stressed that information on this point was contained in the guidance document on registration[10]. The Commission and the European Chemicals Agency were eager to ensure that guidelines provided to stakeholders contained the necessary and appropriate information. If this was not the case, the guidelines could be revised.

143. On whether the non-EC manufacturers who did not export directly to the European Communities were allowed to appoint an "only representative", the representative of the European Communities explained that the issue was being examined and the outcome of these examinations would be made available on the website of the European Chemicals Agency in due course.[11] On the question raised by Japan regarding the interpretation and the scope of article 33 of REACH, he stressed that the information to be provided only concerned substances in the list set out in accordance with Article 59(1) of REACH (Annex XIV, "candidate list"). Article 33 stated that the information which was available to the supplier had to be given upon request to the consumer, and at least the

[9]Information about the REACH Workshop can be found at: http://ec.europa.eu/enterprise/reach/events_en.htm#video

[10] The guidance has subsequently been updated, see http://reach.jrc.it/docs/guidance_document/registration_en.htm

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

name of the substance. Therefore, the obligation for the supplier was to have available the information regarding the name of the substance in the candidate list.

144. On the issue of monomers in polymers, the representative of the European Communities noted that the relevant guidance for stakeholders and economic operators to follow was available on the ECHA website. However, he informed the Committee that a question on the interpretation of this provision had recently been submitted to the European Court of Justice.[12]

145. On the issue of uniform interpretation across the European Communities, the EC representative recalled that the legal instrument chosen for REACH was a regulation, which was directly applicable to all member States. The European Commission was closely examining and following the coherent and consistent application throughout the 27 EC member States. Furthermore, helpdesks had been established both at the ECHA and in several EC member States, which would further contribute to the coherent and consistent implementation of REACH, as well as being a useful tool for interested parties to obtain information.

146. The representative of the European Communities further highlighted that the various guidance documents were available on the websites of the European Chemicals Agency and the European Joint Research Centre[13], which advised the Commission on scientific issues. These documents were not mandatory, nor did they contain specifications for products. Therefore, they did not need to be notified under the TBT Agreement. On the issue of recognition of laboratories raised by Cuba, the representative of the European Communities stressed that tests of laboratories which complied with the OECD guidelines on good laboratory practices would be recognized.

147. It was also noted that the European Commission had drafted a regulation, concerning fees and charges payable to the European Chemicals Agency. This regulation, expected to be adopted in April 2008 and communicated to the Members upon its adoption[14], implemented articles 74 and 132 of REACH. These two provisions already laid down the circumstances under which fees or charges might be levied, as well as the principles that had to be applied to fix the level of fees and charges. According to the draft regulation, there would be fees for the registration and fees for the authorization processes. The level of fees would be related to workload: for example, the level of the fee for registration varied according to the tonnage, and reductions applied in the case of joint submissions. A lower registration fee had also been fixed for the registration of intermediates, as the associated workload would be lower than for other registration dossiers.

148. The basic authorization fee covered one applicant, one substance and one use. Additional fees would be applied in the case of applications covering more than one applicant or more than one substance or more than one use. The agency could also levy charges for services that were not specifically subject to the payment of fees, in particular with respect to the review of an authorization. The level of fees and charges had been fixed taking into account a substantial contribution of the EC budget to the total cost of the Agency. Reductions would apply to micro, small and medium enterprises in the range between 90 per cent and 30 per cent.

149. The representative of the European Communities invited Members which had shown an interest in receiving technical assistance, to direct their requests to the respective delegations of the European Commission in their territory. The requests would be examined also in light of whether they could be met by existing technical assistance programmes or whether further assistance would be needed. Finally, the representative of the European Communities stressed that the principles of non-discrimination and avoidance of unnecessary obstacles to trade had been taken fully into account in

[12] Case C-558-07
[13] http://ecb.jrc.it/reach/
[14] See G/TBT/N/EEC/52/Add.5.

the development of REACH, and that the authorization and registration requirements were not overly restrictive and were workable in practice.

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

150. The representative of Norway informed the Committee that the above-mentioned regulation had not entered into force on 1 January 2008 as previously announced and that comments received in a public hearing were being evaluated by Norwegian environmental authorities. In this hearing process, useful information concerning the application of some of the substances covered by the proposed measure had been received. The Norwegian environmental authorities were also holding meetings with interested stakeholders. Limit values for the different substances and possible exemptions were being evaluated, with the aim of finalizing a decision by the end of 2008.

151. The representative of the United States thanked Norway for the update and highlighted that his delegation would continue to monitor the issue closely.

152. The representative of Korea appreciated the fact that the regulation had not entered into force and believed that the measure could create obstacles to trade. More scientific analysis needed to be conducted before the measure could enter into force.

153. The representative of Israel pointed out that his delegation would monitor the issue closely, especially with respect to the two chemicals of export interest to his country, namely: *tetrabromobisphenol A* (TBBPA) and *hexabromocyclododecane* (HBCDD).

154. The representative of Jordan thanked Norway for the update and stressed that his delegation would welcome any technical consultations with the relevant Norwegian authorities, also with respect to the two chemical substances of interest to his country: TBBPA and HBCDD.

(iv) European Communities - Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS)

155. The representative of the United States drew the Committee's attention to the EC's on-going review of its directive on the restrictions of hazardous substances and recalled that several discussions had taken place in the Committee during the development and initial implementation of this directive, including 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 study showed that smaller companies had devoted a significantly larger percentage of total revenues to RoHS compliance than larger companies – up to 6 per cent of revenues for companies with annual revenues of US$5-10 million and significantly less than 1 per cent for companies with revenues of over US$1 billion per year.

156. The representative of the United States emphasized that, given the costs of compliance and the disproportionate impact on SMEs, EC regulators should ensure a risk and science-based approach to evaluating whether to add additional substances to the list, to broadening the scope of application, and to setting maximum concentration levels for specific products. The European Communities were also encouraged to provide clarity 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, allowing a meaningful opportunity for comment by all interested stakeholders.

157. The representative of the European Communities confirmed that the RoHS directive was being reviewed. The objectives of this review were twofold: first, to present proposals for the

inclusion of medical instruments and control and monitoring equipment within the scope of the directive, as well as to examine the feasibility of extending the ban to other hazardous substances. Second, to simplify the provisions of the directive with the aim of making RoHS easier to apply and to address reported implementation difficulties. She recalled that the review had started with a consultation period with interested stakeholders, who could submit comments and provide relevant information, between March and May 2007. More consultations, setting out concrete policy options, had been terminated in February 2008. Many companies and associations from third countries, including from the United States, had contributed extensively to the consultation process.

