

# WORLD TRADE ORGANIZATION

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Committee on Technical Barriers to Trade

## MINUTES OF THE MEETING OF 18-19 MARCH 2009

Chairperson: Ms Xueyan GUO (China)

Note by the Secretariat<sup>1</sup>

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<sup>1</sup> 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.

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## I. ADOPTION OF THE AGENDA

1. The Chairperson announced that, under Agenda item 8, "Other Business", she would address the process initiated, in February 2009, by the Trade Policy Review Body regarding transparency and the monitoring of recent trade developments associated with the current global financial and economic crisis. She drew the Committee's attention to an exchange of letters with the Chairman of the General Council, Ambassador Mario Matus.

2. The Committee adopted the agenda contained in WTO/AIR/3322.

## II. IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

### A. STATEMENTS FROM MEMBERS UNDER ARTICLE 15.2

3. The Chairperson recalled that latest list of statements submitted under Article 15.2 of the TBT Agreement was contained in document G/TBT/GEN/1/Rev.8, issued on 2 March 2009. Since the last meeting of the TBT Committee, revisions of their original statements had been submitted by Peru (G/TBT/2/Add.29/Rev.2) and Viet Nam (G/TBT/2/Add.98/Rev.1), while El Salvador had submitted a supplement to its original statement (G/TBT/2/Add.78/Suppl.1). In total, since 1995, 117 Members had submitted at least one Statement on implementation under Article 15.2. It was noted that the latest list of enquiry point contacts was contained in document G/TBT/ENQ/35/Rev.1, issued on 11 March 2009.<sup>2</sup>

4. The Committee took note of the information provided.

### B. SPECIFIC TRADE CONCERNS

#### 1. New Concerns

##### (i) *India - Mandatory Certification for Steel Products (G/TBT/N/IND/32)*

5. The representative of Japan raised a concern regarding India's mandatory certification measures for iron and steel products which had been announced by the Indian Government on 9 September 2008. Some of the measures, contained in a First Order relating to six items, were put into effect three days after their announcement, while a second set of measures, contained in a Second Order covering 11 items, would become effective on 12 February 2009. The Japanese delegation appreciated that the Indian Government decided to postpone the implementation of the Second Order for one year after the European Communities, Korea and Japan had expressed significant concerns regarding these measures. However, his delegation was of the view that substantial concerns remained in terms of their consistency with the TBT Agreement, in particular with Article 2.2.

6. The Japanese delegate noted that the two Orders had not been notified to the WTO, although the Indian Government had acknowledged its obligation to do so. Furthermore, he pointed to the risk of the measures creating unnecessary obstacles to international trade, as they might be more trade-restrictive than necessary to fulfil a legitimate objective. He called upon the Indian Government to make efforts to find constructive solutions, including taking into consideration the withdrawal of the measures.

7. The representative of Korea shared the concerns raised by Japan. His delegation expected that Indian authorities would provide the relevant information on certification procedures for

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<sup>2</sup> Regularly updated information on Members' enquiry points is also available on the WTO TBT webpage: [http://www.wto.org/english/tratop\\_e/tbt\\_e/tbt\\_enquiry\\_points\\_e.htm](http://www.wto.org/english/tratop_e/tbt_e/tbt_enquiry_points_e.htm).

exporters, recognize testing reports issued by Korean testing laboratories and facilitate the mutual recognition of certificates of conformity. He also expressed his delegation's appreciation of the decision by the Indian authorities to delay by one year the implementation of the compulsory certification for steel products.

8. The representative of the European Communities shared the concerns expressed by Japan and Korea. She pointed out that the Indian regulations established new requirements which were different from those notified in 2007 under G/TBT/N/IND/32 and also differed from international standards. Moreover, the European Communities was concerned about differences in treatment for domestic and foreign manufacturers. The representative of the European Communities requested the Indian delegation to clarify whether and when India would notify these new requirements to the WTO.

9. The representative of India said that he would check details with the concerned authorities in capital. However, he confirmed that the Indian authorities had decided to postpone the implementation of the Order for one year, thus removing the scope for any immediate concern. He assured the Committee that the comments of all concerned trading partners would be taken into account before the final implementation of the measure.

(ii) *Indonesia - Mandatory Certification for Steel Products (G/TBT/IDN/23-24)*

10. The representative of Japan raised a concern regarding Indonesia's mandatory certification system for steel and steel products. On 6 January 2009, two ministerial decrees had been published that had made compliance with certain Indonesian National Standards (SNI) mandatory. These covered hot-rolled steel sheets and coils, for which mandatory standards would be put into effect on 6 May 2009, and zinc-aluminium-coated steel plates, for which mandatory standards would enter into force on 6 July 2009. Japan considered these measures as a technical regulation which could have a significant effect on trade of other Members and therefore requested Indonesia, in accordance with Article 2.5 of the TBT Agreement, to explain the justification of these measures in terms of the provisions of Articles 2.2 to 2.4 of the TBT Agreement. He requested Indonesia to make continuous efforts to find constructive solutions regarding Japan's concerns, including considering preferential treatment of foreign manufacturers.

11. The representative of Korea welcomed the withdrawal by Indonesia of the implementation of mandatory SNI certification for zinc-coated steel sheets, notified under G/TBT/N/IDN/17 last year. However, he shared the concerns raised by Japan regarding the new compulsory certification measures for certain steel products. He suggested that Indonesia grant a grace period which would allow trading partners to prepare for the certification, to accept test reports issued by Korean laboratories, and to exclude certain products from the regulation, in particular steel sheets used for automobiles. He also suggested that bilateral discussions on this issue be intensified.

12. The representative of the European Communities noted that Indonesia had notified two decrees that rendered certain Indonesian national standards mandatory on 23 February 2009 with the reference G/TBT/N/IDN/23 and 24. She asked if these notifications covered the same issues addressed by Japan and Korea. She also observed that the notifications did not mention any final date for comments nor any explanation as to why such a date could not be mentioned. She requested Indonesia to clarify if the notified measures had already been adopted and on which international standards the Indonesian standards were based.

13. The representative of Chinese Taipei associated her delegation with the comments made by Japan, Korea and the European Communities. She also stressed that the notification circulated on 23 February 2009 did not provide any period for comments. She expressed particular concern about the early entry into force of the measure and the contradictory requirements in SNI standards. She requested Indonesia to provide a period for comments on the notified regulations of not less than 60

days and to provide for an interval of not less than six months between the publication of the measure and its entry into force, so that producers would have sufficient time to adapt to the new requirements, as specified in the Ministerial Decision on Implementation-related issues and concerns adopted on 14 November 2001 (WT/MIN(01)/17) with regard to Article 2.12 of the TBT Agreement. The representative announced that Chinese Taipei would submit comments in writing and urged Indonesia not to adopt the notified measures before concerns were fully resolved.

14. The representative of Indonesia took note of the concerns raised which would be communicated to the capital. He pointed out that Indonesia had held constructive bilateral discussions with Japan and Korea, during which steps to resolve the issue had been identified. His delegation was open to further discussions with all delegations concerned.

*(iii) Thailand -Mandatory Certification for Steel Products*

15. The representative of Japan expressed concerns about Thailand's new criteria for conformity assessment with mandatory standards for steel products which had been put into effect by the Thai Industrial Standard Institute (TISI) on 26 January 2009. It appeared that TISI had abolished these criteria as of 4 March 2009 and released different criteria at the same time which would become effective on 1 May 2009. It had also been announced that TISI would release detailed guidelines in April 2009 after hearing from the relevant private sector stakeholders. The Japanese representative maintained substantial concerns in terms of the new criteria's consistency with the TBT Agreement. The new criteria would still require importers and foreign producers to bear a heavy burden for product certification, as they would be required to provide a number of documents certifying conformity with the mandatory standard, allow TISI to conduct sampling tests for every shipment, and undergo annual TISI factory and facility inspections. He pointed out that the new criteria could potentially create unnecessary obstacles to international trade. He therefore requested Thailand to make efforts to find constructive solutions, including considering withdrawing the measure.

16. The representative of Korea shared the concerns raised by Japan and also urged Thailand to reconsider the measure. More generally, Korea expressed serious concerns regarding some Members' tendency to implement their conformity assessment procedures in a trade-restrictive manner, in response to the downturn of the world economy. Such actions could create a harmful effect on world trade and delay the recovery from the economic crisis further. The Korean representative therefore urged all Members to fully comply with Article 2.2 of the TBT Agreement, which stipulated that "Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective."

17. The representative of Thailand pointed out that TISI's new criteria for certification, which would be effective as of 1 May 2009, were the same in principle as the previous criteria, and only minor changes had been made with the objective of ensuring quality and consumer confidence in products. He highlighted that the new criteria would be applicable to all products of all origins, and thus adhered to the principle of equal treatment for importers and local manufacturers. Nonetheless, importers would enjoy special treatment, as they would have an additional choice for demonstrating compliance. Furthermore, he said that the revised certification criteria observed ISO 9001, as well as ISO/IEC Guides 65 and 67. On 9 March 2009, TISI had held consultations with interested parties, and over 2000 local and foreign representatives participated. A revision had been notified to the WTO.

18. With regard to the specific concerns that had been raised, the Thai representative clarified that the requirement to provide documents would essentially deal with the quality management system ISO 9001. As this system was usually implemented and documented by manufacturers, this should not pose any additional burden for those already in compliance. On shipment sampling, he noted that

TISI would only conduct visual and document inspection. Product sampling for tests would only be necessary when there was an indication of non-conformity or violation. Importers would have the choice of demonstrating compliance through either site visits or importer inspection, while in the case of local manufacturers, an annual visit of the factory was required. Additionally, he noted that the new criteria were still open for review and assured the Committee that Thailand would inform all relevant stakeholders should an additional review become necessary.

(iv) *Malaysia - Conformity Assessment Procedures for Steel Products*

19. The representative of Japan raised a concern regarding the procedure for assessing conformity of steel products with Malaysian mandatory standards that was introduced by Malaysia on 15 November 2008. He said that these measures effectively made it impossible for imports of the 57 steel products concerned to clear Malaysian customs without an excessively cumbersome conformity assessment procedure. Consequently, these measures created *de facto* trade obstacles in terms of stagnant freight distribution and additional fees for storage. As the stated purpose of the new measure was to ensure the safety of steel products for construction use, he suggested that they should be applied only to steel products for such use. He called upon Malaysia to ensure that the new measure be fully consistent with Article 5.1.2 and other Articles of the TBT Agreement and to make efforts to seek constructive solutions to address Japan's concerns, including the consideration of withdrawal of the measures.

20. The representative of Malaysia took note of the concern and would forward it to relevant authorities in the capital as soon as possible for consultation and appropriate action. In the meantime, his delegation would welcome bilateral discussions with Japan on this issue.

(v) *EC - Seal products (G/TBT/N/EEC/249)*

21. The representative of Norway raised a concern about the European Communities' notification G/TBT/N/EEC/249 concerning trade restrictions for seal products. This measure would heavily impact on Norway's trade in seal products, both to the European Communities and transiting through the European Communities to other markets. She noted that the Internal Market Committee of the European Parliament had recently adopted a version of the proposed regulation which was different from the Commission proposal notified to the WTO and would further expand the trade ban. She expressed doubts as to the WTO consistency of both versions. On the original proposal from the European Commission as notified to the TBT Committee, she noted that it contained a ban on imports that did not follow product-related criteria. Instead, exceptions were based on non-product-related process and production method requirements (PPMs). Trade would only be permitted under this proposed regulation if the hunt was performed in a specific way according to criteria determined unilaterally by the European Communities and products would be subjected to labelling. She questioned whether this approach was permissible under Article 2 and Annex 1 of the TBT Agreement. While the Norwegian representative stressed that technical regulations could be based on legitimate environmental concerns, she believed that environmental concerns were not the objective as seal populations were not threatened. Therefore, she questioned whether governmental regulations that distinguish two otherwise like products, based on ethical concerns relating to the way that they were produced, could fulfil the requirements of Article 2.2 of the TBT Agreement.

22. As far as the proposal from the European Parliament was concerned, the Norwegian representative noted that it constituted an out-right ban on seal products except where the hunt was performed by Inuits. While she agreed that the traditional lifestyle of a particular coastal indigenous group should be safeguarded, she pointed out that the traditional seal hunt of other coastal populations should be equally protected. Banning the trade in products hunted by coastal populations living outside the European Communities, while allowing trade in products hunted by coastal populations living within the European Communities could contravene the international obligations of the

European Communities. She also noted that the ban proposed by the European Parliament would have exceptions for "small scale hunting". She highlighted the fact that the proposed regulation - in both versions - claimed that the ban and exceptions were justified under the "public morals exception" in Article XX(a) of the GATT 1994. However, Norway questioned how a ban with exceptions that were based on the persons that hunted and the number of animals that they hunted, rather than the hunting methods, could fulfil the ethical objectives.

23. The representative of Norway further asked the European Communities to explain how a ban on the transit of products through the European Communities could be justified based on consumer perceptions within certain EC member States. She concluded that, as the Norwegian seal hunt was performed to the highest ethical and animal welfare standards, a ban on imports of seal products into the European Union, and on transit through the European Union, could set a dangerous precedent for trade in animal products that were harvested in a sustainable and ethical manner. She also noted that seal products competed in the EC market with products from other animals, such as deer and boar, that were hunted within the European Communities without being subject to the same strict restrictions. She urged the European Communities to ensure that should any regulation be finally adopted, it be fully consistent with the international obligations of the European Communities. She stressed that Norway would have to consider appropriate action under the WTO should its harvest of its natural resources be impeded by unjustified restrictions.

24. The representative of Canada shared the concerns raised by Norway. She commented that, if the regulation that was notified by the Commission was adopted, the European Communities would be unilaterally establishing criteria for animal welfare, not only for products entering their territory, but also for products being transported through its territory. If, on the other hand, the version of the regulation put forward by the Parliamentary Committee was adopted, the European Communities would be prescribing how and for what purposes Inuit communities may use seal products. Both approaches were unacceptable to Canada. In either form, the regulation would be both unnecessary and inconsistent with the WTO TBT Agreement as well as with the EC's own legislation. She pointed to testimonies from Inuit communities as to the damaging effect of the proposed measures and to studies undertaken by the EC which had shown seals could be - and were - killed humanely. She therefore urged the European Communities to reconsider the proposed measure and highlighted that Canada continued to reserve its right to take any appropriate action to defend its rights and interests under the TBT Agreement and other relevant WTO agreements, and would consider all options available to it so as to protect the livelihood of coastal and northern Canadians and their families.

25. The representative of Iceland shared the concerns raised by Norway and Canada.

26. The representative of Brazil asked that the European Communities provide clarifications on the ban on the transit of products through the European Communities.

27. The representative of the European Communities explained that the proposal was notified to the Committee at the request of Norway and Canada at the previous Committee meeting. While the European Communities had done so to ensure transparency, her delegation did not consider this proposal to fall within the scope of the TBT Agreement and therefore believed that it is was not appropriate to discuss it in the TBT Committee. She underlined that her delegation had been in contact with the interested parties on this proposal early in the drafting process and was willing to pursue these bilateral discussions. She noted that the regulation was still in the early stages of the legislative process, as the European Parliament would still have to adopt its position in a plenary session in early April, and the Council likewise. The Commission would only then give its opinion on the suggested amendments. She invited interested Members to submit their comments by the end of the comment period of 11 May 2009.

(vi) *China - Quality Assessment System for Imported Cotton (G/TBT/N/CHN/336)*

28. The representative of the United States raised concerns regarding China's registration and quality assessment system for cotton which was established by Announcement No. 87 on "Administration Measures for the Registration of Overseas Cotton Exporters" of 5 August 2008 and the related "Circular on the Issuing of Administrative Regulations on Quality Credit Assessment of Overseas Cotton Exporters" published on 28 November 2008 by China's Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). He pointed out that the system appeared to be inconsistent with international practice, by establishing a government-run scheme to grade foreign exporters of cotton to China, while in other countries cotton quality was not addressed by the government, but by commercial parties through international contracts and commercial arbitration regimes. Furthermore, the means by which Chinese Government inspectors would assess the quality of imported cotton appeared to diverge from international testing and assessment methods, as well as from the testing and assessment methods used for domestic cotton.

29. The US representative further highlighted that China would assign foreign cotton suppliers a downgraded "B" or "C" rating when government inspectors identified deficiencies in cotton quality or weight in light of contract terms that include cotton quality standards. His delegation was particularly concerned about the fact that such lower ratings could be assigned to an exporter based on a single incident and based on a small and likely unrepresentative sample. AQSIQ had not clarified whether it would publicize cotton exporter ratings, but doing so would risk to unfairly damage the reputation of foreign suppliers. Moreover, it was noted that, while the quality grading system provided an opportunity to appeal a "B" or "C" rating, such an appeal could only be made to the same entity that had issued the initial grade with no opportunity for appeal to an independent entity.

30. Further, the representative of the United States called into question whether registration was effectively voluntary, as claimed by China. He pointed to the fact that exporters that did not register were subject to pre-shipment inspection and were automatically assigned a "C" rating. He also reported that Chinese cotton mills had been refusing to do business with US producers that were unregistered. He suggested that registration could therefore be *de facto* mandatory. Additionally, the United States was concerned that the registration and rating system required the disclosure of confidential business information relating to the trading volume, value, and history of an exporter's business in China, while this information was not sought from domestic cotton producers. He requested that China explain its objective in requiring such information.

31. The representative of the United States also stressed that AQSIQ's registration and quality assessment system seemed to apply only to imported cotton, whereas domestic cotton was not subject to a similar registration or quality assessment system. This provided unequal competitive conditions for imported cotton compared to domestic cotton. He expressed concern that Chinese purchasers of cotton would view imported cotton from a "B" or "C" rated exporter as inferior to cotton from Chinese producers which were not subject to such a rating system. He noted that no other country penalized foreign cotton exporters based on quality or contract performance. He requested clarification from China on the issues raised and suggested a six-month suspension of the measures which had already come into effect on 15 March 2009, so as to provide an opportunity to engage in a dialogue on a workable solution to address China's objectives in a manner consistent with global practices. Furthermore, he requested that China notify the 28 November 2008 "Circular on the Issuing of Administrative Regulations on Quality Credit Assessment of Overseas Cotton Exporters" to the WTO, in order to give Members the opportunity to present comments in writing and provide China an opportunity to make appropriate modifications to its proposed regulations reflecting these comments.

32. The representative of Australia shared the concerns raised by the United States. She noted that the Announcement No. 87 and the quality assessment circular providing details on the



implementation of an import registration system was first notified in general terms to the Committee in February 2008. She expressed appreciation of the constructive approach taken by Chinese authorities, in particular AQSIQ, on this issue and her expectation that further work on the issues would resolve problems that Australia had identified with this system. She called on China to provide additional time for consultation. Further, she requested clarification on several aspects of the measures. She noted that China had notified on 20 February 2008 that "no cotton from the supplying enterprises shall be permitted to enter into mainland China without such registration". She requested China to clarify whether the measures now put into effect were mandatory or voluntary. If they were voluntary, she asked for clarification on the implications for exporters choosing not to obtain registration. She also pointed to the fact that suppliers could be placed into "B" and "C" categories for periods of three to six months on the basis of non-compliance of only one or two inspected shipments. She asked China to provide clarification as to whether these three and six month periods were mandatory minimum periods, or whether it would be possible to consider individual suppliers' records in order to rectify quality issues in a shorter period of time than six months. She also requested additional information on how the views of suppliers would be taken into account in grading decisions, and what formal process existed for an independent appeal of any decision. Furthermore, she requested that China demonstrate that domestic suppliers were subject to similar requirements.

33. The representative of the European Communities noted that her delegation had already outlined its concerns in comments sent to China with regard to this notification. However, this notification had only contained basic information about the planned registration system, while the more precise implementing measures had not been notified. It was the EC's view that quality concerns were not a legitimate objective to justify a system that went beyond a simple registration for producers, but involved a quality credit evaluation system. The evaluation of the quality of cotton could be controlled by economic operators themselves, in particular through commercial contracts; the interference of state authorities did not seem to be necessary or proportionate. She also stressed that the criteria for the quality evaluation were unclear. The European Communities therefore requested China to reconsider the introduction of such a registration and evaluation system and suggested further bilateral consultations.

34. The representative of China explained that, as the largest cotton importing country in the world, China had faced many serious quality and safety problems in imported cotton over the past years. The new registration system was devised to allow for a better demonstration of the qualification of cotton companies and in turn allow more convenient customs clearance for companies with good records while applying stricter administration to others. The measure was therefore a trade facilitation measure. He stressed that China had fulfilled its transparency obligation by notifying the draft measure in February 2008. While, at that time, comments were solicited from other Members, China had not received comments from the United States.

35. The representative of China also pointed to the fact that China had dealt with more than 120 foreign cotton companies' applications and had already approved 104 of them, including those of eight companies from the United States. He explained that the registration was free of charge and had not affected trade in cotton. Cotton exporters that had not registered before 15 March could still apply for registration free of charge. He assured the Committee that business information would be kept strictly within the relevant government authorities and not be shared with any third party. He also highlighted that compared to imported cotton, domestic cotton was subject to stricter market access conditions, as defined in a regulation jointly issued by the State Development and Reform Commission, the State Administration of Industry and Commerce, and AQSIQ in October 2006. He explained that, if a company wanted to appeal the result of the evaluation of the grades, it could do so to the relevant Chinese Government body which would then re-evaluate the grading based on further information provided by the company.

36. The representative of the United States thanked the Chinese delegation for the clarifications provided. Regarding the fact that the United States did not file comments on the measure when it was first notified, he pointed out that the circular which actually contained the quality assessment criteria that AQSIQ inspectors would be using had not been notified, so there had been no chance to officially comment on it. However, US officials had met Chinese officials to discuss the matter many times. Further, he noted that while several US producers had registered, this should not be interpreted as acceptance by US industry of the current system. The registration was made under duress as it was the only way that products that were already on their way could enter into Chinese territory.

37. The representative of China said that companies with a certificate of registration could get more convenient customs clearance treatment, while those which were not registered needed to provide some information and were subject to normal on-site inspection when their products arrived in Chinese ports. They were, however, not prohibited from importing. Hence, the registration was voluntary.

(vii) *Colombia - Quality and Identity Requirements for Distilled Spirits (G/TBT/N/COL/120 and 121)*

38. The representative of the United States, with regards to the notification G/TBT/N/COL/121, pointed out that the measures had the potential of restricting US exports of distilled spirits to Colombia. Colombia had chosen requirements for various elements of spirit manufacture that were different from international practice, such as proposing a maximum alcohol content level. Clarification was sought on Colombia's objective in setting a maximum limit, given that no health and safety concerns had been identified. Additionally, the regulation would also set a minimum alcohol content for liqueurs that was higher than international practice, thus restricting certain liqueur exports to Colombia. The regulation would also define distilled spirits products through the use of minimum and maximum limits on naturally occurring constituents, which could also restrict exports, for example of certain US vodka and gin products because of maximum limits on total congeners, or of certain US rum products because of minimum limits on total congeners. Other proposed parameters could have similar effects, for example, mandating a minimum aging period for whiskey of three years and restricting aging methods for brandy. In addition, the omission of flavored spirits from the regulation raised questions as to whether flavored vodka and rum could be shipped to Colombia. Colombia was requested to clarify its reasons for such provisions.

39. The representative of the United States also noted that draft regulations required that shipments of beverage alcohol be accompanied by a "quality certificate issued by the producer in the country of origin in order to indicate the product's suitability for human consumption." Given that Colombia already had established sanitary requirements, he expressed his delegation's concern that this requirement was redundant and asked for further information on the rationale for additional requirements. Concerning the requirement that the product and brand "must be clearly, visibly and indelibly labelled in Spanish ... ", he requested Colombia to clarify whether it was intended that brand names be translated into Spanish and if so for which reasons. Colombia was also asked to confirm that it intended to recognize Bourbon and Tennessee Whisky as distinctive products of the United States. He asked that Colombian authorities take account of oral and written comments and suggested that technical discussions be held on these issues.

40. The representative of the United States, with regards to the notification G/TBT/N/COL/120, explained his delegation's understanding that Colombia would require most alcoholic beverages entering three special customs zones to be labelled as exclusively for entry and importation in specific ports and that this label would be required until December 2009. He requested Colombia to clarify what would happen once this provision expired. Would special labels no longer be required, would Colombia return to the labelling specifications that were notified, requiring that most alcoholic beverages be labelled with the statement "*Exclusively for import into the Republic of Colombia*"

regardless of port of entry, or was Colombia planning to uphold the current labelling provisions for the three special customs zones?

41. The representative of the European Communities shared the concerns raised by the United States with regard to the Colombian notification G/TBT/N/COL/121 and also expressed concerns regarding notification G/TBT/N/COL/120, which also dealt with alcoholic beverages. She highlighted that both draft measures introduced a number of requirements that diverged from international practice and appeared to constitute an unnecessary barrier to trade, for example regarding the definitions of spirit drinks categories or minimum/maximum alcohol content requirements. Furthermore, she noted her delegation's concerns that the draft regulations would impose overly strict labelling obligations, which would incur important costs for economic operators. The draft resolution notified under G/TBT/N/COL/120 introduced certain specific requirements which appeared to affect only imports and hence would be in breach of Article 2.1 of the TBT Agreement. She therefore requested Colombia to indicate the reasons for diverging from international practice, and for setting strict labelling requirements for alcoholic drinks. Colombia was also asked to clarify the relationship between the two notifications G/TBT/N/COL/120 and 121. Furthermore, Colombian authorities were urged to provide a sufficient transitional period for producers to adapt to the new requirements.

42. The representative of Colombia noted that bilateral consultations had been held with a number of countries, including the United States. The comments that had been received to date had been analysed and studied by the appropriate authorities and detailed responses would be communicated. Comments on the notification G/TBT/N/COL/120 would also be studied by the Colombian Government which had shown in the past to respond to concerns by modifying or withdrawing measures if necessary. With regard to the notification G/TBT/N/COL/121, she asked the European Communities to submit their comments in writing, so that these could be analyzed and appropriately considered by the Colombian Government.

*(viii) Ecuador - Test report and certificate of conformity for industrial products including tyres, steel products and automobile components (G/TBT/N/ECU/41-43)*

43. The representative of the United States raised concerns with respect to the new conformity assessment requirements in Resolutions No. 001-2008, 002-2008 and 003-2008, which implemented various articles of the Ecuadorian Quality Control System Law (No. 2007-76). The resolutions introduced new requirements on a wide-range of products, including apparel and footwear, rubber and tyres, safety glass, transformers, ceramic and porcelain house- and tableware, white goods and appliances, auto parts, cement, plastic, steel and aluminium, matches, batteries, and lubricants. He took note of the 180 day delay in enforcement Ecuador announced pending its development of new procedures to implement these requirements. He also stressed that the initial six-day period between adoption of the measure and its publication and effective date had been insufficient for exporters to respond to the new requirements. He noted that, as the requirements had become effective on the date of publication, and there had been no WTO notification, importers had not been able to comply, and many US manufactured goods had been held at the border. Entry of goods had been delayed until either the importer ensured that the new requirements had been met or provided a substitute certification or the specific product shipment received an exemption from the Ecuadorian authorities.

44. The United States was concerned about the lack of clarity regarding the details of the new requirements with respect to the criteria Ecuador used in listing products subject to the requirements. Clarification was also requested about which certification bodies were qualified to certify conformity with Ecuadorian requirements. The US representative highlighted that companies had been unable to find an accredited certification body for the required scope of certification for certain products because, among other reasons, no country had previously identified a need for such certification. He explained his delegation's assessment that the health, safety, or other rationale that would require third

party certification for these products was unclear and requested clarification in this regard. His delegation appreciated Ecuador's willingness to accept substitute certificates and to issue exemptions as well as the fact that Ecuador had made some equivalency determinations between domestic and international standards. However, he stressed that more time was needed to understand the details of the equivalency determinations and their relationship to the new conformity assessment requirements. He noted that constructive discussions with Ecuador had taken place and suggested that bilateral talks to resolve the issue should continue.

45. The representatives of Colombia and Mexico supported the concerns raised by the United States and called on Ecuador to revise its proposed regulations. Colombia expressed its interest in having bilateral discussions on this issue in the framework of its mutual recognition agreement with Ecuador.

46. The representative of Chile endorsed the comments made by the United States, Colombia and Mexico. She noted that exports of several Chilean companies had been negatively affected by the measure which had been introduced unexpectedly and without an adequate transition period. She stressed that the new requirements were complex and contained a number of confusing provisions. She also noted that a significant delay had occurred in the required procedures. While bilateral consultations had already been held, she expressed the need for further clarifications and dialogue.

47. The representative of Korea associated his delegation with the concerns raised by the US, Colombia, Mexico and Chile. He expressed his delegation's appreciation of the 180-day grace period on compulsory measures granted by Ecuadorian authorities in February 2009. However, even after the postponement of the implementation date, Korean exporters still had concerns that the conformity assessment regulation constituted an excessive burden. He therefore suggested that the regulated items be limited in accordance with Article 2.2 of the TBT Agreement. Regarding the conformity assessment procedure, he suggested that the system of Suppliers' Declaration of Conformity (SDoC) should be maintained.

48. The representative of the European Communities noted that several of their economic operators had indicated that barriers to trade had been encountered because of the new conformity assessment procedure. She also pointed out that the measures had already entered into force when the notifications G/TBT/N/ECU/41-43 were made, in contravention of Article 2.9.2 of the TBT Agreement. Her delegation was analyzing the situation and would send written comments to Ecuador.