158. The representative of the European Communities further highlighted that several studies had been initiated. A first study was related to the inclusion of medical devices as well as monitoring and control instruments within the scope of the directive. Another study covered the innovation and competitive aspects of the RoHS review. Additionally, two on-going studies were examining the need and possibilities of extending the ban to other substances and the exemptions which were granted under the RoHS directive. An impact assessment was also underway and was expected to be concluded in early July. This would lead to the preparation of a proposal by the Commission which would be tentatively adopted or proposed in September. The proposal would be notified to the TBT Committee at a draft stage with the possibility to submit comments. She informed the Committee that the results of the two consultations as well as information on the studies were available on the website of the DG Environment of the European Commission.[15]

(v) Argentina – Measures affecting market access for pharmaceutical products (G/TBT/W/280)

159. The representative of Colombia recalled that at the previous meeting of the Committee, his delegation had expressed concerns relating to the system applied by Argentina for the entry of pharmaceuticals into its market, specifically with regard to the classification of countries and the resulting application of conformity assessment procedures. Concerns had also been raised with respect to the classification and application of tariffs or fees for undertaking verification visits to plants located in the countries of origin of the pharmaceuticals. It was his delegation's view that some of the measures were contrary to the rights and obligations under the TBT Agreement, in particular those related to the principle of national treatment and transparency. He pointed out that no reply had been provided by Argentina on the concerns expressed, and sought clarification on whether Argentina had revised the document submitted which listed the concerns in detail.

160. The representative of Chile recalled that her delegation had also expressed concerns on this issue. She noted that, in spite of the fact that Chile was included in the list of countries whose sanitary and pharmaceutical systems were considered reliable by Argentina, Chilean pharmaceutical products had been denied access to the Argentinean market. Chile had also invited Argentina to visit its facilities. She asked Argentina to take these concerns into account and to take the necessary steps to solve this problem.

161. The representative of Paraguay noted that concerns had been expressed by his delegation on these measures in a regional context in May 2007, and that no progress had been made. His delegation shared the concerns expressed by Colombia and Chile, and was waiting for a review to take place concerning visits, fees and registration to export to the Argentinean market

162. The representative of Argentina noted that the document was being analyzed in capital and that the issue could be addressed through bilateral channels.

[15] http://ec.europa.eu/environment/index_en.htm

(vi) Canada – Compositional requirements for cheese (G/TBT/N/CAN/203)

163. The representative of New Zealand recalled that concerns about Canada's regulation governing compositional requirements for cheese had been expressed by his delegation at the July and November 2007 meetings of the Committee. Despite the bilateral consultations held with Canada, his delegation remained of the view that the new regulations were overly restrictive in nature, both in terms of their allowance for the use of dairy ingredients and their impact on trade. The regulations limited the use of protein sourced from dairy ingredients such as skimmed milk powder. However, such ingredients were widely used and accepted in many countries. The bulk of these ingredients in Canada were imported and the regulations were placing new restrictions on the domestic market for these products.

164. In particular, the representative of New Zealand sought clarification on whether Canada had considered any other options in developing the regulations; on the rationale for adopting regulations that set forth quantitative restrictions on ingredients used in cheese that were inconsistent with the Codex approach towards cheese standards; and, on whether it intended to extend the approach of establishing restrictive compositional standards to other dairy products, such as yoghurt.

165. The representative of Australia reiterated his delegation's concerns about the new regulations on compositional standards for cheese and was disappointed that the regulations had been adopted and would come into effect in December 2008. His delegation believed that the measures were more trade-restrictive than necessary and discriminated against products such as milk protein concentrates, skimmed milk powders and whey protein concentrates, which were mainly imported into Canada. His delegation was also concerned that the regulations deviated substantially from Codex cheese standards. Canada had offered no justification as to why Codex standards were ineffective or inappropriate to fulfil Canada's legitimate objectives as required by Article 2.4 of the TBT Agreement.

166. Moreover, the measures appeared not to meet the objectives identified by Canada. In particular they did not allow for technical advances in cheese production, did not provide for consistency with international food standards, did not provide uniform composition and nutritive value and they had not demonstrated that they could protect consumer interests. Interest was also expressed in receiving answers to the questions raised by New Zealand.

167. The representative of Switzerland shared the concerns expressed. In particular, her delegation could not see how these measures would be useful for consumers and why they were not in accordance with the Codex standards. She stressed that the measures might have a negative impact on market access for milk protein concentrates.

168. The representative of the European Communities recalled that, at the November 2007 meeting of the Committee, Canada had explained that the Canadian Food Inspection Agency was reviewing the comments received, and that these comments would be taken into account. Her delegation regretted that the regulation was adopted in December 2007, shortly after the meeting of the Committee, and was due to enter into force in December 2008, without providing delegations with responses to the comments that had been submitted nor additional information on the status of the revision. She noted that, although in its final publication Canada had made some revisions to the benefit of cheese imports, some of the more serious concerns raised had not been taken into account.

169. It was the European Communities' view that the measure, in particular the licensing system, the new compositional standards and the requirements to prove compliance, would have a negative impact on EC exports to Canada of certain cheeses and basic products such as milk protein concentrates. The representative of the European Communities stressed that the mandatory requirements appeared to create unnecessary obstacles to trade and raised WTO incompatibility

concerns. In this context, the beneficiary of the measure seemed to be the Canadian milk industry. For example, some references were made in the regulatory impact analysis statement attached to the Canadian regulation which referred to the growth of the dairy sector in Canada. She added that the revised regulations were being examined and additional comments in writing would be provided. She urged Canada to take into account the comments made in the Committee and those that would be submitted and amend the regulations.

170. The representative of the United States echoed the concerns raised. While her delegation appreciated the adjustments to the compositional cheese standards to take into account concerns regarding the cheddaring process and "traditional Cheddar Cheese", outstanding concerns with respect to the potential market access implications remained. She noted that the issue was still being reviewed and that the measure's impact on trade flows would be monitored closely.

171. The representative of Canada explained that the revised regulations harmonized the definition of milk products for cheese, in both the Food and Drug Regulations and the Dairy Products Regulations. This change would clarify and provide consistency in the ingredients which could be used in the manufacture of cheese for the Canadian market. She noted that the regulatory initiative was published on 26 December 2007 and that, in order to provide manufacturers and Canadian importers with sufficient time to adapt to the required changes, the amended regulations would come into force on 14 December 2008.

172. The representative of Canada further highlighted that the regulations required a minimum level of casein derived from various milks to produce various cheeses, but allowed the use of other milk products, such as milk protein concentrates, skimmed milk powders and whey protein concentrates. 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.

173. In Canada's view, assertions that the regulations would result in a reduction in imports of milk ingredients, including milk protein concentrates were unsubstantiated. Use of milk ingredients in cheese manufacturing varied between cheese processors and there was no evidence that the minimum quantity of casein required by the regulations would serve as an effective constraint to the existing usage of milk ingredients such as milk proteins concentrates. The representative of Canada further noted that the measure harmonized Canadian regulations with Codex standards by allowing the use of both milk and milk products in the manufacturing of cheese. Previously, the Food and Drug Regulations did not permit the use of milk products in the manufacturing of cheese.

174. The representative of Canada stressed that Members' comments had been taken into account. Specific requirements for "traditional Cheddar Cheese" had been removed and requirements for "aged Cheddar Cheese" added, thereby aligning the measure with Codex standards. Specific provisions had also been made in the final regulation for lower-fat cheeses, which clarified that ultra filtered milks were permitted as ingredients for cheese. She also clarified, in reply to a point raised by New Zealand, that Canada had not initiated any regulatory process for establishing compositional standards for other dairy products. For instance in the case of yoghurt, there were no national compositional standards and none were intended.

175. With respect to the licensing regime, 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. More information would be provided to trading partners on the importer licensing regime as it was further developed in 2008. In concluding, the representative of Canada stressed that comments were welcome and that her delegation was willing to meet with trading partners to discuss any concerns with this regulatory initiative.

(vii) India - Pneumatic tyres and tubes for automotive vehicles (G/TBT/N/IND/20)

176. The representative of the United States appreciated the bilateral discussions held with India, in which his delegation had gained a better understanding of the status of the Bureau of Indian Standards protocol on conformity assessment procedures for tyres. His delegation had sought to clarify the objectives and requirements of this protocol, whether it was mandatory or voluntary, and had encouraged India's continued active membership in UNECE Working Party 29 and conveyed the potential benefits of a UNECE Agreement on a global technical regulation for tyres. He noted that India had confirmed that the scheme was voluntary, and that no decision had been taken to make it mandatory. Relevant developments in the work of the global technical regulation had also been discussed, and the outcome of these discussions would be shared with interested stakeholders in capital. His delegation was open to a continued, constructive dialogue with Indian authorities on this issue.

177. The representative of the European Communities shared the same understanding as the United States with respect to the regulations on tyres and tubes. He expressed his delegation's encouragement for India's active participation in the 1998 UNECE agreement discussions on a global technical regulation for tyres. His delegation was also interested in having further information about the licence fee structure for imported and domestic tyres.

178. The representative of Japan noted that Japanese industry had expressed some concerns regarding this proposed classification system for the regulation of tyres and that his delegation would continue to engage in discussions, especially on specific issues such as the implementation period and conformity assessment procedures.

179. The representative of India appreciated the useful exchange of views with interested delegations and stressed that comments would be conveyed back to his authorities in capital.

(viii) Korea – Fish Heads

180. The representative of New Zealand recalled that at the July 2007 meeting of the Committee his delegation had reported that some progress on the matter had been signalled by Korea, with the announcement of the intention to add hake heads to the national food code and that the issue had been considered by the Korea Food and Drug Administration (KFDA) Food Sanitation Council. However, contrary to expectations, the changes to the Korean food code had not been made. Instead, the Council had again delayed its decision, citing a lack of information on the food safety of the product.

181. The representative of New Zealand stressed that his delegation considered this further delay unacceptable. Over the years, New Zealand had provided ample information to the Ministry of Maritime Affairs and Fisheries on the food safety issues related to this product. He sought the cooperation of Korea to ensure the required changes to the Korean food code were made swiftly and this issue finally resolved. In the meanwhile, he stressed, edible hake heads caught in New Zealand waters and processed by New Zealand boats were still prohibited from entering the Republic of Korea, while hake heads caught in New Zealand waters and processed by Korean boats were allowed

entry into the Korean market. While this situation remained unresolved, his delegation would continue to raise the matter in the TBT Committee.

182. The representative of the European Communities pointed out that, with regards to trade in edible cod heads with Korea, bilateral negotiations were on-going and it was hoped that the two parties would be able to reach an agreement and conclude the matter in the near future.

183. The representative of Korea noted that close bilateral talks between relevant agencies of Members were on-going. The Korean Government was in the process of revising the domestic food code. He would report the concerns back to his capital with a view to solving this long-standing issue as soon as possible.

(ix) Sweden - Restrictions on the use of Deca-bromo diphenylether (deca-BDE) (G/TBT/N/SWE/64)

184. The representative of Jordan sought an update from the European Communities on the bilateral discussions with Sweden on this issue and on the results of these discussions.

185. The representative of Israel reiterated his delegation's position that the prohibition was an unnecessary obstacle to international trade within the meaning of Article 2.2 of the TBT Agreement. Although Sweden had justified the measure invoking the protection human health, the existence of a risk had not been demonstrated. Under the TBT Agreement, Sweden could not recur to a precautionary principle or claim that a potential risk existed. He echoed Jordan's request for an update on the matter.

186. The representatives of the United States and Japan also sought a report on this issue.

187. The representative of the European Communities pointed out that bilateral discussions with Sweden were still on-going and were progressing positively. She stressed that comments by WTO Members were being taken into account and hoped that a solution would be found in the near future.

(x) Norway - Restrictions on the use of Deca-bromo diphenylether (deca-BDE) (G/TBT/N/NOR/6)

188. The representative of Norway recalled that the Norwegian draft regulation on deca-BDE had been sent for a public hearing in the spring of 2005, both nationally and internationally, and then notified to WTO and that it was originally scheduled to enter into force on 1 July 2006. She pointed out that the regulation had been adopted on 9 December 2007 and would enter into force on 1 April 2008. According to the regulation, the manufacture, import, export, sale and use of substances and preparations containing 1 per cent by weight of deca-BDE would be prohibited. The means of transport were exempted by the prohibition.

189. It was stressed that several reports concerning both health and environmental effects supporting the concerns regarding deca-BDE had been published since the notification of the Norwegian draft regulation, and that references were available to interested delegations. An English translation of the provisions regarding deca-BDE, including the amendments made, was also available to interested delegations.

190. The representative of Israel reiterated his delegation's concerns with the measure. In particular, his delegation was of the view that the proposed prohibition was not based on available scientific and technical information and that its application would constitute and unnecessary obstacle to international trade within the meaning of Article 2.2 of the TBT Agreement.