49. The representative of Ecuador explained that the new conformity assessment mechanism that had been put in place in order to ensure that domestic as well as imported products were only marketed in Ecuador if they complied with the quality and safety requirements established by domestic legislation. The new mechanism had been established through resolutions of the National Quality Council, the updating of the list of goods subject to technical regulations, and the recognition of entities emitting conformity assessment certificates. The Ecuadorian delegation believed that the new procedures were both more effective in achieving their objective and in conformity with the TBT Agreement. However, due to the observations and comments made by several Members, Ecuador was re-evaluating these measures in order to establish a mechanism taking into account the concerns expressed in the Committee. Ecuadorian authorities were working on a general framework for conformity assessment which would reform the notified resolutions.<sup>3</sup>

50. Until this new framework was finalized, imported products had to be accompanied by a recognition certificate in one of the following forms: a conformity certificate issued at origin by an accredited organism recognized by the Ecuadorian Accreditation Organisation (OAE), which certified

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<sup>3</sup> A communication was subsequently sent by Ecuador and is contained in G/TBT/W/308.

fulfilment of mandatory Ecuadorian technical standards and regulations; a conformity certificate issued at origin by an accredited body which certified fulfilment of an international standard equivalent to the obligatory Ecuadorian standard or regulation; or a declaration of conformity of the manufacture according to standard ISO 17050-1, dealing with companies registered with the quality system certification ISO 9001, issued by a body duly accredited and recognized by the OEA. In respect of the latter, testing reports certifying conformity with Ecuadorian or international standards also had to be provided. Furthermore, the conformity certificates issued under mutual recognition agreements would continue to be accepted within the terms and conditions of those agreements. Modifications to the measures at issue were being prepared would be notified to Members as soon as possible in accordance with the TBT Agreement.

(ix) *EC - Marketing Standards for Olive Oil (G/TBT/N/EEC/226)*

51. The representative of the United States raised concerns regarding the European Communities' marketing standards for olive oil. He clarified that these concerns did not primarily concern the notification G/TBT/N/EEC/226, but more generally the current EC olive oil marketing requirements. In the view of the United States these requirements appeared to be trade restrictive, as they were based on standards elaborated by the International Olive Council (IOC) which was not an internationally recognized standard-setting body. On the contrary, the IOC standards were developed by predominantly European olive oil producers, as the IOC did not represent all countries that produced olive oil. The representative of the United States mentioned that the IOC survey on which the requirements were based also noted "the poor representivity of the data presented."

52. He pointed out that the values chosen by the European Communities for certain parameters, based on IOC grading standards, often worked to preclude olive oil produced in other regions of the world from being labelled as extra virgin olive oil. He explained that this was caused by the fact that IOC grading standards for fatty acid composition were based on historical data from Europe and did not account for fundamental climatic and geographical factors that could affect key components of fatty acid and sterol composition, such as linolenic acid and campesterol, causing them to vary from region to region. For instance, while the proposed USDA standard of a 1.5 per cent linolenic acid parameter would allow extra virgin olive oils produced anywhere in the world to be labelled as such, the EC parameter of 1.0 per cent would restrict some extra virgin olive oil produced outside the European Communities from bearing that label. He also stressed his delegation's concern that the European Communities was currently seeking to export these requirements into Codex. He urged the European Communities to reconsider its requirements and to refrain from efforts to transform an essentially regional standard into a Codex standard. The EC proposal in Codex raised concerns about whether its purpose, or at least its effect, was to try to unjustly preclude extra-virgin olive oil produced outside the European Communities from bearing the extra virgin label.

53. The representative of New Zealand shared the concerns expressed by the United States and stressed that her delegation also considered the olive oil marketing standards to be more restrictive than necessary to achieve a legitimate objective. She pointed out that not the IOC, but Codex was the pre-eminent food standard setting body, while the IOC only set standards for its mostly European membership which was much smaller than the membership of Codex. She noted that the IOC neither enjoyed the status of Codex nor was it referenced in the SPS and TBT Agreements. Therefore, she expressed her delegation's concern about the systemic implications of the European Communities unilaterally adopting a standard developed by another organization which would effectively subvert the Codex process. She quoted the European Commissioner for Agriculture, Mariann Fischer Boel as saying: "Different agricultural traditions and varied extraction and blending practices mean that the taste of olive oils from different countries can be very distinct." The representative of New Zealand pointed out that, in the same way, the levels of elements such as linolenic acid in high quality olive oil also varied from country to country depending on geographical and climatic conditions and that labelling regulations should take account of the realities in all olive oil producing countries. Her

delegation's main concern was the divergence from internationally accepted standards, similar to the concern the European Communities had previously raised itself regarding Colombia's new requirements for distilled spirits.

54. The representative of the European Communities informed the Committee that a reply to the comments by the United States had recently been submitted and noted that her delegation had not received comments from New Zealand prior to the meeting. The draft Commission regulation amended certain sections of Commission Regulation 1019/2002 on marketing standards for olive oil, mainly by introducing an obligation for the declaration of origin of olive oils destined for retail stage; rules on the labelling of the origin of virgin and extra-virgin oils; and provisions on the labelling of certain characteristics of these oils following the last update in the International Olive Council standards and methods.

55. The EC representative noted that the comments made by the United States and New Zealand related to the Regulation that was currently in force and not to the measure that had been notified. She found this surprising as the measure had been in place for many years and this was the first time that concerns were being raised. Regarding linolenic acid and campesterol limits, she pointed out that the notified draft measure did not contain any provisions on the characteristics of olive oil, which were laid out in different pieces of EC legislation, including Annex I to Regulation 2568/91. She also noted that this issue related directly to the current work of the Codex Committee on Fats and Oils which was in the process of discussing a proposed draft amendment to the standard for olive oils and olive pomace oils, in particular regarding linolenic acid. She was of the view that these issues should be discussed in that context, and not in the TBT Committee, with the objective of finding an agreement by all parties. She invited the United States to submit their comments to the Codex.

(x) *France - Unique Requirements for Ride-on Lawnmowers*

56. The representative of the United States raised a concern regarding France's requirements for ride-on lawnmowers which his delegation believed to be unique and non-transparent. The French Ministry of Agriculture had imposed a requirement that ride-on lawnmowers be fitted with a special piece of equipment known as a "skirt" for bystander protection, while both US and EC industry had argued that there was no accident data to support this requirement and that it could actually increase the potential for safety problems by increasing the risk of fire caused by accumulating debris in the vehicle. He therefore requested France to identify the safety risks for which it had introduced the new requirement and to provide clarification on how the new requirement reduced them, including by revealing the safety data that France had accumulated in support of its position.

57. The US representative further noted that France had not notified the measure to the WTO nor published the requirement. Lawnmower producers had learned of this requirement because retailers had informed them of a memorandum that the Ministry sent them forbidding the sale of lawnmowers that did not have a skirt. Moreover, ride-on lawnmowers without a skirt had been seized by French customs and had not been released until a skirt had been attached. He stressed that, although the French Ministry claimed that this demonstrated acceptance of the requirement, the companies that had installed the skirt had done so only out of necessity to secure the release of their goods from customs.

58. Furthermore, the representative of the United States pointed out that the European Garden Equipment Manufacturers Federation (EGMF) had filed a petition with the European Commission's Directorate General Enterprise challenging the French requirement and its conformity with the Machinery Directive. This petition was still pending. Further, he highlighted that France continued to insist on a skirt, despite a 2008 vote in CEN<sup>4</sup> Technical Committee 144, in which the French

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<sup>4</sup> European Committee for Standardization.

proposal to amend the CEN ride-on lawnmower standard to include a skirt for bystander safety had been rejected.

59. France had originally tried to move the discussion to TC-144 and out of ISO, presumably because non-European companies could not participate in the CEN standards development process. But even in CEN, France was unable to make the case to its counterparts and European industry that the skirt was necessary. Undeterred by CEN's rejection, the French Ministry had published another proposal requiring the skirt in January 2009, which had been rejected by both US and EC industry. It was noted that since that time, US industry was reporting increased actions directed at them by French customs authorities regarding not only ride-on lawnmowers, but also walk-behind lawnmowers. A status update on DG Enterprise's consideration of the EGMF petition was requested. In the meantime, the United States urged France to publish the measure in an official publication and notify it to the WTO for comment, and refrain from enforcing it, including recent customs actions against importers of US lawnmowers, to provide time for consideration of comments.

60. The representative of the European Communities noted that bilateral discussions had taken place and that the European Communities was aware of the issue. He recalled that in June 2004, the French authorities had started a market surveillance action relating to ride-on lawnmowers under the applicable legislation, the Directive on the safety of machinery 98/37/EC. This action had lasted until March 2007 and had covered all models of ride-on lawnmowers placed on the French market, not only imported ones. As part of this action, French customs authorities, acting as market surveillance authorities, had identified some non-conformities concerning the protection of bystanders from access to the moving transmission parts of the machine in some models of imported ride-on lawnmowers. Consequently, those products had been held by French customs, pending the outcome of discussions with the economic operators to find technical solutions capable of remedying those non-conformities.

61. The French authorities had consulted the expert groups set up under the Machinery Directive in which both members State experts and stakeholders were represented, as their interpretation of the relevant essential health and safety requirements of the Machinery Directive relating to access to moving parts had been contested by the manufacturers concerned. At its meeting in March 2007, the machinery working group had agreed that "moving transmission parts of ride-on lawnmowers must be made inaccessible to persons, including operators and other exposed persons (bystanders), as far as possible, taking into account the state of the art. Access to these moving parts shall be prevented by integrated safety measures." In parallel, CEN had begun, on its own initiative, a revision of the relevant European harmonized standard on the safety of lawnmowers, EN 836, with a view to enhancing the clarity of its provisions relating to the protection of bystanders and the related verification methods.

62. The representative of the European Communities further noted that in September 2007, EGMF had filed a complaint with the European Commission with respect to the position taken by the French authorities. The complaint had been examined by the Commission services according to the applicable procedure which required strict confidentiality. The complainant had been regularly informed about the state of play of the investigation and several meetings had also been held with the complainant. The EC representative pointed out that the Commission services were close to finalizing their assessment and that the complainant would be notified of the findings as soon as those were completed and would be given an opportunity to comment. He further explained that no measure had been notified under the TBT Agreement, because no formally binding measure restricting placing on the market of certain models of ride-on lawnmowers had been adopted. The discussions between the French authorities and the respective economic operators had taken place in the context of market surveillance activities in application of an existing technical regulation (the Machinery Directive). He stressed that in the context of such activities, it was normal practice that as soon as national authorities had a doubt regarding the compliance of a product with the applicable requirements, they started discussions with the manufacturers with a view to finding a solution.

(xi) *Turkey - Inspection of Imported Medical Equipment*

63. The representative of the United States raised a concern regarding Turkey's new medical device regulation, the Communiqué for Standardization in Foreign Trade Related to Inspection of Imported Medical Equipment. He pointed out that the draft of the measure had not been notified to the WTO and that the final measure had entered into force on 1 January 2009, one day after it had been published in the Official Gazette, which did not leave a reasonable interval for implementation. He noted that this had led to serious disruptions in the market over the past months, as customs clearance time had expanded from a few days to several weeks or more. He noted that during bilateral discussions, Turkey had explained that the same measure was regularly published at the beginning of every year, so that it could not be seen as a new measure. However, the US delegation stressed that the list of products to which this regulation applied, contained in its annex, varied from year to year, making it effectively a new measure which should be notified.

64. The representative of the United States also pointed out that the regulation did not apply to domestically-produced medical devices. Turkey had however indicated that there was another measure applying to domestic products and the US delegation would review it. He also pointed to the fact that the import inspection measure exempted medical devices manufactured in the European Communities. Further, he noted that the measure neither indicated its objective, nor explained how the list of medical devices in the annex covered by the measure was determined; additional clarification on these issues was needed. He urged Turkey to notify the measure to the WTO and suspend implementation until comments from interested stakeholders had been taken into account and potential discriminatory aspects of the measure had been addressed.

65. The representative of Turkey explained that there were three national regulations on medical devices published by the Ministry of Health in 2007. Their provisions applied to both domestic and imported goods. The Communiqué mentioned by the US delegation aimed at ensuring that necessary safety controls of imported medical devices were performed on a risk basis and according to requirements mentioned in these regulations. He stressed that this was not a new piece of legislation, as all Communiqués on import controls were revised each year, but only for the purpose of reflecting some operational issues such as changes in HS Codes of annexed products. Since there was no change in the medical device regulations, the requirements for the products that had to be fulfilled by the importers remained the same. In accordance with the Communiqué, Turkey controlled all devices contained in the annex, except those produced in the European Communities due to the customs union between the European Communities and Turkey. The list of medical devices contained in the annex to the Communiqué was established by Ministry of Health of Turkey, according to a risk-based methodology and based on information gathered from the users of those products, such as hospitals. Detailed information on this issue would be provided to the delegation of the United States.

(xii) *India - Restriction on Chinese toys (Notification No.82 and 91/(RE-2008)/2004-2009 of Department of Commerce, Ministry of Commerce and Industry of India)*

66. The representative of China raised concerns relating to India's ban and discriminatory measures on almost all Chinese toys introduced through Notification No. 82 and No. 91 issued by the Department of Commerce of India's Ministry of Commerce and Industry. He drew the Committee's attention to document G/TBT/W/304 which outlined the Chinese position with regard to these Indian measures. He noted that the Notification No. 82 imposed a general ban only on toys from China for at least six months without specifying reasons for the restriction. He stressed that the ban was discriminatory and thus in breach of fundamental principles such as the general elimination of quantitative restrictions, and both MFN and National Treatment which were established under GATT 1994 and the TBT Agreement. He also noted that the measure had created unnecessary obstacles to international trade in toys. Although the Notification No. 82 had been replaced by Notification No. 91 which had been issued and implemented on 2 March 2009, the Chinese representative emphasized



that the discriminative nature of the restrictions remained. Notification No. 91 required Chinese toys to conform to certain standards and conformity assessment procedures while toys manufactured in India and originating from other Members were not subject to the same requirements. Therefore, his delegation believed that Notification No. 91 accorded unfavourable treatment to Chinese toys and was inconsistent with India's obligations under the GATT 1994 and the TBT Agreement's Articles 2.1 and 5.1, in particular. He also noted that India had neither notified its Notification No. 82 nor its Notification No. 91 to the WTO and reminded India of its transparency obligations under Articles 2.9, 2.10, 5.6 and 5.7 of the TBT Agreement. While China appreciated the clarifications provided by the Indian authorities in bilateral talks, he urged India to stand by its promises to avoid protectionism despite the economic crisis and to revoke its restrictions on Chinese toys immediately.

67. The representative of India pointed out that the Chinese concerns regarding a potential inconsistency of the Indian Notification No. 82 dated 23 January 2009 had been duly considered by the concerned Indian authorities and thereafter an amended Notification No. 91 had been issued on 2 March 2009. He took note of the fact that the new notification still did not address the Chinese concerns completely. He informed the Committee that a bilateral meeting with China had allowed for an in-depth discussion and a better appreciation of the Chinese position. After the bilateral meeting, the Chinese concerns had been conveyed again to the capital. He also noted that the Chinese deputy trade minister was going to hold a high level discussion with the Indian authorities, so that an amicable solution to the issue could be found.

(xiii) *European Communities – Implementing measures of the Directive on eco-design of Energy-using Products (G/TBT/N/EEC/208, 228, 229, 234, 237)*

68. The representative of China raised concerns regarding several of the European Communities' implementing measures of the Energy-Using Products Directive (Directive 2005/32/EC), which defined eco-design requirements for many products, including electrical and electronic equipments, simple set top boxes, external power supplies and various lamps. He stressed that China fully supported the objective of increasing energy efficiency, but that the European Communities should avoid unnecessary obstacles to international trade. China had submitted detailed written comments on these five notifications and had received three replies to date. He encouraged the European Communities to take into account China's comments and make revisions to the draft regulations.

69. It was pointed out that the measures contained in notifications G/TBT/N/EEC/208 and 228 required that power consumption of equipment in any off-mode and some stand-by modes should not exceed 0.5W. However, Chinese research showed this requirement had no considerable saving effect, as, for example, only 22 kWh per device would be saved within five years for microwave ovens and electric cookers. On the other hand, the requirement would cause additional consumption of resources and energy in the process of design and production. Additionally, costs would increase by about 10 per cent, placing a heavy burden on manufacturers, particularly SMEs. He noted that the International Energy Agency had proposed a "One Watt Plan", seeking to lower stand-by power consumption to no more than one watt per electronic device by 2010, which was supported by many WTO Members, including developed country Members such as the United States and Japan. He therefore urged the European Communities to reconsider the 0.5W requirement in order to avoid unnecessary obstacles to international trade.

70. With regard to notification G/TBT/N/EEC/237, the Chinese representative noted that it contained three functionality requirements in terms of life-time for compact fluorescent lamps ("lamp survival factor at 6000 hours", "number of switching cycles before failure", "permitted failure rate"), whereas the current international standard IEC 60969:2001 only adopted the parameter of "rated average life". He requested the European Communities to adopt a relevant international standard as the basis of their technical regulations, in line with Article 2.4 of the TBT. He also pointed out that the measure notified as G/TBT/N/EEC/229 listed different minimum efficiency values for certain

single-capped fluorescent lamps with the same nominal wattage. He considered it unreasonable to set minimum efficiency values according to the type of the lamps and also stressed that the minimum efficiency values for lamps that were not listed remained unclear. Therefore, he urged the European Communities to set minimum efficiency values in accordance with the nominal wattage rather than the types of the lamps. He also suggested that the European Communities should take into account the special needs of developing country Members and grant more adaptation time.

71. The representative of the European Communities explained that the objective of the Eco-design of Energy-Using Products Directive was to provide coherent EC-wide rules for eco-design and to ensure that differences among member States' regulations did not become obstacles to intra-EC trade. She pointed out that the Directive did not introduce directly binding requirements for specific products. These were laid down by implementing measures that had to be adopted by the European Commission. The concern raised by China was about the first set of implementing measures proposed by the Commission. She stressed that all implementing measures were based on technical, environmental and economic analyses which had been carried out in full transparency and with the participation of stakeholders from around the world, including industry.

72. The EC representative noted that the Commission services had also discussed the measures with international partners, including China. Her delegation believed that the requirements were cost-effective and lead to significant energy saving. She highlighted that, in addition to this extensive analysis, comprehensive impact assessments, which took into account economic, environmental and social impacts, including design/redesign cycles of affected products, had also been carried out for all the measures. The timing of the requirements had been fixed on the basis of these impact assessments. She emphasized that all measures thus contained transition periods sufficient to adapt to the requirements. She concluded by stressing that the European Communities was of the opinion that the measures were justified by environmental protection objectives and in full compliance with the TBT Agreement. She noted that the European Communities had already replied in writing to the comments sent by China concerning notifications G/TBT/N/EEC/208, 228 and 234 and would soon send replies with regard to G/TBT/N/EEC/229 and 237.

*(xiv) Bahrain - Motor Vehicles – General Requirements (G/TBT/N/BHR/40)*

73. The representative of the European Communities raised a concern with regard to the notification by Bahrain, which laid down technical regulations for motor vehicles. The European Communities had sent comments on this notification in May 2008, based on the fact that the draft included certain requirements for tyres, windshields and windows of motor vehicles that deviated from UNECE Regulations. Thus, the regulations could create barriers to trade for motor vehicles being in compliance with UNECE Regulations. She noted that her delegation had not received any reply to its comments and sought clarifications on the state of the proposed regulation and on whether comments had been taken into consideration.

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

74. The representative of the European Communities raised concerns about a proposed Chilean measure intended to amend the existing legislation on the national system for the monitoring of cosmetics. She noted that the draft introduced a registration procedure for low-risk and hygiene products which, according to international practice, were only subject to a notification system. The draft also created a new sub-category for cosmetics called "special cosmetic products" to which special obligations apply. The representative of the European Communities further noted that the measure provided for certain labelling obligations which appeared to be confusing for consumers, in particular those regarding the indication of expiry date and period after opening.

75. Furthermore, it was pointed out that the measure asked for additional local quality controls performed by local laboratories for each batch exported to Chile, even though the product had already been tested by the manufacturer. In this regard, it was not clear when such additional controls could be requested. The EC representative stressed that the above-mentioned requirements seemed to be more trade-restrictive than necessary to fulfil the legitimate objective of human health protection and safety. Written comments had been sent to Chile in February 2009, and her delegation looked forward to receive a reply to them.

76. The representative of Chile recalled that various bilateral meetings had taken place with the European Communities. While the European Communities had asked to extend the deadline for comments, there had already been several comments from various countries during the period of public consultations. She also noted that the period for public consultations had elapsed, and amendments to the proposed regulation were currently being considered. Finally, the Chilean representative stressed that all comments would be taken into account in the review of the draft.

*(xvi) China – Textiles and Apparel (G/TBT/N/CHN/427 and Suppl.1)*

77. The representative of the European Communities raised a concern with regard to a Chinese measure establishing mandatory requirements for textiles and apparel. While her delegation agreed that certain information, like fibre composition or care instructions, should be shown on the label, other information did not seem relevant for the information of consumers. She referred in particular to the indication of product name, effective product standards, safety categories, use and storage precautions. Imposing mandatory labelling of this information would be more trade-restrictive than necessary. Moreover, she asked for clarifications on whether it was sufficient to indicate the name and address of manufacturer on the accompanying documents provided with the product. Her delegation looked forward to receive a reply to its comments and information on whether the draft had already been adopted.

78. The representative of China recalled that the proposed measure had been notified on 15 July 2008, and a sixty day period had been provided. He pointed out that, at the request of the European Communities, another fifteen days had been extended for comments. After the comment period, a Technical Committee analyzed all comments received from domestic industries and foreign stakeholders. Since some of the comments were considered reasonable, the proposed measure was currently under a second review. Should the reviewed draft contain mandatory requirements substantially different from those in the original version, a new notification would be issued and a further period for comments would be granted.

*(xvii) Colombia – Draft Decree Establishing Provisions to Promote the Use of Biofuels (G/TBT/N/COL/96, Add.1-2)*

79. The representative of the European Communities raised concerns about a proposed regulation aimed at promoting the use of biofuels in Colombia. She noted that the notified measure provided that all gasoline-engine motor vehicles should be flexible-fuel vehicles, thus their engines should be capable of being operated with either ordinary gasoline or a blend of up to 85 per cent alcohol fuel. In this regard, a specific timetable was provided: 60 per cent of the annual supply of a brand should support E85 fuel as of 1 January 2012; 80 per cent of the annual supply of vehicles should support E85 fuel as of 1 January 2014; 100 per cent of the annual supply should support E85 fuel as of 1 January 2013 or respectively 2016. While the EC delegation understood the objective of promoting the use of biofuels, it invited Colombia to explain why mandatory technical requirements were considered necessary to address this objective, while a number of other possibilities for measures to promote biofuels were available. Written comments were being prepared and would be sent to the delegation of Colombia.

80. The representative of Colombia explained that the notified measure had been commented on by national and foreign producers and that it would apply both to national and imported vehicles. She pointed out that the measure had been developed on the basis of existing technology and that it was meant to be gradual and carried out over a period of time. It was also noted that various studies showed the satisfactory results of the use of flexible-fuel vehicles, and that several Colombian companies recognized the benefits of introducing such technology. Biofuels were considered a viable and less polluting alternative to gasoline, in particular in countries like Colombia, with geographical and environmental characteristics that required high-powered vehicles. The representative of Colombia encouraged the EC delegation to submit written comments that, once received, would be studied and discussed.

*(xviii) India - Prevention of Food Adulteration (G/TBT/N/IND/34)*

81. The representative of the European Communities referred to a revision of the Indian rules on Prevention of Food Adulteration (PFA), which outlined mandatory labelling guidelines for pre-packaged food. Written comments had been submitted to India in November 2008 and bilateral discussions on this matter had been held before the TBT Committee meeting. Assessing the scope and impact of the proposed changes was very difficult, due to the fact that the original text of the regulation had not been made available. Moreover, the Indian rules on prevention of food adulteration appeared to have been subjected to several further amendments since the above-mentioned measure was first notified to the WTO. In particular, the EC delegation referred to an amendment notified to the SPS Committee (G/SPS/N/IND/59) and other amendments notified to the TBT Committee (G/TBT/N/IND/38 and G/TBT/N/IND/39). The representative of the European Communities encouraged India to clarify what the relationship was between the different notifications, and provide WTO Members with the consolidated version of the rules being amended.

82. The representative of the United States appreciated the revision of the quantitative ingredient declaration requirements in the PFA rules, and asked the Indian delegation whether the revision would be notified to the TBT Committee. Moreover, he asked for clarification on why the latest notified amendment to the PFA rules was notified as an SPS measure (G/SPS/N/IND/59), and encouraged India to clarify which part of the measure was considered to fall within the SPS Agreement. While in both cases the requirements for nutritional labelling had been modified and the same objective had been stated, it was noted that India's previous amendments to the PFA were notified as a TBT measure (G/TBT/N/IND/34). The Indian delegation was therefore encouraged to explain whether the latest amendments would also be notified to the TBT Committee.

83. The US representative asked for further clarifications with regard to whether the PFA rules applied to distilled spirits, in addition to other food products. He noted that in many countries distilled spirits were exempted from such labelling requirements as ingredient listings, best before dates, expiry dates and dates of manufacture and packaging. In this regard, it was his delegation's understanding that the above-mentioned requirements were not applicable to distilled spirits, as they had an indefinite shelf life and the ingredients were not present in the final product after distillation and fermentation. Finally, the US delegation urged India to consider delaying enforcement of the measure notified to the SPS Committee until such time as the process of stakeholders' review and comment would be completed.

84. The representative of India pointed out that the original text of the PFA regulation was available on the Ministry of Health and Family Welfare website. With regard to the consolidated text of the regulation, the issue would be conveyed to the competent authorities for due consideration. Regarding the listing of name, weight and volume of ingredients used at the time of manufacture, raised by the European Communities in previous bilateral meetings, the representative of India confirmed that India decided to withdraw the requirement. With regard to the other issues raised, it was stressed that they would be conveyed to the capital for due response. Finally, regarding the US

concern on the entry into force of the regulation, the Indian representative recalled that the proposed measure was notified in September 2008, giving an adequate six-month comment period. He further stressed that all comments received would be taken into account before finalizing the proposed measure.

(xix) *Korea – Beef (G/TBT/N/KOR/202)*

85. The representative of Australia raised concerns about an amendment to the Ministerial Ordinance for the Livestock Products Processing Act. She pointed out that this amendment entailed a new requirement that for imported beef a Bill of Lading (BOL) number had to accompany products sold by domestic retailers of beef. The notification by Korea indicated that this measure was to be implemented on 22 June 2009, but did not provide for a reasonable period for Members to make comments on the proposed measure and for those comments to be taken into account.

86. The representative of Australia further stated that her delegation was holding constructive bilateral discussions with Korea on this matter, but sought greater clarity on both the intent and implementation of the measures. For example, Korea had indicated in its notification that the objective and rationale of the measure was to prevent deceptive practices. In other discussions, however, there had also been indications that the objectives could also include trace-back, food safety, and consumer confidence. Clarification was sought on the precise policy objective for the measure, and how the use of the BOL number contributed to that objective. Once the policy objective was clarified, a notification of greater detail on how the measure would be implemented in practice would also be welcome.

87. It was Australia's assessment that the requirement to display and record a BOL number for imported beef could not contribute to the achievement of such policy objectives and had the potential to impose unnecessary costs on trade. Such legitimate policy objectives might be met through alternative and less costly means. The Australian representative stressed that, in light of the lack of clarity of the objective and rationale for the measure and how it would be implemented in practice, Korea should formally allow a reasonable period for comments of Members to be provided and taken into account, and further delay implementing any measure until such time that more trade facilitative alternatives could be identified. Australia looked forward to working constructively with Korea to identify an approach that would address its legitimate policy objectives while not imposing unnecessary obstacles on trade.

88. The representative of Mexico shared the concerns expressed by Australia and stressed that measures aimed at protecting legitimate objectives should be in conformity with the rules laid down in the TBT Agreement. He noted that Mexico would send comments once an analysis of the proposed measure, including its trade impact, was concluded. His delegation hoped that Korea would revise its regulation in the light of the TBT Agreement and that it would take into consideration Members' concerns.

89. The representative of the United States supported some of the remarks made by Australia on Korea's new measure requiring the placement of BOL numbers on retail labels or display cards for imported beef. He pointed out that it was unclear what Korea was trying to achieve with this measure. In his delegation's view, it did not address food safety concerns, nor did it provide information that would be helpful in the event of a recall. He urged Korea to reconsider the measure and discuss with importers and retailers alternatives that would address Korea's objectives.

90. The representative of Canada shared the concerns expressed regarding the notified Korean regulatory amendments requiring that the BOL be displayed at the retail level for beef products. In particular, Canada was concerned that these amendments were notified to the WTO without allowing for an appropriate comment period. She sought clarification on the objectives and intent of the

proposed measure. Although not having had time to fully assess, these amendments appeared potentially burdensome to importers and Canada believed that less trade restrictive options could exist to meet Korea's objectives. Furthermore, Canada was concerned that this measure, or one similar in nature, would extend to commodities other than beef and would continue to follow the development and implementation of these regulatory amendments.

91. The representative of New Zealand associated her delegation with the intervention of Australia, United States, Mexico and Canada on the issue of Korea's prolongation of new regulations for requirements of labelling of beef for retail sale, particularly the requirement for the inclusion of a BOL number at the point of sale for imported beef. She sought further information on these requirements and on their consistency with the TBT Agreement, in particular to ensure that measures were not more trade restrictive than necessary and to better understand the implications for New Zealand trade. Specifically New Zealand requested clarification on the specific objectives and rationale of the measures and on how the new labelling requirements met that objective.

92. The representative of New Zealand further pointed out that, based on the information provided so far, the new measures appeared to be more trade restrictive than necessary than current international standards and Codex guidelines that could be considered in developing such new regulations. Her delegation had received no indication that Korea had considered these standards and guidelines, nor consulted with its trading partners in developing its new measure. She stressed that her delegation would provide a formal response to Korea's notification and requested that Korea consider New Zealand's comments and those of other Members before implementing the regulation. While Members' concerns were being considered, Korea should delay the implementation of these new requirements. Finally, she pointed out that an update on how Members concerns were being addressed would be sought at the June TBT Committee meeting.

93. The representative of Korea explained that the objective of the BOL number to imported beef was to announce beef recall immediately if a hazardous accident in the market occurred. He pointed out that consumers' distrust was increasing due to concerns about the mad cow disease and false country of origin labelling. Therefore the recall system needed to be reorganized to provide consumers with correct information, to prevent deceptive practice and to eliminate the hazardous factors resulting from emergency situations. In this regard, while domestic beef would be controlled by animal identification number, imported beef would be controlled by the BOL number.