191. The representative of Japan thanked Norway for the update and regretted that the measure would enter into force on 1 April 2008.

192. The representative of Jordan agreed with Israel that there was not sufficient scientific evidence which proved the impact of deca-BDE on health and the environment and that the restriction was an unnecessary obstacle to the international trade.

(xi) 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

193. The representative of Japan recalled that at the previous meeting of the TBT Committee, in the context of the Transitional Review Mechanism, China had stated that the regulation was being revised and sought an update on the matter.[16] He further invited China to clarify whether importers would be again required to pay the registration fee at the end of the two year registration cycle.

194. The representative of the European Communities recalled the concerns expressed by his delegation at the previous meeting of the TBT Committee in the context of the Transitional Review Mechanism and joined the representative of Japan in requesting an update on the review of the Chinese toxic chemicals legislation.

195. The representative of China recalled that at the November meeting of the Committee his delegation had promised to review this regulation and confirmed that consultations to this effect were on-going in his capital.

(xii) Israel – Infant formula

196. The representative of the United States recalled that his delegation had expressed concerns on the infant formula regime in Israel at the past two meetings of the Committee. He stressed that US infant formula manufacturers were willing to comply with regulations that were published, treated all producers equally, were clear and consistent and based on science. His delegation's understanding was that the Government of Israel was considering the promulgation of new rules. However, reports suggested that the new regulations would not address the expressed concerns, particularly with respect to consistent application to all infant formula entering the Israeli market. He sought further information on the issue and invited Israel to notify any proposed regulations to the WTO.

197. The representative of Israel said that in light of grave public health incidents following imports of infant food, the issue was sensitive. Bilateral contacts were on-going between various Israeli authorities, regulators and different stakeholders in order to find an agreed solution to the concern of the United States.

(xiii) United States – Proposed Rule on Labelling and Advertising of Wines, Distilled Spirits and Malt Beverages (G/TBT/N/USA/290 and Add.1)

198. The representative of the United States recalled that Argentina had submitted comments on the notice by the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the US Treasury Department of its proposed rulemaking on wine labelling, which was notified in August 2007 and for which the comment period had been extended until 27 January 2008. He explained that, through the notice, TTB proposed to amend its regulations to require a statement of alcohol content and a "Serving Facts" panel on alcohol beverage labels. TTB proposed to make these new requirements mandatory three

[16] See G/TBT/M/43, para. 181, in the context of the "Sixth Annual Transitional Review Mandated by paragraph 18 of the Protocol of Accession of the People's Republic of China."

years after the date of publication of the final regulation in the US Federal Register. TTB was considering the comments received and would likely not make a determination until 2009.

199. The representative of the United States further noted that the World Wine Trade Group, of which Argentina was a member, had a labelling agreement which did not prevent a country from establishing a nutritional label. He stressed that, according to experts on this matter, other WTO Member such as Australia, New Zealand and Japan also required some type of labelling on wine.

(xiv) India - Drugs and Cosmetic Rules 2007

200. The representative of the European Communities reiterated his delegation's concerns about India's draft amendment concerning drugs and cosmetics rules. He sought an update with respect to the state of play of the measure and to the intention to notify this draft in accordance with Articles 2.9.2 and 5.6.2 of the TBT Agreement. It was his delegation's understanding that, according to the existing regulation on cosmetics as currently applied in India, prior to importation, products needed to obtain a "non-objection" certificate from the Ministry of Health. To obtain this certificate, comprehensive information about the product had to be submitted.

201. Additionally, the representative of the European Communities noted that there would also be a requirement to register imported cosmetics. Registration would require disclosure of sensitive propriety information and would also imply delays until the imported cosmetics could be marketed in India. It was stressed that, according to the European Communities' preliminary assessment of this draft, the requirement for registration of cosmetic products would be overly restrictive and could be in contrast to the obligations of the TBT Agreement.

202. The representative of the United States shared many of the concerns raised by the European Communities. He noted that his delegation had sought to better understand the objectives and rationale of the proposed new regulations and, in particular, how the regulation requirements were expected to increase product safety for consumers. The concerns of US industry had been conveyed to the Indian authorities, in particular with regards to the perception that the measure would be overly burdensome and could result in costly delays. He also sought clarification on whether the measure would apply to all cosmetics entering the Indian market, imported or domestic sources, and that implementation would not solely target imports He appreciated the efforts made by the Indian delegation to discuss these issues and to convey these views to the Indian authorities and looked forward to further discussions.

203. The representative of India reiterated his delegation's commitment to comply with the principles of the TBT Agreement and stressed that the proposed registration requirement for cosmetic products would be notified at the earliest. The proposed registration requirements were intended to harmonize standards of imported cosmetic products with those applied to domestically products. He recalled that fruitful bilateral discussion had been held with both the European Communities and the United States and assured the Committee that the concerns expressed would be sent to the appropriate authorities in capital for due consideration. His delegation was ready to engage in further bilateral discussions in the future.

(xv) China – Administration on the Control of Pollution Caused by Electronic Information Products (G/TBT/N/CHN/140 and Add.1)

204. The representative of Japan sought clarification on the development process of the national standard for testing methods with respect to the measure above, and reiterated his delegation's hope that the standard would be notified in accordance with the TBT Agreement.

205. The representative of China stressed that the objectives of the measure were to protect the environment and human health, which were legitimate objectives as stated in Article 2.2 of the TBT Agreement. Regarding the relevant detection methods and standards, his delegation would fulfil the transparency obligation in the TBT Agreement.

(xvi) United States – Flammability of Clothing Textiles (G/TBT/N/USA/242)

206. The representative of China recalled that his delegation had submitted comments on the draft regulation on the flammability of clothing textiles, and raised concerns at the July 2007 meeting of the Committee. He recalled that in that meeting, the US delegation had said that the Consumer Products Safety Commission (CPSC) was considering China's comments in its review of the updated regulation. He sought information on whether the review had been finished, and how the Chinese comments had been taken into account by CPSC.

207. The representative of the United States recalled that at the July 2007 meeting, his delegation had explained that CPSC's intent was to update the language of a standard that had been drafted in 1952 to better reflect current practices and technologies, but the intention was not to alter the substantive provisions of the standard. It had also been noted that CPSC's work was at an early stage, and that the revisions were not expected to be imminent. His delegation would keep trading partners informed of developments.

(xvii) China – Draft standards on lithium batteries for mobile phones

208. The representative of Japan recalled that his delegation had raised concerns with respect to China's Ministry of Information Industry's draft lithium battery standards for mobile phones[17] and sought clarification on three issues. First, could China confirm that the standards would be voluntary? Second, could China confirm that, if the standards were to become compulsory, whether by taking off the "IT" suffix or by citation in a different law, these would be notified under the TBT Agreement? Third, while he welcomed the initiative of the Ministry of Information Industry to convene interested companies to provide inputs for a proposed generic safety standard of lithium batteries, he sought clarification about the relationship between such proposed safety standard and the draft standards for mobile phone batteries. Were the mobile phone battery standards still being considered separately from the generic safety standard of lithium batteries, or did one encompass the other? In concluding, he stressed the importance of transparency and harmonization with international standards.

209. The representative of the European Communities supported the comments made by Japan. He underlined that one of the aspects of the proposed standards was the definition of certain sizes and shapes for mobile phones and was of the view that the development of a parallel market of non-original batteries, which would be developed outside the direct control of the handset manufacturers, would entail a significantly higher risk of accident due to battery non-compliance. In turn, this was likely to raise complex issues pertaining to product liability in case of accidents arising from the use of handsets with a non-original battery. Handset manufacturers would not be able to guarantee the safety of the handsets when used with batteries that they had not supplied. China was invited to consider the implications of this proposed standard also from the point of view of product liability.

210. The representative of the United States shared the views of Japan and the European Communities, and sought a status report on the issue from China.

211. The representative of China noted that the standards were intended to protect the interests of consumers and the environment, as well as to promote a sound development of the industry. The

[17] See G/TBT/M/43, para. 161, in the context of the "Sixth Annual Transitional Review Mandated by paragraph 18 of the Protocol of Accession of the People's Republic of China."

standards were open for comments from all stakeholders and were still under discussion. The question on the generic safety standards for lithium batteries raised by Japan would be conveyed to relevant authorities in Beijing.

(xviii) Brazil - Registration requirements for medical devices

212. 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 above-mentioned measure, although his delegation still believed that Resolution 185 should have been notified to the WTO. One issue of concern was related to the difficulties with fulfilling the expansive information requirement as originally formulated and Brazil's efforts to address this, including through additional outreach to industry, were welcome. Nevertheless, he invited Brazil to take official action to clarify guidance for importers without delay. Greater clarity on the objectives of Resolution 185 would also be welcome, so that all involved parties could gain a sense of how those objectives could be met through this measure.

213. The representative of the United States further welcomed Brazil's receptivity to the suggestions made by US industry regarding their perceptions of the burden and uncertainty associated with this regulation. He invited Brazil to improve the ability of US industry to comply with the measure, while minimizing any unnecessary disruption to trade in medical devices through additional denials of commercialization.

214. The representative of the European Communities agreed with the points made by the United States. It was also his delegation's view that the measure should have been notified under the TBT Agreement. He 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.

215. The representative of Canada echoed the comments made and noted that Canadian industry was seeking clear, transparent and predictable guidance for importers.

216. The representative of Switzerland shared the concerns expressed and believed that, since the TBT Agreement was applicable to the Resolution, this should have been notified.

217. The representative of Brazil reiterated his delegation's position that the Resolution 185 was neither a technical regulation nor a conformity assessment procedure. He stressed that the definition of a technical regulation in the TBT Agreement and the Appellate Body decision in the EC Asbestos case[18] were illustrative of how to determine if a regulation was a technical regulation or not. A technical regulation had to be applicable to an identified product or group of products, define the characteristics of the product and determine that compliance with those characteristics was mandatory. While Resolution 185 was applicable to an identified group of products, it did not lay down any product characteristics that medical devices had to comply with. Resolution 185 only required producers to declare some economic information about medical devices.

218. The representative of Brazil stressed that Resolution 185 was not a conformity assessment procedure either, since it did not establish procedures to determine if medical devices fulfilled relevant requirements in technical regulations or standards as provided for in the definition contained in the TBT Agreement. Therefore, Resolution 185 was not covered by TBT provisions and did not need to be notified to the TBT Committee. He pointed out that the *Agência Nacional de Vigilância*

[18] *European Communities - Measures Affecting Asbestos and Products Containing Asbestos* (WT/DS 135/AB/R).

Sanitária (Anvisa)[19], had sought to ensure transparency in the process of elaboration and in the implementation of the measure. Public consultations were held, comments from companies and other stakeholders were taken into account, and time was given for companies to adapt to the new requirements. Representatives from the US, the EC, Canada and the private sector had also met with Anvisa to clarify remaining doubts. His delegation was ready to continue to provide clarification about the measure bilaterally to interested Members.

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

219. The representative of the United States welcomed the actions taken by the Thai authorities in response to the concerns raised, including postponing the implementation of the measure and issuing a revised regulation, as notified in G/TBT/N/THA/215.Add.1. His delegation had taken note of the response provided by the Thai FDA in January 2008 to questions and concerns raised by the United States 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".

220. Although the United States appreciated Thailand's efforts on these revisions and supported Thailand's goal of promoting a healthier citizenry, US industry continued to raise questions as to whether the measure was necessary in light of alternatives. In this regard, 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. Work should be directed towards appropriate and consistent schemes 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.

(xx) China – Domestic Gas Cooking Appliances

221. The representative of the European Communities noted that concerns remained on the proposed national standard on gas cooking appliances. It was his delegation's understanding that the amended standard would be implemented as of 1 May 2008 and he requested China to postpone its implementation until the issue was solved by means of bilateral talks with experts in Beijing. His delegation's main concern was that the requirements for minimum input of burners, as well as minimum temperature resistance of burners, which was set at a specific temperature, would exclude certain aluminium burners from the Chinese market which had been allowed so far. This would also lead to higher risks for the safety of the Chinese users and to an increase in the gas consumption. His delegation considered that the requirement as proposed was not sufficiently justified by a legitimate objective and would not be in line with Article 2.4 of the TBT Agreement.

222. The representative of China noted that his delegation had provided written replies to the European Communities and that comments, including those from other WTO Members, had been taken into account. For example, the revised standards eliminated redundant requirements as all parts and components of the burners had to be made of metal materials with melting point of 700°C. This was done with a view to incorporating the requirements of relevant EC standards and enabled adoption of new materials thereby encouraging innovation. For those comments that had not been accepted, a detailed explanation of the reasons had been provided. For example, with respect to the provision that the fire hole of burners should be made of materials that could withstand temperature over 700°C, he explained that this requirement was aimed at ensuring safe operation of intense fire for quick frying. This was a traditional Chinese way of cooking, so the fire hole was the hottest part of the burners and stricter requirement had to be adopted.