94. The representative of Korea further stressed that this system was the result of comments from importers and distributors, in particular the relevant interest groups including representatives of retailers, who noted that there was no problem in applying this system. In addition, authorities in Korea had taken the relevant Codex standard as the basis for this system. Therefore, Korea believed that the measure was in line with the TBT Agreement. However, his delegation was open to discuss with interested Members any alternative options and hoped to intensify its bilateral talks on this issue.

(xx) *European Communities – Green Paper on Agricultural Product Quality Policy*

95. The representative of Mexico raised an issue with respect to a recent Green Paper by the European Commission which would examine various certification programmes, labelling schemes, geographical indications and regional certification quality measures in use in the European Communities for agricultural products. He noted that the green paper covered issues such as basic requirements for production and marketing standards, specific quality systems, geographical indications, traditional specialities and environmental systems for certification of quality. For his delegation, the Green Paper had raised the following issues: if it became mandatory to indicate the place of cultivation of raw materials and if stigmatization of products that did not comply with various standards for aesthetic reasons was authorized, how would this affect the system of geographical

indications from third countries? How could it improve the EC single market for agricultural products? How would consumers not be confused with certification?

96. The representative of Mexico further pointed out that his delegation had sent preliminary comments to the European Communities about the paper and noted that the draft project contained provisions that could be contrary to the principles of non discrimination, avoidance of unnecessary obstacles to trade, adopting the least trade restrictive measure to achieve a legitimate objective. Also, the green paper was not in compliance with the principles of transparency with regard to the notification of draft technical regulations or conformity assessment procedures when they had an effect on trade of other Members, nor with the obligation to review technical regulations in force to ensure that they could achieve the legitimate objectives, nor with the obligation to use of standards, guides and recommendations as a basis for technical regulation. He asked the European Communities to review the norms in the green paper in line with its WTO obligations, taking into consideration the provisions of the TBT Agreement to take into account the comments submitted in the formulation of the final standard.

97. The representative of the European Communities explained that the Green Paper was a consultation document on the future of agricultural product quality policy, including geographical indications. It was open for consultation from stakeholders, inside and outside the European Communities from 15 October until 31 December 2008. 560 responses, including several from third country administrations, had been received. All contributions had been published and the final summary response had also been published on the EC website. The summary document contained statistics and an introduction on the responses received. She further explained that the responses were being used as input in a communication which would be adopted in May and which would chart the strategic orientations for agricultural products quality policy. However, no legislation was foreseen at this stage. She stressed that, should legislation be considered, it would be drawn up in compliance with WTO rules and in respect of the procedural requirements laid out in the TBT Agreement.

## **2. Previously raised concerns**

- (i) *EC - Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (G/TBT/N/EEC/247 and G/TBT/Notif.00/310, Corr.1) and Sweden - Restrictions on the use of Deca-bromo diphenylether (deca-BDE) (G/TBT/N/SWE/59)*

98. The representative of the United States raised concerns with regard to the European Communities' ongoing review of its Directive concerning restrictions on hazardous substances in electrical and electronic equipment (RoHS Directive) and announced that his delegation would submit comments in writing on the recently notified proposed revision. He expressed concern about the potential magnitude of the cost of compliance, in particular for small and medium sized enterprises, that could result from an expansion of the directive. He also emphasized the need for the EC to ensure a risk- and science-based approach to the RoHS review, for instance when evaluating whether to add substances to the list, set maximum concentration levels for specific substances, or grant exemptions. He noted that the Commission's proposal for a revision of the RoHS directive contained a reference to specific articles of the REACH Regulation, on which a new RoHS substance selection and assessment procedure would be based. It was unclear to the United States' delegation what this reference meant. He noted that any selection and assessment procedure should be based on specific scientific criteria and specific recognized risk assessment processes, and take into account end uses. The U.S. representative also urged the EC to clarify how RoHS and REACH would fit together. He pointed to the potential that the relationship between these measures could create problems as all the substances that were selected for priority assessment under the proposed RoHS revision were also listed on the authorization candidate list for REACH. He requested the European Communities to

clarify which directive would apply in such cases and whether the RoHS Directive would be phased out in order to ensure that conflicts would not develop.

99. The representative of the United States also noted that the Commission's proposal contained provisions for renewable four year exemptions to RoHS compliance. Requests for extension of an exemption would have to be submitted 18 months in advance of its expiration date. He pointed to experience with the current RoHS Directive which showed that, in some cases, the processing of an exemption request could take longer than 18 months. He requested the European Communities to clarify what would happen if a request for extension was made within the prescribed time frame, but the Commission failed to reach a decision before the expiration date. In general, he highlighted that the procedure for granting and renewing exemptions had been non-transparent and unpredictable in duration and therefore called on the European Communities to ensure that a transparent and predictable process be put in place for the treatment of exemptions, including by ensuring meaningful opportunities for comment by all interested stakeholders. He also urged the European Communities to provide a reasonable period of time for suppliers to implement any changes that were made to the directive.

100. The representative of Japan recalled that, regarding the re-examination of the exemption of Deca-BDE, the European Communities had mentioned at the last Committee meeting that this would be addressed in the RoHS Directive revision process, that the best scenario which would minimize the negative impact on trade would be published with the draft revised text shortly and then, asked for their progresses including TBT notification procedure. Moreover, he also noted that four substances (HBCDD, DEHP, BBP, and DBP) were proposed as additional candidate substances of the RoHS Directive revision and were at the same time proposed as substances of very high concern (SVHC) under the REACH Regulation. He pointed out that the EC risk assessment regarding DEHP showed that "risks are not expected" and "risk reduction measures already being applied are considered sufficient" whereas, under the REACH Regulation, after the substances were defined as SVHC, producers and exporters would need authorization to use them. The Japanese representative requested the European Communities to provide clarifications on intended relationship between the revision of the RoHS Directive and the REACH Regulation in terms of above-mentioned aspect.

101. The representative of Israel shared the concerns raised by the United States and Japan in particular with regard to Deca-BDE. He recalled that the ban on the use of Deca-BDE had first been notified to the TBT Committee as a restriction on the use of Deca-BDE by Sweden (G/TBT/N/SWE/59). Deca-BDE had then been exempted from the original RoHS directive following a risk assessment which concluded that Deca-BDE did not represent any significant risk to health or the environment. On the grounds of procedural failures, however, a ruling from the European Court of Justice had annulled this exemption, which meant that Deca-BDE had been banned from use in electrical and electronic equipment in the European Union as of 1 July 2008. The most recent development in this regard had occurred on 3 September 2008 when the European Commission issued a proposal for the revision of the RoHS directive in which Deca-BDE was still included in the list of banned substances in Annex 4. However, the representative of Israel stressed that the scientific results of the EC risk assessment on Deca-BDE had not been called into question and that potential substitutes had not been subject to similar level of scientific scrutiny regarding environmental and health impacts. He stated that Israel therefore considered the maintenance of the proposed restriction on the use of Deca-BDE as running counter to EC obligations under the TBT Agreement. In particular, Article 2.2 and 2.3 prohibited the European Communities from instituting or maintaining a restriction without necessity. He therefore urged the European Communities to follow its own scientific results and avoid the ban of Deca-BDE.

102. The representative of Jordan supported the comments regarding Deca-BDE that been made by Japan and Israel. She stressed that Deca-BDE had been exempted based on scientific evidence and that the evidence that had supported the exemption in 2005 was even stronger today. Her delegation



therefore considered the ban on Deca-BDE unjustified and warned that continuing to apply the restriction would undermine the credibility and usefulness of risk assessments and in turn the scientific foundation of RoHS and similar directives.

103. The representative of the European Communities explained that the RoHS Directive required the Commission to review the measures provided for in the Directive, in particular to examine whether two additional categories of equipment had to be included in its scope, namely medical devices and monitoring and control instruments. It was also required to examine whether the list of substances had to be revised, with the objective of adapting it to technical and scientific progress and ensuring coherence with other pieces of Community legislation, namely REACH. She noted that the main objective of RoHS was to ensure the elimination of certain hazardous substances from electrical and electronic equipment. However, where this was not possible, exemptions could be granted. On the basis of the impact assessment that had been undertaken by the Commission, it had been decided that no new substances be included in the scope of RoHS. The two above-mentioned new categories of products would however be covered by the revised RoHS Directive, after long transitional periods ending in 2014 and 2017.

104. With regard to Deca-BDE, she pointed out that the Commission had maintained the current restriction, based on the existing scientific information, including the revised EU risk assessments. These had concluded that uncertainties remained concerning the toxicity of Deca-DBE and its degradation to other banned substances and had determined the need for further information and/or testing with respect to the risk of Deca-BDE to workers, to humans exposed via the environment and to the aquatic ecosystem. For this reason, the Commission had imposed testing and information requirements on the importers or manufacturers of Deca-BDE for a period of ten years from 2006-2016. Hence, the Commission had assigned the responsibility for producing the additional evidence required. In line with recital 7 of the current proposal, the current restriction of use would be kept under review and, if necessary, adjusted to take account of new technical and scientific information. The representative of the European Communities also pointed out that user industries could apply for temporary exemptions from the ban in accordance with the criteria of article 5.1.b of the proposal. With regard to the four substances Japan had mentioned, the Commission had concluded that it was not necessary to include them in the proposal. However, these substances would be monitored, in particular with regard to potential problems in waste management. The European Communities invited Members to submit their comments in writing before the expiry of the comment period on 10 May 2009.

*(ii) Brazil - Toys (G/TBT/N/BRA//259 and 313)*

105. The representative of China raised a concern about the new Brazilian regulation on toys, Decree 384 notified as G/TBT/N/BRA/313. China had already expressed its concerns about Brazil's Decree 326, notified as G/TBT/N/BRA/259 on 16 October 2007, that had accorded less favourable treatment to imported toys to be implemented for nearly two years despite its alleged emergency and temporary nature. He noted that Brazil had revised the emergency regulation and submitted the new notification G/TBT/N/BRA/313. However, he pointed out that the proposed new decree failed to address the many WTO inconsistencies that had been identified in previous meetings. For example, according to the proposed decree, if original tests were performed abroad, supplementary test would be required on the products' arrival in Brazil. This would be inconsistent with Brazil's WTO obligations, because it would discriminate against imported toys by imposing an additional and redundant test on imported toys alone. In addition, the decree required imported toys to have the required seal placed on them at the time of clearance, rather than at the time and place of manufacture, as was permitted for domestic toys. This would also constitute a discriminatory requirement and impose substantial additional costs for importers. It would also cause practical difficulties as millions of toys imported annually would have to be labelled in bonded warehouses in Brazil that had no space for this activity. He informed the Committee that China had sent written comments to Brazil in

December 2008 and that Brazil replied that all the comments sent were being analyzed and could be incorporated after the closure of the public hearing in Brazil foreseen for January. At that point, the publication of the final version had been scheduled for March 2009 and Brazil had also committed to the final regulation being notified to the WTO. Given that it was already mid-March, the Chinese representative requested an update on this process.

106. The representative of the European Communities shared the comments raised by China. He noted that the European Communities had sent written comments to the Brazilian authorities on 21 January 2009. He also stated that the proposed modifications introduced by the notified text still fell short of addressing the concerns previously raised. He pointed out that the proposed decree would reinstate, with some amendments, the so-called System 5 procedure for imported toys alongside the currently available System 7 procedure, which was welcomed by the European Communities. However, the revised version of System 5 as applied to imported toys also gave rise to a number of concerns. System 5 was based on the evaluation of the manufacturer's quality management system and type-testing of a number of samples taken from the production line. Toy suppliers were given the possibility of having the tests performed either in Brazil by an INMETRO-accredited laboratory or abroad. With respect to the tests carried out abroad, the notified text provided for the acceptance of tests conducted by foreign laboratories accredited pursuant to IAF (International Accreditation Forum) or ILAC (International Laboratory Accreditation Co-operation) rules. However, even where full tests covering all relevant safety requirements had been carried out abroad in accordance with the set conditions, additional tests would be required to be carried out in Brazil at the time of importation by an INMETRO-accredited laboratory on samples taken from each imported batch. These additional tests would cover major aspects such as general, physical and mechanical properties and migration of certain chemical elements.

107. The representative of the European Communities emphasized that this would effectively establish a double-testing obligation on imported toys leading to significant additional costs and delays, while domestic toy suppliers would be able to complete the System 5 procedure prior to placing their products on the market. He stressed that this appeared to be more strict than necessary and would thus create unnecessary obstacles to international trade within the meaning of Article 5.1.2 of the TBT Agreement. Hence, European toy suppliers would continue to be granted less favourable access to the Brazilian market than suppliers of like toys of national origin, in a comparable situation, which was inconsistent with Brazil's obligations under Article 5.1.1 of the TBT Agreement.

108. The representative of the European Communities also noted his delegation's concern over the requirement for the affixing of the conformity marking after importation, as this would require the unpacking of goods upon importation, their storage in local warehouses and a number of operations relating to the affixing carried out locally, thus entailing additional costs. This could be a breach of the national treatment principle referred to in Article 2.1 of the TBT Agreement. The European Communities considered that, in its present form, the draft Decree imposed overly strict marking and labelling requirements, considering in particular that the packaging used for most toys was not exclusively for the Brazilian market and that bonded warehouses typically had no extra space for this activity. He also pointed out that domestic toy manufacturers would be able to affix the mark at the place of manufacture and to print it on the packaging. These requirements would therefore constitute an unnecessary barrier to trade within the meaning of Article 2.2 of the TBT Agreement.

109. The representative of the European Communities thanked INMETRO for its openness and willingness to have bilateral discussions with EC representatives. He requested further information on the date of the public hearing with interested parties which INMETRO had announced. He suggested that alternative ways could be explored with a view to pursuing the legitimate objective of protecting children from risks arising from certain imported toys. In particular, he suggested that Brazilian authorities could consider, rather than strengthening the conformity assessment procedure on unequal terms on imports as compared to domestic production, concentrating on better targeted

enforcement activities on imported products, based on appropriate risk assessment tools, considerations relating to the origin of the product, the track record of the importer or manufacturer, the characteristics of the products, the health and safety risks associated with the product, accident data, and so on. As this approach had been successfully applied by the European Communities for many years, they would be ready to share their experience in this field with the Brazilian authorities.

110. The representative of Thailand expressed similar concerns. Her delegation's assessment also came to the conclusion that the newly notified decree did not come any closer than its predecessor to ensuring conformity with the TBT Agreement. Despite Brazil's assurance at the last meeting that its revised procedure would accept foreign test reports, the conditions for the consideration of foreign test reports did not favour effective acceptance. The foreign laboratory would have to pass stringent accreditation criteria set by Brazil. Additionally, the test reports would have to be accompanied by a certified translation into Portuguese. She noted that this was more trade restrictive than necessary, as an international language such as English was accepted worldwide, especially in technical areas. As already noted by other delegations, Brazil also required that, where foreign testing was used, supplementary testing had to be performed on the same general, physical, mechanical and chemical requirements that had already been tested overseas. She said that this would have to be interpreted as Brazil's non-recognition of foreign testing and international collaboration under ILAC, contrary to the Brazilian claim to accept foreign test report.

111. She further pointed out that the importer had the responsibility to notify the Brazilian authority to sample products for tests, but only after arrival at the port. This implied that the importer had to rent bonded warehouses to store the products in waiting. Additionally, she noted that Article 5 of the new measure required that the conformity identification seal could only be affixed on imported toys after the certification was completed. She emphasized that this effectively meant that exporters would have to hire labour to unload all warehouses, unpack all products, and affix a seal on every individual toy item and packages thereof. They would have to repackage and reload them for transportation out from the port. Substantial additional time, work and costs would have to be spent by all toy importers into Brazil, in contradiction to Article 2.1 of the TBT Agreement, which states that members must be accorded treatment no less favourable than that accorded to like products of national origin. Furthermore, she pointed out that Brazil's new conformity assessment procedure failed to ensure conformity with Article 5.1.1 and 5.1.2 of the TBT Agreement, as it would create unnecessary obstacles to international trade, being more stringent than necessary to give Brazil adequate confidence that imported toys conformed to its requirements. She pointed out that better ways existed to safeguard children safety.

112. The representative of Thailand had noted that her delegation was still awaiting a response to the comments submitted on 24 December 2008. She urged Brazil to consider withdrawing the measure or bringing it into conformity with the TBT Agreement, respecting the principles of Good Regulatory Practice. She also suggested bilateral talks and asked Brazil to acknowledge receipt of the Thai comments and respond to them in writing.

113. The representative of the United States noted his delegation's appreciation of the revisions that Brazil had made to its regulations with a view to ensure that all toy producers, whether foreign or domestic, could utilize either System 5 or 7 to demonstrate that their toys conformed with Brazilian requirements, and that allowed exporters to use ILAC accredited laboratories outside of Brazil to conduct the testing required under either system. However, he also shared the systemic concerns raised by other delegations that the new decree applied an additional in-country testing requirement solely to imported toys. While the United States understood the importance of devising appropriate measures so as to ensure that children were protected from potentially unsafe toys, a continued dialogue would be important in tackling these common challenges confronted by regulators in many countries. He announced that the United States would be willing to facilitate discussions between regulators and to share experiences and discuss alternative approaches.

114. The representative of Brazil recalled that the current Brazilian regulation on toys had been adopted in an emergency situation with the aim of addressing a lack of confidence regarding the conformity of toys. Since the end of 2008, Brazil's toys regulation had been under revision. He noted that a proposed new regulation had been notified to the TBT Committee under G/TBT/N/BRA/313 and Members had had the opportunity to analyse and comment on this draft. He emphasized that imported toys would be allowed to use System 5 certification again. Both imported and domestic producers would be subject to a regular testing as a means of ensuring conformity with safety specifications. He stressed that tests performed by foreign labs accredited by ILAC would be accepted. He informed the Committee that INMETRO had been assessing all the comments received during the public consultation period and would hold a public hearing on the draft regulation in the coming weeks, to which all interested parties were invited. The date of the hearing would be confirmed by INMETRO in the near future and his delegation remained open for bilateral consultations on the subject.

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

115. The representative of Thailand raised concerns regarding the EC measures on dangerous chemical substances. Her delegation shared the objectives of protecting human health and consumers. However, she stressed the importance of having regulations based on solid scientific justification, especially when they could have vast and chain-like effects on competitiveness of developing and least developed countries. She also noted that the European Communities would incorporate the 30<sup>th</sup> and 31<sup>st</sup> Adaptation to Technical Progress (ATP) to the Dangerous Substance Directive 67/548/EEC (DSD) into a new 1<sup>st</sup> ATP to the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP). In this regard, Thailand requested the European Communities to notify the new classification in due time, in order to allow meaningful opportunity for comments from WTO Members. The representative of Thailand also stressed that the industry and trade of her country would be significantly affected if the new classification would be applied under REACH. The European Communities was therefore encouraged to base its regulations on solid scientific finding and procedural thoroughness.

116. The representative of Cuba, speaking on behalf of GRULAC regretted that the European Communities had adopted the 31<sup>st</sup> ATP, despite the procedural and substantive concerns expressed by GRULAC and other WTO Members at the last TBT Committee Meeting, the letters sent on this matter and the bilateral meetings held by several delegations with EC authorities in Brussels. In particular, the European Communities was requested not to proceed with the reclassification of nickel substances under the 30<sup>th</sup> and 31<sup>st</sup> ATPs and to allow sufficient time for scientific information submitted by industry to be properly considered.

117. The representative of Cuba recalled that GRULAC had raised both specific and systemic concerns about the above-mentioned classifications, which had not been satisfactorily addressed by the European Communities. He pointed out that some GRULAC Members possessed the world's largest reserves of nickel, and the reclassification of nickel substances would negatively affect their trade. In particular, this was the case of small and vulnerable economies like Cuba and the Dominican Republic, where nickel exports represented about 50 per cent of total exports of goods. Furthermore, contrary to previous EC statements that the 31<sup>st</sup> ATP only related to labelling and would not result in bans or restrictions on the use of chemical substances in consumer products, the 31<sup>st</sup> ATP would have an immediate legal effect across a wide range of existing regulations, including requirements relating to cosmetics (Directive 76/768/EEC), biocide products (Directive 98/8/EC) and plant protection products (Directive 91/414/EEC). Again, the representative of Cuba remarked that these adverse effects would be particularly severe for developing countries which, given their low level of development and industrialization, relied on a few export products for employment and revenue.

118. The Cuban representative also pointed out that the reclassification of nickel substances was taking place in the context of an economic crisis which was severely affecting developing countries, and which had led to a global contraction of credit, trade, investment and demand. It was also recalled that the international price of nickel had decreased from US\$50,000 per ton to about US\$10,000 per ton in less than two years. In this context, such reclassification would further aggravate conditions in this industry and increase production, transport and insurance costs. The representative of Cuba stressed that the impact of these classifications would be felt not only by nickel producers, but also by other countries which used nickel compounds in a broad range of industries and chemical processes. At the same time, the reclassification of nickel in one of the largest and most important world nickel markets would affect the access of nickel and nickel products not merely to that market, but also to other major markets, as had previously been the case with other standards and classifications.

119. The Cuban representative also expressed concerns regarding the inappropriate level of transparency and lack of scientific rigor of the reclassification, which could have implications in future similar classification processes. In particular, it was noted that the read-across methodology based solely on water solubility could be used as a precedent for taking regulatory decisions about other substances and concentrates produced in developing countries, especially in view of the EC's implementation of REACH and the UN Globally Harmonised System of classification and labelling of chemicals (GHS). Given the significant commercial implications outlined, the European Communities was asked to take into consideration Article 12.3 of the TBT Agreement, which provided that "Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members".

120. While Members of GRULAC recognized the need for authorities to regulate the use of dangerous substances for protecting human health and the environment, it was noted that the read-across methodology and other non-testing methodologies had to be used in a transparent and scientifically justified manner. In this regard, the delegation of Cuba recalled that the grouping and read-across methodology used in the 31<sup>st</sup> ATP did not conform to the criteria established by the OECD or the criteria of the US Environmental Protection Agency (EPA). This was due to the fact that the European Communities disregarded three of the eight essential verification steps established by the OECD guidelines, without providing any scientific explanation as to why those steps were omitted. Furthermore, while the European Communities relied on water solubility as a single data point and primary basis for classifying nickel compounds, no data existed on the water solubility for most of the nickel compounds that were classified in the 31<sup>st</sup> ATP. For both the OECD and the US EPA, establishing categories or groups of chemicals for the purpose of this methodology was a complex process involving the review of a number of elements. In this regard, the European Communities did not appear to have taken such elements into account.

121. Finally, the representative of Cuba drew the attention of the Committee to the timetable established by the European Communities for the adoption of the 31<sup>st</sup> ATP. He considered that the European Communities did not allow sufficient time for consultations to be held, as required under Article 2.9.4. of the TBT Agreement. In particular, he noted that the Technical Progress Committee (TPC) approved the 31<sup>st</sup> ATP on 19 November 2008, within 24 hours of the end of the notification comment period. His delegation therefore believed that the European Communities did not have time to take into account the comments provided by other WTO Members the day before. Cuba urged the European Communities to notify the 1<sup>st</sup> ATP to the CLP regulation, as required under Article 2.9 of the TBT Agreement.

122. The representative of Cuba, speaking on behalf of his own delegation, regretted that the European Communities approved the 31<sup>st</sup> ATP despite the concerns and many requests from WTO Members to extend the period for comments. In this regard, he recalled that the TPC approved the new reclassification within 24 hours of the end of the notification comment period, thus acting inconsistently with the requirements set in Article 2.9.4. of the TBT Agreement. Concerns were expressed about the negative impact that the 31<sup>st</sup> ATP would have on the demand for nickel especially in developing countries, which were highly dependent on nickel exports. This was the case of Cuba, where nickel exports represented, in 2007, more than 50 per cent of the total exports in goods. Furthermore, the reclassification was taking place in the context of a global economic crisis.

123. The representative of Cuba pointed out that the reclassification of nickel substances would trigger a contraction in demand and investment in this industry and an increase in labelling, packaging, transport, processing, storage and insurance costs. Indeed, the adverse effects of the new classifications would also have repercussions on other important markets. Cuba supported the objectives of protecting human health and the environment, however the requirements set by the new regulation appeared to be inconsistent with Article 2.2 of the TBT Agreement.

124. The representative of Cuba recalled that water solubility was only one of the many physical-chemical properties to be considered when making a comparison, but no data existed on these properties for most of the substances that were classified in the 31<sup>st</sup> ATP. He further stressed that there was a different behaviour among the substances of the same class: nickel oxide, for example, was highly soluble in water, whereas green nickel oxide was not.

125. With regard to the read-across methodology, the Cuban representative recalled that the European Communities had disregarded three of the eight essential verification steps established by the OECD guidelines. He further stressed that the European Communities did not offer any scientific evidence to establish a clear causal link between water solubility and toxicity of nickel substances. Moreover, the same substance being used as a reference, nickel carbonate, was already incorrectly reclassified as dangerous, using the same method without any scientific support.

126. The delegation of Cuba believed that the European Communities did not give a satisfactory clarify the many concerns raised on the 31<sup>st</sup> ATP, which appeared to be more trade-restrictive than necessary and therefore incompatible with Article 2.2 of the TBT Agreement. Cuba also believed that the European Communities did not take into account the special needs of developing countries when adopting this regulation, as required by Article 12.3 of the TBT Agreement.

127. The representative of Cuba noted that the European Communities intended to incorporate the 30<sup>th</sup> and 31<sup>st</sup> ATPs to the 1<sup>st</sup> ATP to the CLP regulation, which would be submitted for approval to the EC member States on 25 March 2009. In this regard, the representative of Cuba regretted that the European Communities would notify the draft 1<sup>st</sup> ATP for informative purposes only, because it covered the same substances covered by the 30<sup>th</sup> and 31<sup>st</sup> ATPs to the DSD, which had already been notified to the TBT Committee. He stressed that, since there were no international standards regarding the classification of nickel compounds and the regulation would have a significant effect on trade of WTO Members, the European Communities was obliged to notify the draft 1<sup>st</sup> ATP, as required under Article 2.9 of the TBT Agreement. Moreover, the CLP and the DSD regulations imposed different standards and obligations. For example, the CLP regulation had different rules on format, methodology and information requirements, which could require a different assessment of the substances. Also, the two regulations had different thresholds for high toxicity and different qualitative descriptions, restrictions, rules on packaging, labelling and risk warnings. The European Communities was therefore urged to comply with the obligations set by Article 2.9 of the TBT Agreement, and notify the draft 1<sup>st</sup> ATP at an early appropriate stage, allowing reasonable time for other Members to make comments, discuss these comments and take them into account. Finally, the

European Communities was urged to amend the 31<sup>st</sup> ATP to exclude nickel compounds from the scope of its application, sound scientific evidence of their toxicity was available.

128. The representative of Japan regretted that a satisfactory clarification to the many concerns had not been given by the European Communities at the last TBT Committee meeting. Japan was further concerned that, given the technical nature of the issue, the period granted by the European Communities to comment on the 31<sup>st</sup> ATP was too short. Furthermore, since the CLP regulation came into force on 20 January 2009, Japan requested the European Communities to provide, in advance and extensively, WTO Members with detailed information on the schedule of the related procedures, like the timeline of the 1<sup>st</sup> ATP to CLP and the timing of its notification to the TBT Committee.

129. The Japanese representative recalled that the scientific evidence of the read-across methodology applied to the 30<sup>th</sup> and 31<sup>st</sup> ATPs had been questioned by many WTO Members. Accordingly, he urged the European Communities to discuss the above-mentioned methodology with the countries that raised concerns and take their comments into account to take an appropriate approach to classification that meets with the GHS requirements. It was emphasized that an inappropriate approach to the classification of nickel compounds would have a significant impact both on nickel compounds manufacturers and on their users.

130. The representative of Canada supported the objectives of protecting human health and the environment. However, her delegation regretted that the European Communities did not seem to have taken into account the concerns expressed by trading partners with regard to the reclassification of nickel substances. The Canadian representative stressed that the EC reclassification could have a significant impact on the economy of her country, the economies of the other 21 WTO Members that expressed concerns at the last TBT Committee meeting and the economies of some EC member States. Some other specific concerns on the 31<sup>st</sup> ATP were raised by her delegation. First, Canada requested that the European Communities explain the consequences of the entry into force of the CLP regulation. In this regard, it was Canada's understanding that the 30<sup>th</sup> and 31<sup>st</sup> ATPs were of no legal effect, as they were amendments to the DSD regulation which was repealed before the amendments came into effect, and subsequently replaced by the CLP regulation. Second, Canada urged the European Communities to explain what procedure would be used to add the 30<sup>th</sup> and 31<sup>st</sup> ATPs to the 1<sup>st</sup> ATP to the CLP, and what the expected timeframe was. Third, the European Communities was requested to outline the risk management measures considered for the substances in the 30<sup>th</sup> and 31<sup>st</sup> ATPs.

131. The representative of Canada further stressed that the European Communities should notify the draft 1<sup>st</sup> ATP to the TBT Committee, and allow sufficient time for comments. It was also essential to Canada that any classifications of substances be based on transparent, sound science. Canada expected scientific information on nickel substances to be supplied by its industry under REACH and expected that the European Communities would give serious consideration to such scientific information to conduct a further review of the classifications. The Canadian representative stressed that her delegation looked for information on procedures regarding the implementation of the 30<sup>th</sup> and 31<sup>st</sup> ATPs, and would monitor the introduction of risk management measures to ensure they were not unnecessarily trade restrictive. Finally, she urged the EC delegation to clarify what the regulatory response to the adopted classifications of nickel would be.

132. The representative of Mauritius, speaking on behalf of the ACP Group thanked the EC delegation for its reply to the comments made at the last TBT Committee meeting regarding the decision to classify as hazardous over 100 nickel compounds in the 31<sup>st</sup> ATP directive. However, he noted that the issues raised had not been satisfactorily addressed by the European Communities and introduced a new submission from his delegation containing further comments (G/TBT/W/307).