[19] www.anvisa.gov.br

(xxi) Moldova - quality and control measures for bottled, non-alcoholic beverages including mineral, natural water and soft drinks (G/TBT/N/MDA/13)

223. The representative of the European Communities thanked Moldova for taking into account the comments made by her delegation and for amending the draft measure, which would only cover domestic soft drinks, thereby eliminating any restrictions on imported goods.

C. EXCHANGE OF EXPERIENCES

1. Good Regulatory Practice

224. The Chairman reported on the Workshop on Good Regulatory Practice held on 18-19 March 2008 (Annex 1, below).[20]

225. The representative of Egypt said his delegation appreciated the wealth of information provided at the workshop. He suggested a mechanism be established to enhance exchange of information on good regulatory practice, including between developed and developing countries.

226. The representative of the United States noted one of the main lessons learnt at the workshop was that all Members, regardless of their level of development, needed to continue to advance in the area of good regulatory practice. He drew the Committee's attention to a paper submitted by his delegation on Determining the Need to Regulate (G/TBT/W/285).

227. The various sections in the paper dealt with: identification of the need for a regulation; consideration of legal requirements (including the TBT Agreement); consideration of alternatives; risk assessments; cost-benefit analyses; and, the continual reassessment of need during the regulatory process. The paper also contained a useful list of questions that US regulators asked when determining whether or not to regulate and also provided illustrations involving airbags, child restraints on aircrafts, trees in flight paths and the impact of considering the body's biorhythms in determining safety. The representative of the United States invited comments on the paper and hoped it would stimulate a productive discussion as the Committee entered the Fifth Triennial Review of the TBT Agreement.

228. The representative of Canada noted that much interest had been expressed in the various elements of good regulatory practice, including on Regulatory Impact Assessment (RIAs). Her delegation believed that further discussions in the Committee could be useful. For example, discussions could focus on a better understanding of how RIAs were prepared and how international trade obligations were addressed in RIAs.

229. The representative of the European Communities believed that the workshop had contributed to furthering the Committee's discussions on good regulatory practice, particularly in view of the Fifth Triennial Review. His delegation particularly appreciated the participation and interest taken by developing countries, which, he said, showed that efforts had been undertaken to develop good regulatory practice. Good regulatory practice could become a standing item of technical assistance and his delegation would explore this issue further.

230. The representative of the European Communities said that the workshop had highlighted that there were several facets of good regulatory practice. Some aspects related to the tools to identify the need for regulation and how to ensure transparency, openness and accountability of the process; other

[20] 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

aspects pertained to the intrinsic quality of legislative texts of regulations. Discussions on referencing standards in technical regulations could be continued within the framework of the Fifth Triennial Review.

231. The representative of Zimbabwe welcomed the support provided through the DDA Global Trust Fund and arrangements made to enable developing country Members to attend the workshop. Developing countries were at various stages of implementing the TBT Agreement and the information gathered during the event would help improve regulatory practices.

232. The representative of Senegal supported the comments made by Zimbabwe, adding that capacity building for developing countries was particularly important in the area of good regulatory practice.

2. Conformity Assessment Procedures

233. The representative of Singapore noted that, with reference to Article 6.3 of the TBT Agreement, a multilateral Mutual Recognition Agreement (MRA) on electrical and electronic equipment involving all member countries of the Association of South East Asian Nations (ASEAN) had been developed in year 2000, signed in 2002 and successfully implemented in 2004. The MRA involved issues such as the IECCB Scheme and ILAC and IAF multilateral arrangements on accreditation of testing laboratories and certification bodies. Through the MRA, regulatory bodies of ASEAN countries mutually accepted tests reports and certification by designated conformity assessment bodies, thereby eliminating re-testing and re-certification and improving market certainty. ASEAN was building on this MRA with a view to harmonizing the different regulatory regimes affecting electronic equipment and an ASEAN Electric and Electronic Equipment Agreement had been signed in December 2005. Through this Agreement, Member countries had committed to amend legislation and to put in place a harmonized regime so as to achieve one standard, one test, one certification accepted by all by December 2010.

3. Technical Assistance

234. The Chairman recalled that at its November 2007 meeting, the TBT Committee had a constructive exchange of experiences based on a document submitted jointly by Canada and Costa Rica (G/TBT/W/283). The Committee also heard from UNIDO regarding needs assessment (G/TBT/GEN/63). Discussions held in the context of the Workshop on Good Regulatory Practice were also useful from a training and capacity building perspective: it was valuable to know how other Members were implementing the TBT Agreement.

235. The Chairman further stressed that the Committee attached importance to technical assistance. The 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. The Committee's attention was drawn to a proposal submitted by the United States contained in document Job(08)/15, which related to some of the recommendations contained in the Fourth Triennial Review.

236. The representative of the United States recalled that, at the November 2007 meeting of the Committee, her 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. Introducing the US proposal contained in Job(08/15), the representative of the United States said her delegation recommended a practical approach to examining the role of

international standards in economic development. In this regard, the paper proposed to use case studies to examine avenues through which relevant international standards had improved quality of products, solved specific regulatory problems or facilitated trade in new markets.

237. The representative of the United States 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. There were many experts involved in developing international standards that could convey the technical aspects of their work on a specific product standard in the context of the larger global market dynamics, giving Members new perspectives on the intersection of standards, trade and development. It was her delegation's hope that the Committee would find this contribution to be a constructive one, which could take Members into a deeper dialogue on the shared work in achieving the objectives of the TBT Agreement.

238. The representative of Malaysia welcomed the proposal from the United States and highlighted that low participation of developing countries in international standardization had been raised in past triennial reviews and remained a concern. This issue should be an element in future work that the Committee would undertake.

239. The representative of Egypt believed the paper put forward by the United States raised some important questions that needed to be further developed and analyzed. He shared Malaysia's concerns on the low participation of developing countries in international standardization activities and said the Committee should discuss the issue.

240. The representative of the European Communities said that the proposal from the United States was a useful contribution to furthering the Committee's work on technical assistance; it aimed at implementing an item of Future Work from the Fourth Triennial Review. His delegation would further discuss the proposal and submit comments, including on the workshop programme and identification of experts who could contribute to the event.

241. The representative of Canada said the United States' proposal provided an opportunity for Committee members to engage in a constructive discussion. The case study format and the idea to focus on sectors of interest to developing countries was well suited to providing useful information on available technical assistance. Canada looked forward to contributing to the further development of the workshop.

242. The representative of Japan supported the proposal from the United States. Some points of particular interest were: increasing participation in standards-setting organizations; and, the role of regional standardizing bodies. His delegation would be willing to make a presentation at the workshop, should the Committee proceed with the event.

243. The representative of Korea supported the proposal from the United States. Many international standard-setting organizations had accumulated much experience and know-how and it would be useful to discuss their work. More specific comments would be provided in due course.

244. The representative of China welcomed the proposal. His delegation would refer it to capital and also encourage its consideration by standardizing organizations.

245. The representative of Malawi welcomed the proposal from the United States and agreed with the points made by Malaysia and Egypt on low participation of developing countries in international standardization work.

246. The representative of Chile supported the idea of a workshop as her delegation was convinced of the importance of standards for development. The case studies format was very useful, as concrete problems could be analyzed and this would enable countries to participate in the activities of international standardization bodies.

247. The representative of Brazil said his delegation was analyzing the proposal and comments would be provided in the future.

248. The representative of Colombia supported further work on the proposal from the United States. He agreed with others as to the importance of developing countries' participation in activities of international standardizing organizations. His delegation had had concerns in some instances as to the way discussions were handled and how determination of consensus in international standardizing bodies had been reached.

249. The representative of Chinese Taipei looked forward to participating in the workshop, if the proposal was adopted by the Committee.

250. The representative of Cuba supported the idea of a workshop and said more comments would be provided. The questions put forward by the United States in Job (08)/15 should be further analyzed by the Committee in light of the interest of all Members.

251. The representative of the Central African Republic believed that United States' proposal would be beneficial to his country, where standardization activities were at an early stage of development.

252. The representative of Antigua and Barbuda stressed the importance of looking at information already available, and see how to move forward from there. There had already been workshops on this issue that produced reports and on which there had been no follow-up. Therefore, there should be commitment to follow-up on recommendations from previous activities.

253. The representative of UNIDO informed the Committee that his organization was involved in related technical assistance activities and would look into the possibility of supporting developing countries to share their experiences and actively participate in the workshop.

254. The representative of the United States thanked Members for their support and expressed understanding in respect of the point made by Antigua and Barbuda. The idea was to use case studies of best practices and success stories to show paths that might be taken by all developing countries and organizations, in terms of finding solutions and making standardization an engine for growth in global trade.

D. OTHER MATTERS

(i) Management of Toy Safety – Statement by China

255. The representative of China introduced China's export toy quality and safety control system. Toys were products largely used by families and quality and safety were thus particularly important. With global economic integration and international labour division, toys were traded all over the world. The combination of technical advantage of developed country Members in toy design and labour advantage of developing country Members in manufacturing brought mutual benefits and the common prosperity that the WTO multilateral trading system was pursuing.

256. China was a main toy producer and exporter in the world. With around 90 million pre-school children, China was also itself a big market for toys. China attached great importance to toy quality

and safety control, and an effective management system had been established following efforts over some years. Bearing in mind that 80 per cent of Chinese exported toys were made for original equipment manufacturer, the so-called OEM, the representative of China stressed that his delegation believed that made-in-China toys should always enjoy high quality and safety.

257. First, there existed the legal framework and technical standards to ensure that toys products were safe for all users, children or adults. China had adopted relevant ISO and IEC standards in the toy sector. Second, a sound conformity assessment system guaranteed that all export toys met relevant requirements of the destined market. Export toys had been listed as a compulsory inspection commodity, and toys failing to meet the required standards could not be exported. From 1 June 2007, China's Compulsory Certification System had been applied to six types of toys including electronic toys, dolls and plastic toys. China had also established strict inspection systems, including "Export Toy Quality Registration System", "Export Toy Enterprises Classified Management System" and "Export Toy Routine Monitoring and Inspection System". These systems ensured that toy manufacturers set up production process quality and safety control systems. In case unqualified toys were found, the related enterprises had to correct the problems before their products could regain the qualification of exportation.

258. The representative of China further noted that in 2007, to further increase the safety and quality level of China's export toys, AQSIQ had organized site visits to all 3540 export toy producers in China, and established a registration system for qualified toy paint suppliers. AQSIQ had five professional toy testing centres located respectively in Yangzhou, Guangdong, Shenzhen, Shanghai and Beijing, all of which were accredited by international accreditation organizations. The certificates and testing reports issued by these testing centres were widely accepted all over the world. Other toy exporting regions were also equipped with toy testing laboratories and professional inspectors. The representative stressed that China had the ability to provide quality and safe toys and would continue its efforts in this respect.

(ii) NAMA negotiations

259. The representative of Peru encouraged representatives in the TBT Committee and capital-based officials in charge of TBT to step up their coordination with officials in their capitals working on the NAMA negotiations.[21]

III. THIRTEENTH ANNUAL REVIEW OF:

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

260. The Committee adopted its report of the Thirteenth Annual Review of the Implementation and Operation of the TBT Agreement under Article 15.3 (G/TBT/23).

B. THE CODE OF GOOD PRACTICE FOR THE PREPARATION, ADOPTION AND APPLICATION OF STANDARDS IN ANNEX 3 OF THE TBT AGREEMENT

261. The Chairman introduced the Thirteenth Edition of the WTO TBT Standards Code Directory prepared by the ISO/IEC Information Centre. He also drew the Committee's attention to two lists prepared by the Secretariat. The first (G/TBT/CS/1/Add.12) compiled the standardizing bodies that had accepted the Code of Good Practice in the period under review and the second

[21] Subsequent to the TBT Committee meeting, the Second Revision of the Draft Modalities for Non-Agricultural Market Access was issued. This document contains, in Annex 5, the latest set of NTB textual proposals (TN/MA/W/103/Rev.1).

(G/TBT/CS/2/Rev.14) compiled all the standardizing bodies that had accepted the Code since 1 January 1995.

262. The Committee took note of this information.

IV. TECHNICAL CO-OPERATION ACTIVITIES AND UPDATING BY OBSERVERS

263. The representative of UNECE updated the Committee on work of the UNECE Working Party 6 on regulatory cooperation and standardisation policies. Working Party 6 was an intergovernmental group of experts focusing on trans-national regulatory cooperation. The representative explained that the "International Model for Technical Harmonization" comprised a set of voluntary mechanisms and principles for good regulatory practices that could be used by countries to align their regulatory regimes in specific sectors, product areas or geographic regions. Five new initiatives were under way in the international model for regulatory cooperation, on (i) Explosive Environment Equipment; (ii) Oil and Gas Pipeline Safety; (iii) Telecoms; (iv) Earth Moving Equipment; and (v) CIS Regional Initiative.