133. The ACP Group was concerned that the 31<sup>st</sup> ATP would have immediate legal effect across a wide range of existing European laws. This contradicted previous EC statements, in which the EC delegation pointed out that the 31<sup>st</sup> ATP only related to labelling and would not result in bans or restrictions on the use of substances in consumer products. The ACP Group believed that the reclassification of nickel substances would have a significant negative economic and commercial impact on all nickel producing and exporting countries. These adverse effects would be particularly severe for developing countries which, given their low levels of development and industrialization, tended to rely on a few basic exports for employment and revenue. For example, this was the case of many ACP countries including Botswana, Cuba and the Dominican Republic, which were small and vulnerable economies highly dependent on mineral exports. Also, the 31<sup>st</sup> ATP would seriously affect future investments in the South African mining sector.

134. The representative of Mauritius recalled that the reclassification of nickel compounds took place in the context of a global economic crisis that was severely affecting developing countries. The 31<sup>st</sup> ATP was likely to further aggravate conditions in this industry, and cause increased production, transport and insurance costs. Given the significant commercial implications, it was essential that any classification of nickel compounds took into account the special development, financial and trade needs of developing countries, as required under the TBT Agreement.

135. While the ACP Group recognized the importance of ensuring a high standard of protection for human health and the environment and supported the development of regulatory strategies to achieve such protection, the European Communities had not proved the nickel classifications in the 31<sup>st</sup> ATP was based on a sound and transparent scientific method. In particular, the ACP Group continued to disagree that the grouping and read-across methodology were in conformity with the OECD criteria or the US EPA guidelines. Furthermore, the European Communities' reliance on a single data point, water solubility, as the initial and primary basis for categorizing nickel compounds was not supported by scientific facts, and was contrary to the OECD and US EPA guidelines. It was recalled that the European Communities had not showed the scientific basis for its assertion that water solubility was an "approximation" of the "systemic bioavailability of the nickel ion".

136. The representative of Mauritius stressed that the scientific and commercial issues raised by the nickel classifications in the 31<sup>st</sup> ATP were highly technical and complex. Yet, the legislative timetable of the 31<sup>st</sup> ATP failed to provide sufficient time for meaningful consultation with other WTO Members, as required under Article 2.9 of the TBT Agreement. Finally, the European Communities was encouraged to notify the draft 1<sup>st</sup> ATP to the CLP regulation at an early stage.

137. The representative of the Dominican Republic supported the comments made by Cuba on behalf of GRULAC and Mauritius on behalf of ACP, and reiterated concerns on the reclassification of nickel carbonates and other components of nickel, which her delegation considered to lack sufficient scientific evidence. She also noted that the comments expressed by various delegations at the TBT Committee meetings of March, July and November 2008 had not been taken into account in the amendment of the 30<sup>th</sup> and 31<sup>st</sup> ATPs. The representative of the Dominican Republic stressed that written comments regarding the 31<sup>st</sup> ATP had been sent to the EC delegation on 18 November 2008, and were subsequently circulated to all WTO Members under document G/TBT/W/302. She regretted that her delegation did not receive any response from the European Communities. She also regretted that the TPC approved the 31<sup>st</sup> ATP on 19 November 2008, within only 24 hours of the end of the notification comment period. It was her delegation's view that, having been adopted in these circumstances, the 31<sup>st</sup> ATP did not satisfy the requirements set by Article 2.9 of the TBT Agreement.

138. The Dominican Republic objected to the manner in which the European Communities applied the read-across methodology, which inaccurately transposed the toxic effects of one group of compounds to a broader group of nickel substances. In this regard, the representative of Dominican Republic believed that the European Communities violated Article 2.2 of the TBT Agreement. She



recalled that nickel exports represented, in 2007, more than 50 per cent of the total exports of the Dominican Republic, with a total value of US\$1,153 million, and that the 31<sup>st</sup> ATP would have serious harmful effects for both producers and exporters of nickel substances. Considering the serious drop in nickel prices that had already occurred in 2008, the EC measure would have a negative effect on industry and the economy of the country as a whole. As an example, it was pointed out that, in November 2008, a nickel company of the Dominican Republic was obliged to dismiss more than nine hundred workers. Finally, the European Communities was encouraged to comply with the obligations set by Article 2.9 of the TBT Agreement, and notify the draft 1<sup>st</sup> ATP at an early appropriate stage, allowing reasonable time for other Members to comment.

139. The representative of China echoed the concerns already expressed about the adoption of the 31<sup>st</sup> ATP by various delegations, particularly those of Cuba. While China appreciated the European Communities' reply to China's comments received on 22 December 2008, concerns with regard to the 31<sup>st</sup> ATP still remained. In particular, the Chinese representative noted that the European Communities did not provide any specific data on the water solubility of most nickel compounds. Therefore, China believed that the classification of over one hundred nickel compounds was not scientifically correct.

140. Furthermore, the representative of China invited the European Communities to clarify the procedures, timetables and legal consequences of the incorporation of the 30<sup>th</sup> and 31<sup>st</sup> ATPs into the CLP system. China was particularly interested in the legal consequences of such incorporation on downstream industries and consumer-end products. Finally, China asked the European Communities whether the 30<sup>th</sup> and the 31<sup>st</sup> ATPs would be directly incorporated into the CLP system, or whether more evaluations would be conducted. The European Communities was encouraged to notify the draft CLP at an early appropriate stage, allowing reasonable time for other Members to make comments.

141. The representative of Brazil shared the concerns raised by other WTO Members and supported, in particular, the comments made by Cuba on behalf of GRULAC. While he thanked the European Communities for the bilateral consultations held with his delegation on the 30<sup>th</sup> and 31<sup>st</sup> ATPs, Brazil regretted that the 31<sup>st</sup> ATP had been adopted despite the many concerns raised about the inadequate use of the read-across methodology. In view of the future incorporation of the 30<sup>th</sup> and 31<sup>st</sup> ATPs to the new CLP regulation, Brazil requested the European Communities to notify the draft 1<sup>st</sup> ATP to the TBT Committee, so that Members would have sufficient time to analyze the relationship between the ATPs and the new CLP regulation. In this regard, the representative of Brazil highlighted the differences between the new CLP regulation and the previous DSD. He noted, for example, that the CLP and DSD had different thresholds for acute toxicity of chemicals, and used different definitions. For instance, while Category 1A of the CLP referred to substances known to be carcinogenic, largely based on human evidence, Category 1 of the DSD referred to substances known to be carcinogenic, based on sufficient evidence to establish a *caso association*. Finally, Brazil recalled that new studies on the toxicity of nickel compounds were expected to be published in the coming months, and asked the European Communities to take them into account before enforcing the 30<sup>th</sup> and the 31<sup>st</sup> ATPs.

142. The representative of Colombia associated her delegation with comments made by the delegation of Cuba on behalf of GRULAC. She reiterated her delegation's concerns about the 30<sup>th</sup> and 31<sup>st</sup> ATPs and recalled the overwhelming effects such measures would have for Colombia.

143. The representative of Botswana joined the statement made by Mauritius on behalf of the ACP group, and raised further concerns about the 31<sup>st</sup> ATP. He regretted that the European Communities had adopted the 31<sup>st</sup> ATP, despite the concerns expressed by nickel producers and exporting countries. Concerns were expressed that the reclassification of nickel compounds as dangerous substances would have far reaching implications for the mining industry in his country. It was also recalled that

Botswana was highly dependent on mineral exports, including diamonds, copper, nickel, coal, salt, gold and potash. The mining sector contributed to approximately 40 per cent of Botswana's GDP and about 90 per cent of all merchandise exports. In 2007, nickel contributed substantially to the country's exports and accounted for approximately 48 per cent of all employment in the country's mining sector. The representative of Botswana also noted that copper and nickel mining sectors had benefited from the SYSMIN programme, a system created by the European Communities to stabilize export earnings from mineral products. However, this system would be undermined by the above-mentioned measure.

144. Botswana remained concerned that the reclassification of over 100 nickel compounds as dangerous substances would have an overwhelming impact not only on the mining sector, but would also affect the very livelihood of communities depending on such revenue. In particular, concerns remained about the adoption of the read-across methodology in the 31<sup>st</sup> ATP, which Botswana did not believe to be based on solid scientific arguments. While Botswana recognized the importance of ensuring a high standard of protection for human health and environment, the scientific grounds sustaining the adoption of the read-across methodology remained unclear. In conclusion, the representative of Botswana encouraged the European Communities to delay the implementation of the 31<sup>st</sup> ATP until WTO Members' concerns were fully addressed.

145. The representative of Australia reiterated her delegation's concerns regarding the reclassification of nickel compounds under the 31<sup>st</sup> ATP, and shared concerns raised by other Members. While regulatory decisions with far-reaching commercial implications should be based on sound, defensible and transparent science, Australian authorities remained concerned that the decision to reclassify 117 nickel compounds under ATP 31<sup>st</sup> was based on questionable scientific and procedural grounds. The European Communities was therefore requested to clarify the legal status of the ATP 31<sup>st</sup> and the 117 reclassified nickel compounds listed in it. Furthermore, the Australian representative remained concerned that the adoption of the 30<sup>th</sup> and 31<sup>st</sup> ATPs could set an unwarranted precedent for the manner in which other groups of chemical substances would be classified in future, including under REACH. In particular, it was her delegation's understanding that the new CLP Regulation provided for harmonized classifications, including those coming from REACH, via an ATP procedure. This would create a precedent, and her delegation was concerned about the scientific and procedural grounds of this precedent.

146. The representative of Australia stressed that the reclassification of nickel compounds under the 30<sup>th</sup> and 31<sup>st</sup> ATPs could have a significant economic impact on all nickel producing and exporting countries, including developing countries. She also highlighted the fact that the nickel compounds listed in the 31<sup>st</sup> ATP were used in a large range of processes. For instance, the nickel compounds listed in the 31<sup>st</sup> ATP were used as catalysts in applications such as petroleum refining, hydro-cracking, hydro-processing, steam reforming, food processing, transportation and carbon capture; in electroplating and surface treatment applications and technologies; and, finally, in a large number of applications and technologies such as lithium ion technologies, nanotechnologies, fuel cells, electroforming, semiconductor technology and specialized coating.

147. While Australia appreciated the explanation given by the European Communities that REACH provided for the "possibility of exemptions", concerns remained that: nickel substances and preparations containing such substances would need to be labelled with danger symbols, including the "skull and crossbones", which would potentially contribute to the stigmatisation of nickel and nickel-containing material and could reduce research and investment in important nickel-based technologies and materials; the reclassification of nickel compounds as Category 1 and 2 carcinogenic and mutagenic compounds would trigger a series of downstream regulatory requirements that would impose additional restrictions and prohibition on the substances; the reclassified Category 1 or 2 carcinogenic and mutagenic substances would be deemed "substances of very high concern" (SVHC) under REACH and could result in additional restriction, prohibition, or substitution of nickel; the

planned classification would reduce supply of nickel substances to downstream users and damage the competitiveness of manufactures in critical sectors that rely on nickel substances.

148. Given the significant commercial implications of the proposed reclassification of nickel compounds under the 31<sup>st</sup> ATP, it was essential that any restriction imposed by the European Communities on nickel compounds be based on sound and transparent science which did not put in place unnecessary obstacles to international trade. Australia recognised the importance of ensuring a high standard of protection for human health and the environment, and supported the development of regulatory strategies to achieve such protection. However, in accordance with Article 2.2 of the TBT Agreement, these regulations should not create unnecessary obstacles to international trade.

149. The representative of Zimbabwe associated herself with the comments made by Mauritius on behalf of the ACP group. Zimbabwe urged the European Communities to address the concerns of all nickel producing and exporting countries, also taking into account the special development, financial and trade needs of developing country Members.

150. The representative of Indonesia noted that his country's nickel exports to the European Communities would be significantly affected by the entry into force of the 31<sup>st</sup> ATP. Considering the adoption of the CLP regulation and the preparation of the 1<sup>st</sup> ATP to the CLP, Indonesia urged the European Communities to fulfil its obligations set in Article 2.9 of the TBT Agreement and notify the draft 1<sup>st</sup> ATP at an early appropriate stage, allowing reasonable time for other Members to make comments.

151. The representative of Argentina joined the concerns expressed by previous speakers about the reclassification of nickel compounds. He recalled that measures aimed at protecting human health and the environment should be based on sound science and not represent an unnecessary barrier to trade.

152. The representative of South Africa thanked the European Communities for the replies received in November 2008. However, he supported the concerns already expressed about the adoption of the 31<sup>st</sup> ATP by various delegations, particularly those of Mauritius on behalf of the ACP group, Botswana and Zimbabwe.

153. The representative of the United States reiterated his delegation's concerns regarding the 30<sup>th</sup> and 31<sup>st</sup> ATPs, and regretted that the classification of borates and nickel under the DSD regulation had been finalized. In particular, concerns remained on the legal status of the DSD and CLP regulation, and on how they interacted. The European Communities was therefore requested to clarify the status of the classifications under the 30<sup>th</sup> and 31<sup>st</sup> ATPs. Were those classifications currently binding, did they only become enforceable once added to the CLP regulation by the 1<sup>st</sup> ATP or were they enforceable on some other date? What was the process for adding such classifications to the CLP regulation? Would the European Communities notify the 1<sup>st</sup> ATP to the CLP regulation to the TBT Committee, allow for due comments and reconsider the classifications in light of new information?

154. The representative of the United States noted that the European Communities did not appear to have taken into account the normal handling and use of borates-containing and nickel-containing products when proposing its classification of substances, and emphasized that the EC delegation acknowledged that its classification was entirely hazard-based. In addition, the representative of the United States reiterated his delegation's concern regarding the "skull-and-crossbones" labelling requirements for certain borates-containing products, and the "knock-on" effects under other EC legislation, including REACH.

155. Furthermore, the US representative recalled that, at the last TBT Committee meeting, the European Communities claimed that a risk and impact assessment of downstream uses of borates

under the Marketing and Use Directive would be conducted. In this regard, it was his delegation's understanding that a consultant, Risk and Policy Analysts (RPA), completed such a risk and impact assessment with respect to borates-containing products in November 2008. With regard to the use of borates in fertilizer, the RPA Report found that the risks associated with boron fertilizers were unlikely to be of serious concern and there was a possibility that any potential restrictions on the use of borates as a fertilizer would result in costs to the industry and provide consumers with no or minimal benefit in terms of risk avoided. With regard to the use of borates in soaps and detergents, the RPA Report found that consumer exposures were negligible. Concerning the use of borates in certain other chemical products, the RPA Report found that the risks to consumers were negligible with the restrictions imposing high costs on producers. Lastly, according to the RPA Report the use of borates in glass would be unlikely to result in any significant exposure of borates to consumers and there were no viable alternatives.

156. The United States requested the European Communities to clarify the effect of the above-mentioned Report on the EC determination with respect to restrictions on the use of borates under the Marketing and Use Directive. In particular, the European Communities was asked to confirm that, as a result of the RPA Report, there would be no restrictions on the uses of borates under that Directive. Given RPA's finding, the EC delegation was invited to explain what the basis for requiring skull and crossbones labelling on certain borate-containing products was. Finally, it was emphasized that the United States continued to study the risk and impact assessment for borates, monitor the potential adverse trade impacts both of nickel and borates classifications, and analyze the classification methodology that had led to these classifications in the context of REACH and other EC measures.

157. The representative of Turkey emphasized that the comments of his delegation were valid for both the 30<sup>th</sup> and 31<sup>st</sup> ATPs. While Turkey recognized the importance of ensuring a high standard of protection of human health and safety, concerns remained that the EC classification would not fulfil such objectives and would create unnecessary barriers to trade. The representative of Turkey recalled that his country's authorities had started a study on boron mines, the results of which would be shared with interested Members. He also regretted that the European Communities disregarded the above-mentioned epidemiological study. The results derived from animal tests could not lead to the conclusion that borates caused reproductive toxicity in humans, and this was also demonstrated by the RPA Report mentioned by the US delegation.

158. In particular, the RPA Report indicated that, in an array of exposure scenarios from the lowest level to the highest, the utilization of borates in end-products did not require restrictions due to the negligible level of risks associated with their use. In this regard, concerns remained on the reasoning behind the EC decision to approve the 30<sup>th</sup> and 31<sup>st</sup> ATPs despite the evidence provided by the report and the concerns raised by many WTO Members. The representative of Turkey encouraged the European Communities to recognize the RPA Report as a basis for future steps regarding borates. Furthermore, he reiterated that the classification decisions in both the 30<sup>th</sup> and 31<sup>st</sup> ATP did not have a legitimate objective and had the effect of creating unnecessary obstacles to trade.

159. The representative of Turkey also noted that the 30<sup>th</sup> and 31<sup>st</sup> ATPs required EC member States to "bring into force the laws, regulations and administrative provisions necessary to comply with this Directive" by 1 June 2009. In this context, he recalled that the classification and labelling system provided under the DSD was currently being replaced by the CLP regulation, which entered into force on 20 January 2009 and would completely replace the DSD on 1 December 2010. The new CLP regulation deleted Annex I of the DSD regulation and incorporated it into Annex VI of the CLP. However, Annex VI of the CLP regulation only incorporated Annex I as amended by the 29<sup>th</sup> ATP. The European Communities was therefore encouraged to clarify the process which would be followed for the incorporation of the 30<sup>th</sup> and 31<sup>st</sup> ATPs into the CLP regulation. Considering the differences between the new CLP regulation and the previous DSD, the European Communities was urged to take

into account the concerns raised by WTO Members with regard to the 30<sup>th</sup> and 31<sup>st</sup> ATPs, and consider the findings of the above-mentioned RPA report.

160. The representative of the Philippines joined the concerns raised by other Members on the reclassification of nickel, and encouraged the European Communities to take those concerns into account.

161. The representative of the Russian Federation, speaking as an observer, supported the comments of previous delegations with regard to the nickel classification, and regretted that the European Communities adopted the 31<sup>st</sup> ATP without taking into account the concerns raised by WTO Members. In this context, attention was drawn to the consequences of the EC decision on the nickel industry. Furthermore, the representative of the Russian Federation recalled that the EC regulation lacked scientific consistency and could create unnecessary barriers to trade. She therefore urged the European Communities to remove all nickel classification proposals in the draft 1<sup>st</sup> ATP, and take any decisions regarding classification on the basis of scientific evidence provided by industry.

162. The representative of the European Communities confirmed that the 31<sup>st</sup> ATP had been adopted by the European Commission on 15 January 2009, after the Committee of member States representatives had given its favourable opinion on 19 November 2008. She also noted that all the comments received from WTO Members had been carefully analyzed by EC authorities and EC member States. In full knowledge of these comments, the EC member States voted in favour of the proposal, with no vote against it.

163. With regard to the scientific basis of the methodology used to classify the nickel compounds, the EC delegation recalled that, at the last TBT Committee meeting and at the information session held on 4 November 2008, two experts explained in detail how the read-across methodology had been applied and how existing scientific data had been used. Those explanations could be found in the Minutes prepared by the WTO Secretariat.<sup>5</sup> Additional clarifications could also be found in the extensive reply submitted by the EC delegation to the comments of WTO Members. As indicated in the adopted regulation, new arguments or scientific evidence submitted by WTO Members with regard to this classification would be examined by the European Communities. However, the EC representative stressed that new data had not been received yet, neither from industry nor from third countries. It was also emphasized that the European Communities had not received evidence from downstream users as to the impact this classification could have on their activities.

164. On the issue of the CLP regulation and its link with the 30<sup>th</sup> and 31<sup>st</sup> ATPs, it was noted, first, that the CLP was aimed at implementing the Globally Harmonised System (GHS) of classification and labelling of chemicals. It was also clarified that Annex I of the DSD, which contained the compounds classified under the 30<sup>th</sup> and 31<sup>st</sup> ATPs, had been repealed by Article 55(11) of the CLP regulation as of its entry into force in 20 January 2009. The recently adopted harmonized classifications contained in the 30<sup>th</sup> and 31<sup>st</sup> ATPs were not in force yet but would be introduced as new entries in the CLP regulation via a draft 1<sup>st</sup> ATP proposal. This draft 1<sup>st</sup> ATP had been already notified to the TBT Committee as an addendum to G/TBT/N/EEC/151, G/TBT/N/EEC/163 and G/TBT/N/EEC/212. While several delegations asked the European Commission to notify the above-mentioned measure as a new notification, the EC representative noted that only draft proposals which imposed new requirements had to be notified to the TBT Committee. This "direct" translation, or direct transfer was foreseen in Annex VII of the CLP Regulation and had been likewise applied to all the substances classified under the previous ATPs and covered over 8000 substances. Therefore, Annex VII of the CLP regulation contained the classification of dangerous substances that had been

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<sup>5</sup> See G/TBT/M/46 pp. 21-25.

done on the basis of the GHS criteria, and included the classifications adopted under the previous DSD regulation.

165. With regard to the comments that had been made in reference to the different criteria and safety phrases, the representative of the European Communities noted that these phrases had been harmonized in accordance with the GHS. In particular, Category 1 CMR under the DSD became Category 1 under GHS, Category 2 CMR under the DSD became Category 1(b) under GHS, and Category 3 CMR under the DSD was Category 2 under GHS. The adoption of the 1<sup>st</sup> ATP was expected to take place in July 2009, and industry was expected to implement the obligations in terms of classification and labelling by December 2010.

166. Finally, the representative of the European Communities confirmed that a study had been carried out by an external consultant, the purpose of which was to assist the European Commission in examining whether it was necessary to impose any restrictions on the placing on the market of borates-containing products. This study was finalized in November 2008 and could be found on the website of the European Commission's DG Enterprise and Industry.<sup>6</sup> The study demonstrated that there were no substances or preparations containing borates above the specific concentration limits which were sold in the EU market. Therefore, the European Communities concluded that such classification of borates would have no new impact in terms of production and import of substances and preparations containing borates. In this regard, it was also noted that the use of borates in cosmetic products was already restricted in the European Union. The representative of the European Communities also emphasized that the RPA Report had not yet been concluded yet concerning some minor uses and investigations were ongoing as well regarding the risks related to the use of sodium tetraborate in detergents. New information would be provided when available.

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

167. The representative of Thailand referred to her delegation's previously expressed position on REACH. While Thailand supported the objectives of the protection of human health and the environment, the complexity of REACH was beyond the capacity of many developing and least developed countries to understand and comply with. Such difficulties were particularly evident for SMEs, which represented the majority of Thailand's industry. Concerns were also expressed with regard to the Only Representative (OR) provision, which created unnecessary and unaffordable costs for SMEs.

168. The representative of Japan thanked the European Communities for the response to the comments previously raised on REACH. However, some specific concerns about the REACH regulation remained. First, the Japanese representative urged the European Communities to issue the guidance documents which had been delayed beyond the expected date. Furthermore, it was noted that six EC member States expressed disagreement over the 0.1 weight per cent denominator mentioned in the guidance on "requirements for substances in articles". Since this disagreement could undermine the compliance with REACH and confuse the Japanese industry, he encouraged the European Communities to ensure a unified implementation of REACH across the European Communities and according to the guidelines established under the European Commission and ECHA. The representative of Japan also noted that some EC member States required a pre-registration number for the import of chemicals, where other member States did not, despite the fact that REACH did not clearly stipulate this. In this regard, he emphasized that the operations and regulations for imports by EC member States were different, and there were inconsistencies among different member States. The EC delegation was therefore requested to give further clarification and

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<sup>6</sup> [http://ec.europa.eu/enterprise/index\\_en.htm](http://ec.europa.eu/enterprise/index_en.htm)

unification on the operation of pre-registration such as treatment of pre-registration number information in customs clearance when EC member States import.

169. The representative of Japan noted that, according to REACH, downstream manufacturers and importers of certain types of substances, such as "monomers contained in polymers", "substances which are intended to be released from articles", "re-imported substances" and "recovered substances", were exempted from the registration if the substances were registered by an actor higher up in the supply chain. However, it was noted that the European Chemicals Agency (ECHA) had encouraged downstream companies to pre-register the above-mentioned substances if they were not sure that the substances concerned would be registered by an upstream manufacturer or importer within the pre-registration deadline. Since companies outside the European Union had difficulties to identify whether the substances were registered by an actor higher up the supply chain, the ECHA's recommendation caused the submission of multiple pre-registrations by different companies through the same supply chain.

170. On the Substance Information Exchange Forum (SIEF), the Japanese representative stressed that submitting pre-registration imposed a burden on companies, such as costs involved in joining a voluntary consortium relevant to the SIEF, consultant fees, and securing other human resources to prepare for data-sharing. Concerns remained also on the cost of appointing an Only Representative (OR) and on the impossibility to withdraw from the SIEF without a particular reason. Therefore, Japan requested the European Communities to provide some guidelines on the exemptions from the unnecessary cost-sharing generated by double pre-registrations, on the fees for companies to join a industry voluntary consortium relevant to the SIEF, and on the withdrawal from the SIEF after the conclusion of the upstream registration.

171. The representative of Mexico referred to his delegation's previously expressed position on REACH, and noted that concerns remained with regard to two issues. First, Mexico recalled that there were less trade-restrictive alternatives to the OR requirement, such as extra-territorial inspections that would enable exporters to register chemical substances themselves. Second, the Mexican representative expressed concern on the lack of uniform implementation of REACH among EC member States. In this regard, he brought to the attention of the Committee a recently approved French law, which established criminal and monetary sanctions for non-compliance with REACH. It was his delegation's understanding that sanctions were far too high and were not consistent with WTO provisions. Finally, the Mexican representative urged the European Communities and EC member States to take into account the concerns of WTO Members about REACH and its implementation.

172. The representative of the United States shared the EC concern for protecting human health and the environment. However, the REACH regulation appeared to be overly broad and to adopt a costly and burdensome approach that could unnecessarily disrupt and distort global trade. In particular, the representative of the United States noted that the number of concerns raised by industry was growing exponentially since the pre-registration period had ended. Since all of those concerns involved the lack of transparency of REACH and its implementation, he had found it disappointing that the European Communities had not responded to repeated requests for bilateral technical talks made by the United States. It was noted that the failure of the European Communities to clarify such issues would lead to serious trade disruptions, and that some US companies would have to stop shipping into the EC market. It was also noted that, due to the lack of clarity and transparency of REACH, many companies had decided to pre-register every chemical substance to the European Chemicals Agency (ECHA). As a result, there were approximately three million pre-registrants of over 140,000 substances, which was much larger than what ECHA forecasted. The US industry believed that these large numbers of pre-registrants would make the SIEFs unworkable and extremely expensive, especially for SMEs in both developed and developing countries who in many cases would have to pick and choose which substances they would continue to produce and use since they would not be able to participate in all of the SIEFs.

173. Regarding the issue of cosmetics, the representative of the United States recalled that the European Communities had already recognized that REACH could discriminate against foreign cosmetics producers, as many substances in important cosmetics would not have an EINECS number. The US representative regretted that, despite repeated discussions and the urgency of the issue, the problem remained unresolved.

174. On the Only Representative provision, the representative of the United States regretted that fundamental structural problems remained. In fact, because foreign manufacturers could not themselves register as EC manufacturers could, and instead would need to appoint an OR unless they had an EU presence, the OR provision raised serious concerns for non-EC supply chains, and sensitive commercial information could be compromised depending on who in the supply chain appointed the OR and how the supply chain was set up. It was highlighted that this problem was leading several companies to consider as part of their sourcing policies whether they needed to start purchasing more of their inputs from companies located in the European Union. Foreign chemical distributors were being particularly impacted since they were not permitted to appoint an OR. In this regard, it was recalled that, in his delegation's view, one of the primary objectives of REACH was to increase the competitiveness of the European chemical industry.

175. The representative of the United States also reiterated his concern with regard to the different interpretation of REACH provisions across the EC member States. For example, the ECHA guidance on "notification obligations for substances in articles" noted that producers needed to check with each member State regarding how it would interpret the notification obligations. It was noted that the United States had pointed out the dissenting opinions of several member States on substances in articles on previous occasions, but those concerns had not been addressed.

176. Similarly, differential enforcement of REACH across the EC member States had been observed by the United States. In this regard, the attention of the Committee was brought to the criminal penalties for non-compliance with REACH being developed by France and United Kingdom. Reference was also made to the evidence of pre-registration for imports sought by Belgium and the Netherlands, even though this was not required under REACH. In this regard, the United States believed that actions seeking evidence of pre-registration were potentially problematic for at least two reasons. First, given that REACH allowed six months from the date of import or first manufacture for companies to submit late pre-registrations or for ORs to add new downstream users, these actions could block legitimate trade. Second, pre-registration numbers supplied for purposes of customs clearance could be transmitted to downstream users, who could use them to decipher information about product formulations. Both of these potential problems would only affect imports. Therefore, the US delegation asked the European Communities to clarify what actions were being taken to prevent differential enforcement and interpretation of REACH provisions, so that producers shipping products to the EC market could have legal certainty and be sure that their proprietary formulas were protected. In concluding, the US representative urged the European Communities to take into consideration the concerns which had been expressed by trading partners and other interested parties, and to ensure a meaningful opportunity to reflect the views of other governments and stakeholders in the process.

177. The representative of Korea pointed out that the Korean industry was still facing many difficulties in complying with REACH. He shared the concerns expressed by Japan and the United States, in particular about the differential implementation of REACH among EC member States and the supply chain issue. He stressed that potential exporters were no longer shipping to the EC market because of the complexity of REACH.

178. The representative of Argentina reiterated his delegation's concern with regard to REACH. The complexity and extensive scope of REACH, coupled with the burdensome costs associated, the lack of transparency and appropriate technical assistance, was injuring Argentinean exporters and



constituted a serious impediment to their continued presence in the EC market. It was noted that during the period of pre-registration, which ended on 1 December 2008, both the ECHA and the EC authorities had not satisfactorily responded to the questions that had been raised on technical assistance. Argentinean companies also complained that the lack of uniformity in the information provided by the Enquiry Points of each EC member State had led to different answers to the same questions. In this context, a massive number of pre-registrations had been submitted by a small number of companies, which showed that the competitiveness of the EC market had been seriously distorted. The representative of Argentina reiterated his delegation's request to have the list of companies which had already carried out the pre-registration procedure.

179. In addition, concerns remained on the Substances of Very High Concern (SVHCs) included in Annex XIV of the REACH Regulation. In particular, the Argentinean delegation referred to the candidate list of SVHCs updated on 16 February 2009, which listed 17 chemical substances. While on 14 January 2009 a Press Release of the Commission defined seven of the above-mentioned substances as "priorities" and therefore subjected to public consultation, nothing had been said with respect to the other ten substances. Given the sensitive nature of this topic, Argentina requested the European Communities that all information and requirements discussed in the future be focused in one single Enquiry Point established at the ECHA. On the same topic, Argentina urged the European Communities to clarify whether stakeholders needed to follow up on the news related to the implementation of REACH on the ECHA webpage, or whether the ECHA would directly inform the relevant authorities of the EC member States through regular communications. Finally, the Argentinean delegation held that REACH constituted an unnecessary barrier to trade, as it distorted the competitiveness of the EC market in chemical products and substances.

180. The representative of Canada supported the objectives of protecting health and the environment, but reiterated her delegation's concern about REACH. With respect to the issue of the Only Representative, Canada remained concerned that REACH could have a disproportionate impact on SMEs, and that the OR requirement was biased against non-EU based companies because of the extra costs it entailed. In this regard, Canada believed that a company wishing to comply with REACH had to either hire an OR, open an office in the European Union, attempt to navigate the complexity of REACH on its own, or choose to abandon the EC market. The representative of Canada also asked the European Communities to explain what measures were being taken to protect confidential business information that non-EC firms were expected to provide to their OR.

181. On the subject of test methods regulations, the representative of Canada noted that the European Communities would adopt the OECD test standards. She requested the European Communities to clarify what the timeline for adoption of the test methods and what the practical consequences would be. It was also noted that the European Communities had declared that the OECD test standards would be used except in exceptional circumstances. Canada requested the European Communities to clarify what these exceptional circumstances could be and whether they would be published. The European Commission was further requested to postpone the adoption of any unique or alternative test methods until their review and acceptance by the OECD.

182. On the subject of data submitted by industry, Canada believed that industry would be required to generate a great amount of scientific data to demonstrate the safety of their products. In this regard, the European Communities was encouraged to treat data submitted by industry fairly and objectively and clarify how such objectivity would be safeguarded. For example, what transparency, oversight and peer review measures would be put in place?

183. On the Substance Information Exchange Forum (SIEF), the representative of Canada noted that Canadian companies needed to provide data to ORs which, in turn, could be required to report this data to the SIEF. Since only EC-based companies were able to join the SIEF, this could cause an unfair, potentially prejudicial one-way flow of information that could disadvantage Canadian

companies. In this regard, the Canadian delegation stressed that foreign companies should be allowed to join the SIEF and benefit from the information sharing. Canada requested the EC delegation to clarify how it considered the relationship between mandatory SIEFs, voluntary, pre-existing industry consortia and how the two could fit into the REACH framework. Furthermore, the European Communities was asked to clarify whether data sharing requirements under SIEF applied to non EC-based companies represented by an Only Representative, and provide details on the cost and data sharing rules applicable to SIEF. Since industry still faced many problems with the implementation of this regulation, the Canadian delegation hoped that REACH Help Desks would be widely promoted and be responsive to enquiries.

184. The representative of Chile reiterated her delegation's concerns with regard to REACH. In particular, she recalled that there was still lack of clarity on the product coverage of the REACH regulation. Although her delegation had raised this issue previously, the response of the European Commission had not been satisfactory. Chile further encouraged the EC delegation to clarify the penalties for non-compliance with REACH, which appeared to be different in each EC member State. Moreover, Chile asked the Commission to publish some guidelines for the interpretation of Annexes IV and V of the REACH regulation, and to clarify the issue of cosmetics.

185. Concerns also remained on the treatment of copper and molybdenum under REACH. In addition, Chile expressed concern with regard to the last four digits of the registration number of chemical substances, which identified the producer and the consumer. The representative of Chile stressed that, with such a system, the competitors would gather sensitive information on the consumers, while not resulting in a safer management of chemical substances, which was the main objective of REACH. The European Communities were therefore encouraged to take these concerns into account and modify the legislation accordingly.

186. The representative of Brazil noted that his delegation recognized the importance of protecting human health and the environment. However, concerns remained that the REACH regulation was more trade-restrictive than necessary to fulfil those legitimate objectives. The Brazilian representative highlighted the difficulties and the costs imposed by the registration procedure, testing, and the OR requirement, especially in for SMEs of developing countries. Therefore, he requested the European Communities to provide clarifications on the outcome of the pre-registration phase, and in particular whether it was considered necessary to change the original timeframe of REACH, given the unexpectedly high number of pre-registrations submitted.

187. The representative of China shared the concerns raised by previous speakers about REACH. China was particularly concerned that the participation in the Substance Information Exchange Forum created complex legal consequences with regard to competition and IP law. Considering the current progress of SIEF and the approximation of deadlines, the European Communities was urged to monitor and evaluate the process and consider the possibility of extending the deadlines.

188. The representative of Australia reiterated her delegation's concern about REACH and noted its potential to disrupt and impede global trade in chemicals. While Australia recognized the importance of ensuring a high standard of protection for human health and the environment, the complexity of such a policy and the enormous challenges faced by non-EC companies remained a concern. Australia was particularly concerned that REACH would have a disproportionate impact on SMEs and that the OR provision could discriminate against non-EC companies, placing higher costs on non-EC producers and manufacturers. In particular, Australian SMEs indicated that the costs associated with appointing an OR to pre-register their chemical substances were prohibitive; as a result, many SMEs were unable to continue exporting into the EC market. It was also stressed that non-EC companies continued to require further assistance from EC experts to ensure a correct implementation of REACH. In this regard, the representative of Australia welcomed the development of the REACH guidance documents by the European Communities but noted that these were

continuously subject to change. Australia urged the European Commission to take into consideration the concerns expressed by Members about REACH.

189. The representative of Cuba joined other delegations in concerns expressed about REACH. In particular, she was concerned about the complexity and lack of transparency of the REACH regulation, its information requirements, the OR provision, the differential enforcement of REACH across EC member States, and the overall difficulties faced by SMEs of developing countries in its implementation. Furthermore, she urged the European Communities to provide technical assistance and take into account the special needs of developing country Members. Finally, Cuba suggested that the TBT Committee consider other means of addressing the REACH issue if no progress was made during the regular Committee meetings, for instance through the good offices of the Chairperson.

190. The representative of Chinese Taipei shared the concerns expressed by other Members. Furthermore, she noted that according to Article 14(9) of the REACH regulation, ecotoxicological and toxicological test and analysis were required to be carried out in compliance with the principles of good regulatory practice contained in Directive 2004/10/EC or with other international standards recognized as equivalent by the Commission or the ECHA. Since the OECD GLP accredited laboratories were not the only option available, the European Communities was asked to clarify what alternatives to accreditation systems were available for laboratories. In particular, the EC delegation was requested to provide examples of accredited laboratories which were not accredited by the OECD GLP but were acceptable to the Commission.

191. The representative of Kuwait shared the concerns raised by other WTO Members and supported, in particular, the comments made by the United States. He was especially concerned about the lack of transparency and clarity of the REACH regulation.

192. The representative of Egypt stressed that her delegation had several concerns related to the costs, complexity and burdensome requirements of REACH for both manufacturers and exporters of chemical products. She also reiterated that technical assistance on the interpretation and implementation of REACH was even required by large companies of EC member States.

193. The representative of the Russian Federation, speaking as an observer, joined other delegations in concerns expressed about REACH. While the Russian Federation welcomed the development of the REACH guidance documents by the European Commission, several concerns remained unresolved. In particular, the representative of the Russian Federation recalled that, following the ECHA recommendations, non-EC based companies decided to pre-register nearly all the substances exported to the EC market. As a result, companies pre-registered many more substances than necessary. It was also stressed that companies still had doubts about the status of some substances, and they would be forced to submit enormous data files for the registration phase, bearing burdensome costs for data generation, sharing and registration. The estimated costs reached over US\$300,000 per chemical substance. The European Communities was therefore encouraged to reconsider the REACH regulation, which appeared to be excessively complex, non-transparent and burdensome, particularly in the context of the global financial crisis.

194. Furthermore, the representative of the Russian Federation expressed concerns about the possible discrimination between EC and non-EC based companies in the registration process, which resulted in an additional burden for non-EC companies. Moreover, non-EC companies could not participate in SIEF and consortia. With regard to SIEF, the Russian Federation noted that high volume producers had to submit their registration dossiers to ECHA by the end of 2010, while smaller producers could submit their registration dossiers until 2018. As a result, big producers were allowed to share data and classify substances by the end of 2010, without consultations with smaller producers. The Russian Federation believed that this could discriminate against SMEs. In conclusion, the Russian Federation encouraged the European Communities to take into consideration

the concerns which had been expressed by its trading partners, and to reconsider some unnecessary procedures under REACH.

195. The representative of the European Communities recalled that at the previous meeting of the TBT Committee, two experts from DG Environment and DG Enterprise had provided detailed and comprehensive answers to the concerns raised by WTO Members on REACH.<sup>7</sup> It was also recalled that EC authorities had taken note of the comments expressed and would take them into account in the implementation of REACH, as far as was possible and appropriate. With regard to new developments related to REACH, the representative of the European Communities noted that the pre-registration period under REACH ended on 1 December 2008, and that the ECHA received about 2,7 million pre-registrations for about 150,000 chemical substances. She pointed out that a list of the pre-registered substances had been published on 19 December 2008, and it was available on the ECHA website.<sup>8</sup> It was her delegation's opinion that the high number of pre-registrations proved the effectiveness of the EC's awareness campaign.

196. On the issue of verification and proof of pre-registration numbers, the representative of the European Communities recognized that the REACH Regulation did not regulate on whether pre-registration numbers had to be provided to custom authorities. However, it was emphasized that REACH was providing for the obligation to pre-register and that enforcement authorities of EC member States had therefore the right to control if the obligations of REACH were respected. It was noted that it was up to the enforcement authorities to decide when and how they carry out these checks and companies should be prepared to provide for a possibility to show that the obligations have been respected. It was also stressed that once the necessary information was provided to the authorities, products were released and could be put on the market.

197. On the Substances Information Exchange Forum, the EC delegation clarified that it was made mandatory in order to avoid unnecessary animal testing, but also to reduce testing costs, especially for SMEs. It was further noted that the REACH regulation did not oblige SMEs that had no specific data to take the role of lead registrant or take an active role in the discussion of the SIEF. In many cases, it would be less costly for SMEs participating in the SIEF rather than conducting their own studies. With regard to the question of Canada on the organization of the SIEF, the EC representative referred to the guidance document on "data sharing", which was available on the ECHA website.

198. On the specific issue of the missing guidance documents raised by Japan, the EC representative confirmed that guidance on "preparation of an application for authorization" and the guidance on "socio-economic analysis authorization" were still in preparation. However, it was stressed that the above-mentioned guidance documents were related to authorization under REACH, and there were no substances subjected to authorization yet.

199. With regard to the questions on the candidate list, the EC representative clarified that the Substances of Very High Concern (SVHCs) would be identified and included in the candidate list according to the procedure established by Article 59 of the REACH regulation. It was emphasized that this process consisted of different stages and that at every stage of the process interested third parties were allowed to comment the procedure. It was a very transparent process which allowed to follow which substances would be included in the candidate list. The representative of the European Communities recalled that a first version of the candidate list had been published on 28 October 2008 and contained fifteen substances. Two other substances, tris(2-chloroethyl) phosphate and arsenic and its salts, were not on the candidate list yet but had been added in the registry of intentions available on the ECHA website. The representative of the European Communities confirmed that on 14 January 2009 the ECHA had recommended to prioritise seven substances out of the fifteen, in order to

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<sup>7</sup> See G/TBT/M/46, paras. 179-191.

<sup>8</sup> See <http://echa.europa.eu/>

determine which substances would be subject to authorization. Interested parties were invited to submit comments by 14 April 2009.

200. On the issue of uniform interpretation across the European Communities, the EC representative recalled that the legal instrument adopted for REACH was a regulation, which was directly applicable in all member States and applied uniformly throughout the European Communities. This point was not affected by the dissenting views of some EC member States or by the fact that there had been certain advices for practical reasons to check how certain EC authorities enforced REACH. It was further noted that only the text of REACH was legally binding and only the European Court of Justice would have the competence to provide a definitive interpretation of its provisions. Therefore, in case enforcement authorities interpreted REACH in different ways, operators concerned could start an action at national courts for seeking the views of the European Court of Justice, who would establish which interpretations should prevail throughout the European Union. Therefore, the system contained sufficient instruments to ensure a uniform application of REACH.

201. On the issue of penalties for non-compliance to REACH, the EC representative clarified that sanctions, as usual for EC legislation and as a result of the structure of the EC, fell under the competence of EC member States and information on sanctions would be published in their national official journals according to each member State's legislative system. Member States were currently laying down the provisions on penalties and the Commission was closely monitoring this process. In this regard, she noted that REACH provided that penalties be effective, proportionate and dissuasive and that in consequence, penal sanctions could in principle and certain cases be envisaged.

202. On the specific question about substances that were lawfully on the EC market before 1 June 2008, but which did not have phase-in status under REACH (e.g. cosmetics), the EC representative stressed that REACH was not discriminatory with regard to these substances. In particular, Article 26 of the REACH regulation provided that for non-phase in substances an enquiry to the ECHA had to be carried out prior to the registration. On 12 December 2008 the European Commission had explained in a communication that certain problems existed in practice, since it was impossible to register these substances at the same time as the enquiry. Therefore, the affected operators had been invited to submit the enquiry to the ECHA in order to avoid any disruption of trade. It was stressed that the ECHA was waiting for these enquiries.

203. Regarding the requests for technical assistance, the EC representative noted that technical assistance on REACH either had been already carried out under certain programmes, or there was the possibility to incorporate it in ongoing EC trade-related assistance programs. She invited WTO Members having specific needs for technical assistance programmes, to direct their requests to the respective delegations of the European Commission in their country. Finally, the EC delegation informed the Committee that the European Commission was organizing a conference on the EC Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP) based on the UN Globally Harmonised System (GHS), to be held in Brussels on 17 June 2009. The event would be web streamed and would also be available afterwards on the web<sup>9</sup>.

(v) *Norway – Hazardous substances (G/TBT/N/NOR/17)*

204. The representative of Japan recalled that, at the last TBT Committee meeting, the delegation of Norway clarified that, as a result of a second review of the proposed regulation, eight substances had been removed from the list of the regulation while modifications were being considered for the remaining ten substances. In this regard, he sought an update on the current status of the ten substances under review.

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<sup>9</sup> Further information on [http://ec.europa.eu/enterprise/reach/information/events/index\\_en.htm](http://ec.europa.eu/enterprise/reach/information/events/index_en.htm)

205. The representative of Jordan requested an update from Norway on the restrictions to the use of hexabromocyclododecane (HBCDD).

206. The representative of the United States noted that the proposed measure and the information provided on the risk assessments were being reviewed. However, he reiterated that his delegation continued to have systemic concerns with the proposed regulation because the measure was hazard-based and did not appear to consider whether its benefits would outweigh any risks identified.

207. The representative of Norway made reference to the detailed report given by his delegation at the last Committee meeting. Moreover, he recalled that the proposed regulation had been subject to an extensive hearing process at the national and international level. This process had triggered several comments on the proposal from WTO Members, EU industry and other stakeholders. As a follow-up, a second review of the proposed regulation was conducted by the Norwegian Pollution Control Authority. The regulation had not entered into force on 1 January 2008, as previously proposed in the draft regulation.

208. As a result of the second review, eight substances had been removed from the list of the regulation. The original list of eighteen substances had been thus reduced to include only ten substances. Furthermore, other modifications were being considered for the remaining ten substances, such as limit values or further exemptions. It was also noted that there was no schedule for the conclusion of such work and for the entry into force of the regulation. Finally, the representative of Norway mentioned that further technical information on the substances considered by the regulation were available on request. He took note of the concerns expressed, which would be transmitted to the responsible environmental authorities.

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

209. The representative of Japan pointed out that the CCC system had not yet been opened to foreign-based certification bodies and that his delegation had requested China that foreign certification bodies in China or overseas could be appointed without discrimination, as per Article 6.2 of the TBT Agreement and the Report of the Working Party on the Accession of China, paragraph 195. He sought clarification on the following points: first, he expressed his understanding that, though China had introduced the IECEE/CB scheme as one of the solution in the previous meeting of the Committee, , under the IECEE/CB scheme, China accepted only testing report related to "Safety". He asked whether China planned to accept the testing report of EMC (Electromagnetic Compatibility) and the CoC (Certificate of Conformity) in addition to the acceptance of the testing report of "Safety".

210. Second, the representative of Japan also noted that China had stated that "if the Government of China and the Government of Japan conclude a Mutual Recognition Agreement, foreign based certification bodies can be appointed under the CCC system without discrimination" whereas, according to Article 13 of the Regulations of People's Republic of China on Certification and Accreditation, it was stated that "foreign certification bodies shall not be engaged in certification activities". He asked whether, if Japan had an MRA with China, Japanese certification bodies were excluded from this provision and if not, what Japan needed to do in order for China to accept the CoC (Certificate of Conformity) of foreign certification bodies.

211. Third, the representative of Japan stressed that even if China and Japan concluded a MRA, Japanese certification bodies in China could not make use of it. Therefore, he sought clarification on the way forward for Japanese certification bodies in China to be appointed under the CCC system without discrimination.

212. The representative of the European Communities welcomed the reply by China to the comments his delegation had submitted. The reply contained useful clarifications, for instance with

respect to the indication that flexibility in implementing the CCC certification based on classification management of products and factories would be allowed, the scope of factory inspections for companies holding ISO-9001 certificates and the conditions for exemptions of spare parts from CCC certification. The EC hoped that the final version of the revised CCC regulations would accurately reflect those clarifications. He also welcomed the statement that the Chinese legislation would strictly follow the national treatment principles embodied in the WTO Agreements on the protection of legal rights and interests of foreign-owned certification and testing organizations. He recalled that his delegation had requested China to consider allowing foreign-owned certification bodies legally established in China to be designated for the purposes of the CCC and trusted this statement meant that the Chinese authorities were giving positive considerations to this request.

213. The representative of the European Communities reiterated the call for China to undertake a structural review of the CCC system, on the basis of a risk-based approach to conformity assessment and with a view to reducing the number of products within the scope of the scheme and to ensuring that conformity assessment requirements were modulated according to the level of risk associated with the products. His delegation remained open to bilateral discussions with the Chinese authorities within the framework of the existing bilateral regulatory dialogue. In particular, he suggested continuing to share experiences on product risk assessment and management of conformity assessment systems based on lighter conformity assessment procedures and effective market surveillance. A joint case study on product risk assessment and impact assessment of the proposed CCC implementing regulations could usefully serve to come to a common understanding of risk assessment methodologies and evaluation of the economic impact of conformity assessment procedures.

214. The representative of Switzerland shared the concerns expressed and noted that industry had reported that the CCC system was too complex, costly and time consuming. Switzerland encouraged China to apply a more risk-based approach, in order to reduce the number of products covered by the CCC system. For example, for low risk products, suppliers declarations of conformity (SDoC) would be sufficient.

215. The representative of China highlighted that the objective of the modified regulation was to streamline the currently prevailing compulsory certification in China, based on the experience with the CCC system accumulated in the past 6 years. The proposed substantial changes included: first, expanding the single sample collection model for the sample of type test to three collection models to improve the representativeness of the sample; second, establishing a monitoring and supervision system to ensure consistency of the performance; and third, establishing an effective product recall system. With respect to the recognition of foreign certification bodies and their testing results, China recognised the IEC CB scheme. However, since China was not a member of the EMC scheme, it could not accept results and certification of EMC of foreign conformity assessment bodies.

216. The representative of China further explained that according to the regulations on certification and accreditation, foreign certification bodies qualification for CCC certification bodies could only be acquired through inter-government agreements, agreements recognised by the Chinese Government or agreement with competent authorities within the Chinese Government. With respect to SDoC, he stressed that, as the TBT Committee had discussed in the Second Triennial Review of the TBT Agreement, to ensure the SDoC was being implemented effectively, an appropriate legislative framework, including safeguards against non-compliance of dangerous products such as market surveillance and product liability laws and administrative control, needed to be established in advance. As a developing country Member, China had difficulty in this regard and therefore had not yet established SDoC as an applicable conformity assessment procedure. He noted that the draft regulation was under review and that Members' comments had been taken into due consideration, and some revisions had already been introduced. The final version of the regulation would be published after internal approval procedures were concluded.

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

217. The representative of Japan welcomed the fact that China had delayed the publication of the final implementation rules. However, as it was expressed in the previous meetings, Japan still had serious concerns on this planned regulation on IT security products, which covered a wide range of products for civil use and which would have a significant effect on trade; concerns remain about IPR protection as well. He sought an update about the new time schedule for these regulations. In particular, he sought clarification on: (i) whether the implementation of the regulation, originally planned for 1 May 2009, would be delayed following the delay of the publication of the final implementation rule; (ii) whether consultations could be held before the publication of the final implementation rules; and, (iii) whether a one year period between the publication of the final rules and the implementation of the regulations would still be granted.

218. The representative of the United States reiterated his delegation's position that these regulations went substantially beyond global norms by mandating testing and certification of information security in commercial information technology products, not only in products for sensitive government use or those used in national security applications. His delegation appreciated the willingness of officials from China's Certification and Accreditation Administration (CNCA) and China's Ministry of Commerce to maintain an open line of communication with government officials and industry groups from the United States and other countries. He also welcomed China's commitment to delay publication of final technical regulations while Chinese and foreign experts continued to discuss possible approaches to the regulation of information security. He understood that China was working on the proposed revisions to the thirteen regulations and sought information on the substance of potential amendments, including the possible timeframe for adoption. Finally, he urged China to continue to delay publication of final measures and not implement them on 1 May 2009, so that technical discussions between experts could continue.

219. The representative of Korea also welcomed the postponement of the publication of the final rules and stressed that certification should not be applicable to commercial information security products, since important security information could be leaked on account of disclosing the source code. This could result in an obstacle to international trade.

220. The representative of the European Communities shared the positions expressed by the other delegations, recalled the concerns expressed by his delegation at the previous meeting of the Committee and sought confirmation that the adoption and publication of the final implementation rule would be delayed. His delegation appreciated the open channel of communication on this issue and China's willingness to start an expert dialogue in order to share experiences with foreign industry and governments about current practices in managing risks arising from information security. He sought information on the proposed revisions which were currently under considerations and on the expected timeline and invited China, in case the final decision was to implement nonetheless mandatory rules, to notify any substantial amendment to the proposed scheme to the TBT Committee in order to give interested Members an opportunity to comment.

221. The representative of Canada echoed the comments made by previous speakers and looked forward to the on-going discussion on the subject.

222. The representative of China noted that his country had been open and transparent in the process of developing information security products compulsory certification scheme, by notifying the proposed regulations and soliciting comments from stakeholders, both domestically and abroad. Bilateral communications between China and other interested trading partners, including the United States, the European Communities and Japan had taken place and China was committed to being open and transparent in the remaining process, so as to ensure that the final scheme was science-based and reasonable. He stressed that the objective of the proposed information security products compulsory



certification scheme was in compliance with the legitimate objectives in the TBT Agreement. In particular, information security was closely related to consumer interests as well as to the country's security and certification schemes for information security products had been established in many countries.

223. The representative of China further stressed that his delegation attached great importance to other trading partners' concerns with the proposed regulations and, in this respect, the decision had been made to postpone the adoption date of the proposed regulations, so as to leave more time for further technical communication and discussion among the regulators and experts. He noted that a joint introductory meeting about the proposed scheme was being arranged with the US information technology organization and invited all interested parties to participate in that meeting to obtain more information and share their views about the matter.

*(viii) China – Draft standards for lithium batteries for mobile phones*

224. The representative of Japan appreciated the fact that the Chinese Electronics Standardization Institute (CESI) had created a working group where experts, including from Japan, had met to discuss the draft standards for lithium batteries. He pointed out that the draft standards under consideration also dealt with types of material and the methods of manufacturing, despite the fact that they were characterized as safety standards. Therefore, his delegation continued to have concerns with these measures, in particular with respect to their consistency with international standards and to the protection of intellectual property rights, and believed that the draft standards should be limited to safety. He requested China to ensure a cooperative relationship with foreign manufactures and harmonization with international standards in the drafting process. He also sought information on the current status of these standards on mobile phones and laptops.

225. The representative of the European Communities joined Japan in requesting an update on the state of play of the standards and urged the Chinese responsible standardization bodies to limit this standard to safety aspects only.

226. The representative of China pointed out that this issue went beyond the competencies of the TBT Committee. The standards setting process was taking place at national level, and openness and transparency in the process had already been guaranteed. He also noted that, as mentioned by Japan, experts, including from Japan, had participated several times in related working group meetings where all technical issues were discussed. He stressed that the formal draft text of the standards was still under development and suggested that interested Members participate in the already established national procedure rather than raising the issue in the TBT Committee.

*(ix) China – Energy efficiency and energy efficiency grades for copy machines (G/TBT/N/CHN/331/Rev.1 and Suppl.1)*

227. The representative of Japan reiterated his delegation's concerns on the Chinese measure on energy efficiency grades for copy machines. In particular, he believed that the measure would make it difficult to measure energy efficiency accurately, since in the proposed standard energy efficiency was measured by copy mode, even if copy-based machines had the function of printer. This was despite the fact that the regulation was based on the international Energy Star Program which stipulated that energy efficiency in machines equipped with the function of a printer should be measured by printer mode. He recalled that at previous meetings of the Committee his delegation had pointed out that it was difficult to decide whether machines were to be considered as copy machines or printers, and that China had responded that this would have to be decided on the basis of fundamental function of the machine, and that it intended to publish guidelines for the application of the measure. He enquired about the progress of the announced guidelines.

228. The representative of Japan further noted that, in the Chinese measure, there were three levels of energy efficiency and that, at the beginning, only the lowest one would be mandatory. However, three years after the entry into force of the measure, the second one would become mandatory as well despite that China explained that the second level threshold was based on the international Energy Star Program, which was a voluntary scheme. China was requested not to include this voluntary standard in its mandatory regulation. Additionally, he enquired about the progress, including with respect to TBT notifications, of the standard on printers and fax machines, which China had expressed its intention to develop. He stressed that these standards should be harmonized with international standards.

229. The representative of China stressed that the objective of this measure was to save energy and protect the environment, which was fully in line with the legitimate objectives of the TBT Agreement. The measure was applicable to copy machines as well as to multifunctional machines with copying as a fundamental function. If the machine was a printer with copy as a secondary function, the standard would not be applicable. The criteria for such distinction were specified in the standard itself. He further explained that the measure stipulated three grades of energy efficiency, with the lowest grade (grade 3) being the compulsory requirement. Grade 2, which was based on the Energy Star Program, would become mandatory after three years, thereby giving an adequate time to industry to adapt. Therefore, the standard would not create an unnecessary obstacle to international trade. With respect to similar standards for printer and fax machines mentioned by Japan, they were still under preparation and some Japanese companies were also involved in the technical consultations. Once a draft was ready, this would be notified to the TBT Committee and an opportunity to make comments would be provided.

(x) *India – Pneumatic tyres and tubes for automotive vehicles (G/TBT/N/IND/20)*

230. The representative of Japan was concerned about India's mandatory certification for pneumatic tyres. His delegation believed that the regulation caused unfair excessive testing and certification costs as well as time constraints for foreign-based firms. Furthermore, the testing and certification capacity within India was insufficient to meet the needs. Japan also believed that there should be a longer implementation period in order to allow industry to adapt.

231. The representative of the European Communities appreciated India's clarifications at the previous TBT Committee meeting, as well as in bilateral talks, and especially the information that the measure had not yet been adopted. She stressed, however, that her delegation had still not received clarifications on whether the license fee for tyres was calculated in a different way for tyres produced in India and for imported tyres. Clarifications were also still outstanding on whether tyres could be certified in other laboratories than the only accredited laboratory in India (notably the Central Institute for Road Transport), and if tyres complying with UN-ECE Regulations would be recognized. She also sought clarification about the entry into force of the measure, in particular whether the measure had been adopted or if it was under revision.

232. The representative of India recalled that the proposed mandatory requirements for imported tyres were notified on 17 July 2006 and that the objective of these requirements was to ensure quality and safety. He stressed that the mandatory certification was in the public interest and was not intended to treat imported tyres any less favourably than domestic tyres as the same would also be applicable to Indian tyre manufactures. With respect to the fee structure or costs for imported manufacturers and domestic manufactures, he pointed out that the marking fee structure was common for all items under BIS certification pertaining to Foreign Manufactures Certification Scheme. Some additional costs for manufactures of imported goods were due to extra expenses borne by the certification agency for administering the scheme. Also, conformity assessment procedures were the same for domestic as well as foreign manufactures.

233. With respect to the laboratories from which test reports could be accepted, he highlighted that India had a well established laboratory for testing of the tyres. Test reports from accredited laboratories abroad could also be accepted, provided that these were carried out per the test methods prescribed in the relevant Indian standard and that accreditation was based on ISO IEC 17025, by a body which was a part of the MRAs with ILAC APLAC on a reciprocal basis. He pointed out that the measure was not yet in force. With respect to the request by Japan for a longer implementation period, he recalled that the notification was sent to the WTO in July 2006, and that it provided 60 days for comments. Three years later the measure was not yet in force, and this could not be considered as a short implementation period. Comments would be conveyed to capital for due consideration before the measure entered into force.

(xi) *Brazil – Regulation on Identification and Quality Standards of Ethyl Alcohol and other Spirits (G/TBT/N/BRA/276-278 and Suppl.1)*

234. The representative of Mexico pointed out that the regulation set forth a definition for tequila with specifications which were below what was allowed for under Mexican legislation. In addition, the measure limited the types of tequila which could be marketed in Brazil, at the same time laying down specifications which would allow for the marketing of a product of inferior quality to the product produced in Mexico under the name "tequila". He stressed that Mexico believed that this ran counter to several provisions of the WTO including GATT 1994, the TBT Agreement and the TRIPS Agreement. He recalled that, at the TBT Committee's meeting held in July 2008, his delegation had expressed concerns about the measure in question. Industry involved and the Mexican Government had jointly presented their comments and expressed their opposition to the measure both to the Brazilian Enquiry Point as well as to the Ministry of Agriculture Farming and Supply of Brazil. He recalled that concerns had also been reiterated at the Committee's meeting in November 2008 and that a reply from Brazil to the comments made was still awaited.