264. It was emphasised that these initiatives enjoyed broad participation and that Working Party 6 was open to all UN member states and non-government organisations approved by UN ECOSOC. Members of the TBT Committee were also welcome to participate in the work. The annual session of Working Party would be held in November 2008. Following a request from Kenya, two additional panel sessions would be organized on private standards.

265. Other relevant activities included the use of market surveillance infrastructure as a complementary means to protect consumers and users against counterfeit goods. It was noted that relevant information on these items as available on UNECE website[22].

266. The representative of the ITC recalled a proposal made at the Fifth Special Meeting on Procedures for Information Exchange on a coaching program for national enquiry points.[23] "Coaches" would be the experienced managers of national enquiry points in developed or more advanced countries and the "coached staff" would be the staff of less advanced national enquiry points in developing and least developed countries. He invited delegations who were interested in this program to provide written expressions of interest and recalled that some delegations had indicated their willingness to act as coaches and share their experiences and know-how in information dissemination services.

267. The representative of UNIDO highlighted three issues. First, four needs assessment case studies were being finalized. Second, in relation to conformity assessment and discussions about REACH, UNIDO was working on a EC-funded project in Thailand for upgrading chemical laboratories in order to comply with REACH requirements. Third, UNIDO had developed, with the support of the Government of Austria, a chemical leasing business model approach.

268. The representative of IEC updated the Committee on the relevant activities undertaken by her organization (G/TBT/GEN/68).

269. The representative of Codex provided information on activities of the Codex Alimentarius Commission (G/TBT/GEN/69).

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[22] www.unece.org
[23] See G/TBT/M/43, Annex I para. 89-98. See also G/TBT/M/43, Corr.1.

V. DATE OF NEXT MEETING

270. The next regular meeting of the Committee will take place on 1-2 July 2008.

ANNEX 1
REPORT BY THE CHAIRMAN ON WORKSHOP ON GOOD REGULATORY PRACTICE

Report by the Chairman (Mr. Raiminder S. SIDHU)
at the Regular Meeting of the TBT Committee of 20 March 2008[1]

1. At the Fourth Triennial Review of the TBT Agreement, concluded in November 2006, the TBT Committee agreed to share experiences on a number of aspects relevant to good regulatory practice with a view to deepening understanding of the contribution good regulatory practice can make to the implementation of the TBT Agreement. In this regard, a Workshop on Good Regulatory Practice was held at WTO Headquarters on 18 and 19 March 2008. Participation of 102 capital-based officials from developing countries was sponsored through the WTO Global Trust Fund.

2. Discussions at the Workshop were held in four panel sessions dealing with: general approaches of Members to good regulatory practice when implementing the disciplines of the TBT Agreement (Session 1); internal transparency and consultative mechanisms (Session 2); regulatory impact assessment (Session 3); and regulatory cooperation initiatives between Members (Session 4). The final programme is contained in document G/TBT/GEN/67/Rev.1 and a background note by the Secretariat is in document Job(08)/7.

3. A key message in the First Session – and one that recurred throughout the two days – was the importance of established processes and procedures as a means of giving effect to good regulatory practice. In other words, although there are many different ways of implementing the TBT Agreement, having a basic process backed by some form of legal instrument (such as a Decree in Chile, a Guide in Brazil, Acts or Executive Orders in the United States) can strengthen efforts to integrate good regulatory practice into Members' regulatory structures.

4. In the first session participants also discussed ways to reference standards in technical regulations, based on the Canadian experience, and several issues were raised in this regard, including: the advantages (and potential challenges) of directly referencing standards in legislation; the cost of using the standards; and how to adapt a standard to fulfil the legitimate objective of the regulatory measure. Some Members pointed at constraints for developing countries, such as difficulties in demonstrating compliance with standards – particularly in cases where accreditation infrastructure is lacking.

5. In the Second Session, it was observed that transparency, openness and accountability are relevant to many, if not all, aspects of good regulatory practice. The Session focussed particularly on mechanisms to enhance transparency in the development stage of proposed regulations. Benefits were highlighted. It was stressed, for instance, that participation by stakeholders helps ensure legitimacy to what the government does and the measures it chooses to implement. Consultative processes enhance predictability and clarity providing certainty for traders and also helps to increase awareness about government actions. There are challenges as well and sometimes traps that need to be avoided. It is important, for instance, that consultative processes are not dominated by particular interest groups. As well, consultation should *not* be considered by regulators as a burden but rather as an instrument that adds legitimacy to regulatory decision making.

[1] A Summary Report of the Workshop on Good Regulatory Practice is contained in G/TBT/W/287.

6. The Third Session focused on how regulatory impact assessments can assist decision-making. As was stated by one participant: a regulatory impact assessment induces governments to think harder about how to solve problems; it is a decision-making *tool*. One important benefit of RIAs is that they facilitate the identification of the need for regulation. In this regard presenters stressed the importance of considering alternatives - and, perhaps, reconsidering the need for regulation in the first place. It was noted that RIAs do not need to be complex, they can be flexible and adaptable in nature. When functioning well, they can help filter the flow of new regulations and help ensure that these are less likely to create trade problems. It was also pointed out that because regulatory impact assessments are public, they boost accountability. In this sense, again, RIAs are also a tool for transparency. Finally, attention of participants was also drawn to the APEC-OECD Integrated Checklist on Regulatory Reform.

7. In the Fourth Session participants heard a number of examples of regulatory cooperation activities between Members. Many factors – all regarded as important to fostering cooperation between Members – were highlighted, including: promotion of dialogue (including at senior level); acting early to avoid trade problems before they arise; and providing resources to support cooperation and political commitment. It was pointed out that a fundamental component to regulatory cooperation is confidence-building: personal contacts are also essential. Cooperation also has a capacity building component in that it helps build up understanding of different systems thereby contributing to the convergence of regulations.

8. Looking back on the two days of the Workshop, one general message stands out: regulation is a legitimate part of government activity and a major and increasingly important policy tool of government today. Emphasis has shifted somewhat from de-regulation to "smart" or "better" regulation – it is the quality of regulation that matters. And this process of becoming better at regulating is an ongoing process – for *all* Members. In other words, although at different levels, all Members face challenges. There is scope here for Members to learn from each other in this regard and I can only encourage continued exchanges in this area between Members.

9. Let me again thank participants to the workshop for their engagement. I believe the discussions over the last two days have significantly contributed to deepening Members' understanding of the contribution good regulatory practice can make to the implementation of the TBT Agreement.