235. The representative of Brazil informed the Committee that the proposed regulation on spirits was in the process of being updated. He stressed that public consultations had been held and additional time for comments had been granted to interested parties. All comments received would be analysed before the final regulation was published. Specifically, on the issue of tequila, he pointed out that, in Brazil, "tequila" was considered a generic name since 1973, when decree 73/267 had set quality and identity standard for this kind of spirit. Therefore, Brazil disagreed with Mexico's allegation that Brazil's proposed regulation on tequila violated TRIPS provisions. Considering tequila as a generic name in Brazil was fully in compliance with Article 4.4 of the TRIPS Agreement, which allowed Members to use geographical indications of another Member if it had been doing so for at least ten years preceding 15 April 1994. He reassured Members that the proposed regulations would not affect market access conditions for exports, nor limit the sale of tequila in Brazil.

(xii) *United States – Country of origin labelling (G/TBT/N/USA/25, G/TBT/N/USA/83 and Corr.1, G/TBT/N/USA/281, Add.1, Add.2 and Add.3)*

236. The representative of Mexico recalled that his delegation had expressed concerns that COOL imposed a technical barrier to trade and was not compatible with the TBT Agreement. In particular, his delegation believed that the system did not aim at protecting consumers, but, rather, manufacturers. Furthermore, the regulation was not based on the CODEX standard on pre-packaged products and foods. He also recalled that, on 17 December 2008, Mexico had requested consultations on the regulation in the framework of WTO Dispute Settlement Understanding. Consultations had been held on 27 December, in which Mexico's concern about the negative effect of the measure on bilateral trade had been discussed.

237. The representative of Mexico further noted that the United States had recently published the final regulations. However, confusion remained with respect to the entry into force of the measures.

Additionally, a letter by the Secretary of Agriculture, Mr. Thomas Vilsack to processors and packers of meat which required voluntary labelling that was more restrictive than the Final Rule had also generated uncertainty. He stressed that the legitimate objective of this measure was still not clear and that his delegation believed that trade among WTO Members should be carried out in conformity with the provisions of the WTO Agreements. Mexico had sent several questions to the United States on the status of the requirement of the measure and was awaiting a response.

238. The representative of Canada was concerned with the apparent contradiction regarding the implementation of the country of origin labelling measure. In particular, the Final Rule notified in G/TBT/N/USA/281/Add.3 was in contradiction with the Secretary of Agriculture's letter to industry of 20 February 2009, which called for the voluntary adoption of stricter labelling practices than what was required in the COOL statutory provisions and the Final Rule referenced above. Her delegation believed that it was unusual for industry to be encouraged to follow stricter requirements than those set out under the formal rule-making process in the United States: particularly so when that encouragement was accompanied by a threat that if industry did not do so, the final rule could be modified. She stressed that this had created uncertainty in the market, particularly among the covered commodity producers and processors, as well as at the retail level.

239. The representative of Canada further pointed out that her delegation's concerns were not limited to questions of legal uncertainty. Canada believed that COOL - especially as laid out by the U.S. Secretary of Agriculture in his letter to industry - would increase production costs all along the beef and pork value chains, with no obvious benefits, and would unravel years of progress made in creating an efficient, integrated and competitive market. This was not helpful for industries, especially in difficult economic times. Canada further viewed COOL as imposing unnecessary obstacles to trade and establishing less favourable treatment for imported commodities: Canadian industry had incurred negative economic impacts following the entry into force of COOL under the Interim Final Rule on 30 September 2008 (G/TBT/N/USA/281 Add.1). She stressed that Canada continued to believe that COOL was fundamentally flawed and should be repealed for all products, and requested the United States to clarify the requirements of COOL, including how it would be administered and implemented. She asked the United States to also clarify the objectives of the measure: was it, as stated in the WTO notifications, a measure for consumer information, or, as more recently stated by Secretary Vilsack and by USTR, a food safety measure?

240. The representative of the United States informed the Committee that the amendments to the COOL program consequent to the 2008 Farm Bill were now law, and that the Final Rule had been published in the U.S. Federal Register on 15 January 2009 and had taken effect on 16 March 2009. He noted that Secretary Vilsack was aware of those concerns raised by Canada and Mexico. He also pointed out that the objective of the rule was unchanged and that the United States remained committed to implementing COOL in a fair and balanced manner. Finally, he clarified that the Final Rule was what was legally operative under U.S. law. The letter was voluntary, and USDA would allow industry to use the voluntary guidance in the letter as it deemed appropriate.

(xiii) *United States – Requirements to combat illegal logging (G/TBT/N/USA/424, Corr.1 and Add.1)*

241. The representative of Mexico recalled that the above-mentioned measure was notified to the TBT Committee in November 2008, with the objective of protecting the environment. In February 2009, further amendments to the measure were made and a new period for comment was provided until 6 April 2009. He noted that, under this measure, it was considered illegal to import, export, transport, sell, receive, acquire or purchase certain plants and plant products, both within the United States and between the United States and third countries, with limited exceptions. The measure required the presentation of a declaration of import, which should include information relating to the scientific number, the value of the import, the quantity and the name of the country from which the

plant was harvested. Implementation would be carried out in three phases, through a electronic register.

242. The representative of Mexico further stressed that, while his delegation supported the objective of protecting the environment and had also undertaken specific actions to combat illegal logging, the requirements of the Lacey Act were excessive and would have a negative impact on bilateral trade. Furthermore, his delegation did not believe that the measure was the least trade restrictive option, in accordance with the provisions of the TBT Agreement. For example, there was a significant number of industries, including paper industry, which used recycled wood in the production of products for fibreboard whose identification was not possible under the Lacey Act. He requested the United States to look at the possibility of excluding industries which used recycled materials from the application of the measure. He was also concerned about the treatment that would be provided to wood packaging and noted that to date the United States had not defined what it meant by "common crops". He asked the United States to provide answers to the concerns raised.

243. The representative of Japan pointed out that, although it agreed that preventing illegal logging was important, the measure should not be more restrictive than necessary as stipulated in the TBT Agreement. His delegation would follow up the progress on this issue.

244. The representative of the United States pointed out that the Lacey Act, as amended, was an important tool to support the efforts of other countries, as well as the U.S. States, in the conservation of protected plant and wildlife resources, including ongoing efforts to combat illegal logging. Through a variety of activities the United States had also continued efforts to assist countries to improve forest law enforcement and governance, in order to combat illegal logging at its source. Examples of these efforts to assist countries in combating illegal logging included bilateral development assistance, cooperation in the context of bilateral and regional trade agreements, and capacity building through organizations such as the International Tropical Timber Organization (ITTO). He highlighted that most countries had joined high level statements or commitments to cooperate to combat illegal logging.

245. The representative of the United States further noted that the declaration mentioned by Mexico, while it required the scientific name of the plant, quantity and value of importation and name of the country where the timber had been harvested, did not require information on legality, nor require certification of any kind. The declaration was made by the importer and was not issued by a government agency. He recalled that at the previous meeting of the Committee concerns were raised that there was not a positive list of products, that more time to comply was required, and about the scope of the measure. These comments had been taken into account by the United States. He explained that the revised plan for phased-in enforcement of the plant import declaration requirement had been published in the US Federal Register on 3 February 2009. This contained a positive list of products and phase-in would take place over six month intervals.

246. It was also noted that Animal and Plant Health Inspection Service (APHIS) and other agencies involved in enforcing the provisions of the Act were working together on the phase-in and enforcement, and that an electronic system to collect the information would be available on 1 April 2009 or soon thereafter. In particular, the enforcement of the plant import declaration required for the import of goods would focus, for the next two years, on timber and wood products. A copy of the declaration was available on the APHIS website<sup>10</sup> and most importers were expected to use the electronic system to file the declaration. The process of consultations with trading partners on all aspects of implementation of the Lacey Act would continue, and prohibitions applied to domestic commerce as well as trade.

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<sup>10</sup> <http://www.aphis.usda.gov>

247. Finally, the representative of the United States noted that the revised regulation had been notified as an addendum to the original notification<sup>11</sup> and this had been done in an effort to be fully transparent, even though it was his delegation's view that the plant import declaration was neither a technical regulation nor a conformity assessment procedure. With respect to Mexico's concern about recycled inputs, these would be transmitted to capital and discussed with the relevant regulators.

(xiv) *China – Excessive Packaging (G/TBT/N/CHN/321 and G/TBT/N/CHN/447 and Suppl.1)*

248. The representative of the United States supported China's stated objective of environmental protection and economization of resources. Indeed, Members such as Korea, Japan, Chinese Taipei, Canada, Australia, and New Zealand, as well as some US states, had chosen to reduce the effect of waste on the environment by linking packaging costs to specific targets for recyclable content and reuse materials. However, his delegation remained concerned about the efficacy of restricting packaging in relation to product cost, as China had done, to meet its objective. The cost of environmentally friendly packaging (i.e., packaging which had the highest recyclable content or reuse percentage) often far exceeded that of traditional packaging. Thus, if China limited the total cost of packaging, the result could be that industry would be forced to package more products in cheaper materials that could not be recycled or reused. Less expensive packaging could also contain higher levels of heavy metal contaminants and other potentially hazardous materials. Further, packaging designed to protect safety, such as child safety seals, increased packaging costs.

249. The representative of the United States further stressed that industry remained concerned that, if China was to go forward with the proposed measure, limiting total packaging costs to a certain percentage of the ex-factory price of the product would have an adverse effect on the ability of the food industry to properly deliver a safe and well-packaged product to consumers. Lastly, concerns also remained about the fact that the required reporting of ex-factory price and packaging costs would force companies to divulge confidential business information. What procedures did the Chinese Government have in place to assure the confidentiality of such information? The United States delegation requested that China re-evaluate its approach to this technical issue or revert to its earlier position that compliance with the percentage limit was voluntary. China was encouraged to consider some of the methods employed by other WTO Members to meet its environmental goals, and the US delegation offered to discuss this issue with China.

250. The representative of the European Communities shared the concerns expressed by the United States with regard to the mandatory cost requirements of the Chinese measure, which had also been expressed at previous Committee meetings. Her delegation was of the opinion that such cost requirements did not effectively contribute to the legitimate objective of the reduction of waste and the protection of the environment. Instead, the measure could have the contrary effect and prevent the use of more expensive, but more environmentally friendly packaging. She also stressed that the required data would be difficult to provide for importers, since foreign contracts would need to be provided. Additionally, prices were often calculated in foreign currencies, which had changing exchange rates. Therefore, it would be difficult to respect and to control the cost requirements. She invited China to make the cost requirement voluntary. Her delegation was open to continue to discuss alternatives and less trade restrictive solutions bilaterally with China.

251. The representative of China noted that the objectives of the measure were to restrict waste costs by excessive packaging, to save resource and encourage reasonable consumption. These served the need to protect the environment which was one of the legitimate objectives in the TBT Agreement. He recalled that China had notified the measure in its draft stage and had solicited comments from other Members. After the meeting of the Committee held in November 2008, China had replied individually to comments sent by the Distilled Spirits Council and the National Institute of

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<sup>11</sup> G/TBT/N/USA/424/Add.1

Standards and Technology of the United States, and also to those sent by the European Communities. Comments had been taken into due consideration and the original requirement of 15 per cent had been increased to 20 per cent.

252. The representative of China further stressed that the draft standards would apply equally to both domestic and imported products. In fact, China was more concerned about the excessive packaging of domestic products rather than imported products. China would also take into account the request of an interim period for the products already put on the market and a reasonable adaptation period would be accorded after the adoption of the standard. His delegation remained open to any constructive suggestions from China's trading partners and to discussing how to better fulfil China's legitimate objectives.

(xv) *European Communities – Regulation on Certain Wine Sector Products (G/TBT/N/EEC/15, Corr.1-2, G/TBT/N/EEC/57 and G/TBT/N/EEC/252 and Add.1)*

253. The representative of the United States continued to have serious concerns about the EC measures that restricted the ability of non-EC wine to use common or descriptive and commercially valuable terms, on the grounds that those terms were traditional to European wines. This was particularly concerning when some of these terms did not have a common definition across all EC member States and there was no effort to monitor or limit the use of those terms within the European Communities. He pointed out that the European Communities was trying to claim exclusive rights to use terms commonly included on wine labels, such as "chateau", "vintage" and "superior", except under certain limited circumstances where the exporting country regulated use of the terms to the satisfaction of the European Communities. The urgency of the issue had increased, given the negative trade impact that would result from the EC's failure to extend the derogation for the use of such terms on US wines sold in the EC market, which expired on 10 March 2009.

254. The US representative also stressed that concerns were further heightened due to a EC communication in December 2008 to one particular US wine producer that owned a trademark containing the word "chateau" in the United States that was also registered as a trademark in certain European member States. Specifically, in this communication it was noted that only those trademarks containing European traditional terms that were registered or had obtained "use-based" rights prior to 4 May 2002 could continue to be used on the European market after the expiration of the US derogation. The implications of this letter seemed to be that any trademark containing a traditional term that had been accepted and validly registered by various EC member States' national trademark offices prior to 4 May 2002 would continue to be protected, but only in those member States where they were registered, and not in the rest of the European Communities and that any such trademark registered after 4 May 2002 would be invalid under the terms of the regulation. He urged the European Communities to clarify whether that was the case.

255. Furthermore, the representative of the United States pointed out that, while the European Communities attempted to justify limitations on the use of traditional terms by indicating that consumers could be misled by their use, these terms had been used on the EC market on US wines for many years with no problems. Adding to the US industry concern was the fact that the European Communities had not indicated how it intended to enforce the limitations with respect to imported wines. For example, would the European Communities or its member States take action to block importation of US wines bearing a traditional expression?

256. It was further noted that the European Court of Justice had expanded the scope of the measures and, contrary to previous assurances, the traditional terms were now protected in languages other than the one for which protection had been identified. Additionally, it was pointed out that the European Communities claimed that it was working on a proposal to resolve the matter. However, a proposed regulation which would have to be notified for comment to the WTO would not be in place

in time to mitigate the trade impact of the expiration of the derogation. It was stressed that if the European Communities wanted to work constructively towards a resolution, it should continue to extend the derogation as provided for under the bilateral wine agreement while discussions on the matter continued.

257. The representative of Argentina reiterated his delegation's concerns as outlined in document G/TBT/W/290 and also expressed in previous meetings of the Committee with respect to the implementation of regulation 753/02 of the European Communities and its amending regulation 316/2004, in relation to the exclusive use of a series of traditional expressions used by various member States of the European Communities in each of their respective languages. His delegation also shared the concerns expressed by other members in this respect, and the United States in particular. He stressed that the regulations continued to pose obstacles to products that included labels with additional quality comments on Argentinean wine. As his delegation had previously pointed out, these additional quality comments referred to production methods or quality characteristics that were not under protection of intellectual property rights in the framework of the TRIPS Agreement. Their use was therefore governed by the TBT Agreement.

258. The Argentinean representative further highlighted that the restriction on the use of traditional expressions was not compatible with Article 2 of the TBT Agreement and requested that the European Communities review the regulation to put it into conformity with the Agreement. His delegation had taken note of previous statements made by the European Communities in the previous meeting of the Committee, according to which implementing measures for the new regulation were being developed which were also being examined by working groups in the European Council by EC member States. It was Argentina's hope that the new provisions would consider the concerns expressed by Members.

259. The representative of New Zealand stressed that her delegation had taken a close interest in the EC new regime for regulation of its wine market, which affected wine trade with the European Communities. Her delegation was waiting with interest for the notification of the full set of draft implementation regulations and looked forward to discussing them with the European Communities when consultations with third countries started and sought an update in terms of the timing of these consultations. She recalled that New Zealand had previously noted with concern some elements of the wine regulation itself and had made a submission to the European Commission in April 2008 accordingly. A reply from the Commission had been received in July 2008 and further clarification was sought from the EC TBT Enquiry Point in November 2008, in respect of the intended third country provisions for the use of Geographical Indications (GIs). A formal response to this question had not yet been received and it was New Zealand's hope that this response could be expedited now that some progress has been made with regard to notifying the implemented regulation, particularly given the fact that the implementation date of the new regulations was approaching.

260. The New Zealand representative further noted that her delegation's assumptions remained in light of informal indications received from the Commission's officials that the new EC wine regulations implementing regulations and any transitional arrangements included in these, particularly those related to wine labelling, would result in rules for the wine trade that fully complied with the provisions of the TBT Agreement, as well as other principles and disciplines contained in other relevant WTO Agreements. Consequently, there would be no adverse affect on market access for non-members of the European Communities as a result of the implementation of the regulations. She sought formal confirmation of this point.

261. The representative of Canada was also concerned about the status of traditional terms in the marketing of wine in the European Communities. Her delegation believed that existing consumer protection legislation was capable and better suited to address the possibility that consumers could be misled by the use of certain labelling terms on wine products. Canada was in the process of examining Draft Commission Regulation 479/2008 more closely.



262. The representative of the European Communities recalled that the Council Regulation on wine common market organisation contained new rules for the labelling of wines and established that these would be further developed by implementing rules. She noted that her delegation had recently notified the implementing rules on oenological practices.<sup>12</sup> Under the new rules, imported wines had to comply with the OIV recommendations or with the EC rules on oenological practices, giving third countries more flexibility. She invited delegations wishing to submit their comments to do so within the set deadline.

263. The EC representative further pointed out that a draft proposal laying down detailed rules for the protection of geographical indications, traditional terms, labelling and presentation of certain wine products had been finalised and would soon be notified to the Committee<sup>13</sup>. She explained that the provisions on labelling had been simplified and clarified and that they would apply to both categories of wine, with or without a Geographic Indication (GI). With regard to the use of traditional terms, the draft regulation established that their use on third countries' products was allowed, provided they fulfilled the same or equivalent conditions to those required from member States in order to ensure that consumers were not misled. Her delegation was willing to discuss this draft proposal and provide additional information at the next Committee meeting. She invited interested delegations to submit comments in writing within the deadline.

264. With regards to the comment raised by New Zealand, a reply would be sent shortly to the New Zealand Enquiry Point. Finally, on the comments from the US regarding the suspension of the derogation on the use of the traditional terms, she highlighted that it was unfortunate that the US had not agreed to continue the discussions of the bilateral agreement.

*(xvi) Israel – Infant formula*

265. The representative of the United States noted that his delegation's continued concerns that Israel had not published a draft regulation on its measures related to infant formula for comments, nor notified it to the WTO. Industry in the United States continued to have concerns that Israel's unpublished requirements for infant formula discriminated against imports and were unduly costly, burdensome and unpredictable. He stressed that while Israel denied these allegations, it had failed to publish the measures. The issue could not be resolved until at least Israel published draft measures governing infant formula for comment.

266. The US representative further stressed that the lack of published requirements governing the quality and safety of infant formula, as well as related conformity assessment procedures and labelling provisions, was particularly concerning given the 2003 Remedial incident. It was a difficult position to maintain that infant health in Israel was more protected by keeping the Ministry of Health infant formula requirements secret, rather than by publishing them for the public to review and comment, which was the most basic of all TBT and good regulatory practice principles. It was his delegation's hope that upcoming bilateral discussions with the Ministry of Health in Israel would help to resolve this issue in the near future.

267. The representative of Israel recalled the highly sensitive nature of the issue in his country. He appreciated the willingness of the United States to discuss the issue bilaterally with Israel's health authorities and was hopeful that this bilateral process would facilitate the prompt resolution of this matter.

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<sup>12</sup> G/TBT/N/EEC/252 and Add.1.

<sup>13</sup> G/TBT/N/EEC/264, notified on 1 April 2009.

(xvii) *European Communities – Production and Labelling of Organic Products: Regulation N° 834/2007 (G/TBT/N/EEC/101 and Add.1)*

268. The representative of Argentina reiterated his delegation's concerns about the EC Regulation 834/07 on the production and labelling of organic products and recalled the two documents submitted by his delegation in this respect (G/TBT/W/284 and G/TBT/W/291). He stressed that the assertion by the European Communities that Article 24 of the regulation would not enter into force until 2010 was not enough to address the concerns. He recalled that the regulation established that the label of an organic product had to contain an indication of origin of the raw materials and that it would take one of the following forms: "EU Agriculture", where the agricultural raw material had been farmed in the EU; "non-EU Agriculture", where the agricultural raw material had been farmed in third countries; "EU/non-EU Agriculture", where part of the agricultural raw material had been farmed in the Community and a part of it has been farmed in a third country. The country from which raw materials had been obtained could also be mentioned.

269. The representative of Argentina pointed out that this compulsory identification of the origin of products processed in the territory of the European Communities was not necessary to ensure that there was no confusion among European consumers about the properties in an organic product. To be considered as an organic product, the quality of the raw materials was already guaranteed through compliance with the EC requirements. This legislation generated uncertainty about the nature and qualities of the products on offer that was unjustified. Finally, it was his delegation's view that regulation was not in compliance with WTO Agreements and that it was not based on Codex standards.

270. The representative of Ecuador supported the concerns expressed by Argentina. The proposal of differentiating about the label of origin of the raw materials between the European Union and third countries could generate confusion among consumers. His delegation was of the view that this requirement was not in line with the TBT Agreement, in particular with Article 2.2. He urged the European Communities to take concerns into account and to re-evaluate the implementation of the regulation under the current parameters.

271. The representative of Cuba agreed with Argentina that postponing the entry into force of the regulation to 2010 was not enough to address the concerns expressed. Her delegation believed that the regulation was not in line with the TBT Agreement.

272. The representative of the European Communities stated that the regulation on the labelling of organic products had gone into effect on 1 January 2009 and clarified that it was a voluntary scheme and that its provisions only needed to be fulfilled if a producer wanted to sell its products labelled as "organic" in the European Communities and at least 95 percent of the ingredients of the product were organic. Non-organic products would be entitled to indicate on the label that they contained some organic ingredients.

273. The EC representative noted that the comments raised by Argentina referred to the labelling of origin for organic products produced in the European Communities containing raw materials from third countries. She pointed out that, as of July 2010, pre packaged food products that used the Community organic logo and contained raw materials from non-EU countries would have to carry the "EU/non-EU agriculture" statement on the label. While some countries feared that this could influence the choice of consumers, the European Communities had analysed the concerns and had concluded that there was no evidence to support the argument that the labelling requirements could negatively affect the sales of third countries in the European Communities. Her delegation remained available to discuss this matter further with interested delegations.

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

274. The representative of the European Communities informed the Committee that, in bilateral discussions, her delegation had received assurances from the Canadian authorities regarding Canada's flexibility on the implementing rules of these standards. Her delegation continued to have concerns regarding the overall nature of the measure and would monitor its implementation closely, to make sure that the negative impact on the cheese exports was minimized. She appreciated Canada's willingness to discuss the issue and hoped to continue this bilateral dialogue.

275. The representative of the United States recalled his delegation's concerns expressed in previous meetings regarding the market access impact and potential cost burden of Canada's compositional requirements for cheese. He stressed that, as these issues were of great concern to US industry, the United States would continue to review developments closely, including the new litigation in Canadian domestic court and the implementation of the import licensing scheme, and would be monitoring the measure's impact on trade flows.

276. The representative of New Zealand recalled that concerns about the restrictive nature of these requirements had been raised both bilaterally and at previous TBT Committee meetings. Her delegation continued to hold the view that the new regulations were overly restrictive in nature, both in terms of their allowance for the use of various ingredients and their impact on trade. The regulations limited the use of proteins sourced from dairy ingredients at a time when such ingredients were widely used and accepted in many countries and where the Codex Alimentarius Commission had not prescribed any limitations on their use. She noted that Canadian cheese processors had filed a joint application in the Federal Court challenging the new cheese regulation, and understood the hearing would be held in late March or early April. She requested that Canada reported on the outcome of the Court challenge at the next TBT Committee meeting in June.

277. The representative of Australia continued to share the concerns expressed by other delegations on Canada's requirements concerning the compositional standards for cheese. Australia would continue to monitor the implementation of Canada's measures to ensure there was no negative impact on trade.

278. The representative of Switzerland recalled the concerns expressed by her delegation at previous meetings of the TBT Committee.

279. The representative of Canada recalled that discussions on this issue had been held before and stressed that her delegation was of the view that the revised regulations were consistent with Canada's obligations. She noted that the on-going bilateral dialogue with the European Communities had been helpful to EC technical experts and stressed that any other delegation wishing to have a similar dialogue would be welcomed. She also pointed out that her delegation was willing to explain the implementation rules in more detail and looked forward to reporting on the Federal Court case at the next meeting of the Committee.

*(xix) Peru – Labelling of footwear (G/TBT/N/PER/19)*

280. The representative of the European Communities recalled that, at the last Committee meeting, her delegation had expressed concerns with regard to the above mentioned notification, which maintained the existing requirement to indicate on the label of footwear the fiscal number of the importer. The required information about the fiscal number was considered irrelevant to consumers, and it would be more appropriate to require this indication on the accompanying documents, and not on the permanent footwear label, which was very costly for producers and exporters.

281. The EC representative further stressed that concerns remained in particular about the special testing requirements for footwear manufactured abroad which were laid down in Article 6 of the regulation. It was not clear if these testing requirements were compulsory and if European testing methods, using ISO standards, would be accepted. She recalled that, at the last TBT Committee meeting, Peru delegate had said that the comments would be transmitted to capital and that a reply would soon be given. However, her delegation had not received any reply and she urged Peru to inform the European Communities whether the regulation had been adopted and whether the EC comments had been taken into consideration.

282. The representative of the United States shared some of the concerns raised by the European Communities with respect to Peru's regulation on footwear. Of particular concern was the special testing requirements set out in Article 6 of the regulation, which appeared to apply only to imports. It was his delegation's view that there could be a less trade restrictive procedure for ensuring that footwear labels matched the material content of footwear than requiring a chemical analysis report on each part of the footwear - the upper, lining, insole, and sole - and requiring that analysis to be conducted by a single laboratory in Peru. Peru's approach could cause delays to market for imports. He was not aware of other countries requiring this type of procedure and sought clarification from Peru as to what led to the imposition of these requirements.

283. The representative of Peru explained that, regarding Article 4 of the draft technical regulation which set forth that the label should include the fiscal number of the importer, the aim was the prevention of practices that could mislead consumers. Her delegation believed that consumers had the right to receive all the necessary information to take appropriate purchase decisions. Also, in cases when information provided was not correct, it was important to be able to identify who was responsible. The Peruvian authorities therefore thought that it was important to include in the technical regulation the fiscal number in order to identify the product. This was in line with the objectives of the technical regulation. In addition, information on the fiscal number could also identify labels which could be put on the product by the importer.

284. With respect to Article 6 of the technical regulation, which related to material content, the representative of Peru pointed out that the EC comments had been taken into account in the new version of the regulation. With respect to Article 7 which determined material content of footwear, she noted that the draft technical regulation referred to the testing procedures. The European Communities could provide information on their testing procedures to see whether they were acceptable to the Peruvian authorities.

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

285. The representative of the European Communities reverted to a previously raised concern about the maximum levels of sulphur dioxide in wines established in the above-mentioned Chinese measure. Her delegation had raised this issue in the past three Committee meetings and various European operators continued to complain about the difficulties they were facing in exporting to the Chinese market due to the overly strict specifications. The European Communities had been informed by the Chinese authorities that the standard was being reviewed and that the relevant international standards would be taken into account in the revised version. However, in a bilateral meeting, the Chinese authorities had confirmed that the maximum allowed level of sulphur dioxide considered in this revision would be set at 250mg per litre. She sought confirmation that this was indeed the case and stressed that, if so, the limit of 250mg per litre would fall considerably short of the maximum allowed limits outlined in the relevant Codex international standards. Lastly, she sought an indication from China about when the process would be completed and when the revised measures would be notified to the TBT Committee.

286. The representative of China pointed out that the TBT Committee was not the appropriate forum to discuss the concern about the levels of sulphur dioxide in wine. Useful bilateral discussions had been taking place on the margin of the SPS Committee meeting the previous month. He stressed that the limit of sulphur dioxide had already been revised through a notice published by China's Ministry of Health on 11 December 2008. According to the notice, sulphur dioxide had been increased to 250mg per litre, which was consistent with Hygiene Standards for Food Additives. In the meanwhile, with a view of reducing risk of contaminants caused by food additives, an approach of reviewing applications established by Administrative Rules on Food Additives had been taken in China. According to this approach, if wine producers wished to increase the limit of sulphur dioxide used in wine, they could still make an application to Ministry of Health for review. Decision could be foreseen within a reasonable time period.

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

287. The representative of the European Communities reiterated her delegation's concerns related to the Indian Order laying down a registration procedure for imported cosmetics products. She appreciated India's explanation concerning the necessity of the measure due to quality and safety concerns provided at the last TBT Committee meeting and in bilateral meetings. She also recalled that India had promised to send additional written information in order to provide further clarification, which had not been received. The EC representative sought an update of the state of play of the measure and stressed that her delegation would still appreciate receiving a written reply to its detailed comments submitted to India in July 2008.

288. The representative of India explained that the manufacture, import and distribution of drugs and cosmetics in India were governed by the Drugs and Cosmetics Act and the rules made there under. At present, a large quantity of cosmetics were being imported into the country without any appropriate control on quality and safety. Therefore, the proposed import registration was to ensure quality and safety aspects. The system of registration of imports of drugs was already in place while that for cosmetics was being introduced and was based on public health concerns. He further stressed that the measure did not discriminate against foreign manufacturers, as similar provisions existed already for domestic manufacturers. The proposed registration would only bring in harmonization of imported cosmetics. He reiterated India's commitment to comply with the transparency obligations under the TBT Agreement. The draft measure had not yet been finalized and all comments received in response to the notification would be taken into consideration.

(xxii) *European Communities – Novel foods (G/TBT/N/EEC/188)*

289. The representative of Peru reverted to a previously raised concern on the EC measure on novel foods and the draft amendment which was being reviewed. Peru had taken note that there had been an exclusion of special treatment of traditional foods for which a specific request had been made. This was a backward step which would have a negative effect on market access to Europe for traditional products from Peru which had a high level of consumption. He referred to the special procedure for traditional products and stressed that Peru's comments in this respect should be taken on board. Like Colombia had expressed at the previous meeting of the Committee, his delegation also believed that the reply by the European Communities was general and did not address the particular comments made by each country. Therefore, he asked the European Communities to provide a specific reply to Peru's comments.

290. The representative of Ecuador supported Peru's statement and said that concerns were also raised by his delegation in the SPS Committee.

291. The representative of Bolivia believed that the EC regulation on novel food presented an obstacle to the export of traditional safe foods from various countries, which was very important for

developing economies. She requested the European Communities to include the proposed modifications in the final version of the regulation, so as to facilitate market access for these traditional products.

292. The representative of Cuba was also concerned about the EC measure on novel foods, in particular with the exclusion of traditional foods, which posed a market access problem for developing countries. Like Peru, she believed that the European Communities should provide replies to the comments made and pointed out that this was particularly important in light of the possibility of requesting technical assistance and also to guarantee diversity of products.

293. The representative of Colombia joined the concerns expressed by Peru and the other delegations and stressed that this issue was very important for Andean countries. She pointed out that the relevant representatives in Brussels were formally presenting to the European Parliament a proposed amendment, providing for a simplified procedure which would facilitate the entry of fruits and vegetables which had a safe tradition of consumption in various countries and would allow for the marketing of these products. She urged the European Communities to consider this request positively.

294. The representative of Brazil shared the concerns expressed. His delegation would continue to monitor the trade impacts of this measure.

295. The representative of the Bolivarian Republic of Venezuela joined the concerns raised by Peru and other delegations and requested the European Communities to provide specific replies in order to resolve the issue and to clarify the economic impact of the measure.

296. The representative of the European Communities recalled that at the last meeting of the Committee Members had been informed that the proposal was under discussion in the European Parliament and Council. An agreement in first reading had not been found and therefore the proposal was now under second reading. Several of the issues mentioned by these delegations were currently under discussion. However, given that there was yet not agreement on them, she was not in a position to provide further details. A number of other issues would be developed through implementing provisions once the regulation was adopted. She invited delegations to submit their comments in writing so that these could be examined and taken into account in the next steps of the legislative procedure.

*(xxiii) United States – Consumer Products Safety Improvement Act*

297. The representative of China again raised concerns on the US Consumer Product Safety Improvement Act (CPISA). China agreed with the objective of protecting human health and appreciated the cooperative attitude of the US Government to discuss this issue. However, his delegation remained concerned with WTO inconsistencies in this Act and its impact on international trade. He recalled that, at the previous meeting of the Committee, the United States had explained that this Act had been signed into law and that it had no obligation to notify it to the WTO. He also stressed that the Act should be notified to the TBT Committee. In fact, the definition of a technical regulation contained in Annex I of the TBT Agreement stipulated that a technical regulation was a "document which lays down product characteristics and production methods including the applicable administrative provisions with which compliance is mandatory". Additionally, the Appellate Body in the *EC-Asbestos*<sup>14</sup> and the *EC-Sardines*<sup>15</sup> cases had set forth three criteria to identify a technical regulation: (i) the document had to apply to an identifiable product or group of products; (ii) the product had to lay down one or more characteristics of the product; (iii) compliance with the product

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<sup>14</sup> WT/DS/135/AB/R

<sup>15</sup> WT/DS/231/AB/R

characteristics had to be mandatory. He pointed out that the US CPSIA applied to a number of consumer products, including children's product and health care products, it laid down a number of technical requirements for those product with which compliance was mandatory. Therefore, CPSIA met the criteria of a technical regulation and should be notified to the WTO, providing other Members an opportunity to submit comments.

298. The representative of China further pointed out that the total limit of lead established in CPSIA was not based on science. It was known that total lead content included both soluble lead and insoluble lead. Insoluble lead was impossible to be absorbed and therefore was not harmful to human health. Reducing the total lead content and reducing it from 600 ppm to 100 ppm would create significant unnecessary obstacles to international trade, thus violating the less trade restrictive principle contained in Article 2.2 of the TBT Agreement. Moreover, he recalled that the United States had indicated that third party laboratories included governmental laboratories, and that it stood ready to engage with any governmental laboratory to work through issues related to additional criteria. However, the method for evaluating governmental laboratories in CPSIA did not include accreditation, as also indicated in notification G/TBT/N/USA/421. With regard to requirements for accreditation of third party conformity assessment bodies under CPSIA, the evaluation method for governmental laboratories was neither transparent nor operable. Moreover, the additional requirements for governmental laboratories were very stringent and it was difficult for governmental laboratories of other Members, including China, which were accredited under ILAC and used ISO 17025 as their basis to be assessed and accredited. He urged the United States to accord equal favourable treatments to governmental laboratories and to provide a practical method for their evaluation and accreditation.

299. The representative of the United States pointed out that eight implementing regulations of the Consumer Product Safety Improvement Act had already been notified (G/TBT/N/USA/421, 436, 439, 444, 447, 448, 449 and 450). The Consumer Product Safety Commission (CPSC) website<sup>16</sup> contained a special section on toy safety setting out numerous documents, including test procedures, accreditation requirements, a list of accredited laboratories, general counsel advisory opinions, and additional guidance for small businesses.

300. With respect to the issue of lead concentration limits, the US representative noted there were provisions and procedures to exempt many products from the limits based on inaccessibility and technological feasibility and to review the limits as a whole based on a transparent notice and comment process, where available evidence and peer reviewed scientific and technical information were considered. Regarding China's concerns with respect to government laboratories, he stressed that Chinese Government laboratories were not being singled out in any way. CPSC had not accredited any government laboratory worldwide because CPSC had not yet established the process regarding the evaluation of a government laboratory according to statutory criteria. In any case, thirty-two laboratories based in China had been accredited by CPSC. He also pointed out that CPSC staff recommendations with respect to government laboratories were under review by the commissioners of CPSC.

301. Additionally, it was stressed that the United States had opted for a highly trade facilitative approach, which was based on international standards, including ISO 17025, and acceptance of test results from ILAC accredited laboratories outside the United States. Under this approach CPSC had already accredited 32 laboratories based in China. It was also noted that there were only 32 laboratories accredited by CPSC for this purpose in the United States, and this could be a model for other countries, including China, that required third party testing. Given the US recognition of Chinese laboratories, China was invited to provide information on when it would be recognizing test results from US laboratories under the CCC system.

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<sup>16</sup> <http://www.cpsc.gov/>

302. With respect to timeframes, the US representative noted that CPSC was still willing to accept comments and that his delegation was open to arranging additional discussion. Finally, he pointed out that on 30 January 2009, CPSC had agreed to stay enforcement of most of the testing and certification requirements regarding the lead limits on children's products until 10 February 2010, which represents a 12-month delay in enforcement.

*(xxiv) Argentina – Measures affecting market access for pharmaceutical products*

303. The representative of Colombia recalled the concerns expressed by her delegation at previous meetings of the Committee, outlined in document G/TBT/W/280 of 29 October 2007. She noted that the Argentinean Decree of 1993 established a procedure for the evaluation of conformity for countries that were classified in Annex 1 and 2. However, other countries, including Colombia, were excluded from these annexes, which made it difficult for Colombian products to have access the Argentinean market. The concern expressed had not received a positive response from Argentina. She reiterated the request for technical studies related to country's risk and the studies to establish the fees and the classification of countries within this same area. These had been requested on several occasions. The main request from Colombia to Argentina remained that a review of the Decree be carried out to include Colombia in the Annexes 1 or 2 and to establish a fee for laboratory visits in accordance with article 5.2.2 of the TBT Agreement. It was Colombia's hope that there would be a prompt response from Argentina, so as to avoid going to the Dispute Settlement Body.

304. The representative of Argentina took note of the comments made, which would be transmitted to the authorities in capital. He also noted that on going bilateral negotiations with trading partners, including Colombia, were being held. His delegation hoped that these consultations would ensure that the concerns expressed be given a prompt and satisfactory response.

C. EXCHANGE OF EXPERIENCES

305. The Chairperson drew the Committee's attention to document G/TBT/1/Rev.9, which contained all the Decisions and Recommendations that the TBT Committee had made to date and covers all the areas of work of the Committee so far, namely: (i) Good Regulatory Practice; (ii) Conformity Assessment; (iii) Standards; (iv) Transparency; (v) Technical Assistance; and, (vi) Special and Differential Treatment. This document could be a useful reference for delegations.

**1. Good Regulatory Practice**

306. The Chairperson recalled that, on good regulatory practice, the Committee had heard, at its previous meeting, about New Zealand's experience with the establishment of a new model for regulatory coordination: the Regulatory Forum. A submission by New Zealand on this topic was contained in document G/TBT/W/294. Also, the United States had informed the Committee about new developments with respect to good regulatory practice.

307. The representative of the European Communities updated the Committee on some recent developments in the field of good regulatory practice. Specifically, he explained that the European Communities had finalized at the end of January 2009 its third strategic review of Better Regulation in the European Union. A package of documents, namely three communications from the Commission to the European Council and the Parliament as well as a revised guideline on impact assessment, were available on the website of the Secretariat-General and of DG for Enterprise and Industry of the European Commission.

308. The representative of the European Communities stressed that his delegation believed that good regulatory practice had to remain an essential part of the response to the current economic and financial crisis. Governments had to regulate only where there was a need to do so, and in a manner



which was as straightforward as possible, based on dialogue with stakeholders. The burden on businesses and citizens should therefore be kept to the minimum necessary. With respect to impact assessment, revised guidelines had been adopted on 15 January 2009. These guidelines integrated the recommendations made in the joint paper produced in 2008 by the European Commission and the US Office of Management and Budget, in the framework of the EU/US regulatory cooperation.

309. The objective of the joint paper was to compare the EC and US respective systems for assessing impact on trade and investment of proposed regulations. As a result, the revised guideline aimed at re-enforcing analysis of proposed regulations on international trade by considering, for example, how the regulatory options considered were likely to affect trade or investment flows between the European Communities and third countries, or how international obligations, including under the WTO, would be affected. Also, the guideline suggested that consideration should be given to international standards or whether common regulatory approaches existed in areas where regulatory action was needed, and to what extent the proposed rules were likely to affect developing countries at different stages of development.

310. It was also explained that consideration had been given to how to ensure that substantive amendments to the legislative proposals agreed by the European Parliament and Council were subject to impact assessment as well, and the three institutions of the European Communities were committed to completing a joint review of their common approach to impact assessment by the end of 2009. Other areas which were being analysed were measures taken to reduce administrative burdens for businesses in connection with compliance with new legislation and Member States implementing legislation. These measures would be part of a broader programme of simplification of the EC regulatory environment. As well, initiatives to enhance stakeholder consultation in view of developing new legislation, for instance on complex or sensitive proposals, were also being considered.

311. Finally, the EC representative drew the Committee's attention to a Communication that the European Commission had adopted on 16 December 2008 on the "External Dimension of the Legal Strategy for Growth and Jobs", reporting on market access and setting the framework for more effective international regulatory cooperation. The Communication discussed the various tools which were being implemented in EC trade policy, with a view to keeping effective market access opportunities in third countries and also within the European Communities, ranging from free trade agreements, mutual recognition agreements to bilateral cooperation dialogues seeking regulatory convergence, and more ambitious forms of economic integration like the agreements on conformity assessment and acceptance of industrial products which were being negotiated with Mediterranean and Eastern European countries. He announced that his delegation would report about these developments in writing, also in light of the Fifth Triennial Review of the TBT Agreement.

## **2. Conformity Assessment Procedures**

312. The Chairperson recalled that a useful exchange of information had taken place in the previous meeting of the Committee based on the submission by New Zealand entitled "A Menu of Options: New Zealand's Approach to Mutual Recognition Arrangements (MRAs) and Regulatory Cooperation Arrangements", contained in document G/TBT/W/295. This document also contained a proposal relevant to the work of the Committee in the context of the Fifth Triennial Review.

## **3. Transparency**

313. The Chairperson stressed that transparency was an area where many practical decisions and recommendations had been made by the Committee over the years. She noted that, at the previous meeting of the Committee, some delegations had stressed the importance of looking at how the existing body of recommendations on transparency is being applied by Members, and had stressed the

importance of the Committee focusing on achieving a correct and complete implementation of existing provisions and recommendations, while remaining open to possible improvements.

#### 4. Standards<sup>17</sup>

314. The representative of the United States introduced her delegation's paper on "Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Article 2, 5 and Annex 3 of the Agreement: the experience of the United States" (G/TBT/W/305). She explained that the paper discussed developments relating to international standards with respect to promoting harmonization and innovation as well as the "qualified heaven" provided by Article 2.5 of the TBT Agreement. The paper also discussed cooperative efforts to build technical infrastructure in developing countries.

315. While standards had many purposes, the TBT Agreement referred in particular to their role in facilitating trade, increasing productive efficiency and transferring technology. The first section of the paper analyzed how these concepts related to efforts to promote harmonization and innovation. Harmonization could facilitate trade and, as the global economy had become increasingly integrated, standards could also facilitate trade by conveying information throughout the value chain, which extended across countries with varying regulatory structures and technical infrastructure development. Standards had to adapt rapidly to technical innovations and scientific advances, and international standardization activities had to respond to these needs.

316. The US representative stressed that the six principles of the TBT Committee's Decision – openness, transparency, impartiality and consensus, relevance and effectiveness, coherence and development dimension – provided a model for standards developing organization to follow in order to be globally relevant. Her delegation would welcome greater attention to these principles, including by the trading partners which maintained various policies which restricted participation or use of standards. In particular, she noted that recent studies indicated that harmonizing to regional standards or regulations carried adverse implications for TBT principles.

317. The paper also reviewed recent trends in international standardizing organizations in relation to the effective implementation of the TBT Agreement, particularly with respect to Article 2.5. In this regard, the representative of the United States noted the current efforts in international standardizing bodies to embed broad regulatory and public policies and principles in standards. She drew Members' attention to the work on the ISO 26000 standard and stressed that her delegation was interested in other Members' views on the potential misuse of such standards, including with respect to Article 2.5 and 2.9<sup>18</sup>. She also asked for delegations' views as to whether international standardizing organizations were suitably structured to properly weigh disparate social claims or interpret treaties.

318. Additionally, the paper called attention to claims made by certain standardizing bodies that the use of their standards carried automatic TBT consistency. While the US delegation welcomed and encouraged standardizing bodies' efforts to provide accurate and informative capacity building materials, it was concerned when the nature of TBT obligations were mischaracterized in such documents. Concerns had been conveyed to the ISO/IEC about their Guide to Using Standards in Technical Regulations.

319. The last section of the paper related to the cooperative efforts in the development of technical or quality infrastructure. To have a lasting impact, such assistance needed to be demand-driven, formulated with the context of sector-specific national priorities and compatible with the level of

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<sup>17</sup> For details of the discussion on the Workshop on the Role of International Standards in Economic Development see section II(D)(2).

<sup>18</sup> See also section II(D)(3).

technical infrastructure development. The paper emphasized the importance of the OECD Paris Declaration on Aid Effectiveness in the area of technical infrastructure development assistance and the importance of cooperative professional *fora* that offered developing countries stakeholders access to a variety of viewpoints and independent technical assessments.

320. The representative of Canada welcomed the US paper, which her delegation would analyze more in detail. She believed that the workshop held on 16-17 March was particularly relevant to the topics addressed in the US submission.

321. The representative of the European Communities believed that the US and the Secretariat documents taken together provided a lot of information and his delegation could come back to them at the next meeting with additional comments. Some points seemed, from his delegation's perspective, to be of great relevance to the discussion on standards. The first was how standards could support legislation. In this respect, he highlighted that a joint effort was underway with the United States in the framework of the bilateral cooperation to compare the methods of referencing standards in legislation. A joint study was currently being prepared.

322. Another issue that had been highlighted at the workshop was the fragmentation in the standard-setting process in some sectors. This was particularly evident in the IT sector. In the European Communities a reflection had started on how to address this issue and on what kind of relationship could be established between the consortia, private-setting bodies, which involved only a small number of players, and the traditional standard-setting bodies. The representative of the European Communities further informed the Committee that the European Commission had issued in 2007 a communication on the contribution of standards to innovation, addressing specifically the role of standards in promoting innovation and the difficulties that the standard setting bodies faced in adapting to the changing needs of certain industrial sectors which needed fast standards in order to cope with the fast pace of technological innovation. Another challenge was how the standardization system adapted and responded to innovation and how the necessary resources to adapt could be found. In the European Communities, a more general reflection on the European standardization policy and standardization bodies had also started, and an expert panel had been set up with the mandate to come forward with proposals and recommendations by the end of the year. His delegation would keep the Committee informed on the outcome of those reflections.

323. The representative of Japan appreciated the US document and agreed that securing that the six principles in the Committee's Decision were followed was of great importance in terms of developing globally relevant international standards.

324. The representative of the OIML pointed out that the OIML tried to ensure that the procedures for adoption of standards complied with those which were specified in the Annex 3 to the TBT Agreement, although international standard setting organizations were not obliged follow it. The OIML publications were recommendations, although they were interpreted as international standards from the point of view of the TBT Committee. These recommendations were, in fact, intended to be model technical regulations to be implemented by the member states of the organization.

#### D. OTHER MATTERS

##### 1. Consideration of Specific Trade Concerns

325. The representative of Cuba invited Members to reflect on the consideration of specific trade concerns in the TBT Committee. She noted that Members had announced they would raise approximately fifty-four specific trade concerns, of which at least twenty-five had previously been raised (Job(09)/19). In 2008, the total number of specific trade concerns raised had been, according to document G/TBT/GEN/74/Rev.1, fifty-nine. She found that the increasing number of specific trade

concerns raised in a single meeting called for reflection. In particular, she mentioned that the European Communities was the Member whose measures had been raised for discussion most frequently. In her view, this perhaps because concerns may have not been properly addressed. On the other hand, the case of the tyres regulation by India<sup>19</sup> showed that the measure had not been enforced for three years while comments were considered and taken into account, in compliance with WTO rules.

326. The Cuban representative further noted that in other cases, often involving the European Communities, although concerns about consistency with the TBT Agreement and had been repeatedly raised by delegations, these had not properly been responded to. She stressed that in times of economic downturn, it was particularly important that all Members abide by WTO rules. Consolidation of the multilateral trading system depended on Members' respecting the rules that had been established. In light of this, it was particularly important to give proper consideration to comments expressed and concerns raised, and to provide replies to them.

327. The representative of Cuba further suggested that document G/TBT/GEN/74/Rev.1 could usefully include, in future revisions, a description of the trade concerns expressed, including their outcome. For instance, if bilateral consultations were underway as a result of a specific trade concern raised in the Committee, this could also be mentioned in that document. Additionally, she referred to Article 13 of the TBT Agreement, which included the possibility of establishing working groups. She also pointed out that some of the concerns listed in G/TBT/GEN/74/Rev.1, such as "Korea – Fish Heads" or "European Communities – REACH" had been on the Committee's agenda for several years, and that a solution had not been found. A mechanism to solve these long-standing specific trade concerns should be found, to avoid concerns becoming disputes under the DSB. She believed that the Committee should analyze this possibility in a detailed manner. The representative of Cuba concluded by noting that, if concerns were not properly addressed, as had been the case for REACH, they would be likely to be raised again at the following meeting of the Committee.

328. The representative of the European Communities stated that the intervention made by Cuba highlighted some fundamental points. First, what was the role of the TBT Committee in discussing STCs, and, in particular, how far discussions on STCs could go after a notified text had been adopted and where several rounds of discussions had already been held? Second, he stressed that the TBT Agreement required Members to give an adequate opportunity for comments, to discuss these comments upon request with interested Members and to take those comments into account. However, there was no obligation to modify a notified text if the comments received were considered not to be relevant or sufficiently substantiated to justify a substantial modification. In the same way as Cuba, his delegation could also call into question the usefulness of the approach that certain delegations had been taking in discussing repeatedly some issues in the TBT Committee.

329. With respect to the allegations made by Cuba that his delegation had not been willing to enter into a dialogue or that it had not properly addressed the concerns raised, the representative of the European Communities stressed that the European Communities was one of the most transparent WTO Members. The fact that there were many specific trade concerns raised on EC measures had to do with the transparent way in which the European Communities worked. All technical regulations were notified in due time and ample opportunity for WTO Members to become aware of any draft legislation which was in the pipeline was given. Moreover, the EC lawmaking process had been considerably improved in the last few years, through the implementation of the so-called "Better Regulation". In this framework, all legislative proposals were based on extensive stakeholder consultations, impact assessment which analyzed in a balanced way the economic, environmental and social impact of the proposed measures and, in this context, extensive consultations with foreign

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<sup>19</sup> See paragraphs 230-233.

stakeholders and foreign governments were also held. This preceded any notification to the TBT Committee.

330. With respect to REACH and to the 31<sup>st</sup> ATP Directive, the representative of the European Communities stressed that his delegation had brought, on several occasions, technical experts to the TBT Committee to reply to specific questions. An information session had also been organized by his delegation ahead of the November 2008 meeting of the TBT Committee, where participation and the questions and comments raised had been disappointing. Therefore, he rejected any allegation that the European Communities had been unwilling to enter into fruitful discussions. Additionally, he stressed that every time scientific evidence substantiating concerns had been requested, this evidence had never been forthcoming. He reaffirmed the right of any WTO Member to confirm its initial regulatory choice if the evidence submitted by those Members raising concerns was not enough to make regulators change opinion.

331. On REACH, the representative of the European Communities believed that it remained an important topic of discussion because it was a complex framework legislation which needed implementation over the years. However, for the purpose of an efficient use of time and also in order to respect the role of the Committee, he suggested that the discussion should focus mainly on new issues and not on old issues which had been discussed several times and where the EC legislation had been adopted.

332. The EC representative noted that the European Communities was often at the forefront in promoting regulatory solutions that set ambitious legitimate policy objectives, for example in the field of environmental protection, in the field of energy, in the field of risks arising from chemical substances from industrial products. He stressed that the TBT Agreement allowed Members to set the appropriate level of protection in order to pursue a legitimate policy objective. While the European Communities was often a frontrunner in promoting ambitious regulatory solutions, these were then often followed by other Members. This posed a challenge, but the challenge was not in terms of TBT consistency, but in terms of what measures could be put in place to facilitate implementation. With respect to the challenges faced by developing countries, there were instruments that could facilitate compliance with the rules enacted by developed countries. For example, the European Communities had committed to providing technical assistance in order to build capacity in developing countries. In concluding, he invited Members to reflect on what the role of the Committee was in discussing specific trade concerns. His delegation believed that once a text had been adopted and issues had been discussed, the TBT Committee was no longer the proper forum for addressing those issues. Bilateral dialogue was the proper platform for pursuing these discussions. This did not mean that Members would refrain from having further discussions with other Members but that those discussions should take place in a different framework.

333. The representative of Cuba appreciated the detailed explanation by the European Communities. She agreed that when discussions were exhausted in the TBT Committee they could be moved to another body, not necessarily the DSB. She invited Member to reflect on Article 13.2 of the TBT Agreement on the creating of working groups as a possible solution. She believed that the fact that there had only been one dispute related to TBT did not necessarily mean that the mechanism of discussing specific trade concerns was working effectively. Rather, it was a sign of Members' good faith, while questions and comments were repeatedly raised if not answered or addressed. She suggested that comments and questions on specific trade concerns should be sent in advance to the Member concerned as well as to all WTO Members, so as to be better prepared at the meetings of the Committee and to save time. Finally, the representative of Cuba agreed that the TBT Committee was a forum for exchange of information and to solve trade concerns in an amicable way. This space should be maintained in the Committee and no Member should be prevented from presenting specific trade concerns. At the same time, comments should be taken into account. Her delegation was open to discuss with other Members about solutions to improve the efficiency of TBT Committee's work.

334. The Chairperson noted that discussions of specific trade concerns in the TBT Committee provided Members a good opportunity to exchange views and information on the concerns they had with respect to their trading partners' measures. At the same time, several bilateral or plurilateral meetings were taking place at the margins of TBT Committee meetings, showing that Members were constructively working towards resolutions of trade concerns. Although she believed that the mechanism was working effectively, she agreed that discussions could be held in the Committee more efficiently. In this respect, she invited delegations not to repeat each time the statements which were already contained in the minutes of the previous meetings. She also believed that fruitful bilateral discussions could help reducing the list of trade concerns raised at the meeting. She agreed with the suggestion that delegations should provide comments and answers in advance of the meeting, and noted that some delegations had already started doing so. She suggested that the issue should again be discussed at the June meeting of the Committee.

## **2. Workshop on the Role of International Standards in Economic Development**

335. The Chairperson reported on the Workshop on the Role of International Standards in Economic Development (Annex 1). It was noted that the Secretariat had prepared two background notes for the Workshop on International Standards and Economic Development held on 16-17 March. One provided an overview of standards and the TBT Agreement (Job(09)/15), the other focused on the economic rationale for standardization (Job(09)/17). A Summary Report of the Workshop is contained in document G/TBT/W/310.

336. The representative of the United States believed the workshop was an important step for the TBT Committee to further the discussion of how the challenges and opportunities related to the development and use of international standards affected the implementation of the TBT Agreement. Her delegation appreciated the wealth of information provided in terms of approaches to improving trade through standards and the rich range of topics and the variety of concerns presented, as well as the numerous possible paths to increasing participation of developing countries in standards development. As indicated in the Chairperson's summary, the workshop had also identified many ideas that should be given further consideration and reflection. She noted that abilities to identify, participate in, implement and use international standards, including in technical regulations, varies considerably among WTO Members. However, the willingness of all Members to work collaboratively to advance standardization as a tool for economic development indicated that there was much to gain from diversity. The TBT Committee could play an important role in this work, although other key actors, such as the domestic stakeholders in the private sector, the national standards bodies and standards developing organizations, had a lead in addressing challenges and in enabling opportunities in international standardization and conformity assessment activities. She encouraged TBT Committee Members to focus on practical and effective ways to deepen coordination with these actors. In order to take the valuable information from the workshop forward, her delegation offered some suggestions for consideration by other Members.

337. First, the Committee could identify ways to enable WTO Members to be aware of information on trade-related studies on effective outreach and engagement, particularly with small and medium sized enterprises in standards development, and on analytical tools to assess the economic value of standards at the firm level. The TBT Committee could also identify best practices and guides for effective implementation, including in relation to incentives provided by national governments to increase SMEs' activity in standardization and their ability to implement standards. The Committee could also encourage further efforts on technical cooperation. Twinning had been identified in previous triennial reviews as important in this regard, and continued work towards greater effectiveness in twinning, as well as the broader concept of partnering, should be encouraged. The Committee could also welcome efforts by standards developing organizations to explore ways to strengthen on-line collaborative tools, to encourage meetings to be held in developing countries and to

promote greater access to expertise, recognizing that to be truly effective, these had to be matched by developing country stakeholders to be active participants and to take ownership of achieving results.

338. Furthermore, the US representative suggested that the TBT Committee could underscore the critically important contribution of cooperative efforts in technical organizations, both regional and international, including by encouraging Members to provide reports of those groups that could be of interest to the broader Committee membership. In addition, the Committee could consider transmitting the report of the workshop to the Committee on Trade and Development (CTD) for consideration at its 2 April meeting on Aid for Trade and encourage stakeholders in the Aid for Trade process to take account of the value of standards activities in building productive capacity.

339. Another suggestion made was that the Committee could request the World Bank to transmit its analysis on the return to investment in standards work to the CTD session on Aid for Trade as well and include information on the importance of incorporating work on quality infrastructure into national development plans. Finally, the Committee could reaffirm its decision on the six principles on the development of international standards a key driver for standards that have positive economic value.

340. The representative of Cuba found the workshop useful and appreciated the opportunity of having had a participant from capital funded through the Global Trust Fund to participate at this event. She stressed that it was important to exchange experiences as it had been done at the workshop and that it was even more important to put lessons learned into practice. Therefore, the workshop should serve as a basis for future work. She also believed that discussions on the challenges identified in the Chairperson's report should continue at following meetings of the Committee. In particular, she recalled that many participants at the workshop had expressed concerns with the proliferation of private standards. A more in-depth discussion on this issue should be conducted in the TBT Committee, so that specific actions could be undertaken.

341. The representative of Korea appreciated the workshop and agreed with the Chairperson's report that, in times of economic crisis, standards and regulations should not be implemented in a manner that restricted trade.

342. The representative of Antigua and Barbuda found the workshop very useful and was particularly interested in how to improve use of information technology to enhance participation of developing countries in international standardizing activities and to exchange information. Since participation of developing countries in international meetings was often depending of available funding, IT tools could usefully serve as substitutes to meetings and alleviate dependency on external funding.

343. The representative of Canada believed that the workshop had highlighted the importance of continuing to explore the value of standardization and had provided very interesting case studies on how particular standards were being implemented in several countries. Her delegation recognised the challenges faced by developing countries in the implementation of international standards and participation in their development. The presentations delivered by developing countries at the workshop had been particularly valuable in this regard.

344. Looking forward, the representative of Canada suggested that the Committee should continue to examine ways for developing countries to improve their participation in international standards development, by taking advantage of the technical assistance available through many international organizations and thereby leverage the demonstrated benefits that such participation entailed, such as increased international trade. Canada remained committed to assisting developing countries in that regard. She also suggested that the TBT Committee should take stock of the success stories presented at workshop: this would help the Committee achieve the goals set out in the Third Triennial Review

to use Members' experiences of technical assistance received and provided to develop elements of good practice in the development of technical assistance in the TBT field.

345. The representative of Mexico also appreciated the workshop and the report by the Chairperson. He referred to the issue of private standards and to the many concerns voiced at the workshop with respect to their proliferation and effect on trade. He noted that the SPS Committee had been discussing this issue for some time, and believed that discussions should take place in the TBT Committee as well. The work of both Committees could merge and come to some conclusion as to the applicability of WTO rules to private standards.

346. The representative of Pakistan was thankful that the workshop had provided her delegation an opportunity to bring a representative from capital to participate in the activity and learn from other countries. Organizing these types workshops was a very useful exercise and was in itself capacity building, because for developing countries it was not easy to bring officials from their capitals to attend technical meetings. The very fact that one person from capital had participated in the workshop and TBT Committee meeting and had learnt about the various experiences of different countries was very encouraging.

347. The representative of Pakistan agreed with the proposals made by the United States. These suggestions could feed into Aid for Trade, by encouraging increased participation of developing countries in standards-setting process, so that they could have greater ownership and could be in a better position for implementing standards.

348. The representative of the European Communities thanked the United States for taking the initiative to set the process in motion and pointed out that the Chairperson's report and the suggestions made by the United States captured his delegation's view about the outcome of the workshop. He joined Canada in stressing the importance of sharing information on success stories in the field of technical assistance, as regards raising expertise in developing countries, assisting experts from developing countries to participate effectively in the international standard setting process and building capacity in developing countries. Without building capacity in terms of infrastructure, developing countries would not be able to reap the full benefits of the international standard-setting process in which they had participated, and would not be able to support their exporters.

349. The representative of the European Communities encouraged Members to share information how their technical assistance activities were pursuing those objectives. The Committee should also try to identify some best practices from the ongoing efforts of the international organizations who are active in this field, such as UNIDO, the World Bank, the various programmes in the ISO and the IEC and the Aid for Trade initiative. On private standards, the EC representative believed that this topic fell outside the scope of the TBT Agreement and that the TBT Committee was not the appropriate forum to hold discussions on this issue. He referred to the detailed statement made by his delegation in that regard at the Workshop.

### **3. ISO 26000**

350. The representative of Mexico raised concerns with respect to the draft ISO standard 26000 on social responsibility and noted that ISO had circulated the draft text for comments with a view to approving it as a draft international standard (DTIS). He stressed that there was confusion in this document about concepts of responsibility in government and private sector. The document covered, among other matters, issues such as culture, human resources, environment and this had brought about confusion over its implementation and application. Furthermore, it went beyond ISO's mandate. He warned other countries of the risk that this standard could pose to international trade if it was adopted as an international standard and looked forward to an exchange of information with other Members in this respect.



351. The representative of the United States agreed with Mexico on the potential misuse of the document, given its wide coverage of issues. She referred to the paper submitted by her delegation titled "Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement (G/TBT/1/Rev.9 Annex B): The Experience of the United States" (G/TBT/W/305) in which systemic issues with this type of standards activity were raised. She looked forward to hearing other Members' views on this issue.

352. The representative of the ISO, in relation to on going work in ISO on social responsibility (ISO 26000), pointed out that the decision to prepare work on this standard was the result of a strong wish on the part of developing countries to have such a document agreed upon through the consensus-based process of international standardization. He explained that, since the process had started, there had been a significant increase in the involvement of developing countries: from twenty-one developing countries involved in 2005, the number had increased to forty-eight in 2008. ISO, through donor funding, had supported developing country experts from six stakeholder categories, including the private sector and governments, to participate in the standardization process. In 2008, the number of experts involved in the working group from developed and developing countries was 143 and 210 respectively, which illustrated the high number of experts overall involved in the drafting process.

353. The representative of the ISO further pointed out that the issue of misuse of the standard had been a constant concern among experts, and that several clauses had been included in the text to provide guidance as to its final use. Thus, the future standard would be a guidance document and not intended to be used for certification. Besides, at the last plenary meeting of the working group in September 2008, a specific clause was agreed upon to indicate that the standard was not intended to create a non-tariff barrier to trade. The standard was not meant to suggest policy guidelines to governments, although governmental bodies could use relevant sections in their institutions if deemed appropriate. He concluded by informing the Committee that the next plenary meeting of the working group would be held in Canada on 18-22 May 2009. Voting by participating national standards bodies on the committee draft had been completed and showed that more than two-thirds of the votes were in favour of moving the document to the DIS (draft international standard) phase. He pointed out that the efforts deployed by all parties to ensure the widest representation possible had been successful.

### **III. PREPARATION OF THE FIFTH TRIENNIAL REVIEW**

354. The Chairperson recalled that the Committee was scheduled to conclude the Fifth Triennial Review of the Operation and Implementation of the TBT Agreement at its meeting on 5-6 November 2009, in line with the mandate in Article 15.4 of the TBT Agreement. The Chairperson also recalled that, at November 2008 meeting, the Committee had agreed on a timeline for the Fifth Triennial Review, which was contained in the report of the Committee's meeting, G/TBT/M/46, page 69, which would guide the Committee to the adoption of the Triennial Review Report in November. She drew the Committee's attention to a background note circulated by the Secretariat, containing two proposals received to date from New Zealand and Canada. The document was contained in Job(09)/16. More recent submissions had also been received by New Zealand on "Mutual Recognition, Regulatory Cooperation and other Trade Facilitation Arrangements" (G/TBT/W/306) and Japan on the "Global Relevance of International Standards" (JOB(09)/25).

#### **1. Mutual Recognition, Regulatory Cooperation and Other Trade Facilitation Arrangements**

355. The representative of New Zealand introduced her delegation's paper on "Mutual Recognition, Regulatory Cooperation and other Trade Facilitation Arrangements" (G/TBT/W/306)

and recalled the previous submission on "A Menu of Options: New Zealand's Approach to Mutual Recognition Agreements (MRAs) and Regulatory Cooperation Arrangements" (G/TBT/W/295).

356. The representative of Chile welcomed New Zealand's contributions. She believed that the tools identified would facilitate trade and reduce transaction costs. Chile did not have much experience with respect to these tools, therefore sharing of experience with other countries which had had good results was particularly important. In Chile, the possibility of starting to use this type of tool was currently being assessed, also in light of the numerous existing trade agreements. She supported New Zealand's second proposal to develop practical guidelines on how to design efficient and effective trade facilitation arrangements within the context of risk management approaches. This type of guideline would be particularly beneficial in the design of these types of arrangements, especially to developing countries.

357. The representative of Mexico supported New Zealand's proposals and stressed that it would be beneficial to discuss these matters in more detail with a view to facilitating trade. He thought that it was a mandate provided for in the TBT Agreement, in particular Articles 2.7 and 5 which encouraged Members to recognize each other's technical regulations as equivalent or to enter into negotiations for the mutual recognition of conformity assessment results. He explained that Mexico was initiating a process of regulatory cooperation with its trading partners and to identify how greater interaction in the interpretation of technical standards could be achieved. In this respect, the experience of other Members would be useful and his delegation looked forward to contributing to the discussions.

358. The representative of Japan agreed that MRAs were important and about the necessity to exchange information in this regard. However, his delegation believed that MRAs were often not utilized efficiently, and that it was very costly to conclude such agreements. Therefore, a right balance should be struck between costs and benefits of MRAs.

359. The representative of Singapore found New Zealand's list of approaches to facilitating acceptance of the results of conformity assessment procedures to be very useful. In particular, New Zealand proposal for the Committee to continue to exchange information on MRAs was especially interesting. Singapore's experience with MRAs in sector's such as electrical and electronic products had been largely positive. Companies had reported strong utilization of these MRAs and had benefited from reduction in business costs due to saving from unnecessary testing and certification. Her delegation would be happy to share the success stories of such companies and exchange experiences on MRAs with interested Members.

360. The representative of Chinese Taipei welcomed New Zealand's proposals and supported the view that engagements between regulators delivered considerable benefits to international trade.

361. The representative of the United States welcomed New Zealand's submission and pointed out that, in the United States, success with MRAs had been mixed. The United States was experiencing similar situation as New Zealand, as its business community was strained by compliance and transaction costs and was calling for practical solutions. Therefore, it was important for Members to continue to share ideas and experiences to find way to address real trade concerns. This was particularly relevant with respect to the engagement between developed and developing economies. The suggestion for the need to develop a more flexible approach to deal with the reality of the global trading system was an area where the greatest challenges lied. Building trust and confidence among regulators was critical, as it was bringing new perspectives into the over arching risk management framework and its interface with the trade facilitation framework. She also agreed on the need to build mechanisms for long term cooperative relationships among regulators: sharing experiences and successes in this regard would be useful.

362. The representative of Cuba agreed that continuing to exchange information on mutual recognition arrangement, regulatory cooperation arrangements and other arrangements that aimed at facilitating trade was important. She stressed that the second part of the proposal, the development of practical guidelines on how to design efficient and effective trade facilitation arrangements within a context of risk management approaches, was particularly important.

363. The representative of the European Communities agreed that the topic was interesting and referred to his previous statement about the preliminary critical assessment of existing tools for trade facilitation which was being conducted in the European Communities. His delegation's assessment showed that there was not a single approach that could be useful in all cases. It depended on the objectives that were being sought, and also the level of development of the countries which were building cooperative relations. For instance, if the objective was regulatory convergence, regulatory cooperation could be a very good tool. However, if the objective was to harmonize legislation and link specific sectors and different economies in specific areas, then a long period would be necessary and a formal agreement would have to be concluded based on the alignment on the related legislations of the partners. This could be considered as a new generation of mutual recognition agreements, based on equivalence or alignment of legislation. In the EC view, traditional MRAs had not worked too well, because they had provided a disincentive of the approximation of the regulatory environment of partner countries. Where differences in regulatory approaches were significant the agreements were prevented from functioning because the necessary confidence for those agreements to operate was never achieved. Therefore, he believed that the range of trade facilitation arrangements was quite diverse and depending on the objectives being sought and the situations of regulatory environment and economic development of the countries involved.

## **2. Global Relevance of International Standards**

364. The representative of Japan introduced his delegation's proposal on "Global Relevance of International Standards" contained in document Job(09)/25. He noted that, since the TBT Committee had adopted its Decision on the six principles for the development of international standards<sup>20</sup> the ISO and IEC had been discussing the issue of the global relevance of international standards. He believed that the Triennial Review was the appropriate time for the Committee to look into this issue and that the TBT Committee should consider the global relevance of international standards from the viewpoint of how much the "International Standards" were being used and implemented in markets around the world.

365. Essentially, if "International Standards" were used and implemented as broadly as possible by affected industries and other stakeholders in markets around the world, the following results could be expected, which would improve the efficiency of production and facilitate the conduct of international trade, thereby achieving the objectives of the TBT Agreement: (i) "International Standards" which were used globally should be defined as international standards so that it would be easier to encourage Members to align their national standards and regulations with international standards; (ii) "International Standards" which had no global relevance should be abolished; (iii) developing countries' participation in developing international standards should be promoted; and, (iv) developing countries' circumstances should be taken into account when international standard bodies develop international standards.

366. The representative of Korea supported the proposal from Japan, in particular that international standards which had no global relevance should be abolished.

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<sup>20</sup> "Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relations to Articles 2, 5 and Annex 3 of the Agreement", G/TBT/1/Rev.9, page 37.

367. The representative of the United States welcomed the proposal from Japan and noted that some of the broad themes put forward were also echoed in the US paper on "Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Article 2, 5 and Annex 3 of the Agreement: the experience of the United States" (G/TBT/W/305). The Committee's decision was an example of how the TBT Committee could encourage the various international standards developing organizations to strengthen and clarify their rules, to promote better implementation of the Agreement. She noted that the concept of market relevance had been at the heart of the US standards strategy, which promoted a bottom-up, private sector-led approach to standards development. This allowed standards to embody technical excellence and embrace technological innovation in responses to market and regulatory needs. Her delegation looked forward to working with Japan, in particular to refine and clarify the Committee's considerations of global relevance and the related implications and effects on the concept of international standards.

### **3. Proposal on Specific Trade Concerns**

368. The representative of Canada recalled that her delegation had put forward a proposal contained in a room document on the Committee's consideration of specific trade concerns. She invited Members to submit comments, so that a final proposal could be submitted.

369. The representative of Brazil supported the proposal by Canada, which would enhance transparency and predictability in the Committee's work.

370. The representative of Cuba recalled her statement under Agenda Item 2(D)(1) on the consideration of specific trade concerns and noted that her delegation had approached Canada to make comments on its proposal.

371. The representative of Ecuador agreed that specific trade concerns to be raised at a meeting should be indicated in writing. He believed that the timeframe of seven days suggested by Canada should be fifteen days instead.

372. The representative of Japan, Chinese Taipei and Australia supported the proposal from Canada. Japan noted that it would contribute to a more constructive discussion of specific trade concerns in the Committee. Chinese Taipei stressed that delegations would be better prepared to provide responses when specific trade concerns were raised.

373. The representative of the United States noted that the proposal from Canada suggested that the Annotated Agenda of the Committee should be issued five days prior the meeting, and stressed that the practice in other Committees was to issue it ten days in advance. This timeframe would be better in ensuring consistency and also to ensure sufficient time to properly vet the specific trade concerns internally and to facilitate discussion in the Committee. She also recalled that part of the suggestion was that there would be a brief outline of the concern. However, this was not necessary in all cases. For instance, if the measures had been notified, reference to the notification number would be sufficient. In a case when the measure had not been notified, the title of the measure and the reference to the document number would suffice. If there was no title a brief explanation could be provided. She also suggested that Members wishing to raise a specific trade concerns after the agenda was closed should still be able to raise them under the agenda item on specific trade concerns, after all the concerns on the agenda had been discussed. There could be situations where an urgent concern could arise shortly before the Committee meeting, and this should not be relegated to "other business".

#### 4. Transparency

374. The representative of the European Communities recalled that, at the last meeting of the Committee, his delegation had flagged the intention of submitting a paper on transparency and announced that this would be done shortly.<sup>21</sup> The paper would share the EC experience on how internal practices had been modified where necessary, in order to give effect to the Committee's recommendations in the field of transparency. The paper would also submit concrete proposals on possible improvements to the implementation of the transparency provisions and the Committee's recommendations in some areas. The topics which had been taken into consideration were the functioning of notification and enquiry points; the level of compliance with the obligation to notify draft technical regulations and conformity assessment procedures; various issues in relation to the access to the notified text, including translations, the availability of the original language version of the text; and amendments to original notifications. The obligation to notify text at sub-state level, various issues related to the handling of comments and the publicity given to the comments received and made on the notified text were also assessed.

375. The representative of Cuba recalled that at the previous meeting of the Committee the European Communities had suggested that the Committee could "consider developing a questionnaire for Members as a way of gathering information about the practical application of the Committee's recommendations".<sup>22</sup> She sought clarification from the European Communities regarding the scope and status of this questionnaire.

376. The representative of the European Communities noted that it was his delegation's sense that the proposal of developing a questionnaire would not receive support from Members. He believed that statistical information produced by the Secretariat was and would continue to be helpful in gathering information about implementation of Committee's recommendations. He encouraged Members to submit comments to the forthcoming EC paper.

#### IV. FOURTEENTH ANNUAL REVIEW OF:

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

377. The Committee adopted the Fourteen Annual Review of the Implementation and Operation of the TBT Agreement, as contained in document G/TBT/25.

##### B. THE CODE OF GOOD PRACTICE

378. The Committee's attention was drawn to two lists prepared by the Secretariat to facilitate consideration of matters relating to the operation of the Code of Good Practice. The first list, contained in document G/TBT/CS/1/Add.13, compiled the standardizing bodies that had accepted the Code in the period under review. In the reported period, four standardizing bodies from four Members had accepted the Code of Good Practice<sup>23</sup> and three standardizing body had withdrawn from the Code.<sup>24</sup> The second list, contained in document G/TBT/CS/2/Rev.15 compiled all the standardizing bodies that had accepted the Code since 1 January 1995. Since 1 January 1995, 159 standardizing bodies from 119 Members had accepted the Code of Good Practice.

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<sup>21</sup> Subsequently submitted as G/TBT/W/309, dated 11 May 2009.

<sup>22</sup> G/TBT/M/46, para. 357.

<sup>23</sup> G/TBT/CS/N/173, G/TBT/CS/N/174, G/TBT/CS/N/175. Viet Nam notified its acceptance of the Code of Good Practice in January 2009 (G/TBT/CS/N/176).

<sup>24</sup> G/TBT/CS/N/107/Corr.1, G/TBT/CS/N/14/Corr.1, G/TBT/CS/N/121/Corr.1. In addition, two standardizing bodies notified the ISO/IEC Information Centre of their withdrawal from the Code— Pro Telecom, Association Suisse des Télécommunications (Switzerland) and the Australia Gas Association (AGA).

379. Additionally, the ISO/IEC Information Centre had prepared the Fourteenth Edition of the WTO TBT Standards Code Directory, which contained information received according to paragraphs C and J of the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 of the Agreement.

380. The Committee took note of these documents.

## V. TECHNICAL COOPERATION ACTIVITIES

381. The representative of Uganda requested the Secretariat to provide an update on the voluntary notification of technical assistance needs and responses and to share with Members the list of Members that had submitted such notifications and benefited from this initiative. He wondered if there were evolutions with respect to this mechanism.

382. The representative from the Secretariat recalled that the format for the voluntary notification of technical assistance needs and responses was contained in document G/TBT/16. Five countries had submitted such notification (Jamaica, Armenia, Costa Rica, Uganda and Dominican Republic)<sup>25</sup>. Although in discussions held in the Committee there was a general feeling that many technical assistance initiatives were taking place already at bilateral level, Members were welcome to continue using the voluntary notification.

383. The representative from the Codex pointed out that, as regards participation in standardization activities, the Codex trust fund was in operation. It had been initiated in 2004 and it facilitated participation of developing countries in the standard setting activities of the Codex Alimentarius Commission. A complete report would be provided at the next meeting of the TBT Committee. She drew the Committee's attention to regional Codex coordinating committee for Africa which had been held in Ghana in February 2009 to a workshop organized by FAO and WTO on the issues of interest to the region. In conjunction with coordinating committees, the Codex often organized workshops on various topics. An e-learning tool was also available in several languages on the FAO website.

384. The representative of the ISO presented his organization's actions in support of developing countries (G/TBT/GEN/83).

385. The Chairperson expressed appreciation that several of the participants at the First Specialized Course on the TBT Agreement organized by the WTO Secretariat which had taken place in October-November 2008 had attended the Workshop on International Standards and participated in the meeting of the Committee. She also welcomed the Swedish Mentorship Programme, which supported seven East African countries and aimed at enhancing the implementation of the TBT Agreement. The programme allowed, among other things, capital-based officials from the beneficiary countries to attend the meetings of the TBT Committee.

## VI. UPDATING BY OBSERVERS

386. The representative of the IEC welcomed the Workshop on the Role of International Standards in Economic Development which had been followed with great interest by her organization. She acknowledged the need for international standard-setting organizations to continue their efforts to enhance the participation of developing countries in standard setting activities. She encouraged all developing countries to use the IEC Affiliate Country Programme to its full extent as was highlighted in the presentations made by Ms Odour from Kenya and Mr. Rodriguez from Costa Rica during the

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<sup>25</sup> G/TBT/TA-1/JAM, G/TBT/TA-2/ARM, G/TBT/TA-3/CRI, G/TBT/TA-4/UGA and G/TBT/TA-5/DOM.

Workshop. She informed the Committee that, to date, the IEC had distributed 7500 standards to 60 developing countries, of which 3000 have been adopted.

387. The representative of the IEC further noted that a new version of the guidelines on IEC Conformity Assessment for developing countries was available in English and French.<sup>26</sup> She also highlighted an article on the success of Affiliate countries using IEC standards in Botswana, Gambia and Zambia which was published in the March edition of the IEC Newsletter. Further information on all IEC activities was available on the IEC website.<sup>27</sup> She stressed that the IEC was ready to participate in WTO workshops if there was a request by Members in this regard.

388. The representative of UNECE updated the Committee on the activities of the UNECE Working party on Regulatory Cooperation and Standardization Policies (WP6), including the recent brochure on sectoral initiatives aimed at eliminating technical barriers to trade.<sup>28</sup> The Committee was also informed on UNECE's work in market surveillance and counterfeit goods and the development of a general market surveillance procedure which will serve as a guide for market surveillance authorities. Delegations interested in the preparation of the guide were invited to contact the Secretariat. Delegations were also invited to participate at the next session of the Working Party which would take place on 24-26 November 2009 and would be followed by a conference on Risk Assessment and Management.<sup>29</sup>

389. The representative of Codex drew the Committee's attention to document G/TBT/GEN/81 containing an update of relevant Codex's work. In addition, she updated the Committee on the state-of-play of the standards for olive oil, which were revised and adopted by the Codex Commission in 2003 and were entirely harmonized with the International Olive Oil Council, apart from the provision related to Linolenic acid which was still under discussion. This would be raised again at the next Committee on Fats and Oils in February 2011.

390. The representative of Codex also updated the Committee on the Codex Committee on Methods of Analysis and Sampling where, after many years, important guidelines were finalized on the settlement of disputes arising from methodology analysis results. This Committee had also finalized a glossary on analytical terminology and was continuing its discussion on how to interpret measurement and sampling uncertainty in relation to standards, and also in relation to food control and inspection for imports and exports.

391. The Chairperson drew the Committee's attention to the document on relevant on-going work in the OIML<sup>30</sup>.

## VII. OTHER BUSINESS

392. The Chairperson informed the Committee of a letter from the Chairman of the General Council, Ambassador Mario Matus, about a process initiated at the informal meeting of the Trade Policy Review Body on 9 February 2009 on the monitoring of recent trade developments associated with the current global financial and economic crisis. Ambassador Matus was seeking input from the TBT Committee in respect of notifications and information flows.<sup>31</sup>

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<sup>26</sup> [http://www.iec.ch/affiliates/acp\\_conformity-e.htm](http://www.iec.ch/affiliates/acp_conformity-e.htm)

<sup>27</sup> <http://www.iec.ch>

<sup>28</sup> [http://www.unece.org/highlights/what\\_ECE\\_does/2009/18\\_what\\_regulations\\_WP6.pdf](http://www.unece.org/highlights/what_ECE_does/2009/18_what_regulations_WP6.pdf)

<sup>29</sup> Further details are available on the UNECE website:  
[http://www.unece.org/trade/wp6/documents/2009/2009\\_ConferenceRisk.htm](http://www.unece.org/trade/wp6/documents/2009/2009_ConferenceRisk.htm)

<sup>30</sup> G/TBT/GEN/84.

<sup>31</sup> A copy of the letter and of the reply were made available as room documents.

393. In the reply, which was communicated to Ambassador Matus under the Chairperson's own responsibility, the continuous work the TBT Committee was undertaking in the area of transparency had been emphasized – both with respect to the transparency procedures and recommendations, which were regularly being refined, as well as the Committee's discussions of specific trade concerns.

**VIII. DATE OF THE NEXT MEETING**

394. The next regular meeting of the TBT Committee will take place on 25-26 June 2009.

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## ANNEX 1

### REPORT BY THE CHAIRPERSON ON THE WORKSHOP ON THE ROLE OF INTERNATIONAL STANDARDS IN ECONOMIC DEVELOPMENT

Report by the Chairperson (Ms Xueyan GUO) at the  
Regular Meeting of the TBT Committee of 18-19 March 2009<sup>1</sup>

The TBT Committee held a Workshop on the Role of International Standards in Economic Development on 16 and 17 March 2009. Participation was high. Some 70 developing country capital-based officials were sponsored by the WTO through the DDA Global Trust Fund. In total, over 200 TBT experts attended. The Workshop provided opportunity for delegations to share experiences on the development and use of international standards.

**Mr. Harsha V. Singh**, Deputy-Director General of the WTO, opened the Workshop. In his opening remarks, Mr. Singh provided an overview of issues related to standards, trade and the WTO. He stressed the economic benefits of standardization and highlighted some of the costs; he underscored the importance of the disciplines in the TBT Agreement as they apply to standardizing bodies and to Member governments and he also drew our attention to the increasing importance of addressing non-tariff barriers to trade in the WTO, including in the negotiating context.

The workshop focused first on the **economics of standards**. A synopsis of current work on the topic of standards, trade and economic growth was provided. In particular, based on studies undertaken in Germany, the United Kingdom, Canada, Australia and China, we heard expert views from both academia and governments on the benefits and costs of standardization activities – and efforts to quantify these. The gist of the findings of various studies presented showed that standards, as a pool for technological know-how, can contribute positively to economic growth. It was pointed out that standards promote innovation and technical progress and are an important instrument to facilitate competition in markets and transfer of technology. But these benefits remain difficult to quantify and need to be better understood, both in qualitative and quantitative terms – more research is therefore needed, also with respect to aligning methodologies and assessment tools. Of course, there are also costs associated with the use of standards, these are somewhat more tangible. Participants were urged to circulate widely any case studies on the impacts of standards, regardless of methodologies used.

Several participants reflected on the relevance of standards to the crisis that is affecting the global economy today. It was pointed out that in times of crisis it is ever more important to ensure that standards are not used for protectionist purposes. Instead, standards should be seen as an opportunity. For instance, well crafted standards as the basis for regulatory measures may increase confidence in markets and serve to boost trade. As well, it was pointed out that standards are an important link between research, innovation and markets; in effect, an efficient tool for the transfer of technology. For companies in particular, participation in standardization processes could potentially compensate for a downturn in R&D spending. This is particularly important today in the areas of sustainability and environmental technology.

It was also pointed out that standards need to be maintained to stay relevant: they have to be up to date with current technology and science – they should not lag behind technology. Science does not stay still. So timing is therefore important. Standards that arrive too late can lock in old technology and be counter-productive in terms of innovation.

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<sup>1</sup> A Summary Report of the Workshop on the Role of International Standards in Economic Development is contained in document G/TBT/W/310.

A number of **practical case studies** that illustrate how the use of standards has contributed to economic and social development, in particular in developing countries, were presented and discussed. For instance, in the agricultural sector, we learned how international standards have been used to increase exports of asparagus and coffee from Peru. Egypt illustrated how the adoption and use of international standards in general had facilitated trade, leading to increases in both imports and exports. We were given the example of how the Pakistani textile sector had increased exports subsequent to the use of international quality standards.

We also heard how standards can have other benefits. The case of the US-Brazil cooperation to develop testing and measurement methods on biofuels, and the application of Chilean standards on energy efficiency showed how the standards can contribute to address global environmental challenges. Standards can also successfully address public safety issues, as illustrated by Colombia in the presentation on building codes and construction. Kenya's experience showed how the adoption of international standards in the electro technology field had contributed to improvement in the quality and safety of *imported* products.

A common element in several of the cases presented was the importance attributed to collaborative work between the public and private sectors; government support for standardization activities was considered important, particularly in developing countries. It was also important to have the absorptive capacity to implement standards (not only participate in their development), and, sometimes, to tailor them to local or regional circumstances.

Participants considered efforts to address developing country **capacity constraints** in respect of the use of international standards. Clearly, participation in international standards-setting activities is considered essential and remains a constraint. In this respect, several initiatives by international standardizing bodies, regional bodies, bilateral donors and other international bodies such as UNIDO to increase participation were mentioned. Kenya suggested that developing countries should to a greater extent be hosting working groups and technical committees developing standards. However, it was also pointed out that participation in and of itself serves no purpose: it has to be effective. Building *expertise* in developing countries and filling information gaps has to be done in ways that reflect the needs of each individual country.

Several participants expressed concern about the proliferation of private standards that could result in unnecessary barriers to trade that created confusion in the market place. It was pointed out that initiatives existed and were underway in other organizations, such as UNIDO, to help countries comply with such schemes, and that the issue was being addressed in the WTO SPS Committee.

The importance to identify best practices for technical cooperation in the standards-setting field was stressed. Aid effectiveness meant that Aid for Trade in the standards setting world has to be driven by needs, be sector-specific and include the effective participation of all stakeholders. As an example of Aid for Trade applied to standards, the relevant work of the Standards and Trade Development Facility (STDF) in the SPS area was presented.

Many key **challenges** remain with respect to standardizing activities. At the end of the workshop, in my capacity as Chair, I pointed at a few challenges that have arisen in the discussion; among these, I would stress the following:

- **Quantifying the benefits of standards:** The studies and experiences shared at the outset of the workshop show the significant positive role standards can play in promoting innovation and technical progress. The use of standards makes production more efficient. Yet measuring and expressing the benefits of standards remains a key challenge. I would encourage Members, through this Committee, to share case studies that consider the economic benefits of the use of standards.

- **Involving all stakeholders:** Creating awareness among all relevant stakeholders, including SMEs, of the importance of being involved in standard-setting activities is crucial. Broad stakeholder involvement ensures an open and transparent process, in line with the disciplines on standardizing bodies contained in the TBT Agreement. On various occasions during the workshop, speakers and participants pointed out that government support and involvement in standardization is important, particularly in developing countries – where standardization may not always be given priority, and the strategic importance of standards is not always appreciated. It is important to find incentives to increase support and promotion of standardizing activities in developing countries.
- **Participation in international standard-setting activities:** Actual participation in standards-setting activities by developing countries remains a challenge, both financially and technically. Only a small proportion of developing countries are responsible for the management of working groups and technical committees, where the nuts and bolts of international standardization work takes place. Although we heard of various initiatives, finding *effective* ways of increasing such participation remains a challenge. It was pointed out that an essential component of making participation effective at the country level is a two-way exercise. On the one hand – at the national level – it is important to raise levels of expertise in selected areas of importance to the participating developing country. And, on the other hand – and at the international level – it is important to engage that local knowledge and expertise in the international standard-setting community.
- **Building up standards-related infrastructure.** Standards development is part of a bigger whole – part of a quality infrastructure that includes: metrology, standards development and conformity assessment activities, including accreditation. It is not obvious that all components of this infrastructure is needed everywhere; for instance, it was pointed out that in the Caribbean efforts are underway to build quality infrastructure at the regional level. Therefore, it is important that countries prioritize and are selective about where efforts to build capacity should be concentrated. The Committee may consider developing good practices for setting up quality infrastructure. Expertise could be drawn from both Members and international organizations working in this area.

I would finish by stressing a point that several speakers and participants reverted to in the course of the workshop. In this time of economic crisis, we, in the TBT Committee need to guard cases where standards are used as a basis for non-tariff barriers that are unnecessary. Continued effective use of our transparency provisions is crucial in the respect. We also need to reinforce and boost the beneficial, confidence-building aspects of standards. The use of international standards should serve the purpose of facilitating international trade, as envisaged in the WTO TBT Agreement.

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